ENDOCARE INC
Form 10-K
March 15, 2004

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO

SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2003; or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition period from to .

Commission File Number 000-27212

Endocare, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0618093**
(State of incorporation)	*(I.R.S. Employer Identification No.)*
201 Technology, Irvine, CA	**92618**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code: (949) 450-5400

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value

Rights to Purchase Shares of Series A Junior Participating Preferred Stock

(Title of Class)

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 o No þ (2) Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this

Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes þ No o

The aggregate market value of the common stock of the Registrant held by non-affiliates as of June 30, 2003, was approximately $84,468,749 (based on the last sale price for shares of the Registrant s common stock as reported in the Pink Sheets for that date). Shares of common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed affiliates. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the Registrant, or that such person is controlled by or under common control with the Registrant.

There were 24,139,504 shares of the Registrant s common stock issued and outstanding as of March 1, 2004.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Definitive Proxy Statement related to the Registrant s 2004 Annual Meeting of Stockholders, which Definitive Proxy Statement is to be filed under the Securities Exchange Act of 1934, as amended, within 120 days of the end of the Registrant s fiscal year ended December 31, 2003, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Certain exhibits filed with our prior registration statements and Forms 10-K, 8-K and 10-Q are incorporated herein by reference into Part IV of this Annual Report on Form 10-K.

Endocare, Inc.

Form 10-K

For the Fiscal Year Ended December 31, 2003

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PART I

This Annual Report on Form 10-K may contain forward-looking statements that involve risks and uncertainties. Such statements typically include, but are not limited to, statements containing the words believes, intends, anticipates, expects, estimates, should, could, may, planned and words of similar import. Our actual results could differ materially from any such forward-looking statements as a result of the risks and uncertainties, including but not limited to those set forth below in Risks Related to Our Business and in other documents we file from time to time with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q. Any such forward-looking statements reflect our management s opinions only as of the date of this Annual Report on Form 10-K, and we undertake no obligation to revise or publicly release the results of any revisions to these forward-looking statements. Readers should carefully review the risk factors set forth below in Risks Related to Our Business and in other documents we file from time to time with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q.

You are further cautioned that we have determined that in certain cases we misinterpreted or misapplied GAAP in our 2001 and 2000 consolidated financial statements and, accordingly, we have restated our consolidated financial statements as of December 31, 2001, and for the years ended December 31, 2000 and 2001. Furthermore, because these restatements also impacted our 2002 results, the information previously filed in our quarterly reports on Form 10-Q for the quarters ended March 31, 2002 and June 30, 2002, and in our prior periodic reports, should not be relied upon. Detailed information regarding these restatements is disclosed in notes 3 and 16 to our consolidated financial statements filed in our annual report on Form 10-K for the year ended December 31, 2002.

AutoFreeze™, CGC™, Cryocare®, Cryocare CS™, Cryocare Surgical System®, CryoDisc®, CryoGrid™, Cryoguide®, Direct Access™, Endocare®, ErecAid®, Esteem®, FastTrac®, Horizon Prostatic Stent®, Integrated Ultrasound™, RigiScan®, SmartTemp™, SnapGauge™, SurErec™, Targeted Ablation™, Targeted Ablation of the Prostate TAP®, Targeted Ablation Therapy TAT®, Targeted Cryoablation of the Prostate TCAP®, Targeted Cryoablation Therapy TCAT®, TEMPprobe®, ThermaStent™, and Urethral Warmer™ are trademarks of ours or our wholly-owned subsidiary, Timm Medical Technologies, Inc., or Timm Medical. This Annual Report on Form 10-K may also include trademarks and trade names owned by other parties, and all other trademarks and trade names mentioned in this Annual Report on Form 10-K are the property of their respective owners.

Item 1. ***Business***

Overview

We are a specialty medical device company focused on improving patient s lives through the development, manufacturing and distribution of health care products related to our core competencies in the areas of cryoablation and vacuum technology. Our strategy is to achieve a dominant position in the prostate cancer market while achieving penetration across horizontal markets with our proprietary cryosurgical technology and maintaining our dominant position in vacuum technology for erectile dysfunction.

We were formed in 1990 as a research and development division of Medstone International, Inc. a manufacturer of shockwave lythotripsy equipment for the treatment of kidney stones. Medstone, formerly a public company traded on Nasdaq under the trading symbol MEDS, was acquired on February 20, 2004, by Prime Medical Services, Inc. We were incorporated under the laws of the State of Delaware in May 1994. On January 1, 1996, we became an independent, publicly owned corporation upon Medstone s distribution of our stock to its existing stockholders.

Between 1996 and 1998, we concentrated on developing and establishing a market for devices used in cryosurgical treatment of prostate cancer. We began selling our Cryocare Surgical System in July 1999 following Medicare s initiation of national reimbursement coverage of cryosurgery for the primary treatment of localized prostate cancer. Effective July 2001, Medicare approved reimbursement of secondary cryosurgical treatment for men who have been unsuccessfully treated with radiation therapy.

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Today, our FDA-cleared Cryocare Surgical System occupies a growing position in the urological market for treatment of prostate cancer. Because of our initial concentration on prostate and renal cancer, the majority of our sales and marketing resources are directed towards the promotion of our technology to urologists. In addition, we contract directly with hospitals and health care payors to perform cryoablation procedures using our proprietary device and disposable products on a fee-for-service basis. We believe our proprietary cryosurgical technologies have broad applications across a number of surgical markets, including for the treatment of tumors in the lung, liver and bone. In November 2003, we formed a dedicated sales and marketing team focused on marketing percutaneous cryoablation procedures related to kidney, liver, lung and bone cancer to radiology physicians throughout the United States. We intend to continue to identify and develop new markets for our cryosurgical products and technologies, particularly in the area of tumor ablation.

Through our acquisition of Timm Medical in February 2002, we acquired several products used in the treatment and diagnosis of erectile dysfunction. We have a dedicated sales, customer service and marketing team focused on our ErecAid line of vacuum therapy systems, which include the ErecAid Classic system and the ErecAid Esteem system leading non-pharmaceutical treatment devices for erectile dysfunction. Our ErecAid devices are marketed directly to consumers, as prescription devices, and to durable medical equipment providers, physicians and pharmacies. Our principal diagnostic tool is the RigiScan, an ambulatory device marketed to physicians that measures the frequency, rigidity and duration of both nocturnal and provocative erections.

Primarily through our acquisition of Timm Medical, we significantly expanded the ranks of our urology sales force. We have deployed these employees in both sales of our cryosurgical products and sales of our ErecAid products. We believe this sales force will be a valuable asset as we pursue building our business in the areas of tumor ablation and vacuum therapy treatment of erectile dysfunction.

We acquired or obtained marketing rights to a number of other urological products in the Timm Medical purchase, many of which we have divested or may divest in the future. In April 2003, we sold the Dura II penile implant devices to American Medical Systems, Inc., or AMS. In October 2003, we sold our products used in the diagnosis and management of urinary incontinence to SRS Medical, Inc.

We maintain our executive offices at 201 Technology, Irvine, California 92618, and our telephone number at that address is (949) 450-5400. Financial information regarding our financial condition and results of operations can be found in a separate section of this Annual Report on Form 10-K, beginning on page F-1.

Recent Developments

Internal Review. In October 2002, our Audit Committee retained legal and financial experts to conduct an internal review of various accounting and other matters. In July 2003, our Audit Committee engaged independent counsel to review and evaluate the results of the initial investigation. The investigation and review process resulted in our undertaking certain modifications to our internal controls, accounting policies and procedures, disclosure controls and procedures and corporate governance policies and procedures in order to, among other things, enhance the quality and consistency of our financial information and reporting. We also determined to make, and subsequently did make, certain changes to our senior management team and Board of Directors. Detailed information regarding these statements is disclosed in notes 3 and 16 of our consolidated financial statements filed in our annual report for the year ended December 31, 2002 filed on Form 10-K.

Legal Proceedings. Beginning in November 2002, we, together with certain former officers and certain current and former board members, became parties to various shareholder class-action and derivative lawsuits and other legal proceedings. We, as well as certain of our current and former directors and officers, are also under investigation by the Securities and Exchange Commission, or SEC, and Department of Justice, or DOJ, to determine whether we have violated any federal securities laws, and we are fully cooperating with those investigations. For a further description of the nature and status of these legal proceedings see below under Item 3 Legal Proceedings.

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Nasdaq Delisting. Effective January 16, 2003, our common stock was delisted from The Nasdaq Stock Market. One result of this action is a limited public market for our common stock. Trading is now conducted in the over-the-counter market in the Pink Sheets. We are working towards compliance with all listing requirements of The Nasdaq Stock Market, and we will seek to be relisted once we are in full compliance with our obligations as a reporting company pursuant to the Securities Exchange Act of 1934, as amended.

New Independent Accountants and Restatements of Financials. In March of 2003, we dismissed KPMG LLP as our independent accounting firm. We then engaged Ernst & Young LLP as our new independent accounting firm to audit certain of our historical consolidated annual financial statements and to review our historical consolidated unaudited interim financial statements. As a result of this audit and our internal review, we have made various restatement adjustments to our historical financial statements. Detailed information regarding these restatements is disclosed in notes 3 and 16 of our consolidated financial statements filed in our annual report on Form 10-K for the year ended December 31, 2002.

Management Changes. In December 2003, we appointed Craig T. Davenport as our new Chief Executive Officer. In March 2003, we appointed a new President and Chief Operating Officer, William J. Nydam, and a new Chief Financial Officer, Katherine Greenberg. In March 2003, Paul W. Mikus vacated his position as our Chief Executive Officer and in September 2003 he vacated his position as our Chairman. In March 2003, John V. Cracchiolo vacated his positions as our Chief Financial Officer and Chief Operating Officer, and in July 2003 he vacated his position as President of our Interventional Radiology business group.

Board Changes. Over the past year, the membership of our Board of Directors has changed significantly: Thomas R. Testman joined our Board in May 2003 to fill a then-existing vacancy; Terrence A. Noonan joined our Board in September 2003, filling a vacancy created by Mr. Mikus resignation; and Mr. Davenport and John R. Daniels joined our Board in January 2004, filling vacancies created by the resignations of Peter F. Bernardoni and Benjamin Gerson, M.D.

Strategic Divestures and Product Abandonments. We are narrowing the focus of our business on the development of minimally invasive technologies for tissue and tumor ablation and vacuum technology. As part of this strategy, we have begun divesting certain non-core product lines. Our first significant divestiture occurred on April 7, 2003, when our wholly-owned subsidiary, Timm Medical sold its Dura-II positionable urological prosthesis product line to AMS. Under the terms of the agreement, the transaction, valued at approximately $2.2 million, included, among other things, the intellectual property, customer lists and production equipment related to the product as well as the then current Dura-II inventory. Our second significant divestiture occurred on April 14, 2003, when we sold our cardiac-related product manufacturing operations and licensed the related intellectual property to CryoCath Technologies Inc., or CryoCath. Under the terms of the agreement, we transferred all of our manufacturing assets and inventory related to the cardiac product line to CryoCath and are exclusively licensing to CryoCath for cardiovascular uses our proprietary argon gas based technology associated with the SurgiFrost system a cryoablation system designed to treat cardiac arrhythmias. Terms of the agreement also include the payment by CryoCath to us of $10 million during 2003. The agreement also calls for the payment by CryoCath to us of a nine-year descending royalty stream based on net sales of products incorporating the licensed technology. We believe CryoCath s leadership position in the field of cardiovascular cryotherapy puts them in strong position to exploit the opportunities for our technology in this highly competitive arena. Our most recent divestiture occurred on October 15, 2003, when Timm Medical sold its urodynamics and incontinence product lines to SRS Medical Corp, or SRS. Under the terms of the agreement, the transaction, valued at approximately $2.7 million to be paid over a number of years, included, among other things, the transfer of the intellectual property, customer lists and production equipment related to the EasyPro, EasyFlo, C3, StepFree and Profilometer products, as well as the then current inventory relating to those products.

Prior to 2003, we had devoted significant resources to the development of a proprietary urological stent, the Horizon Prostatic Stent, to provide temporary and immediate relief for patients who undergo thermal therapy or other procedures to treat benign prostatic hyperplasia, or BPH, also known as prostate enlargement. We had also explored the development of another stent, the ThermaStent that physicians could use to deliver

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heat to destroy excess prostate tissue in patients with moderate to severe BPH. During 2003, in view of the significant investment needed to bring the Horizon Prostatic Stent to market and the fact that it is outside of our strategic focus on cancer treatment, we have decided to abandon further efforts to obtain FDA approval of our Horizon Prostatic Stent and have also ceased development of our ThermaStent. We are actively looking for a buyer for the patent and product portfolio related to our stent products.

Additionally, in connection with our divestiture strategy, we have terminated or allowed to lapse our rights to certain other product offerings including the FastPack® System, a proprietary prostate cancer test developed by Qualigen, Inc., the Thermoflex® System, an office-based thermal therapy for BPH developed by ArgoMed, Inc., the NMP22™ POC Test, a bladder cancer detection test developed by Matritech, Inc., and the urodynamic products, including the Andromeda Ellipse Monitor, developed by Andromeda Medizinische Systeme, GmbH of Munich, Germany. Also, we are in the process of dissolving one of our BPH treatment partnerships. Furthermore, we no longer market our StayErec product line and intend to discontinue our SnapGauge diagnostic tool for erectile dysfunction product line once current inventory levels are exhausted. As part of our strategy to focus our business on our core technology-cryoablation of cancer-we may divest additional product lines in the future.

Introduction of New Cryocare CS System. We recently introduced the next generation of our Cryocare Surgical System, the Cryocare CS. The Cryocare CS is a fully integrated cryosurgical planning, placement and treatment system designed to simplify our FDA-cleared Targeted Cryoablation of the Prostate, or TCAP, procedure. We shipped the first Cryocare CS System in December 2003 and it was in clinical use by the end of the year. See below under Our Solution: The Cryocare Surgical Systems.

Prostate Cancer/ Urology Market Background

The prostate is a walnut-size gland surrounding the male urethra, located below the bladder and adjacent to the rectum. Prostate cancer is one or more malignant tumors that begin most often in the periphery of the gland and, like other forms of cancer, may spread beyond the prostate to other parts of the body. If left untreated, prostate cancer can metastasize to the lung or bone and potentially other sites, resulting in death.

The number of men diagnosed with prostate cancer has risen steadily since 1980 and it is now the second most common cause of cancer-related deaths among men. Prostate cancer is most prominent in North America and northwestern Europe and less common in Asia, Africa, Central America, and South America. The American Cancer Society estimates there will be approximately 230,855 new cases of prostate cancer diagnosed and approximately 29,089 deaths associated with the disease in the United States during 2004. Prostate cancer incidence and mortality increase with age. Prostate cancer is found most often in men who are over the age of 50. According to the American Cancer Society, more than 70% of men diagnosed with prostate cancer are over the age of 65. In addition to age, other risk factors are linked to prostate cancer, such as genetics and diet.

The dramatic increase in prostate cancer diagnoses has led to heightened awareness of the disease, which, in turn, has led to increased rates of testing and improved diagnostic methods. The American Cancer Society recommends that men without symptoms, risk factors and a life expectancy of at least 10 years should begin regular annual medical exams at the age of 50, and believes that physicians should offer as a part of the exam, the prostate-specific antigen, or PSA, blood test and a digital rectal examination in which the physician places a gloved finger into the rectum and examines the prostate for lumps. The PSA blood test determines the amount of prostate specific antigen present in the blood. PSA is found in a protein secreted by the prostate, and elevated levels of PSA can be associated with, among other things, prostatitis, a non-cancerous inflammatory condition, or a proliferation of cancer cells in the prostate. Transrectal ultrasound tests and biopsies are typically performed on patients with elevated PSA readings to confirm the existence of cancer.

We believe that over 85% of prostate cancer patients are eligible for our cryosurgical treatment. The U.S. market for prostate cancer treatment for newly diagnosed patients is estimated to be approximately $1.3 billion in 2001 and is expected to grow to $2 billion by 2006. We also believe the market for secondary cryosurgical treatment of patients with recurring prostate cancer is significant.

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Non-Cryosurgical Treatment Options

Therapeutic alternatives for patients with prostate cancer have been both limited and unattractive. Current treatment options include radical surgery, radiation therapy, hormone or other therapies, watchful waiting, and cryotherapy. These options are evaluated using a number of criteria, including the patient s age, physical condition and stage of the disease. Due to the slow progression of the disease, however, the decision for treatment is typically based upon the severity of the condition and the resulting quality of life.

Radical prostatectomy has been used for over 30 years and is most often the therapy of choice due to the surgeon s high degree of confidence in surgically removing the cancerous tissue. The procedure is dependent on the skill of the surgeon and is often associated with relatively high incidence of post-operative impotence and incontinence and can even result in operative mortality.

Radiation therapy for prostate cancer includes both external radiation beam and interstitial radioactive seed therapies. External beam radiation therapy emerged as one of the first alternatives to radical prostatectomy; however, studies have shown that the success rate of this procedure is not comparable to that of radical prostatectomy. Interstitial radioactive seed therapy, also referred to as brachytherapy, is the permanent placement of radioactive seeds in the prostate. Brachytherapy has been shown to be most effective for localized tumors caught in the early stage of disease development.

Other therapies, primarily consisting of hormone therapy and chemotherapy, are used to slow the growth of cancer and reduce tumor size, but are generally not intended to be curative. These therapies are often used during advanced stages of the disease to extend life and to relieve symptoms. Side effects of hormonal drug therapy include increased development of breasts and other feminine physical characteristics, hot flashes, impotence and decreased libido. In addition, many hormone pharmaceuticals artificially lower PSA levels in patients, which can interfere with the staging of the disease and monitoring its progress. Side effects of chemotherapy include nausea, hair loss and fatigue. Drug therapy and chemotherapy require long-term, repeated administration of medication on an outpatient basis.

Watchful waiting is recommended by physicians in certain circumstances based upon the severity and growth rate of the disease, as well as the age and life expectancy of the patient. The aim of watchful waiting is to monitor the patient, treat some of the attendant symptoms and determine when more active intervention is required. Watchful waiting has gained popularity among those patients refusing treatment due to side effects associated with radical prostatectomy. Watchful waiting requires periodic physician visits and PSA monitoring.

The History of Cryosurgery

Cryosurgery, freezing tissue to destroy tumor cells, was first developed in the 1960 s. During this period, the use of cold probes, or cryoprobes, was explored as a method to kill prostate tissue without resorting to radical surgery. Although effective in killing cancer cells, the inability to control the amount of tissue frozen during the procedure prevented broad use and development of cryotherapy for prostate cancer. These initial limitations in the application of cryosurgery continue to contribute to a lack of widespread acceptance of the procedure today.

In the late 1980 s, progress in ultrasound imaging allowed for a revival in the use of cryosurgery. Using ultrasound, the cryoprobe may be guided to the targeted tissue from outside the body through a small incision. The physician activates the cryoprobe and uses ultrasound to monitor the growth of ice in the prostate as it is occurring. When the ice encompasses the entire prostate, the probe is turned off. This feedback mechanism of watching the therapy as it is administered allows the physician more precise control during application. Published studies suggest that cryosurgery may be able to deliver disease-free rates comparable to radical surgery and radiation, but with the benefit of lower rates of incontinence and mortality, shorter recovery periods and relatively minimal complications.

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Our Solution: The Cryocare Surgical Systems

We have developed our proprietary Cryocare Surgical System to allow the urologist to treat prostate cancer in a minimally invasive manner. We designed the Cryocare Surgical System to freeze tissue much faster and with more control than previous cryosurgical systems.

The Cryocare Surgical System incorporates enhanced control mechanisms to minimize the risk of unintended damage to tissue surrounding the prostate. The argon gas-based cryoprobes stop freezing instantly. During cryosurgical procedures, six to eight temperature probes are selectively placed in the prostate near the rectal tissue, sphincter muscles, which control continence, and neurovascular bundles, which control potency. These temperature probes enable the physician to monitor temperatures of tissue adjacent to the prostate in real time.

A large percentage of our cryosurgical procedures to date have been performed in medium to high-risk patients. In these procedures, the urologist intentionally ablates the neurovascular bundles to prevent the recurrence of cancer, typically resulting in impotence. We have developed a nerve-sparing procedure for lower risk patients, which utilizes a combination of early detection and improved cryosurgical techniques. Several clinical studies are in process to determine the disease-free rates that are attainable with this procedure.

Our Cryoguide, a software-controlled ultrasound planning and mapping system is a significant advancement in targeted cryoablation of the prostate We sell the Cryoguide as an accessory to the Cryocare Surgical System and as a standard component in our new CS system. The Cryoguide control unit consists of a computer console and display screen designed to be compatible with standard ultrasound equipment. The Cryoguide allows physicians to visualize the prostate in three dimensions and uses a grid system to facilitate the precise placement of our cryoprobes in the optimal position in the prostate. Our Cryoguide incorporates a visualization and planning process allowing the surgeon to simulate cryoablation of the prostate. This simulation allows validation of the positioning of the cryoprobes prior to initiating treatment and tailoring the ice ball formation for individual patients, improving patient outcomes. The Cryoguide creates a standardized repeatable procedure and decreases procedural time.

Our proprietary cryoprobes are engineered to consistently produce sculpted ice conforming to the unique anatomy of the prostate. Our efficient argon gas-based system delivers lethal ice in a controllable and repeatable fashion. We have also developed a percutaneous access device, named FastTrac, which allows a simplified one step insertion of our cryoprobes to significantly reduce procedure time.

We continue to evaluate, develop and implement technology that will refine and improve the Cryocare Surgical System. In April 2003, we unveiled the next generation of our Cryocare Surgical System, the Cryocare CS. The Cryocare CS is a fully integrated cryosurgical planning, placement and treatment system designed to simplify our FDA-cleared Targeted Cryoablation of the Prostate TCAP procedure. It consists of the AutoFreeze, a computer-controlled automated freezing mechanism that utilizes optimal power settings based upon target endpoint temperatures and continual feedback from the thermocouple tips. Along with AutoFreeze, Cryocare CS includes new Integrated Ultrasound technology that provides an internal view of the prostate gland. It also features patented CryoGuide planning software that assists physicians in determining optimal treatment of the entire gland as well as targeting specific cancerous areas of the prostate. The new system also includes a new Urethral Warmer, along with the vacuum-insulated Direct Access CryoProbes and CryoGrid, a grid similar to that used in brachytherapy, which is affixed to the ultrasound stepper. The CryoGrid aids the physician with placement of the cryoprobes ensuring that ice formation and lethal temperatures occur where necessary to destroy cancerous tissue but do not affect areas where tissue damage could cause harm. We believe the Cryocare CS is the most sophisticated cryotherapy system currently available and it brings a new level of safety, ease of use and reproducibility to the use of cryotherapy in the treatment of prostate cancer.

Cryosurgery is the first minimally invasive procedure that urologists can perform themselves. With radiation therapies, urologists must refer the patient for treatment to a radiation oncologist. Cryosurgery offers the urologist both the opportunity to maintain continuity of patient care and to generate additional revenue.

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Key Advantages of Our Cryocare Surgical System

Our Cryocare Surgical System provides the following significant clinical advantages relative to other principal treatment options for prostate cancer:

Effective for a broad range of low to high-risk prostate cancer patients. In low risk cases, the success of cryosurgery, including our Cryocare Surgical System, is comparable to radiation therapy and radical surgery. In medium to high-risk cases, results of cryosurgery are at least equivalent and appear to be superior to radiation therapy and radical surgery.

High quality of life following treatment. Our minimally invasive procedure offers patients the shortest recovery period of any definitive prostate cancer therapy and may result in a lower incidence of certain side effects, including incontinence.

Treatment of patients who have failed radiation therapy. Patients who have failed radiation therapy have limited options. Cryosurgery is a potentially curative treatment option that can be used to treat these patients effectively with significantly fewer side effects than radical surgery.

Treatment can be performed more than once. Regardless of what therapy is chosen there is always a chance that the cancer will recur. Unlike radiation therapy or surgery, cryosurgery can be repeated without increased morbidity.

Erectile Dysfunction Market Background

Erectile dysfunction, or impotence, is the inability to achieve or maintain an erection sufficient for sexual intercourse. Worldwide sales for erectile dysfunction products are estimated at $1.2 billion annually. Approximately 30 million men in the United States suffer from erectile dysfunction, primarily those over the age of 40. A variety of physical and psychological conditions can cause erectile dysfunction, including diabetes, high blood pressure, high cholesterol, nervous system disorders, complications from surgery, medication, alcoholism, spinal cord injuries, depression and other psychological conditions. Erectile dysfunction is most often caused by physical problems, rather than psychological problems.

Men suffering from erectile dysfunction generally have five treatment options: drug therapy, vacuum systems, needle injection therapy, urethral suppositories and penile implants. Historically, it is estimated that fewer than 10% of men afflicted with erectile dysfunction sought treatment for their condition. The introduction and advertising of oral drug therapies in 1998, however, significantly increased the population of patients seeking treatment. This trend is expected to continue during the next five years as patients become increasingly comfortable in seeking treatment. Although the success of oral drug therapies has had a positive impact on the diagnosis and treatment of patients suffering from erectile dysfunction, a significant number of patients do not respond, experience side effects or are not proper candidates for drug therapies. We believe that these patients will turn to alternative treatments for erectile dysfunction, including vacuum systems.

Our Erectile Dysfunction Offerings

Through our acquisition of Timm Medical, we now have an erectile dysfunction product line consisting of diagnostic and treatment products.

Diagnostic Products

We now market a leading tool for the diagnosis of erectile dysfunction. The RigiScan Plus Rigidity Assessment System is an ambulatory diagnostic tool used to measure the frequency, rigidity and duration of both nocturnal and provocative erections. It is a non-threatening, non-invasive, cost-effective method for a physician to differentiate between organic and psychological erectile dysfunction and support the treatment program of choice.

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Treatment Products

We also offer a leading line of vacuum therapy systems for the treatment of erectile dysfunction. Even with the success of oral drug therapies, this product line continues to appeal to a growing patient population. Target patient populations include individuals who have not responded to or have conditions contraindicated for existing drug therapies, patients who are not eligible for third-party reimbursement under their present healthcare plans and those patients concerned with the side-effects of drug therapies.

We hold a leading market position in vacuum therapy systems. We offer a full line of products, including the ErecAid Classic system and ErecAid Esteem system. Vacuum therapy involves the use of a mechanical system that creates a vacuum around the penis, causing the erectile bodies to fill with blood. A constriction ring is then placed around the base of the penis to impede blood drainage and maintain the erection. These systems are over 90% effective and represent a low cost treatment for erectile dysfunction.

Marketing and Strategy

Cryosurgical Products

Our objective in urology is to establish cryosurgery as a primary treatment option for prostate and renal cancer. Our earlier commercial efforts were focused on direct and distributor sales of these systems to service entities who would provide systems and technicians to hospitals where cryosurgical procedures were performed. Disposable devices used in cryosurgical procedures (cryoprobes and temperature probes) were sold in bulk to hospitals and distributors or provided as part of a procedure fee or kit sold either by us, our distributors or our service partners to hospitals and other health care providers.

A cryosurgical procedure kit includes the necessary disposable devices in addition to a service component. Transportation and rental of equipment used in the procedure, plus the services of a technician to assist the urologist with use and monitoring of this equipment, comprise the service component of a procedure kit. In addition to the use of a Cryocare Surgical System, an ultrasound device is needed for visual monitoring of the prostate and ice formation. Tanks of argon and helium gas are needed for freezing and warming during the procedure. Frequently, this equipment is not stored on site but is mobilized and brought into the hospital for procedures.

In 2003, we re-directed our strategy for cryosurgical products away from driving acceptance of the technology through sales of capital equipment into the urology market toward a focus on development and exploitation of our core technological competence in the area of tumor ablation. Our primary objective for the urology portion of our business is now to grow market share, measured in terms of procedures, through establishment of cryosurgery as a primary treatment option for prostate cancer. In fiscal year 2003, we derived a significant percentage of our revenues from recurring sales of disposable supplies used with the Cryocare Surgical System.

We continue to sell the disposable devices to hospitals either in the form of procedure kits or separately, that is, without the service component. We also continue to sell our Cryocare Surgical Systems both to hospitals and service partners, although we will often place a system with a new customer under our placement program for purposes of generating additional procedure fees.

Our single greatest challenge in the prostate cancer market is to overcome initial reluctance on the part of urologists to embrace cryosurgery. Part of this reluctance is due to clinical failures experienced during earlier efforts to introduce the technology by other companies. See above under The History of Cryosurgery. In addition, we are competing with other therapies that have proven effective in treating prostate cancer. Over 30 years of clinical data exist documenting the safety and efficacy of radical surgery for prostate cancer. There are 20 years of clinical data supporting use of various forms of radiation treatment options; brachytherapy and beam radiation treatments are used to treat approximately one third of all prostate cancer cases each year in the United States.

We believe we have clinical advantages for many patients over both forms of treatment. While there are long-term clinical data available on radical surgery, this treatment approach, typical of surgery in general, is

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characterized by a long recovery period combined with a relatively high incidence of side effects, including impotence and urinary incontinence. The appeal of radiation as a treatment alternative, particularly to patients, is that it is less invasive than surgery. Like radiation, cryosurgery is less invasive and therefore has potentially fewer side effects than radical surgery. Unlike radiation treatments, however, cryosurgical treatments can be repeated on the same patient. In fact, our initial clinical successes in prostate cancer treatment were in treating patients who had failed radiation therapy.

Key elements in our strategy for overcoming the challenges we face in establishing cryosurgery as a primary treatment option for prostate cancer are:

Increasing awareness in the urological community regarding the clinical benefits of cryosurgery through our presence at significant technical meetings and trade shows, publication of numerous scientific papers and articles on cryosurgery and formation of a scientific advisory board to provide guidance and counsel to us regarding clinical matters and physician education;

Conducting ongoing clinical studies to further demonstrate the safety and efficacy of cryosurgery as a primary treatment of cancer of the prostate, as well as its value in treating prostate cancer patients who have failed radiation;

Conducting clinical studies to further demonstrate the safety and efficacy of cryosurgery as a treatment for renal tumors; this is another important component of the urology market for cryosurgery;

Creating 50 to 100 new practicing cryosurgeons each year through our physician education program;

Working toward ensuring that reimbursement for cryosurgery by Medicare and other payors is appropriate given the costs and benefits of the treatment;

Driving patient awareness through our direct-to-consumer advertising programs; and

Marketing our products to physicians and hospitals through our direct sales force.

Because of our initial concentration on prostate cancer, the majority of our sales and marketing resources are directed towards the promotion of cryoablation technology to urologists for the treatment of prostate and renal cancer. We are also, however, expanding the reach of our technology across a number of other markets, including for ablation of tumors in the kidney, lung and liver, as well as for managing pain related to metastatic bone cancer. Procedures for treatment of these cancers are typically performed percutaneously, using CT scanning technology, and are done by interventional radiologists, not urologists. In order to better understand and address the distinct needs of this new market, we have formed a dedicated marketing and sales team to work in developing these opportunities for application of our cryosurgical technology.

Key elements in our strategy to establish new markets for cryosurgical treatment of tumors, specifically in the interventional radiology and radiation oncology markets, are:

Conducting numerous clinical studies to demonstrate the safety and efficacy of cryosurgery as a primary treatment for lung and liver tumors as well as for pain management of bone metastases;

Formation of a dedicated sales and marketing group focused on the opportunities for cryosurgical treatment approaches in these new markets; and

Continuing to enhance our Cryocare Surgical System to improve its ease of use across a broad range of tissue ablation applications.

In line with the renewed focus of our cryosurgical business on tumor ablation in 2003, we made the decision to divest or discontinue certain product lines unrelated to this strategy. In April 2003 we sold the manufacturing rights to SurgiFrost, a product we had developed for treatment of cardiac arrhythmia, to CryoCath. Part of this transaction included licensing our technology and intellectual property rights related to cryosurgical applications in the cardiology market. As part of this transaction, we sold all inventory and fixed assets related to the SurgiFrost line. In addition, we made the decision in early 2003 to discontinue development and clinical testing of our Horizon Prostatic Stent, designed for treatment of BPH also known as prostate enlargement.

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Erectile Dysfunction Products

In the first quarter of 2002, we added to our urology product portfolio through the purchase of Timm Medical. Among products acquired in the Timm Medical transaction was a line of vacuum therapy systems, including the ErecAid Esteem and ErecAid Classic systems, for the non-pharmacological treatment of erectile dysfunction. These devices hold a dominant market position among products using vacuum technology in treating this condition. Our goal for this product line is to maintain our dominant market position and to identify opportunities to leverage sales of our vacuum pump devices through our cryosurgery customer base.

Regardless of the treatment method, temporary or long-term impotence frequently occurs following treatment for prostate cancer. Accordingly, there is an obvious link between sales of our cryosurgical products and sales of our erectile dysfunction products. In addition, we are currently investigating the potential therapeutic benefits of our ErecAid products in restoring potency following treatment for prostate disease, including prostate cancer. We are currently planning to undertake clinical studies designed to establish whether a connection exists between use of our vacuum technology following treatment for prostate cancer and faster or more frequent restoration of potency. Depending on the outcome of these studies, we may have an even greater opportunity to channel sales of ErecAid devices through our existing cryosurgical customer base. Another product acquired in the Timm Medical transaction is the RigiScan Monitor, a device used in the diagnosis of erectile dysfunction. This product continues to be marketed to physicians, clinics and hospitals.

Also purchased with Timm Medical were the Dura II™ positionable penile prosthesis (implant) for treatment of erectile dysfunction, the ProDynamic™Monitor, the UroBreeze ™ Urodynamics Monitor and the EasyFlo™ Urometry System for diagnosis and treatment of urinary incontinence in both men and women. Consistent with our emphasis on developing the market for our ErecAid products and exploiting available synergies with our cryosurgical products, we made the decision to divest certain of these other product lines acquired from Timm. In April of 2003, we sold the intangibles and inventory associated with the Dura II™ to American Medical Systems, Inc. and in October 2003 we sold the intangibles and inventory related to the line of urinary incontinence and urodynamics products to SRS Medical Corp. See the discussion of strategic divestitures above under Recent Developments.

Strategic Alliances and other Arrangements

We have used and will continue to use marketing collaborations, distribution alliances and licensing arrangements to exploit the market for our Cryocare Surgical System in areas outside our sales and marketing focus of urology and radiology, as well as to expand our distribution channels within our target markets.

Arrangement with U.S. Medical Development, Inc. and its Affiliates

On June 30, 2001, we issued 213,010 shares of our common stock with a fair market 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, Inc. and approximately 5% of the Class A Units on a fully-diluted basis. U.S. Medical Development, Inc. is a national urology group representing more than 150 urologists across the nation. We simultaneously entered into a distribution agreement with U.S.M.D., Ltd., formerly U.S. Medical Devices, Ltd., a subsidiary of U.S. Medical Development, Inc., under which U.S.M.D., Ltd. received exclusive sales rights to our Cryocare Surgical System and associated disposable products in 16 states. U.S.M.D., Ltd. also had 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.

In September 2002, we terminated our distribution agreement with U.S.M.D., Ltd. and acquired the mobile prostate treatment businesses owned by U.S. Medical Development, Inc., and its affiliates, U.S.M.D., Ltd. and U.S.M.D. I, L.L.C., collectively referred to as USMD. The transaction allowed us to sell directly to the large base of USMD customers via an experienced sales force with established physician relationships. We purchased the mobile prostate treatment businesses in exchange for a total consideration of approximately

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$11.2 million in the form of cash, assumption of debt and forgiveness of debt. The debt forgiveness component of the purchase consideration is structured in the form of an earn-out. According to the terms of the Purchase Agreement executed in August and September 2002, the balance of $7.7 million owed to us by USMD at the purchase date was to be forgiven, pro-rata, upon the achievement of $12 million in gross revenues by the businesses purchased from USMD during the period between October 1, 2002 and December 31, 2005. The earn-out provision of the 2002 Purchase Agreement has now been restructured. In February 2004 we and USMD executed an amendment to the 2002 Purchase Agreement which provides that we will extend the forgiveness period for the unearned balance of $7.7 million until December 31, 2008.

Distribution Arrangement with Sanarus Medical, Inc.

In October 1999, we entered into a strategic alliance with Sanarus Medical, Inc., a privately held medical device company, to commercialize our proprietary cryosurgical technology in the treatment of breast cancer, benign breast tumors and gynecological diseases. The terms of the related agreements included an equity investment by us in Sanarus totaling $300,000, which represented 6.8% of all outstanding voting securities on the investment date. We also received a warrant to acquire at that time approximately 52.0% of Sanarus voting stock on an as-converted, fully-diluted basis, in consideration for entering into a manufacturing, supply and license agreement. In June 2001, we provided a bridge loan to Sanarus in the principal amount of $250,000, which accrued interest at the rate of 8% per annum, compounded annually. This amount was subsequently repaid in July 2001 upon Sanarus receipt of additional equity financing. This financing along with other financings by Sanarus reduced our ownership percentage to approximately 1.8% of Sanarus voting stock on an as-converted basis and reduced our maximum potential ownership percentage in Sanarus to approximately 20% on an as-converted, fully-diluted basis. In April 2003, we and other investors entered into a bridge loan financing with Sanarus in which Sanarus issued to us a convertible promissory note in the aggregate amount of $600,000 and a related stock purchase warrant with an aggregate exercise price of up to $300,000. In October 2003, we and other investors participated in an equity financing with Sanarus in which Sanarus issued to us shares of preferred stock in exchange for our cancellation of the indebtedness evidenced by our convertible promissory note. This financing along with other financings by Sanarus increased our percentage ownership to approximately 2.7% of Sanarus voting stock on an as-converted basis and reduced our maximum potential ownership percentage in Sanarus to approximately 7.9% on an as-converted, fully-diluted basis.

Licensing Arrangement with CryoCath

In September 2001, we entered into an exclusive market access and supply agreement with CryoCath, a publicly traded company listed on the Toronto Stock Exchange focused on developing minimally invasive, catheter-based, cryotherapy products to treat cardiovascular disease. Under this agreement, CryoCath obtained an exclusive, worldwide right to market, sell and distribute our cryosurgical technologies for the targeted treatment of cardiac arrhythmias. The agreement required CryoCath to pay license fees and to make minimum product purchases. We were obligated under the agreement to undertake product development projects, maintain regulatory approval for the products in the United States and Europe and indemnify CryoCath in the event of some third-party claims. We had the right to reduce CryoCath s rights to a non-exclusive license if CryoCath failed to meet certain minimum purchase requirements. In February 2002, we received FDA clearance for use of our cryosurgical technologies for the treatment of cardiac arrhythmias. CryoCath marketed the system as the SurgiFrost system.

On April 14, 2003, we sold our cardiac-related product manufacturing operations and licensed the related intellectual property to CryoCath. In connection with this sale and license, we terminated our exclusive market access and supply agreement with CryoCath. Under the terms of the sale and license agreement, we transferred all of our manufacturing assets and inventory related to the cardiac product line to CryoCath and will exclusively license to CryoCath for cardiovascular uses our proprietary technology associated with the SurgiFrost system a cryoablation system designed to treat cardiac arrhythmias. Terms of the agreement also include the payment by CryoCath to us of $10 million during 2003. The agreement also calls for the

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payment by CryoCath to us of a nine-year descending royalty stream based on net sales of products incorporating the licensed technology. We believe CryoCath s leadership position in the field of cardiovascular cryotherapy puts them in a strong position to exploit the opportunities for our technology in this highly competitive arena.

Products

We currently market the following products:

Product Name	Function
Prostate Cancer	
Cryocare Surgical System 8 Probe System	Cryosurgical system with eight cryoprobe capability
Cryocare CS System	Cryosurgical system with onboard ultrasound
CryoGuide	Computerized cryoprobe placement, simulation and guidance system for cryosurgery
Cryoprobes	Disposable probes used with the Cryocare Surgical System
FastTrac	Percutaneous access device that allows one step insertion of cryoprobes
Additional Cryosurgical Markets	
Cryocare 4 Probe System	Cryosurgical system with 4 probe capability for general surgery
Erectile Dysfunction	
RigiScan Monitor	Diagnostic tool for erectile dysfunction
ErecAid Esteem System	Vacuum therapy system
ErecAid Classic System	Vacuum therapy system

Raw Materials

We rely on third-party suppliers to provide certain critical components for all of our product lines. In a number of cases, these suppliers are our sole source of supply for these components. Our policy is to enter into long-term supply agreements that require suppliers to maintain adequate inventory levels and that contain other terms and conditions protecting us against unforeseen interruptions in their production. In addition, we maintain buffer stock at our own locations to ensure an uninterrupted source of supply. Wherever possible, we actively seek to establish secondary sources of supply or other manufacturing alternatives. Nevertheless, despite these efforts, it is possible that we may experience an interruption in supply of one or more of our critical components resulting in backorders to our customers. If such a supply interruption proves lengthy or should no manufacturing alternative be quickly identified, we could experience a significant reduction in revenues, net income and cash flows.

Patents and Intellectual Property

As of the end of December 2003, we have rights to 33 issued U.S. patents relating to cryosurgical ablative technology. Included within these 33 issued U.S. patents are 5 patents in which we have licensed-in rights. The remainder of the patents is assigned to us. Most of these patents relate to our cryoprobe technology for creating the freeze zone and precisely controlling the shape of the freeze zone produced by the cryoprobes. Additionally, our patents relate to our computer guided system for assisting surgeons in properly placing cryoprobes in a patient, a computer controlled cryosurgery apparatus and method, a cryosurgical integrated control and monitoring system and urethral warming technology. We also have 13 pending U.S. patent applications relative to cryosurgical ablative technology. Additionally, we have 25 foreign patents and pending foreign patent applications in this technology area. The earliest of our patents do not expire until 2011. Most of the earliest patents in our core technology area do not expire until about 2016.

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We have rights to 15 issued U.S. patents relating to our stent product line. Included within these 15 patents are 3 licensed-in patents. The remainder is assigned to us. We also have 2 pending U.S. patent applications relative to the stent product line. Additionally, we have rights to 7 foreign patents and pending foreign patent applications in this technology area. The earliest of our stent patents do not expire until about 2016.

We own 22 issued U.S. patents relating to our erectile dysfunction product line. We also have 1 pending U.S. patent application relative to this product line. Additionally, we have 14 foreign patents and pending foreign patent applications in this technology area. Some of these patents will expire within the next few years.

Our policy is to secure and protect intellectual property rights relating to our technology through patenting inventions and licensing others when necessary. While we believe that the protection of patents and licenses is important to our business, we also rely on trade secrets, know-how and continuing technological innovation to maintain our competitive position. Given our technology and patent portfolio, we do not consider the operation of our business to be materially dependent upon any one patent, group of patents or single technological innovation.

Our policy is to sell our products under trademarks and to secure trademark protection in the United States and worldwide where possible. We believe the protection of our trademarks is important to our business.

No assurance can be given that our processes or products will not infringe patents or other intellectual property rights of others or that any license required would be made available under any such patents or intellectual property rights, on terms acceptable to us or at all. From time to time, we have received correspondence alleging infringement of intellectual property 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 we could be prevented from practicing the subject matter claimed or could be required to obtain licenses from the owners of any such intellectual property rights to avoid infringement.

In December 2000, we settled a patent lawsuit against Cryomedical Sciences, Inc., now known as BioLife Solutions, Inc., or BioLife, and in March 2001 we settled two patent lawsuits against Israel-based Galil Medical, Ltd. and its U.S. affiliate, Galil Medical (USA), Inc. The lawsuits against BioLife and Galil concerned the infringement of our patent for an integrated cryosurgical system. The settlements resulted in cross-licensing agreements between Galil and us and BioLife and us.

We seek to preserve the confidentiality of our technology by entering into confidentiality agreements with our employees, consultants, customers and key vendors and by other means. No assurance can be given, however, that these measures will prevent the unauthorized disclosure or use of such technology.

Research Strategy

Our research goal is to develop innovative cryoablation technology, which dramatically improves patient outcomes. Our primary focus is on developing devices for the treatment of prostate, kidney, lung, liver and bone tumors. To that end, we plan to develop innovations, which improve the speed and efficacy of our Cryocare Surgical System.

We spent approximately $2.5 million, $2.9 million and $1.3 million for the years ended 2001, 2002 and 2003 respectively, on research and development activities.

Sales

We sell our products primarily to physicians and hospitals and have both domestic and international customers. In April 2003, we sold our cardiac-related product manufacturing operations and the licensed the related intellectual property to CryoCath. In connection with this sale and license, we terminated the original supply arrangement with CryoCath. None of our customers accounted for in excess of 10% of our net revenues

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in 2003. The following products and services account for 15% or more of total revenues for each of the years ended December 31:

	2001	2002	2003
Cryoablation and urological products:			
Cryocare Surgical Systems	56%	*	*
Cryoprobes, disposables and procedures	44%	41%	59%
Cardiac products (CryoCath)	*	*	*
Urological products (Timm Medical)	*	41%	36%

* These products account for less than 15% of total revenues.

We currently sell our cryosurgical products domestically through our direct sales force, which, as of December 31, 2003 consisted of 48 people, including 32 sales representatives and sales managers and 16 cryosurgical field technicians. Our strategy is to focus marketing and sales efforts and generating physician access to and awareness of the Cryocare Surgical System. We also intend to create patient demand by providing education regarding the benefits of cryosurgical therapy versus alternative treatment options and by further expanding our national advertising and other programs targeted directly at prostate disease patients.

In December 2002, we began to test market direct consumer response via 800 number call-in advertisements placed on televised segments of CNN Headline News. Based on initial call volume and consumer interest, we expanded direct-to-consumer advertising throughout 2003. Due to the continued success of this strategy, we plan to invest additional resources in 2004 in building this program.

Internationally, our cryosurgical products are sold primarily through independent distributors. Our international sales represented approximately 8%, 14.7% and 10.6% of our consolidated revenue in 2001, 2002 and 2003, respectively.

Our ErecAid products are sold through a dedicated sales force for our vacuum therapy line. We have one national sales manager in charge of this sales organization, which consisted of 15 sales representatives as of December 31, 2003. The devices are primarily sold by prescription directly to end users. We also distribute the product through durable medical equipment manufacturers, pharmacies, physician offices and through our contract with the Veterans Administration.

We derive our revenues from the following geographic regions for each of the years ended December 31 (in thousands):

	2001	2002	2003
		(In thousands)	
United States	$11,988	$26,369	$27,257
International:			
China	593	402	469
Canada		2,104	331
Other	456	2,041	2,440
Total international	1,049	4,547	3,240
Total revenues	$13,037	$30,916	$30,497

Reimbursement

We sell our Cryocare Surgical System and related disposable temperature probes 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 patients occasionally pay for cryosurgical procedures directly, virtually all patients depend upon third-party payors, including Medicare, Medicaid, Tricare and other federal health care programs, as well as private insurers to pay for their procedures.

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Accordingly, our revenue is dependent upon third-party reimbursement, particularly Medicare, since an estimated 70% of patients receiving cryosurgical treatments using our proprietary technology are Medicare beneficiaries.

Medicare reimbursement for cryosurgical procedures using our products as a primary treatment alternative for localized prostate cancer began in 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.

Outpatient reimbursement for cryosurgical procedures for Medicare beneficiaries is in accordance with the Hospital Outpatient Prospective Payment System, or HOPPS. Under HOPPS, the hospital is paid on a per procedure basis, based on the ambulatory payment classification, APC, for the procedure. The payment to the hospital 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 temperature probes and cryoprobes.

Medicare makes additional payments to hospitals under HOPPS when certain qualifying new medical devices are used to perform a procedure or service on a program beneficiary on an outpatient basis. These pass-through payments help to compensate hospitals for the additional costs of utilizing new technology in treating Medicare beneficiaries on an outpatient basis. Our temperature probes and cryoprobes were previously paid on a pass-through basis, but these payments ended on December 31, 2003.

Items qualifying for pass-through payment continue to be eligible for at least two, but not more than three, years. After the pass-through status of an item expires, the relevant APC groupings, weights and payments are updated to include costs associated with former pass-through items. Effective January 1, 2004, cryosurgery of the prostate is reimbursed under APC 674 as a single payment, including the cryoprobes and temperature probes previously reimbursed on a pass-through basis. This integrated payment for outpatient procedures for Medicare patients is a reduction of approximately 15 percent from previous HOPPS reimbursement rates to hospitals for prostate cryosurgery. Many hospitals, however, did not routinely or accurately bill Medicare for the disposables. In these cases, the effect of reduced reimbursement will not be as great. Nevertheless, we can provide no assurance that the new HOPPS payment levels will not adversely impact our revenues, net income and cash flows.

We are exploring percutaneous ablation of cancerous tissue in bone, kidney, lung and liver. Clinical studies are underway and as soon as studies are complete coverage decisions and unique reimbursement codes will be sought from Medicare and private payors.

Our ErecAid Esteem and ErecAid Classic Systems, which we sell through Timm Medical, are also reimbursed by Medicare and other federal health care programs, as well as private insurers. Timm Medical provides certain items to patients on a prescription basis and bills the patient or third-party payor directly, including Medicare and private insurers. Consequently, Timm Medical s business would be directly impacted by any changes in either coverage policies or reimbursement amounts adopted by Medicare or other third-party payors.

Approval of a new device or technology by the FDA does not guarantee payment by Medicare or other payors. Future devices and technology that we develop would have to be approved for coverage by Medicare after we obtain FDA approval or clearance. The Medicare approval process is lengthy and there is no assurance that Medicare approval would be granted. Each private insurer makes its own determination whether to cover a device or procedure and sets its own reimbursement rate.

Backlog

As of December 31, 2003, we had minimal backlog for either our cryosurgical products or our vacuum therapy products. Our policy is to carry enough inventory to be able to ship most orders within a few days of

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receipt of order. Historically, most of our orders have been for shipment within 30 days of the placement of the order. Therefore, we rely on orders placed during a given period for sales during that period. Backlog information as of the end of a particular period is not necessarily indicative of future levels of our revenue.

Government Contracts

Timm Medical has entered into a contract with the Department of Veterans Affairs Prosthetics and Sensory Aids Service pursuant to which Timm Medical became the national mandatory source for vacuum erection devices for the Veterans Affairs network of hospitals and clinics through March 31, 2005. In 2003, Timm Medical recognized approximately $1.4 million in revenues under this contract. The Department of Veterans Affairs can terminate this contract on 30 days notice.

Manufacturing

We manufacture our Cryocare Surgical System and related disposables internally at our facilities in Irvine, California. We moved our executive offices and transferred our manufacturing activities to our existing facility in Irvine, California in April 2002. The new facility has been inspected by the California Department of Health Services and has been issued a Device Manufacturing License.

Our current manufacturing facility was subjected to Quality System Regulation compliance inspections by the FDA in September 2002 and again in February and March 2003. Both audits have been successfully closed by the FDA. We have received ISO 9001, ISO 13485, and CE Marking certifications, indicating compliance with European standards for quality assurance and manufacturing process control.

The erectile dysfunction products we acquired through our acquisition of Timm Medical are assembled, packaged and shipped in our Minneapolis facility. Injection molding of the devices as well as manufacturing of certain other components is outsourced to third-party suppliers.

Government Regulation

Governmental regulation in the United States and other countries is a significant factor affecting the research and development, manufacture and marketing of medical devices, including our products. In the United States, the FDA has broad authority under the federal Food, Drug and Cosmetic Act, the FDC Act, to regulate the distribution, manufacture, marketing and sale of medical devices. Foreign sales of medical devices are subject to foreign governmental regulation and restrictions that vary from country to country.

We are also required to register as a medical device manufacturer with state agencies, such as the State of California Department of Health Services, or CDHS. As such, we will be inspected by such regulatory agencies and authorities for compliance with applicable regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner.

Noncompliance with applicable requirements can result in, among other things, warning letters, proceedings to detain imported products, fines, injunctions, civil and criminal penalties against us, our officers and our employees, recall or seizure of products, total or partial suspension of production, refusal of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals and a recommendation by the FDA that we not be permitted to enter into government contracts.

Medical devices intended for human use in the United States are classified into one of three categories, depending upon the degree of regulatory control to which they will be subject. Such devices are classified by regulation into either Class I general controls, Class II special standards or Class III pre-market approval depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device.

Most Class I devices are exempt from premarket notification or approval. Class II devices are subject to the premarket notification requirements under Section 510(k) of the FDC Act. For a 510(k) to be cleared by the FDA, the manufacturer must demonstrate to the FDA that a device is substantially equivalent to another legally marketed device that was either cleared through the 510(k) process or on the market prior to 1976. It

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generally takes four to twelve months from the date of submission to obtain 510(k) clearance although it may take longer, in particular if clinical trials are required. Class III devices generally include the most risky devices as well as devices that are not substantially equivalent to other legally marketed devices. To obtain approval to market a Class III device, a manufacturer must obtain FDA approval of a premarket approval application, or PMA. The PMA process requires more data, takes longer and is more expensive than the 510(k) procedure.

Our Cryocare Surgical System, RigiScan and ErecAid products have been cleared for marketing through the 510(k) process.

We can provide no assurance that we will be able to obtain clearances or approvals for clinical testing or for manufacturing and sales of our existing products for all applications in all targeted markets, or that we will be able to obtain clearances or approvals needed to introduce new products and technologies. After a device is placed on the market, numerous regulatory requirements apply. These include:

quality system regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; and

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

fines, injunctions, and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or premarket approval of new products;

withdrawing 510(k) clearance or premarket approvals that are already granted; and

criminal prosecution.

Medical device laws are also in effect in many of the countries outside of the United States in which we do business. These laws range from comprehensive device approval and quality system requirements for some or all of our medical device products to simple requests for product data or certifications. The number and scope of these requirements are increasing. In June 1998, the European Union Medical Device Directive became effective, and all medical devices must meet the Medical Device Directive standards and receive CE mark certification. CE mark certification involves a comprehensive Quality System program, and submission of data on a product to the Notified Body in Europe.

We have obtained CE Mark for distribution of our Cryocare Surgical System and our Horizon Prostatic Stent in Europe and product registration for distribution of our Cryocare Surgical System in Canada, Australia and New Zealand. The ErecAid and RigiScan are both CE Marked for distribution in Europe and registered for distribution in Canada and Australia. In addition, RigiScan is sold in Asia.

Health Care Regulatory Issues

The health care industry is highly regulated and the regulatory environment in which we operate may change significantly in the future. In general, regulation of health care-related companies is increasing. We anticipate that Congress and state legislatures will continue to review and assess alternative health care delivery and payment systems. We cannot predict what impact the adoption of any federal or state health care reform measures may have on our business.

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We regularly monitor developments in statutes and regulations relating to our business. We may be required to modify our agreements, operations, marketing and expansion strategies from time to time in response to changes in the statutory and regulatory environment. We plan to structure all of our agreements, operations, marketing and strategies in accordance with applicable law, although we can provide no assurance that our arrangements will not be challenged successfully or that required changes may not have a material adverse effect on our business, financial condition, results of operations and cash flows.

The following discussion briefly summarizes some, but not all, of the current regulatory schemes that could be applicable to our business. Complying with these regulatory schemes may involve expense to us, delay in our operations, and/or restructuring of our business relationships. Violations could potentially result in the imposition upon us of civil and/or criminal penalties.

Anti-Kickback Laws

The federal health care program anti-kickback law prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or in order to induce, (i) the referral of a person for services, (ii) the furnishing or arranging for the furnishing of items or services or (iii) the purchase, lease, or order or arranging or recommending purchasing, leasing or ordering any item or service, in each case, reimbursable under any federal health care program. Because our products are reimbursable under Medicare, Medicaid and other federal health care programs, the anti-kickback law applies. Many states have similar anti-kickback laws, and in many cases these laws apply to all patients, not just federal health care program beneficiaries. Noncompliance with, or violation of, the federal anti-kickback law can result in exclusion from federal health care programs and civil and criminal penalties. Similar penalties are provided for violation of state anti-kickback laws. Several federal courts have held that the anti-kickback law is violated if just one purpose of payment is to induce the referral of patients. To the extent that we are deemed to be subject to these federal or similar state laws, we believe that our activities and contemplated activities will comply in all material respects with such statutes and regulations.

Regulations to the federal anti-kickback law specify payment practices that will not be subject to prosecution under the anti-kickback law. These are known as the safe-harbors. Failure to comply fully with a safe-harbor does not mean the practice is per se illegal. Rather, if a practice does not fit within a safe harbor, no guarantee can be given that the practice will be exempt from prosecution; it will be viewed under the totality of the facts and circumstances.

We believe that our current structure and business and our contemplated future operations comply and will comply with the federal anti-kickback law. It does not appear, however, that certain of our business practices fit or will fit within a safe harbor and there is no assurance that if viewed under the totality of the facts and circumstances, our structure and business would not be challenged, perhaps even successfully, as a violation of the anti-kickback law. Mere challenge, even if we ultimately prevail, could have a substantial adverse effect on us.

Patient Referral Laws

The Stark law prohibits a physician from referring a Medicare patient for a designated health service to an entity with which the physician has a direct or indirect financial relationship, whether in the nature of an ownership interest or a compensation arrangement, subject only to limited exceptions. The Stark law also prohibits the recipient of a prohibited referral from billing for the designated health services provided pursuant thereto. Designated Health Services include inpatient and outpatient hospital services, durable medical equipment and prosthetic devices. The entity that bills Medicare for the designated health service is considered to be the provider of the designated health service for Stark law purposes. Therefore, we are not (except with respect to certain Timm Medical products) providers of designated health services, nor are the physician-owned entities that purchase or lease our equipment. Rather the hospitals where the procedures are performed are the providers of designated health services, because they bill Medicare for the procedures, and inpatient and outpatient hospital services are designated health services. Physicians who have an ownership or compensation relationship with the entities (such as mobile vendors) that furnish our equipment to hospitals,

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and the hospitals that obtain equipment and services directly or indirectly from such entities, are considered to have an indirect compensation relationship, and are thus subject to the Stark law prohibitions.

We believe that the arrangements we have established with physician-owned entities and hospitals comply with applicable Stark law exceptions. However, if any of the relationships between physicians and hospitals involving our services, or, in the case of Timm Medical, any of our financial relationships with referring physicians, do not meet a Stark law exception, neither the hospital nor we would be able to bill for any procedure resulting from a referral that violated the Stark law. Although, in most cases we are not the direct provider and do not bill Medicare for the designated health services, any Stark law problem with our business arrangements with physicians and hospitals would adversely affect us as well as the referring physician and the hospital receiving the referral.

Many states also have patient referral laws, some of which are more restrictive than the Stark law and regulate referrals by all licensed health care practitioners for any health care service to an entity with which the licensee has a financial relationship unless an exception applies. Such laws in particular states may prohibit us from entering into relationships with physicians and physician-owned entities, which may limit business development.

We believe that our business practices comply with the Stark law and applicable state referral laws. No assurance can be made, however, that these practices would not be successfully challenged and penalties, such as civil money penalties and exclusion from Medicare and Medicaid, and or state penalties, imposed. And, again, mere challenge, even if we ultimately prevail, could have a substantial adverse effect on us.

HIPAA and Other Privacy Laws

As of April 14, 2003, the privacy regulations developed under the Health Insurance Portability and Accountability Act of 1996, referred to as HIPAA , took effect. The privacy regulations place limitations on the use and disclosure of identifiable patient information, including research data. We have adopted policies and procedures governing our status as a covered entity (in the case of Timm Medical) or as a business associate (in the case of certain other activities). We believe that we have implemented appropriate measures to ensure compliance with HIPAA. However there are many uncertainties remaining about how HIPAA applies to the medical device business, and no assurance can be made that HIPAA will not be interpreted in a manner that will hamper our ability to conduct medical research and detail medical information for other purposes as well.

Other United States Regulatory Requirements

In addition to the regulatory framework for product approvals, we are and may be subject to regulation under federal and state laws, including requirements regarding occupational health and safety, laboratory practices and the use, handling, and disposing of toxic or hazardous substances. We may also be subject to other present and future local, state, federal and foreign regulations.

Seasonality

We believe that holidays, major medical conventions and vacations taken by physicians, patients and patient families may have a seasonal impact on our sales of cryosurgical products since cryosurgical procedures can be scheduled in advance. We are continuing to monitor and assess the impact seasonality may have on demand for our products.

Competition

The medical device industry is subject to intense competition. Significant competitors in the area of prostate cancer therapies include ONCURA, Theragenics Corporation and North American Scientific, Inc. Significant competitors in the area of erectile dysfunction include American Medical Systems Holdings, Inc., Mentor Corporation, Augusta Medical Systems, LLC and Pfizer, Inc. In addition, other companies are

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developing urological products that could compete with our Cryocare Surgical System and other urological products. Many of these competitors have significantly greater financial and human resources than we do.

We believe the principal competitive factors in the cryoablation product market include:

the safety and efficacy of treatment alternatives;

acceptance of a procedure by physicians and patients;

technology leadership and superiority;

price;

availability of government or private insurance reimbursement; and

speed to market.

Employees

As of December 31, 2003, we had a total of 163 employees. Of these employees, 7 are engaged directly in research and development activities, 11 in regulatory affairs/quality assurance, 28 in manufacturing, 87 in sales, marketing and customer service (including 16 clinical technicians) and 30 in general and administrative positions. We expect to increase employment in sales and marketing to grow market share, measured in terms of procedures. In addition, we will build the infrastructure needed to support more robust internal controls and improved financial reporting processes and systems. We have never experienced a work stoppage, none of our employees are represented by a labor organization, and we consider our employee relations to be good.

Although we conduct most of our research and development using our own employees, we occasionally have funded and plan to continue to fund research using consultants. Consultants provide services under written agreements and typically are paid based on the amount of time spent on our matters. Under their consulting agreements, such consultants are required to disclose and assign to us any ideas, discoveries and inventions created or developed by them in the course of providing consulting services.

Available Information

Our website address is www.endocare.com. All filings we make with the SEC, including our annual report on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and any amendments thereto, are available at no charge through links displayed on our website as soon as reasonably practicable after they are filed or furnished to the SEC. Please note that we do not currently intend to amend prior filings based on the restatements to our historical financial statements. Detailed information regarding these restatements is disclosed in Notes 3 and 16 to our consolidated financial statements filed in our annual report on Form 10-K for the year ended December 31, 2002. The reference to our website address does not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

Risks Related to Our Business

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

Our success will depend on our ability to attract and retain key personnel.

In order to execute our business plan, we need to attract, retain and motivate a significant number of highly qualified managerial, technical, financial and sales personnel. If we fail to attract and retain skilled scientific and marketing personnel, our research and development and sales and marketing efforts will be hindered. Our future success depends to a significant degree upon the continued services of key management personnel, including Craig T. Davenport, our Chief Executive Officer, William J. Nydam, our President and

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Chief Operating Officer, and Katherine Greenberg, our Senior Vice President and Chief Financial Officer. None of our key management personnel is covered by an insurance policy of which we are the beneficiary.

Our management members have spent considerable time and effort dealing with internal and external investigations and re-auditing of financial statements.

In addition to the challenges of the SEC investigation, the DOJ investigation, a shareholder class-action and a derivative lawsuit and other legal proceedings described below, our new management members have spent considerable time and effort dealing with internal and external investigations involving our previous internal controls, accounting policies and procedures, disclosure controls and procedures and corporate governance policies and procedures. The significant time and effort spent has adversely affected our operations and may continue to do so in the future.

We face risks relating to our liquidity.

Over the past 16 months we have incurred significant costs related to, among other things, legal, accounting and other professional fees associated with our internal review of various accounting and other matters, the ongoing investigation of us by the SEC and DOJ, various shareholder class-action and derivative lawsuits and other legal proceedings described below. In addition we are making significant investments in the development and implementation of sound internal controls and corporate governance policies and procedures designed to enhance the accuracy, quality and consistency of our financial information and reporting. We will continue to incur significant related expenses in the future.

If we are not able to significantly grow market share, improve our gross margins and reduce our operating expenses, or if we become subject to significant judgments or settlements in connection with the legal proceedings described in Item 3 of this Annual Report on Form 10-K, we will require additional financing. Additional equity or debt financing may not be available on acceptable terms, or at all, in part because our common stock was delisted from The Nasdaq Stock Market. If we are unable to obtain additional capital, we may be required to reduce our sales and marketing activities, reduce the scope of or eliminate our research and development programs, relinquish rights to technologies that we might otherwise seek to develop or commercialize, or sell certain assets.

We recently made several significant payments that have reduced our cash reserves. On March 8, 2004, we paid to our former Chief Executive Officer an aggregate of $750,000, which we owed to him under a separation agreement and consulting agreement that we previously executed. Also on March 8, 2004, we paid to our former Chief Financial Officer an aggregate of $616,000, which we owed to him under an employment agreement we previously executed. At the request of the SEC, these payments were deposited into escrow accounts during the fourth quarter of 2003 and released upon termination of the related escrow agreements. Additionally, on February 20, 2004, we paid approximately $1.5 million in directors and officers liability insurance premiums. Furthermore, as described below in Item 3 of this Annual Report on Form 10-K, in February 2004 we paid approximately $1.9 million to BioLife to settle litigation.

If we fail to adequately address our liquidity concerns, then our independent auditors may issue a qualified opinion, to the effect that there is substantial doubt about our ability to continue as a going concern. A qualified opinion could itself have a material adverse effect on our business, financial condition, results of operations and cash flows.

For a further description of the nature of the risks relating to our liquidity see, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources.

We have limited operating experience and a history of net losses, and we may never reach or maintain profitability.

We have limited experience in manufacturing, marketing and selling our Cryocare Surgical System in commercial quantities. In addition, during 2002, we completed our acquisitions of Timm Medical, the

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cryosurgical assets of BioLife, and our acquisition of the mobile prostate treatment businesses owned by USMD. As a result, we have a short history in marketing and selling the products we acquired or have rights to commercialize through these acquisitions or to market our products on the scale required by these acquisitions. In addition, we have limited experience in managing the complex demands of a business with multiple entities and locations, a large workforce and diverse information technology systems.

We have incurred annual operating losses each year since our inception. For the fiscal years ended December 31, 2001, 2002 and 2003, we had losses from operations of approximately $11.4 million, $42.5 million and $34.0 million, respectively. As of December 31, 2003, our accumulated deficit was approximately $114.4 million. It is possible that we will not generate sufficient revenues from product sales and service revenues to achieve or sustain profitability. Even if we do achieve significant revenues from our product sales and service revenues, we expect that increased operating expenses will result in significant operating losses over the next several quarters, as we, among other things:

expand our infrastructure to support more robust internal controls, including policies and procedures related to our accounting practices, disclosure controls and corporate governance;

incur costs related to legal proceedings, including ongoing government investigations;

expand our sales and marketing activities as we attempt to gain market share for our Cryocare Surgical System; and

continue our research and development efforts to improve our existing products and develop new products.

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

If we require future capital, we may not be able to secure additional funding in order to expand our operations and develop new products.

If we fail to achieve and maintain profitability and positive cash flow, or if we undertake or accelerate significant research and development projects for new products or pursue corporate acquisitions, we may need additional outside financing. We may raise these additional funds by selling one or more lines of business or products, selling our equity securities, incurring debt or entering into collaborative arrangements. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may involve interest expense and restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish rights to some of our technologies, products or marketing territories. Our failure to raise capital when needed could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We cannot assure you that we will not discover additional instances of historical breakdowns in controls, policies and procedures affecting our previously issued financial statements.

We have made significant changes in our internal controls, accounting policies and procedures, disclosure controls and procedures and corporate governance policies and procedures. While we believe that our newly implemented controls, policies and procedures will help to prevent the occurrence of financial reporting problems in the future, it is possible that we may discover additional instances of historical breakdowns in our internal controls, policies and procedures of the types that led to restatements of our financial statements for the years 2000 and 2001 and for the first two quarters of 2002. In the event such breakdowns are discovered they could impact both historical financial statements and future reported results.

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We face risks related to investigations by the SEC and DOJ and related to other legal proceedings.

The SEC and the DOJ are conducting investigations into allegations that we and certain of our current and former officers and directors issued or caused to be issued false and misleading statements regarding our revenues and expenses in press releases and SEC filings. Although we have fully cooperated with these governmental agencies in these matters and intend to continue to fully cooperate, these agencies may determine we have violated federal securities laws. We cannot predict when these investigations will be completed or their outcomes. If it is determined that we have violated federal securities laws or other laws or regulations, we may face sanctions, including, but not limited to, significant monetary penalties and injunctive relief.

In addition, we and certain former officers and certain current and former board members have been named defendants in a class action and a derivative lawsuit. The findings and outcome of the investigations described above may affect the class action and the derivative lawsuit that are pending. We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in some of these lawsuits. We are unable to estimate what our liability in these matters may be, and we may be required to pay judgments or settlements and incur expenses in aggregate amounts that could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We have $20 million of directors and officers liability insurance coverage. The coverage is provided in four $5 million policies issued by a primary insurance carrier and three excess insurance carriers. For claims asserted during the period from June 10, 2002 through June 10, 2003, one of the excess carriers has reserved the rights to disclaim coverage and to rescind the policy if it is determined that, at the time they signed the policy application, our former management was aware of facts that might have resulted in future claims under the policy. The other two excess carriers have declined coverage on the same ground. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our investors, customers, vendors and suppliers may react adversely to the restatement of our historical financial statements and our inability to timely file all of our SEC filings.

Our future success depends in large part on the support of our investors, customers, vendors, and suppliers. The restatement of our historical financial statements and our inability to timely file all of our SEC filings has resulted in negative publicity about us and has, and may continue to have, a negative impact on the market price of our common stock. The restatement of our historical financial statements and our inability to timely file all of our SEC filings also could cause some of our customers or potential customers to refrain from purchasing or to defer or cancel purchases of our products. Additionally, our current and potential vendors and suppliers may re-examine their willingness to do business with us, to develop critical interfaces for us or to supply products and services if they lose confidence in our ability to fulfill our commitments.

Our common stock was delisted from the Nasdaq Stock Market and, as a result, trading of our common stock has become more difficult.

Our common stock was delisted from The Nasdaq Stock Market on January 16, 2003. One result of this action is a limited public market for our common stock. Trading is now conducted in the over-the-counter market in the so-called Pink Sheets. Consequently, selling our common stock is more difficult because smaller quantities of shares can be bought and sold, transactions can be delayed and security analyst and news media coverage of us may be reduced. These factors could result in lower prices and larger spreads in the bid and ask prices for shares of our common stock as well as lower trading volume. Although we will seek to have our common stock relisted on The Nasdaq Stock Market once we are in full compliance with our obligations as a reporting company, we can provide no assurance that we will be relisted.

As a result of the delisting of our common stock from The Nasdaq Stock Market, our common stock has become subject to the penny stock regulations, including Rule 15g-9 under the Securities Exchange Act of 1934. That rule imposes additional sales practice requirements on broker-dealers that sell low-priced securities

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to persons other than established customers and institutional accredited investors. For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser s written consent to the transaction prior to sale. Consequently, the rule may affect the ability of broker-dealers to sell our common stock and affect the ability of holders to sell their shares of our common stock in the secondary market. To the extent our common stock remains subject to the penny stock regulations, the market liquidity for the shares will be adversely affected.

We expect to derive a significant portion of our future revenues from our cryosurgical products, which could fail to achieve market acceptance or generate significant revenue.

We introduced our Cryocare Surgical System to the market in July 1999. We derived a significant portion of our revenues in 2001, and 2002 from sales of Cryocare Surgical Systems and related disposable cryoprobes and temperature probes, as well as from per-procedure fees. In 2003, we shifted our business model to focus on sales of procedures and disposable devices rather than on sales of Cryocare Surgical Systems. We expect sales of cryosurgical products and the related procedure fees will constitute a significant portion of our revenues for the foreseeable future, although we expect revenue from system sales to fluctuate from quarter to quarter and decrease, over time, as a percentage of our revenue.

Our success is reliant on the acceptance by doctors and patients of the Cryocare Surgical System as a preferred treatment for tumor ablation. Cryosurgery has existed for many years, but has not been widely accepted primarily due to concerns regarding safety and efficacy and widespread use of alternative therapies. Because the technology previously lacked precise monitoring capabilities, cryosurgical procedures performed in the 1970s resulted in high cancer recurrence and negative side effects, such as rectal fistulae and incontinence, and gave cryosurgical treatment negative publicity. To overcome these negative side effects, we have developed ultrasound guidance and temperature sensing to enable more precise monitoring in our Cryocare Surgical System. Nevertheless, we will need to overcome the earlier negative publicity associated with cryosurgery in order to obtain market acceptance for our products. In addition, use of our Cryocare Surgical System requires significant physician education and training. As a result, we may have difficulty obtaining recommendations and endorsements of physicians and patients for our Cryocare Surgical System. We may also have difficulty raising the brand awareness necessary to generate interest in our Cryocare Surgical System. Any adverse side effects, including impotence or incontinence, recurrence of cancer or future reported adverse events or other unfavorable publicity involving patient outcomes from the use of cryosurgery, whether from our products or the products of our competitors, could adversely affect acceptance of cryosurgery. In addition, emerging new technologies and procedures to treat cancer, prostate enlargement and other prostate disorders may negatively affect the market acceptance of cryosurgery. If our Cryocare Surgical System does not achieve broad market acceptance, we will likely remain unprofitable.

If we are unable to continue to develop and enhance our Cryocare Surgical System, our business will suffer.

Our growth depends in part on continued ability to successfully develop enhancements to our Cryocare Surgical System. We may experience difficulties that could delay or prevent the successful development and commercialization of these products. Our products in development may not prove safe and effective in clinical trials. Clinical trials may identify significant technical or other obstacles that must be overcome before obtaining necessary regulatory or reimbursement approvals. In addition, our competitors may succeed in developing commercially viable products that render our products obsolete or less attractive. Failure to successfully develop and commercialize new products and enhancements would likely have a significant negative effect on our financial prospects.

Our strategy of divesting non-core product lines may not be successful.

We are refocusing our business on the development of minimally invasive technologies for tissue and tumor ablation. As part of this strategy, we have begun divesting certain non-core product lines, as evidenced by our sale of our Dura II Penile Prosthesis product line, our sale of our urodynamics and urinary incontinence product lines and our licensing of our cardiac technology and sale of related assets. We can provide no

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assurance that our strategy of focusing on our core technologies for tumor ablation applications and our divestitures of non-core technologies and product lines will be successful.

There is uncertainty relating to third-party reimbursement, which is critical to market acceptance of our products.

Hospitals and other health care providers in the United States generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of medical procedures involving our products. While private health insurers in some areas of the United States provide reimbursement for procedures in which our products are used, we can provide no assurance that private insurance reimbursement will be adopted nationally or by additional insurers. Furthermore, those private insurance companies currently paying for procedures in which our products are used may terminate such coverage. If reimbursement levels from Medicare, Medicaid, other governmental health care programs or private insurers are not sufficient, physicians may choose not to recommend, and patients may not choose, procedures utilizing our products.

Previously, reimbursement under Medicare for our cryosurgical disposable products used in outpatient procedures was provided on a so-called pass-through basis. This enabled the hospital or other health care provider to obtain separate reimbursement for our disposable devices in addition to reimbursement for the procedure fee. Pass-through status was terminated on December 31, 2003. As a result, the cost of our disposable products now is incorporated into HOPPS and there will be no separate reimbursement for the disposables.

Given the end to pass-through status for our disposable cryoprobes and temperature probes, we expect total Medicare reimbursement for our products used in outpatient settings to decrease by approximately 15%. This may influence reimbursement rates for our products by private insurers as well. We can provide no assurance that this change in outpatient reimbursement rates will not affect our ability to negotiate favorable charges for our products to hospitals.

International market acceptance of our products may depend, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. Our failure to receive international reimbursement approvals may negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Furthermore, from time to time significant attention has been focused on reforming the health care system in the United States and other countries. Any changes in Medicare, Medicaid or third-party medical expense reimbursement, which may arise from health care reform, may have a material adverse effect on reimbursement for our products or procedures in which our products are used and may reduce the price we are able to charge for our products. In addition, changes to the health care system may also affect the commercial acceptance of products we are currently developing and products we may develop in the future. Potential approaches that have been considered include controls on health care spending and price controls. Several proposals have been made in the United States Congress and various state legislatures recently that, if adopted, would potentially reduce health care spending, which may result in a material adverse effect on our business, financial condition, results of operations and cash flows.

We have limited sales and marketing experience with our Cryocare Surgical System and any failure to significantly expand sales of this product will negatively impact future revenue.

We primarily handle the marketing, distribution and sales of our Cryocare Surgical Systems through our own work force. We have limited experience marketing and selling our Cryocare Surgical System in commercial quantities or on a nationwide basis. We will face significant challenges and risks in training, managing and retaining our sales and marketing teams, including managing geographically dispersed efforts and adequately training our people in the use and benefits of our Cryocare Surgical System. We may not be able to hire significant additional personnel or deploy sufficient other resources needed to create increased

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demand for our Cryocare Surgical System. In addition, we have distribution arrangements, some of which are exclusive, for the sale of our Cryocare Surgical System both domestically and internationally, and we are dependent upon the sales and marketing efforts of our third-party distributors. These distributors may not commit the necessary resources to effectively market and sell our Cryocare Surgical System. If we are unable to expand our sales and marketing capabilities or if our senior sales and marketing personnel are not retained, we may not be able to effectively commercialize our Cryocare Surgical System.

We recently acquired Timm Medical, the cryosurgical assets of BioLife and the mobile prostate treatment businesses of USMD and face risks associated with integrating these businesses into our existing business operations.

We continue to face numerous risks and expenses related to integration of the businesses we acquired from Timm Medical, BioLife and USMD. In addition, the acquired businesses have suffered because management s resources have been consumed by, among other things, the internal and external investigations involving various accounting and related matters as well as the work involved in re-auditing and restating our consolidated financial statements for the years ended December 31, 2000 and 2001 and for the first 2 quarters of 2002. The businesses acquired from Timm Medical have suffered because resources have been diverted in divesting certain non-core product lines and in downsizing our Eden Prairie operations. The businesses we acquired from USMD have suffered for many of the same reasons in addition to the fact that we recently assumed administrative responsibility for management of these complex businesses. If we do not successfully integrate and grow the acquired businesses, our business will suffer.

Introduction of alternative therapies may affect our revenues.

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

We could be difficult to acquire due to anti-takeover provisions in our charter, our stockholders rights plan and Delaware law.

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

If we fail to protect our intellectual property rights, our competitors may take advantage of our ideas and compete directly against us.

Our success will depend to a significant degree on our ability to secure and protect intellectual property rights and to enforce patent and trademark protections relating to our technology. From time to time, litigation may be advisable to protect our intellectual property position. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that we will not have sufficient resources to fully pursue this litigation or to protect our other intellectual property rights. It could result in the rejection or

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invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could have a material adverse effect on our business, financial condition, results of operations and cash flows. Also, even if we prevail in litigation, the litigation would be costly in terms of management distraction as well as in money. In addition, confidentiality agreements with our employees, consultants, customers, and key vendors may not prevent the unauthorized disclosure or use of our technology. It is possible that these agreements will be breached or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Enforcement of these agreements may be costly and time consuming. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

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

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

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

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

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

We have limited experience manufacturing our products and if we are unable to meet customer demand, we may not become profitable.

We use internal manufacturing capacity and expertise to manufacture our products. We have limited experience in producing our products in commercial quantities. We may encounter difficulties in scaling up production of new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel. Our failure to overcome these manufacturing problems could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our success will depend in part upon our ability to manufacture our products in compliance with the FDA s Quality System regulations and other regulatory requirements in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs.

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We are dependent upon a number of third-party suppliers to manufacture our products and the loss of any of these suppliers could harm our business.

We depend upon a number of unaffiliated third-party suppliers for components and materials used in the manufacture of our products and, as such, our business would be seriously harmed if we were unable to develop and maintain relationships with suppliers that allow us to obtain sufficient quantities and quality materials and components on acceptable terms. If our principal suppliers cease to supply the materials and components we need to manufacture our products, the qualification of additional or replacement suppliers could be a lengthy process and there may not be adequate alternatives to meet our needs, which will have a material adverse effect on our business, financial condition, results of operations and cash flows. We may not be able to obtain the necessary components and materials used in our products in the future on a timely basis, if at all.

If we fail to obtain or maintain necessary regulatory clearances or approvals for products, or if approvals are delayed or withdrawn, we will be unable to commercially distribute and market our products or any product modifications.

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

Regulatory approvals, if granted, may include significant limitations on the indicated uses for which our products may be marketed. In addition, to obtain such approvals, the FDA and foreign regulatory authorities may impose numerous other requirements on us. FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory standards or unforeseen problems following initial marketing. We may not be able to obtain or maintain regulatory approvals for our products on a timely basis, or at all, and delays in receipt of or failure to receive such approvals, the loss of previously obtained approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our products may be subject to product recalls even after receiving FDA clearance or approval, which would harm our reputation and our business.

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

We could be negatively impacted by future interpretation or implementation of the federal Stark law and other federal and state anti-referral laws.

The federal Stark law prohibits a physician from referring medical patients for certain services to an entity with which the physician has a financial relationship. A financial relationship includes both investment

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interests in an entity and compensation arrangements with an entity. Many states have similar and often broader laws prohibiting referrals by any licensed health care provider to entities with which they have a financial relationship. These state laws generally apply to services reimbursed by both governmental and private payors. Violation of these federal and state laws may result in prohibition of payment for services rendered, loss of licenses, fines, criminal penalties and exclusion from governmental and private payor programs, among other things. We have financial relationships with physicians and physician-owned entities, which in turn have financial relationships with hospitals and other providers of designated health services. 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. For a further description of the federal Stark law see above under Item 1 Health Care Regulatory Issues.

If we become subject to claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. We are also subject to various other claims as described below in Item 3 Legal Proceedings. While we believe that we are reasonably insured against these risks, we may not be able to maintain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, any product liability claim likely would harm our reputation in the industry and our business.

We have $20 million of directors and officers liability insurance coverage. The coverage is provided in four $5 million policies issued by a primary insurance carrier and three excess insurance carriers. For claims asserted during the period from June 10, 2002 through June 10, 2003, one of the excess carriers has reserved the rights to disclaim coverage and to rescind the policy if it is determined that, at the time they signed the policy application, our former management was aware of facts that might have resulted in future claims under the policy. The other two excess carriers have declined coverage on the same ground. A claim in excess of our insurance coverage would have to be paid out of cash reserves, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We are faced with intense competition and rapid technological and industry change, which may make it more difficult for us to achieve significant market penetration.

The medical device industry generally, and the urological disease treatment market in particular, are characterized by rapid technological change, changing customer needs, and frequent new product introductions. If our competitors existing products or new products are more effective than or considered superior to our products, the commercial opportunity for our products will be reduced or eliminated. We face intense competition from companies in the cryosurgical marketplace as well as companies offering other treatment options, including radical surgery, radiation therapy and hormone therapy. If we are successful in penetrating the market for treatment of prostate cancer with our cryosurgical treatment, other medical device companies may be attracted to the marketplace. Many of our potential competitors are significantly larger than we are and have greater financial, technical, research, marketing, sales, distribution and other resources than we do. We believe there will be intense price competition for products developed in our markets. Our competitors may develop or market technologies and products, including drug-based treatments, that are more effective or commercially attractive than any that we are developing or marketing. Our competitors may obtain regulatory approval, and introduce and commercialize products before we do. These developments could have a material

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adverse effect on our business, financial condition, results of operations and cash flows. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

Fluctuations in our future operating results may negatively impact the market price of our common stock.

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

impact of legal proceedings;

costs of expanding our infrastructure to support more robust internal controls, including more effective policies and procedures;

related to our accounting practices, disclosure controls and corporate governance;

market acceptance of our existing products, as well as products in development;

timing of payments received and the recognition of such payments as revenue under collaborative arrangements and strategic alliances;

ability to manufacture products efficiently;

timing of our research and development expenditures;

timing of customer orders;

changes in reimbursement rates for our products and procedures by Medicare and other third-party payors;

potential impact of acquisitions;

timing of regulatory approvals for new products;

outcomes of clinical studies by us or our competitors;

competition from other treatment modalities; and

physician and patient acceptance of cryosurgery.

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

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.

We may acquire one or more businesses or lines of business. 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 have limited experience 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 cash flow and operating results may suffer because of acquisition-related costs, amortization costs, restructuring or impairment of acquired goodwill and other intangible assets. There is also a risk of loss of key employees, customers and vendors of recently acquired businesses. Finally, in connection with any future acquisitions, we may incur debt or issue equity securities as part or all of the consideration for the acquired company s assets or capital stock. We may be unable to obtain sufficient additional acquisition financing on favorable terms or at all. In addition, any equity issuances may be dilutive to our existing

stockholders.

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Our stock price may be volatile and your investment could decline in value.

Our stock price has fluctuated significantly in the past and is likely to continue to fluctuate significantly, making it difficult to resell shares when investors want to at prices they find attractive. The market prices for securities of emerging companies have historically been highly volatile. Future events concerning us or our competitors could cause such volatility including:

actual or anticipated variations in our operating results;

developments regarding government and third-party reimbursement;

changes in government regulation of our products and business practices;

developments concerning government investigation of us;

developments concerning proprietary rights;

developments concerning litigation or public concern as to the safety of our products or our competitor s products;

technological innovations or introduction of new products by us or our competitors;

investor and analyst perception of us and our industry;

general economic and market conditions; and

physician and patient acceptance of cryosurgery.

In addition, the stock market is subject to price and volume fluctuations that affect the market prices for companies in general, and small-capitalization, high technology companies in particular, which are often unrelated to the operating performance of these companies.

Future sales of shares of our common stock may negatively affect our stock price.

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

Our intangible assets and goodwill could become impaired.

Intangible assets acquired in a purchase, such as intellectual property or developed technology, are generally amortized over various periods depending on their anticipated economic benefits or useful lives. Long-lived assets, including amortizable intangibles, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. Following a review, if such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying value of the assets exceeds the fair value of the assets.

We had no reported goodwill prior to January 1, 2002. With the adoption of Statement of Financial Accounting Standards No. 142 Goodwill and Intangible Assets, goodwill can no longer be amortized against earnings. Goodwill balances are subject to an impairment review on an annual basis or sooner if indicators of potential impairment exist. The test for impairment requires us to first compare the fair value of the net assets of each reporting unit to their carrying value, including goodwill. If the fair value of the reporting unit is less than the carrying value, goodwill of the reporting unit is potentially impaired and we next calculate the implied fair value of goodwill by deducting the fair value of all tangible and intangible net assets of the reporting unit from the fair value of the reporting unit. If the implied fair value of goodwill is less then the carrying amount of goodwill, an impairment loss is recognized equal to the difference. We completed our annual goodwill impairment test as of October 1, 2002 and 2003 for all of our reporting units. We utilized an independent

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third-party appraiser to assess the fair values of each reporting unit and compared the fair values of the reporting units to their carrying values. Based on our evaluation we recognized an impairment charge of $18 million in the fourth quarter of 2002 to reduce the carrying value of the goodwill acquired in the Timm Medical acquisition. We determined that a charge for goodwill impairment was not required in 2003. Significant estimates, including assumptions regarding future events and circumstances that cannot be easily predicted are required to perform an analysis of the value of goodwill. These estimates and assumptions may differ materially from actual outcomes and occurrences. Furthermore, no assurance can be given that we will not have further impairment charges related to Timm Medical or other acquisitions.

In the fourth quarter of 2002, we also recorded a $2.3 million other-than-temporary loss in the value of our investment in U.S. Medical Development, Inc. acquired in June 2001. The loss was based on our assessment that the investee is unable to sustain an earnings capacity sufficient to justify the carrying amount of the investment. We can give no assurance that we will not incur further impairment charges related to our goodwill or other intangible assets.

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

During 2001, 2002 and into 2003, the United States and other international markets experienced a significant economic downturn. In addition, the United States and other countries suffered significant acts of hostility, terror and war. Such acts may increase or prolong such negative economic conditions. The economic downturn may impact our ability to maintain or increase profitability by negatively affecting growth in demand for our products. There can be no certainty as to the degree or severity of the duration of this downturn. We also cannot predict the extent and timing of the impact of the economic downturn in the United States and in other countries and geographic regions in which we conduct our business.

Our facilities and systems are vulnerable to natural disasters or other catastrophic events.

Our headquarters, cryosurgical products manufacturing facilities, research facilities and much of our infrastructure, including computer servers, are located in California, an area that is susceptible to earthquakes and other natural disasters. Our erectile dysfunction products are assembled, packaged and shipped in our Minneapolis facility. A natural disaster or other catastrophic event, such as an earthquake, fire, flood, severe storm, break-in, terrorist attack or other comparable problems could cause interruptions or delays in our business and loss of data or render us unable to accept and fulfill customer orders in a timely manner, or at all. In addition, as our Minneapolis facility is located in an area that is susceptible to harsh weather, a major storm, heavy snowfall or other similar event could prevent us from delivering products in a timely manner. We have no formal disaster recovery plan and our business interruption insurance may not adequately compensate us for losses that may occur. In the event that an earthquake, natural disaster or other catastrophic event were to destroy any part of our facilities or interrupt our operations for any extended period of time, or if harsh weather conditions prevent us from delivering products in a timely manner, our business, financial condition and operating results would be seriously harmed.

Item 2. ***Properties***

In April 2002, we moved our executive offices, as well as our principal manufacturing and research facilities for our Cryocare Surgical System, to a 28,000 square foot facility in Irvine, California. The lease for this facility expires in 2007, with an option to extend the lease for an additional five years.

Through our acquisition of Timm Medical in February 2002, we obtained offices, manufacturing and research facilities for our erectile dysfunction products in a 28,066 square foot building in Eden Prairie, MN. During 2003, we divested several non-core product lines acquired when we purchased Timm Medical. In June 2003, we transferred certain manufacturing operations and administrative functions previously performed at this location to our Irvine, California manufacturing facility and outsourced certain other operations. At the end of 2003, we revisited the decision to outsource the assembly and packaging of our vacuum therapy line and returned theses operations to our Minnesota facility. The lease on the Eden Prairie

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facility expires in April 2004. As a result of the net downsizing of our Minnesota operations, we do not intend to renew this lease. Rather, we will continue to rent this space on a temporary basis until we complete negotiations on the lease of a smaller facility to handle all remaining Eden Prairie operations.

We believe that our property and equipment are generally well maintained, in good operating condition and are sufficient to meet our current needs.

Item 3. ***Legal Proceedings***

We are a party to lawsuits in the normal course of our business. Litigation and governmental investigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. We can provide no assurance that significant judgments or settlements in connection with the legal proceedings described below will not have a material adverse effect on our business, financial condition, results of operations and cash flows. See Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations. Other than as described below, we are not a party to any material legal proceedings.

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

On November 26, 2002, BioLife filed an action against us in the Delaware Court of Chancery seeking damages for alleged breaches of contract stemming from our acquisition, pursuant to an asset purchase agreement dated May 28, 2002, of the tangible and intangible assets related to BioLife s cryosurgical business. In the action, styled as BioLife Solutions, Inc. v. Endocare, Inc., Del. Ch., C.A. No. 20057-NC, BioLife alleged that we failed to timely register 120,022 shares of our common stock that were provided to BioLife in connection with the asset purchase agreement, in violation of a registration rights agreement relating to the shares that was executed in conjunction with the asset purchase agreement. BioLife sought damages of approximately $1.6 million. We defended the action on the grounds that our obligation to register the shares was excused for various reasons, including as a consequence of BioLife s failure to transfer assets in accordance with the asset purchase agreement. Trial on all but one of the claims in the action was held during the week of March 31, 2003. On October 1, 2003, the Delaware Court ruled in favor of BioLife, awarding BioLife $1,648,000, plus pre-judgment interest and costs (including legal fees), and requiring BioLife to surrender the 120,022 shares of our common stock to us. That ruling became an appealable final order and judgment on October 10, 2003. On February 20, 2004, we agreed with BioLife to settle all claims. As part of the settlement: we paid to BioLife $1,887,474, which represented a discount of $150,000 from the total judgment amount (including accrued interest and costs); BioLife returned to us the 120,022 shares of our common stock referred to above; and we agreed to abandon our appeal.

On December 6, 2002, Frederick Venables filed a purported derivative action against us and certain former officers and certain current and former board members in the California Superior Court for the County of Orange alleging breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. On April 17, 2003 the court issued an order staying the action until resolution of the anticipated motion to dismiss the consolidated complaint in the federal securities action pending in the Central District of California. Pursuant to this order, no deadline is currently set for our response to the complaint. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding our revenues and

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expenses in press releases and SEC filings. We intend to defend the case vigorously, but cannot assure you that it will be resolved in our favor.

On December 19, 2002, we filed a demand for arbitration before the American Arbitration Association in Minnesota against Joseph Hafermann, the former General Manager of our Minnesota subsidiary. Our complaint included various claims in response to which Mr. Hafermann made several counterclaims. On December 30, 2003, we agreed with Mr. Hafermann to a confidential settlement of all claims on mutually acceptable terms without the admission of liability by any party.

On March 17, 2003, we were notified by the United States Department of Labor that a letter of complaint had been presented against us; our former Chairman and Chief Executive Officer, Paul Mikus; and our former Chief Financial Officer, John Cracchiolo, by counsel for Mr. Hafermann. The letter from Mr. Hafermann s counsel alleged that we, Mr. Mikus and Mr. Cracchiolo had violated 18 U.S.C. §1514A by improperly retaliating against Mr. Hafermann. Pursuant to our settlement with Mr. Hafermann described above, Mr. Hafermann withdrew his letter of complaint, and the Department of Labor has indicated that it considers this matter closed.

The SEC is currently conducting an investigation to determine whether any federal securities laws were violated in connection with the filing of our financial statements for 2001 and the first two quarters of 2002, including investigation into allegations that we and certain of our current and former officers and directors issued or caused to be issued false and misleading statements regarding our revenues and expenses in those SEC filings. We are cooperating fully with this investigation. We cannot assure you that this matter will be resolved in our favor.

The DOJ is currently conducting an investigation into allegations that we and certain of our current and former officers and directors intentionally issued or caused to be issued false and misleading statements regarding our revenues and expenses in SEC filings. We are cooperating fully with this investigation. We cannot assure you that this matter will be resolved in our favor.

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

We held our Annual Meeting of Stockholders on Tuesday, December 30, 2003. Our stockholders adopted the following matters at the Annual Meeting by the votes indicated:

1. The stockholders elected the following seven 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
Peter F. Bernardoni	21,115,788	409,843
Robert F. Byrnes	21,117,988	407,643
Benjamin Gerson, M.D.	21,119,188	406,443
Ronald A. Matricaria	21,149,580	376,051
Terrence A. Noonan	21,146,080	379,551
Michael J. Strauss, M.D.	21,141,680	383,951
Thomas R. Testman	21,149,080	376,551

2. The stockholders approved an amendment and restatement of our 1995 Stock Plan to increase the maximum number of shares with respect to which options and stock purchase rights may be granted to any participant in the 1995 Stock Plan in any fiscal year from 100,000 to 1,500,000 shares:

	Number of Shares
For	8,066,347
Against	5,477,742
Abstain	65,593

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3. The stockholders ratified the selection of Ernst & Young LLP as our independent auditors for the fiscal year ended December 31, 2003:

	Number of Shares
For	21,404,646
Against	105,740
Abstain	15,245

PART II

Item 5. ***Market for Our Common Equity and Related Stockholder Matters***
Market Information

On January 16, 2003, our common stock was delisted from The Nasdaq Stock Market. The symbol under which we trade in the Pink Sheets is ENDO.PK. Accordingly, there is no established public trading market for our common stock. From January 1, 1999 to May 22, 2000, our common stock was traded on The Nasdaq SmallCap Market and from May 23, 2000 to December 12, 2002, our common stock was traded on The Nasdaq National Market. From December 12, 2002 through January 15, 2003, trading of our common stock was halted by The Nasdaq Stock Market.

The following table sets forth for the fiscal quarters indicated, the high and low sales prices for our common stock as quoted on The Nasdaq National Market, or the high and low bid prices as reflected in the Pink Sheets, as applicable. Such prices represent inter-dealer prices without retail mark up, mark down or commission and may not necessarily represent actual transactions.

	High	Low
Year Ended December 31, 2003		
First Quarter	$ 3.10	$ 0.35
Second Quarter	6.35	2.42
Third Quarter	5.70	3.50
Fourth Quarter	5.22	3.80
Year Ended December 31, 2002		
First Quarter	$20.00	$13.42
Second Quarter	21.05	11.30
Third Quarter	14.31	9.78
Fourth Quarter	14.29	2.58

Holders

As of March 1, 2004, there were 287 holders of record of our common stock. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the names of various dealers, clearing agencies, banks, brokers, and other fiduciaries.

Dividends

We have never paid any cash dividends on our capital stock. We anticipate that we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of the Board of Directors and will depend on existing conditions, including our financial condition, contractual restrictions, capital requirements and business prospects.

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Recent Sales of Unregistered Securities

Pursuant to a consulting agreement dated May 21, 2003, we issued to Peter Littrup, M.D., 5,000 shares of common stock for services rendered in connection with radiology training and product development. This issuance was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act in that the issuance did not involve a public offering.

In addition, in 2003 we issued an aggregate of 35,000 shares of common stock to four current and former employees and consultants upon their exercise of options. These issuances were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act in that these issuances did not involve a public offering.

Item 6. ***Selected Consolidated Financial Data***

The selected financial data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operation and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data as of and for the years ended December 31, 1999, 2000 and 2001, has been restated. Detailed information regarding these restatements is disclosed in Notes 3 and 16 to our consolidated financial statements filed in our annual report on Form 10-K for the year ended December 31, 2002. Our historical results are not necessarily indicative of operating results to be expected in the future.

	1999	2000	2001	2002	2003
	(In thousands, except per share data)				
Revenues:	$ 3,514	$ 6,568	$ 13,037	$ 30,916	$ 30,497
Costs and expenses:					
Cost of revenues	1,790	3,757	6,208	16,484	16,058
Research and development	2,618	2,371	2,544	2,900	1,257
Selling, general and administrative	9,231	13,436	15,728	33,770	47,189
Goodwill impairment and other charges				20,311	
Total costs and expenses	13,639	19,564	24,480	73,465	64,504
Loss from operations	(10,125)	(12,996)	(11,443)	(42,549)	(34,007)
Gain on divestitures, net					8,631
Loss on minority investment			(250)		
Interest income (expense), net	(541)	(832)	241	1,007	548
Loss before minority interests	(10,666)	(13,828)	(11,452)	(41,542)	(24,828)
Minority interests				(444)	(619)
Net loss	$(10,666)	$(13,828)	$(11,452)	$(41,986)	$(25,447)
Net loss per share of common stock basic and diluted	$ (0.98)	$ (1.08)	$ (0.68)	$ (1.76)	$ (1.05)
Weighted-average shares of common stock outstanding	10,838	12,757	16,741	23,822	24,162

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	1999	2000	2001	2002	2003
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	$ 7,365	$22,016	$81,887	$40,361	$23,977
Working capital	6,532	20,885	84,999	37,021	19,004
Total assets	13,394	29,183	95,094	92,628	71,997
Long-term obligations(1)	10,153	8,574			
Total stockholders equity (deficiency)	(48)	15,871	90,881	78,623	55,321

(1) Long-term obligations include convertible debentures, a note payable and other liabilities, net of current balances.

Item 7. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion should be read in conjunction with Item 1 Business, Item 6 Selected Consolidated Financial Data and Item 8 Financial Statements and Supplementary Data, as well as our consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based on our current expectations. There are various factors many beyond our control that could cause our actual results or the occurrence or timing of expected events to differ materially from those anticipated in these forward-looking statements. Some of these factors are described below and other factors are described elsewhere in this Annual Report on Form 10-K, including above under Risks Related to Our Business in Item 1 of this Annual Report on Form 10-K. In addition, there are factors not described in this Annual Report on Form 10-K that could cause our actual results or the occurrence or timing of expected events to differ materially from those anticipated in these forward-looking statements. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statements.

Overview

We are a medical device company focused on developing, manufacturing and selling cryosurgical products with the potential to improve the treatment of cancer and other tumors and on manufacturing and marketing vacuum technology as a non-pharmacological option for treatment of erectile dysfunction.

Our cryosurgical product, the Cryocare Surgical System, employs a computerized device and disposable probes to freeze cancerous tissue or other tumors through our proprietary argon gas-based technology. We recently introduced the next generation of our Cryocare Surgical System, the Cryocare CS. See above in Item 1 under Our Solution: The Cryocare Surgical Systems.

Our erectile dysfunction products include the ErecAid Esteem and the ErecAid Classic for treatment of impotence as well as the RigiScan for diagnostic evaluation of this condition.

Currently, our cryosurgical products are sold chiefly to hospitals for the treatment of prostate cancer. In addition, we are exploring the application of our cryosurgical technologies for ablation of other tumors, specifically in the treatment of tumors of the kidney, lung, liver and for pain management related to metastatic bone cancer. We sell our vacuum therapy products for treatment of erectile dysfunction primarily to individual patients on a prescription basis. Our RigiScan products are sold to physicians.

We have incurred significant operating losses and negative cash flows from operations in each full fiscal year since January 1, 1996. We incurred net losses of approximately $42.0 million in 2002 and $25.4 million in 2003. As of December 31, 2003, we had an accumulated deficit of $114.4 million. We expect to incur additional losses as we expand our sales and marketing efforts, strengthen our infrastructure, improve our financial reporting processes and controls and continue to develop new products.

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Results of Operations

The following table sets forth, for the periods indicated, financial data as a percentage of revenues.

	Year Ended December 31,		
	2001	2002	2003
Revenues	100%	100%	100%
Costs and expenses:			
Cost of revenues	48	53	53
Research and development	19	9	4
Selling, general and administrative	121	109	155
Goodwill impairment and other charges		66	
Total costs and expenses	188	237	212
Loss from operations	(88)	(137)	(112)
Loss on minority investment	(2)		
Interest income	6	3	3
Interest expense	(4)		
Gain on divestitures, net			28
Loss before minority interests	(88)	(134)	(81)
Minority interests		(2)	(2)
Net loss	(88)	(136)	(83)

Revenues and cost of revenues related to the following products and services for the three-year period ended December 31, 2003 are as follows (in thousands):

	2001	2002	2003
		(In thousands)	
Revenues:			
Cryocare Surgical Systems	$ 7,358	$ 3,422	$ 1,283
Cryoprobes, disposables and bundled procedure fees	5,679	12,601	17,930
Cardiac products (CryoCath)		2,104	331
Urological products (Timm Medical)		12,789	10,953
	$13,037	$30,916	$30,497
Cost of Revenues:			
Cryocare Surgical Systems	$ 2,200	$ 1,480	$ 466
Cryoprobes, disposables and bundled procedure fees	4,008	8,111	10,626
Cardiac products (CryoCath)		1,539	399
Urological products (Timm Medical)		5,354	4,567
	$ 6,208	$16,484	$16,058

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Revenues. We generate revenues from sales of our Cryocare Surgical Systems, disposable cryoprobes and other disposable devices used in cryoablation procedures. We also contract with hospitals and other health care payors for the use of our Cryocare Surgical Systems in cryoablation treatments for which we charge a per-procedure fee.

The procedure fee typically includes a procedure kit containing cryoprobes and other disposables needed to perform a cryosurgical procedure, in addition to a service component. The service component of the

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procedure fee generally consists of rental and transport of a Cryocare Surgical System as well as the services of a technician to assist the physician with the set-up, use and monitoring of the equipment. In certain instances, we will provide the service component of the procedure to the hospital as well as the devices. At other times, we will contract with third parties to perform the service component of the procedures and will remit a service fee to the third party upon invoicing the hospital. Approximately 38% of our prostate cancer cases were serviced by third-party service providers.

Prior to 2003, we concentrated heavily on selling the capital equipment component of our Cryocare Surgical System, often referred to as the box, primarily to distributors and service providers. These distributors and service providers were often entities in which our trained cryosurgeons had invested. Since hospitals were frequently reluctant to invest in capital equipment, trained cryosurgeons who desired to introduce our technology into a hospital often had to invest in the equipment themselves.

Due to the significant start-up costs involved in forming a new cryosurgical service provider, however, this strategy proved, in some cases, to be a barrier to the adoption of our technology. In addition to purchasing our Cryocare Surgical System, a service provider would require a van and an ultrasound monitor and would need to employ or contract with a clinical technician. Frequently, there were issues related to financing of the equipment and the creditworthiness of these new ventures.

In 2003, we shifted our emphasis for the urology market from equipment sales to procedure growth. Through our placement program, we provide equipment to hospitals with high-volume potential for cryosurgery procedures and charge them a per-procedure fee for use of the equipment.

There were approximately 190 Cryocare Surgical Systems in service in the United States as of the end of 2002. This number grew to 203 as of the end of 2003. These figures include Cryocare Surgical Systems owned by our customers as well as Cryocare Surgical Systems that are part of our placement program. There were approximately 275 United States physicians trained and using the Cryocare Surgical System as of the end of 2002 and approximately 536 at of the end of 2003. The number of cryoablation procedures performed domestically was 2,474 in 2002 and increased to 3,504 in 2003. These numbers include estimates of the number of procedures performed by hospitals who purchase only probes from us, without the service component. We estimate the number of procedure equivalents based on our knowledge of the number of probes normally required to complete a procedure. Our blended average selling price for those periods was approximately $4,500 per procedure in 2002 and $4,700 per procedure in 2003. This average reflects the lower prices we charge where we sell probes only, without the service component.

We also sell other urological products acquired when we purchased Timm Medical, a urological device manufacturer, in the first quarter of 2002. We continue to sell our ErecAid vacuum therapy systems and RigiScan monitors, although in 2003 we either divested or discontinued the remaining product lines acquired from Timm Medical. See above in Item 1 under Recent Developments. The reduction in year-over-year sales of our Timm urology products is primarily attributable to these divestitures.

Revenues for the year ended December 31, 2003 decreased $0.4 million to $30.5 million from $30.9 million in 2002, representing a reduction of 1.3%. Significant shifts in product mix, driven by a strategic re-alignment of our business, including the shift in focus for our prostate related cryosurgery business and divestitures of several product lines, are significant factors underlying the year-over-year change in revenues. Divestiture of several Timm Medical products and sale of the SurgiFrost products to CryoCath resulted in a $3.4 million reduction in 2003 sales compared to 2002. Revenues from sales of Cryocare Surgical Systems also decreased $2.1 million in the same period. Revenues from ongoing product lines, excluding Cryocare Surgical Systems and the divested product lines, were up $5.1 million in 2003 over 2002.

Sales of Cryocare Surgical Systems decreased $2.1 million or 62.5% from $3.4 million in 2002 to $1.3 million in 2003. We sold 21 Cryocare Surgical Systems in 2002 compared to 12 in 2003. The principal reason for the reduction in system sales was a shift in our strategy to focus on procedural growth rather than driving adoption of cryosurgical technology through sales of capital equipment as discussed above.

Growth in sales of cryoprobes, other disposables and bundled procedure fees increased $5.3 million or 42.3% from $12.6 million in 2002 to $17.9 million in 2003. The number of procedures performed domestically

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increased 41.6% from 2,474 in 2002 to 3,504 in 2003. In addition, our blended average selling price per procedure increased 4.4% from approximately $4,500 per procedure in 2002 to $4,700 in 2003. We expect that average selling prices may soften somewhat in 2003 as a result of Medicare reimbursement of outpatient procedures moving from pass-through status to an APC code. See above in Item 1 under Reimbursement. Sales of other urology products related to our Timm Medical business were 14.4% lower in 2003 than in 2002, falling $1.8 million from $12.8 million to $11.0 million. Due to our strategy of divesting some of the smaller urologic product lines, future revenues of Timm Medical urological products were expected to decrease initially. The Dura II line of penile implants and the urinary incontinence and urodynamics lines were divested in April 2003 and October 2003, respectively. Sales of these divested products accounted for approximately $3.3 million and $1.6 million in combined revenues during 2002 and 2003 respectively. We expect sales of the remaining RigiScan and ErecAid products for the diagnosis and treatment of erectile dysfunction to grow modestly in 2004.

The $1.8 million reduction in sales of cardiac products in 2003 compared to 2002 is due to the April 2003 agreement to transfer certain rights and assets related to this product line to CryoCath as discussed above. We sold SurgiFrost products to CryoCath throughout 2002 under a pre-existing distribution agreement, whereas we discontinued sales of this product in 2003 following the divestiture. Under the terms of our April 2003 agreement with CryoCath, we are entitled to receive a descending royalty stream from CryoCath of from 10% to 3% of net sales from the products incorporating the licensed technology during the period from 2004 to 2012.

Cost of Revenues. Cost of revenues consists of fixed and variable costs incurred in the manufacture of our products in addition to depreciation of Cryocare Surgical Systems placed in the field with customers under our placement program or with our sales and service personnel. We incur an additional cost of revenues in the form of a fee for equipment usage and other services when a procedure is performed on a box owned by an unrelated service provider. That portion of the procedure fee remitted to the third-party service provider is charged to cost of revenues when the procedure is performed and billed. We retain a larger profit on procedures performed on systems owned by us where no outside service fees are incurred. In addition, we have incurred charges for product warranties as well as excess and obsolete inventory, shrinkage and other inventory carrying costs. Also included in cost of revenues are costs of maintaining patents or other intellectual property rights to processes or technologies related to our products, royalties on product sales and amortization of developed technology acquired in connection with our acquisition of Timm Medical.

Cost of revenues decreased $0.4 million or 2.6% from $16.5 million in 2002 to $16.1 million in 2003. Part of the divestiture of several Timm Medical products and the Surgifrost line sold to CryoCath account for a $1.4 million reduction in cost of sales, while a reduction in the number of Cryocare Surgical Systems sold in 2003 compared to 2002 caused a $1.0 million decrease in this number. These reductions in cost of revenues were partially offset by an increase of $2.0 million due to growth in sales of cryosurgical probes and procedures. Also affecting cost of revenues is the reduction in Cryocare Surgical Systems sold in 2003 compared to 2002. Cost of revenues for Cryocare Surgical Systems as a percentage of related revenues decreased from 43.2% in 2002 to 36.3% in 2003. This was mainly due to the fact that in 2002 we recorded $0.6 million in cost of sales for which the corresponding sales could not be recorded under our revenue recognition policy. Conversely, in 2003, we collected and recorded $0.6 million of revenue for sales of systems where approximately $0.1 million in cost of sales had been recognized in the periods when the systems were originally shipped.

Cost of revenues for cryoprobes, other disposables and procedure kits as a percentage of related revenues decreased from 64.4% in 2002 to 59.2% in 2003. This was primarily due to an increase in the blended average selling price per procedure from $4,500 in 2002 to $4,700 in 2003, and a reduction in write downs of excess and obsolete inventory.

There was also an increase in year-over-year depreciation and amortization expense due to an increase in placement of Cryocare Surgical Systems and other inventory located in the field. The number of placement

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systems grew from 109 at December 31, 2002 to 133 at December 31, 2003. In 2002 we took a charge of $1.0 million for inventory written down as a result of excess production and changes in product design.

Gross Margins. Gross margins on revenues increased from 46.7% for the year ended December 31, 2002 to 47.3% for the year ended December 31, 2003. Factors contributing to the improvement in gross margins are related to the changes in both revenues and cost of sales that are discussed above.

Research and Development Expenses. Research and development expenses include expenses associated with the design and development of new products as well as significant enhancements to existing products. These expenses consist primarily of salaries and related benefits and overhead costs for staff engaged in research and development activities, costs for materials and supplies used in performing research and development activities, costs of clinical trials conducted for the purpose of obtaining regulatory approval of our products, consulting and advisory fees for outside service providers directly involved in research and development activities, and depreciation on equipment used directly for research and development activities. We expense research and development expenses when incurred. Our research and development efforts are periodically subject to significant non-recurring expenses and fees that can cause some variability in our quarterly research and development expenses.

Research and development expenses for the year ended December 31, 2003 decreased $1.6 million or 56.6% from $2.9 in 2002 to $1.3 million in 2003. Development costs were incurred in 2002 but not 2003 for the Horizon Prostatic Stent and the SurgiFrost system purchased by CryoCath. In early 2003, we halted development of the Horizon Prostatic Stent. Also, as discussed above, we sold our manufacturing assets and inventory associated with the SurgiFrost system to CryoCath in April 2003. Research and development expenses in 2003 were primarily related to design, development and testing of our new CS System for the prostate cancer market.

Selling, General and Administrative Expenses. Selling, general and administrative expenses primarily consist of salaries, commissions and related benefits and other overhead costs for employees and activities in the areas of sales, marketing, customer service, clinical services, finance, information technology, human resources and administration. Fees for attorneys, independent auditors and certain other outside consultants and suppliers are included where their services or products are related to selling, general and administrative activities. Costs of insurance premiums, including directors and officers liability and products liability insurance, are also included in this category. Expenses associated with advertising, trade shows, promotional and training costs related to marketing our products are also classified as selling, general and administrative expenses as are the costs of conducting clinical research studies for the purpose of collecting clinical data used in promoting our products.

Selling, general and administrative expenses for the two year period ended December 31, 2003, by line of business, are shown below. Costs related to the cryosurgery component of our business are on the left, while costs related to products acquired in our February 2002 purchase of Timm Medical are shown on the right under other urology. Other urology relates primarily to our erectile dysfunction products, but also includes the urological prosthesis and incontinence products through their divestiture in 2003.

	Year Ended December 31, 2003		
	Cryosurgery	Other Urology	Total
	(In thousands)		
Sales and marketing	$16,025	$2,841	$18,866
General and administrative:			
Ordinary course of business	10,998	3,070	14,068
Non-recurring	14,255		14,255
Total general and administrative	25,253	3,070	28,323
Total selling, general and administrative	$41,278	$5,911	$47,189

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	Year Ended December 31, 2002		
	Cryosurgery	Other Urology	Total
		(In thousands)	
Sales and marketing	$11,539	$4,035	$15,574
General and administrative:			
Ordinary course of business	13,076	2,919	15,995
Non-recurring	2,200		2,200
Total general and administrative	15,276	2,919	18,195
Total selling, general and administrative	$26,815	$6,954	$33,769

Selling, general and administrative expenses increased $13.4 million or 39.7% to $47.2 million for the year ended December 31, 2003 compared to $33.8 million for the year ended December 31, 2002. Costs related to the investigations by our audit committee, the SEC and the DOJ into possible accounting irregularities, including related legal fees and settlements and audit expenses and severance payments to former executives, explain most of the year-over-year increase. Through December 31, 2003 costs related to these investigations amounted to approximately $16.5 million of which $14.3 million were expensed in 2003. These costs appear in the above table in the column under Cryosurgery. Included in the 2003 costs was $3.6 million related to severance agreements with various executives, including $3.2 million for our former CEO and CFO. Approximately $1.8 million of the total severance-related costs was in the form of cash payments and $1.8 million was a non-cash charge taken for equity-based compensation for two former employees.

Non-recurring costs in 2002 included a $1.5 million charge taken for a judgment entered against the Company in October 2003 in the matter of Biolife Solutions, Inc. v. Endocare, Inc. The remaining $0.7 million in 2002 were costs related to investigations into our historical accounting and financial reporting by our audit committee, the SEC and the DOJ. We have incurred and expect to incur further costs related to these investigations in 2004 and perhaps subsequent periods as we resolve all outstanding legal matters stemming from these investigations. See above under Item 3 Legal Proceedings. We believe that a portion of the legal fees and costs associated with these legal matters should be reimbursed to us under our directors and officers liability insurance coverage. However, we have not received any reimbursement of these fees and costs to date, and the insurance carriers may dispute all or a portion of these fees and costs.

Also in 2003, we consolidated a number of general and administrative functions previously performed in multiple locations. In early 2003, we made a decision to absorb certain general and administrative functions duplicated at our Eden Prairie, MN offices where our Timm Medical business is headquartered. Certain accounting, human resources, information technology and other positions were eliminated and their duties were absorbed by employees in Irvine, CA. This transition was completed in June 2003. Costs savings related to the downsizing of our Eden Prairie, MN operations enabled us to keep our general and administrative expenses constant for the other urological component of our business. In real terms, our rate of spending in this area has decreased. The 2002 costs for the urological portion of our business included only 10 months of operations following the February 2002 acquisition, while 2003 represented 12 months of expenses. We expect to see further savings in future periods from this downsizing.

In March 2003, we also transferred the billing services performed by our Advance Medical Procedures division, located in Winter Park, FL, to our Irvine, CA office. In addition, in July 2003 we assumed accounting and administrative support for the thirteen entities in which we became general partner or managing member through our purchase of certain interests in these entities from USMD in 2002. These services were previously outsourced.

As a result of consolidating various operations and reducing duplicative overhead, we reduced the total number of employees from 194 at December 31, 2002 to 163 at December 31, 2003.

Looking forward at our general and administrative costs, we anticipate making investments in building an organization and infrastructure to support improvements in internal controls, financial reporting and corporate governance. We also expect to incur expenses associated with satisfying the listing requirements of The

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Nasdaq Stock Market should our common stock be relisted and in connection with implementing the requirements of the Sarbanes-Oxley Act of 2002, in particular, Section 404 thereof, which requires management to report on, and our independent auditors to attest to, the effectiveness of our internal controls.

Overall, however we anticipate net reductions in general and administrative costs due primarily to the winding down of activities related to various investigations of accounting and financial reporting matters. In addition, we expect the full-year benefits from elimination of redundant functions at our subsidiaries and centralizing them at our Irvine, CA headquarters.

Sales and marketing expenses increased $3.3 million or 21.1% to $18.9 million for the year ended December 31, 2003 compared to $15.6 million for the year ended December 31, 2002. The primary reason for this increase is investment in our cryosurgery sales force. The large sales force we acquired in our purchase of Timm Medical had to be cross-trained in cryosurgical products and their applications. In 2003, we incurred approximately $1.2 million in training workshops, travel, salaries and other costs related to developing our cryosurgical sales force.

We also incurred $0.7 million in costs related to forming a dedicated interventional radiology sales and marketing group, which focuses on application of our cryosurgical products in treating tumors of the lung and liver as well as for pain management in patients with metastatic bone cancer.

Sales and marketing expenses in 2003 included salaries, benefits and travel for the cryosurgical field technicians who joined our staff when we purchased interests in several mobile cryosurgical businesses from USMD in September 2002. We incurred approximately $0.9 million of salary and benefits costs and travel expenses for these technicians in 2003. Additionally, we increased our investment in training cryosurgeons from $1.8 million in 2002 to $2.2 million in 2003, in our effort to continue to grow the market for our cryosurgical products. These increases were partially offset by a reduction in marketing costs of $0.9 million in 2003 compared to 2002, primarily related to reduced expenditures for printed materials such as sales brochures.

We also incurred a full year of sales and marketing expenses in 2003 for the erectile dysfunction line, compared to ten months in 2002, as a result of the Timm Medical acquisition. This resulted in $0.7 million of additional sales and marketing expenses in 2003 over 2002.

We have planned new investments in sales and marketing activities in 2004 to increase market share for our cryosurgical products and to support our strong position in the market for non-pharmacological treatment of erectile dysfunction. Promotions related to our new Cryocare CS system, and the use of our products in the interventional radiology arena, in addition to broader national advertising programs and continued training of new cryosurgeons are among the strategies we will emphasize for our cryosurgical business in the current fiscal year. Clinical studies and investments in field sales are areas in which we plan to invest for our erectile dysfunction business in 2004.

Goodwill Impairment and Other Charges. We took a charge of approximately $18 million in October 2002 for impairment in the goodwill recorded in connection with our purchase of Timm Medical. In October 2002, we also recorded an other-than-temporary decline in the value of our minority investment in U.S. Medical Development, Inc. of approximately $2.3 million. We took no further write-downs of goodwill nor did we determine that any additional charges for impairment in other assets were required during 2003.

Interest Income (Expense), Net. Interest income net of interest expense was $0.5 million for the year ended December 31, 2003 compared to $1.0 for the year ended December 31, 2002. The drop in net interest income in 2003 compared to 2002 resulted from declining cash balances throughout 2003 combined with lower interests rates, which were primarily driven by reductions in the Federal Funds Rate in November 2002 and June 2003 of 50 basis points and 25 basis points, respectively.

Minority Interests. Minority interests represent earnings attributable to minority investors in the mobile prostate treatment businesses we acquired from USMD on September 30, 2002. Minority interests increased 39% from $0.4 million in 2002 to $0.6 million in 2003. The increase is due to results for 2002 including only the 3 post-acquisition months, while in 2003 minority interest represents 12 months of earnings. This was

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offset by a reduction in earnings from the entities dedicated to mobile treatment of BPH and the withdrawal of limited partners from certain other entities.

Gain on Divestitures, Net. In 2003 we recorded a net gain of $8.6 million related to the divestiture of several product lines and related assets. As discussed above, in April 2003, we licensed our intellectual property and manufacturing rights for the SurgiFrost line, and sold inventory and other assets to CryoCath for a total gain of $10.0 million. Also in April 2003, we sold the intangibles and inventory related to our Dura II products to American Medical Systems for $2.2 million resulting in a $35,000 loss and we sold the inventory and assets associated with our urinary incontinence products to SRS Medical, Inc. resulting in a loss of $1.3 million.

Net Loss. Net loss for the year ended December 31, 2003 was $25.4 million, or $1.05 per share. For the year ended December 31, 2002 the net loss was $42.0 million or $1.76 per share. Reasons for the higher net loss in 2002 included higher cost of revenues combined with $20.3 million in impairment charges related to goodwill and investments. In 2003, significant non-recurring costs related to accounting investigations were partially offset by the net gain on divestitures.

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Revenues. We generate revenues from sales of our Cryocare Surgical Systems as well as from the recurring sales of our disposable cryoprobes and other disposable devices used in cryoablation procedures. We also contract with hospitals and other healthcare payors for the use of our Cryocare Surgical Systems in cryoablation treatments for which we charge a per-procedure, or bundled, fee. The bundled fee typically includes a procedure kit containing cryoprobes and other disposables needed to perform a cryosurgical procedure, in addition to a service component. The service component of the bundled fee generally consists of rental and transport of a Cryocare Surgical System as well as the services of a technician to assist the physician with the set-up, use and monitoring of the equipment. During the fiscal year ended December 31, 2002, we also sold a number of other urological products acquired when we purchased Timm Medical, a urological device manufacturer, in the first quarter of 2002. While we have divested a number of those urological product lines acquired from Timm Medical, we continue to sell our ErecAid vacuum therapy systems and RigiScan monitors. Also in 2002, we sold cryoablation systems and disposables we developed for treatment of cardiac arrhythmias to CryoCath, a company specializing in the sales distribution of these products into the cardiology market.

Revenues for the year ended December 31, 2002 increased $17.9 million or 137.7% to $30.9 million from $13.0 million in 2001. Of this increase, $12.8 million related to Timm Medical and $2.1 million was from sales to CryoCath. Sales to CryoCath were not significant in 2001. Excluding Timm Medical and CryoCath, sales of Cryocare Surgical Systems decreased $4.0 million or 54.1% from $7.4 million in 2001 to $3.4 million in 2002. In 2001, 45 Cryocare Surgical Systems were sold compared to 21 Cryocare Surgical Systems in 2002. Termination of the exclusive distribution agreement with U.S.M.D., Ltd. explains part of the year-over-year reduction in sales of Cryocare Surgical Systems. U.S.M.D., Ltd. purchased 19 units in 2001 versus five units in 2002, prior to our acquisition of the mobile prostate treatment businesses from USMD on September 30, 2002. In connection with this acquisition, the distribution agreement was terminated and USMD exited the cryosurgical market.

The reduction in sales of Cryocare Surgical Systems was offset by growth in sales of cryoprobes, other disposables and bundled procedure fees, which increased $6.9 million or 121.1% from $5.7 million to $12.6 million. The growth is due to an increase in the number of Cryocare Surgical Systems in operation from 113 in 2001 to 190 in 2002, including both systems purchased by third parties and systems in our placement program. The number of procedures performed domestically increased from 1,093 in 2001 to 2,474 in 2002. In addition, our blended average selling price per procedure increased from approximately $2,900 per procedure in 2001 to approximately $4,500 per procedure in 2002. This was primarily due to a shift in our business model in mid-2001 from selling only probes and other disposables used in a cryosurgical procedure to our customers, without a service component, to invoicing for a bundled procedure including both the disposable devices and a service fee for use of the equipment and technical assistance.

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Due to our divestiture strategy, future revenues relating to the Timm Medical urological products are initially expected to decrease. The penile implants product lines and the urinary incontinence and urodynamics product lines divested in April and October 2003, respectively, accounted for approximately $3.4 million in combined revenues during 2002. In addition, we terminated our CryoCath distribution agreement effective April 2003 upon the sale of our cardiac-related product manufacturing operations, and our license for cardiovascular uses of our proprietary argon-based technology, to CryoCath. Under the sale agreement, we are entitled to receive a descending royalty stream from CryoCath from 10% to 3% of net sales from the products incorporating the licensed technology during the period 2004 to 2012. However, we cannot estimate the amount of future royalty payments at this time.

Cost of Revenues. Cost of revenues consists of fixed and variable costs incurred in the manufacture of our products, depreciation of Cryocare Surgical Systems placed in the field with customers or with our sales and service personnel, excess and obsolete inventory, shrinkage and other inventory carrying costs, royalties on products sales, and costs of maintaining patents or other intellectual property rights to processes or technologies related to our products and product warranties.

Cost of revenues for the year ended December 31, 2002 increased $10.3 million or 166.1% from $6.2 million in 2001 to $16.5 million in 2002. Of this increase, $5.4 million related to Timm Medical and $1.5 million related to the cardiac-related products sold to CryoCath. Cost of revenues for Cryocare Surgical Systems as a percentage of related revenues increased from 29.9% in 2001 to 43.2% in 2002 due to an increase in the number of Cryocare Surgical Systems shipped to customers in 2002 over 2001, for which no revenues were recognized as discussed below. Cost of revenues for cryoprobes, other disposables and bundled procedures as a percentage of related revenues decreased from 70.6% in 2001 to 64.4% to 2002. This was primarily due to an increase in the blended average selling price per procedure from $2,900 in 2001 to $4,500 in 2002 partially offset by increase in the number of procedures performed on Cryocare Surgical Systems owned by third parties where we incur an additional cost of revenues in the form of a fee for equipment usage and other services. The portion of the procedure fee remitted to the third-party service provider is charged to cost of revenues when the procedure is performed and billed. We retain a larger profit on procedures performed on systems owned by us where no outside service fees were incurred.

Also included in cost of revenues for 2002 was approximately $0.6 million in manufacturing costs for 16 Cryocare Surgical Systems shipped to customers, for which no corresponding sales revenue was recognized pursuant to our revenue recognition policy. Of the 16 Cryocare Surgical Systems, 11 were shipped and billed during the first and second quarters of 2002. Sales of these units, previously recognized in the quarters when they were invoiced, were reversed for reasons discussed in note 3 to our consolidated financial statements. The remaining five systems were shipped and billed in the third and fourth quarters of 2002, but no revenue has been recognized in accordance with our revenue recognition policy. The cost of revenues in 2001 included approximately $0.4 million in manufacturing costs for 10 Cryocare Surgical Systems, the sales revenue of which were also reversed for reasons discussed in note 3 to our consolidated financial statements. Although the sales of these systems have been reversed and excluded from revenues as discussed above, the manufacturing costs for these systems were not reversed and remained in 2002 and 2001 cost of revenues since these units were still held by customers, and had not been returned to us.

In April 2002, we relocated our headquarters and manufacturing operations to a new, larger facility in Irvine, California. A total of $2.1 million was invested in improvements to the leased space and in furniture and equipment for the facility. The increase in rent, utilities and other facilities related costs, as well as additional depreciation and amortization expenses, are partially reflected in the higher cost of revenues through increased manufacturing overhead. There was also an increase in year-over-year depreciation and amortization expense due to an increase in placement of Cryocare Surgical Systems and other inventory located in the field. The number of placement systems grew from 23 at December 31, 2001 to 109 at December 31, 2002. Additionally, there was an increase in reserves for excess and obsolete inventory taken in 2002, as compared to 2001, due to excess production and changes in product design.

Gross Margins. Gross margins on revenues decreased from 52.4% for the year ended December 31, 2001 to 46.7% for the year ended December 31, 2002. This was due to the fact that revenue growth from 2001

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to 2002 did not keep pace with the increase in costs of revenues. Factors contributing to the significant increase in cost of revenue are discussed above.

Research and Development Expenses. Research and development expenses include expenses associated with the design and development of new products as well as significant enhancements to existing products. These expenses consist primarily of salaries and related benefits and overhead costs for staff engaged in research and development activities, costs for materials and supplies used in performing research and development activities, costs of clinical trials conducted for the purpose of obtaining regulatory approval of our products, consulting and advisory fees for outside service providers directly involved in research and development activities, and depreciation on equipment used directly for research and development activities. We expense research and development expenses when incurred. Our research and development efforts are periodically subject to significant non-recurring expenses and fees that can cause some variability in our quarterly research and development expenses.

Research and development expenses increased $.4 million or 16.0% from $2.5 million in 2001 to $2.9 million in 2002. This increase was primarily due to development costs for the Horizon Prostatic Stent and the SurgiFrost system purchased by CryoCath. In early 2003, we halted development of the Horizon Prostatic Stent. Also in early 2003, we sold our manufacturing assets and inventory associated with the SurgiFrost system, and licensed the related proprietary argon gas based technology for cardiac uses, to CryoCath.

Selling, General and Administrative Expenses. Selling, general and administrative expenses primarily consist of salaries, commissions and related benefits and other overhead costs for employees and activities in the areas of sales, marketing, customer service, finance, information technology, human resources and administration. Fees for attorneys, independent auditors and certain other outside consultants and suppliers are included where their services or products are related to selling, general and administrative activities. Expenses associated with advertising, trade shows, promotional and training costs related to marketing our products are also classified as selling, general and administrative expenses as are the costs of conducting clinical research studies for the purpose of collecting clinical data used in promoting our products.

Selling, general and administrative expenses increased $18.1 million or 115.3% to $33.8 million for the year ended December 31, 2002 compared to $15.7 million for the year ended December 31, 2001. Included in the 2002 expenses was $7.0 million related to Timm Medical and a $1.5 million charge related to an adverse verdict in the BioLife litigation as discussed below. A significant portion of the increase in costs was driven by staffing. The number of employees grew from 94 at the end of 2001 to 194 at the end of 2002. As a result of the Timm Medical acquisition, 94 employees were added. The acquisition of Timm Medical was intended, in part, to provide us with an expanded sales force and service personnel with experience in the urology market. Of the 100 new employees in 2002, 71 were added in selling, general and administrative areas, primarily in sales and customer service. Sales personnel increased from 18 employees at the end of 2001 to 57 at the end of 2002, while customer service staff increased from 10 to 25 employees during the same period.

Another factor in the year-over-year growth of our selling, general and administrative expenses was the investment in training new physicians in the use of our products. The cost of training a doctor through our cryosurgical program averages between $15,000 and $20,000. In 2002 we trained an estimated 109 cryosurgeons compared to approximately 47 in 2001.

Also, as discussed above, we moved our headquarters and manufacturing operations to a new facility in April 2002. Higher rent, utilities, depreciation and amortization costs also contributed to the increase in selling, general and administrative expenses. Other increases in selling, general and administrative costs included legal, tax, accounting and facility expenses related to the operations of Timm Medical.

Further, we incurred approximately $1.1 million in legal and accounting fees associated with the audit committee s internal review of various accounting and other matters as well as the related legal proceedings. Additionally, we recorded a charge of $1.5 million in the fourth quarter of 2002 to reflect the ruling by a Delaware Chancery court relating to a dispute arising from our agreement to acquire certain assets from BioLife in May 2002. The ruling requires us to pay BioLife approximately $1.6 million, plus pre-judgment interest and costs (including legal fees), and requires BioLife to surrender to us 120,022 shares of our common

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stock. The ruling was issued on October 1, 2003. In February 2004 we agreed to settle this case for a cash payment to BioLife of $1.9 million and return to us by BioLife of 122,022 shares of our common stock.

Looking forward, we expect to incur significant additional expenses related to the investigations and legal proceedings in which we continue to be involved. In addition, we anticipate making substantial investments in building an organization and infrastructure to support improvements in internal controls, financial reporting and corporate governance. We also expect to incur significant expenses associated with satisfying the listing requirements of The Nasdaq National Market should our common stock be relisted and in connection with implementing the requirements of the Sarbanes-Oxley Act of 2002, in particular, Section 404 thereof, which requires management to report on, and our independent auditors to attest to, the effectiveness of our internal controls.

Goodwill Impairment and Other Charges. We took a charge of approximately $18 million in October 2002 for impairment in the goodwill recorded in connection with the purchase of Timm Medical. In October 2002, we also recorded an other-than-temporary decline in the value of our minority interests in U.S. Medical Development, Inc. of approximately $2.3 million.

Interest Income (Expense), Net. Interest income net of interest expense was $1.0 million for the year ended December 31, 2002 compared to $241,000 for the year ended December 31, 2001. The net increase was due to an increase in cash of approximately $72.6 million following our secondary public equity offering in November 2001. The increase in cash was partially offset by operating losses and $24.1 million in cash used for significant business acquisitions during 2002. In addition, all our significant borrowings were eliminated in 2001 with the conversion of $8 million in debentures and repayment of funds drawn under a credit facility.

Minority Interests. Minority interests represent fourth quarter 2002 earnings attributable to minority investors in the mobile prostate treatment businesses we acquired from USMD on September 30, 2002.

Net Loss. Net loss for the year ended December 31, 2002 was $42.0 million, or $1.76 per share. For the year ended December 31, 2001 the net loss was $11.5 million or $0.68 per share. Reasons for the higher net loss in 2002 included a steep increase in cost of revenues and in selling, general and administrative expenses, combined with $20.3 million in impairment charges related to goodwill and investments. The increases in operating expenses were partially offset by revenue growth.

Liquidity and Capital Resources

Since inception, we have incurred losses from operations and have reported negative cash flows. As of December 31, 2003, we had an accumulated deficit of $114.4 million and cash and cash equivalents of $24.0 million. We currently have no long-term debt, and no long-term financial obligations other than under operating leases and purchase commitments for raw material used in manufacturing our products. Although we believe that our existing cash and cash equivalents will be sufficient to fund our working capital requirements, capital expenditures and other obligations through the next 12 months, there are certain risks and uncertainties that could, in the future, change our opinion regarding the adequacy of our capital resources.

We recently made several significant payments that have reduced our cash reserves. On March 8, 2004, we paid to our former Chief Executive Officer an aggregate of $750,000, which we owed to him under a separation agreement and consulting agreement that we previously executed. Also on March 8, 2004, we paid to our former Chief Financial Officer an aggregate of $616,000, which we owed to him under an employment agreement we previously executed. At the request of the SEC, these payments were deposited into escrow accounts during the fourth quarter of 2003 and released upon termination of the related escrow agreements. The escrow of these payments caused the amount of these payments to be classified as restricted cash and included in prepaid expenses and other current assets as of December 31, 2003, instead of being included in our December 31, 2003 cash and cash equivalents balance of $24.0 million.

In addition to the payments described in the prior paragraph, in February 2004 we paid approximately $1.5 million in directors and officers liability insurance premiums, and we paid approximately $1.9 million to BioLife to settle litigation, as described above in Item 3 of this Annual Report on Form 10-K.

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We face the possibility that there will be additional material cash payments required in connection with resolving matters related to the investigations into our historical accounting and financial reporting. We and certain former officers and certain current and former board members have been named defendants in a class action and a derivative lawsuit. We are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in these lawsuits. At this point in time we are unable to provide a reasonable estimate of our potential liability in these lawsuits.

We may be required to pay judgments or settlements and to incur expenses in defending against these claims that could be material. Further, while we carry $20 million of director s and officers liability insurance coverage, this coverage may not be adequate to cover all costs related to these lawsuits, including any resulting judgments or settlements. As described above under Risks Related to Our Business, two of our excess carriers have denied us coverage for these claims, and the third excess carrier has reserved the right to deny us coverage for these claims. Any of these unfavorable outcomes could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Beyond the factors described above, we expect to face significant demands on our capital resources related to the execution of our 2004 operating plan, regaining compliance with the SEC rules and regulations required of publicly traded companies, including Section 404 of the Sarbanes-Oxley Act of 2002, and fulfilling requirements prerequisite to becoming relisted on The Nasdaq Stock Market. We are currently projecting an operating loss for fiscal 2004, as well as a net use of cash.

We will continue to use cash reserves to finance our projected 2004 cash flow deficit. Our 2004 forecast provides for an increase in revenues and improvement in gross profit as well as a significant reduction in general and administrative expenses. The reduction in general and administrative costs is due primarily to the winding down of activities related to various investigations of accounting and financial reporting matters. In addition, we have trimmed general and administrative costs through the elimination of redundant functions at our subsidiaries and centralizing them at our Irvine, California headquarters.

At the same time, however, we have planned new investments in sales and marketing activities to increase our market penetration as well as in inventory related to the introduction of our new Cryocare CS System. Additionally, we expect to incur additional research and development costs to improve our existing products and develop new ones. We have also planned expenditures on staffing and infrastructure improvements in finance and information technology to ensure that we will be able to comply with internal control and other SEC requirements.

As part of our overall strategy to improve operating results and conserve cash, we plan to attempt to negotiate reduced per-procedure service fees for service providers with whom we contract to make Cryocare Surgical Systems and technicians available to hospitals where cryosurgical procedures are performed. In addition, we are contemplating several other cost-cutting initiatives for the current fiscal year. We cannot provide any assurance that these cost-cutting efforts will be successful, nor that we will achieve our budgeted results. We may need to implement more extensive cost-cutting measures in order to ensure that our cash balances are adequate to fund operations for the next 12 months.

Although we believe that our current cash balances will be sufficient to fund our operations for at least the next 12 months, we may require additional financing sooner than expected if we fail to achieve our operating objectives. Further, we may identify new opportunities to invest in our core technology or to accelerate market share and revenue growth that require external sources of funding.

We fully expect that, to meet our long-term capital requirements, we will need to raise substantial additional funds from one or more of the following sources: leveraging or pledging our assets, selling equity or debt securities to public or private investors, selling certain of our products or lines of business, or licensing our technologies for applications outside our existing target markets. We are currently exploring various fund-raising alternatives and strategies. There are risks associated with any of these fund-raising strategies. In the event that we 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.

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Additional equity or debt financing may not be available on acceptable terms, or at all. Our common stock was delisted from The Nasdaq Stock Market on January 16, 2003. One result of this action is a limited public market for our common stock. This reduced liquidity will likely make it difficult to raise additional capital.

If we are unable to obtain additional capital, we may be required to divest additional product lines, reduce our sales 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.

Furthermore, if we fail to adequately address our liquidity concerns, then our independent auditors may issue a qualified opinion, to the effect that there is substantial doubt about our ability to continue as a going concern. A qualified opinion could itself have a material adverse effect on our business, financial condition, results of operations and cash flows.

Contractual Obligations

In the table below, we set forth our contractual obligations as of December 31, 2003. Some of the figures we include in this table are based on management s estimates and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. Because these estimates and assumptions are necessarily subjective, the contractual obligations we will actually pay in future periods may vary from those reflected in the table.

	Payments Due by Period			
	Total	2004	2005-2006	2007-2008
	(In thousands)			
Non-cancelable operating leases(1)	$1,710	$ 663	$970	$ 77
Purchase commitments(2)	2,483	2,483		
	$4,193	$3,146	$970	$ 77

(1) We enter into operating leases in the normal course of business. We lease office space as well as other property and equipment under operating leases. Some lease agreements provide us with the option to renew the lease at the end of the original term. Our future operating lease obligations would change if we exercised these renewal options and if we entered into additional operating lease agreements. For more information, see note 12 to our consolidated financial statements.

(2) These purchase commitments relate to agreements to purchase goods or services to manufacture our products. The agreements included in the table include open purchase orders in excess of $100,000. These obligations are not recorded in our consolidated financial statements until contract payment terms take effect. We expect to fund these commitments with cash flows from operations and from cash balances on hand. The obligations shown in the above table are subject to change based on, among other things, our manufacturing operations not operating in the normal course of business, the demand for our products, and the ability of our suppliers to deliver the products as promised.

Critical Accounting Policies

The following discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of the financial statements requires management to make estimates and assumptions in applying certain critical accounting policies. Certain accounting estimates are particularly sensitive because of their significance to our consolidated financial statements and because of the possibility that future events affecting the estimates could differ significantly from current expectations. Factors that could possibly cause actual amounts to differ from current estimates relate to various risks and uncertainties inherent in our business, including those set forth under Risk Related to Our Business in Item 1 of this Annual Report on Form 10-K. Management believes that the following are some of the more critical judgment areas in the application of accounting policies that affect our financial statements. The

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restatements described in note 3 of our consolidated financial statements filed in our annual report for the year ended December 31, 2002 filed on Form 10-K relate to certain of the critical accounting policies described below.

Revenue Recognition. We follow the provisions of Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101), for revenue recognition. Under SAB 101, four conditions must be met before revenue can be recognized: (i) there is persuasive evidence that an arrangement exists, (ii) delivery has occurred or service has been rendered, (iii) the price is fixed or determinable and (iv) collection is reasonably assured.

Revenues for Cryocare Surgical Systems shipped to company controlled locations for interim storage are deferred until subsequently shipped and accepted by our customers. We also reduce our revenues for customer concessions, and defer revenue recognition for minimum procedure guarantees and contingent payment arrangements until a future date when the contingencies are resolved.

Where we own the equipment used in the procedure, we bill the hospital or other payor and retain the entire procedure, or bundled, fee. In many instances, however, the equipment is owned by a third-party who contracts with us to perform the service component of the procedure. Third-party service providers are usually entities owned or controlled by urologists who perform cryosurgical procedures. In the latter case, we still invoice the payor but we remit a portion of the procedure fee to the third-party service provider. The procedure fee is recorded as revenue in the period when the procedure is performed and, where applicable, the fee paid to a third-party service provider is included in cost of revenues for the same period.

Where a third-party service provider is not involved, we earn the entire procedure fee, both the portion related to providing the disposable kits and the portion related to providing mobile or placement Cryocare Surgical Systems to customers. Providing loaner or placement equipment to customers is a strategy aimed at promoting broader acceptance of our technology and driving sales of disposable components faster than would be possible if we restricted use of the device only to customers willing to make a significant capital investment in a Cryocare Surgical System. In these situations, we either loan a mobile Cryocare Surgical System to a hospital or consign a stationary Cryocare Surgical System with the hospital under our placement program and charge a fee for each procedure in which the equipment is used. Cost of revenues includes depreciation on the Cryocare Surgical Systems owned by us over an estimated useful life of three years.

We routinely assess the financial strength of our customers and, as a consequence, believe that our accounts receivable credit risk exposure is limited. Accounts receivable are carried at original invoice amount less all discounts and allowances, and less an estimate for doubtful accounts and sales returns based on a periodic review of outstanding receivables. Allowances are provided for known and anticipated credit losses as determined by management in the course of regularly evaluating individual customer receivables. This evaluation takes into consideration a customer s financial condition and credit history as well as current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Purchase Accounting. Our acquisitions of Timm Medical and certain general and limited equity interests in the mobile prostate cancer and BPH treatment businesses of U.S.M.D. have been accounted for under the purchase method of accounting for business combinations. We are required to allocate the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. The judgments made in determining the estimated fair value and expected useful lives assigned to each class of assets and liabilities acquired can significantly impact periodic amortization expense and net income.

Determining the fair value of certain assets and liabilities acquired is judgmental in nature and often involves the use of significant estimates and assumptions, especially with respect to intangibles. Critical estimates in valuing certain intangible assets include: future expected cash flows from customer contracts, customer lists and distribution agreements and acquired developed technologies and patents; brand awareness and market position, as well as assumptions about the period of time the brand will continue to be used in our product portfolio; and discount rates. To assist in this process, we obtained appraisals from independent

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valuation firms for certain significant tangible and intangible assets and liabilities. While our estimates of fair value are based upon assumptions believed to be reasonable, these estimates are inherently uncertain and unpredictable, and as a result, actual results may differ from estimates. Other estimates associated with the accounting for acquisitions may also change as additional information becomes available regarding the assets acquired and liabilities assumed.

Goodwill Impairment. We test for goodwill impairment in the fourth fiscal quarter of each year, or sooner if events or changes in circumstances indicate that the carrying amount may exceed the fair value. The goodwill impairment test is a two-step process, which requires management to make judgments in determining what assumptions to use in the calculation. The first step of the process consists of estimating the fair value of each reporting unit, which we base on a weighted combination of the (i) guideline company method (GCM) that utilizes revenue multiples for comparable publicly-traded companies, and (ii) a discounted cash flow (DCF) model that utilizes future net cash flows, the timing of these cash flows, and a discount rate (or weighted average cost of capital which considers the cost of equity and cost of debt financing expected by a typical market participant) representing the time value of money and the inherent risk and uncertainty of the future cash flows. If the estimated fair value is less than the carrying value, a second step is performed to compute the amount of the impairment by determining an implied fair value of goodwill. The determination of a reporting unit s implied fair value of goodwill requires us to allocate the estimated fair value of the reporting unit to the assets and liabilities of the reporting unit. Any unallocated fair value represents the implied fair value of goodwill, which is compared to its corresponding carrying value. Goodwill totaled $17.5 million at December 2002 and 2003, and represented 19% and 24% of our total assets, respectively. In 2002, we recognized an impairment charge of $18.0 million to reduce the carrying value of the goodwill acquired in the Timm Medical acquisitions. The impairment resulted from the termination or abandonment of three of the acquired distribution agreements for urological products following the acquisition. In 2003, we concluded that the estimated fair value of each reporting unit exceeded the carrying amount, so goodwill was not impaired. If the exit market multiples used in the GCM had been reduced by up to 10%, or the discount rate used in the DCF model were increased by 100 basis points, or both, the fair value would continue to exceed the carrying value for all of our reporting units.

Impairment of Long-Lived Assets. We have a significant amount of property, equipment and amortizable intangible assets primarily consisting of purchased patents and acquired technology. In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long Lived Assets,* we review our long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability of long-lived and amortizable intangible assets to be held and used is measured by a comparison of the carrying amount of an asset to the undiscounted future operating cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying value of the assets exceeds their fair value. At December 31, 2002 and 2003, we did not determine that a write down for impairment of any of our long-lived assets was required.

Legal and Other Loss Contingencies. In the normal course of business, we are subject to contingencies, such as legal proceedings and claims arising out of our business that cover a wide range of matters, including tax matters, product liability and workers compensation. In accordance with SFAS No. 5, *Accounting for Contingencies*, we record accruals for such contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. A significant amount of management estimation is required in determining when, or if, an accrual should be recorded for a contingent matter and the amount of such accrual, if any. Due to the uncertainty of determining the likelihood of a future event occurring and the potential financial statement impact of such an event, it is possible that upon further development or resolution of a contingent matter, a charge could be recorded in a future period that would be material to our consolidated results of operations, financial position or cash flows.

Other Investments. We review our equity investments for impairment based on our determination of whether the decline in market value of the investment below our carrying value is other than temporary. In making this determination, we consider Accounting Principles Board Opinion (APB) No. 18, *The Equity*

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Method of Accounting of Investments in Common Stock, which set forth factors to be evaluated in determining whether a loss in value should be recognized. Factors include the investee s operational performance, indictors of continued viability, financing status, liquidity prospects and cash flow forecasts. We also consider our ability to hold the investment, the market price and market price fluctuations of the investment s publicly traded shares and the ability of the investee to sustain an earnings capacity which would justify the carrying amount of the investment.

Income Taxes. In the preparation of our consolidated financial statements, we are required to estimate income taxes in each of the jurisdictions in which we operate, including estimating both actual current tax exposure and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. Assessment of actual current tax exposure includes assessing tax strategies, the status of tax audits and open audit periods with the taxing authorities. To the extent that we have deferred tax assets, we must assess the likelihood that our deferred tax assets will be recovered from taxable temporary differences, tax strategies or future taxable income and to the extent that we believe that recovery is not likely, we must establish a valuation allowance. As of December 31, 2003 we have established a valuation allowance of $40.3 million against our deferred tax assets. In the future, we may adjust our estimates of the amount of valuation allowance needed and such adjustment would impact our provision for income taxes in the period of such change.

Inflation

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

Item 7A. ***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, accounts and notes receivable, investments, accounts payable and accrued liabilities. At December 31, 2003, the carrying values of these financial instruments approximated their fair values.

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

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

Item 8. ***Financial Statements and Supplementary Data***

Our financial statements and schedule, as listed under Item 15, appear in a separate section of this Annual Report on Form 10-K beginning on page F-1.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

Effective March 7, 2003, we dismissed KPMG LLP as our independent auditor. Disclosure with respect to this Item was included in our Definitive Proxy Statement filed on December 3, 2003. We are not aware of any transactions or events similar to those previously reported and described in our prior disclosure with respect to this Item, which were accounted for or disclosed in a manner different from that which our former accountants apparently would have concluded was required.

Item 9A. ***Controls and Procedures***

(a) *Evaluation of Disclosure Controls and Procedures.* As required by Securities and Exchange Commission Rule 13a-15(b), our Chief Executive Officer and our Senior Vice President, Chief Financial

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Officer have evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on their evaluation, our Chief Executive Officer and our Senior Vice President, Chief Financial Officer have concluded our disclosure controls and procedures are not yet effective because we are not currently able to timely file all reports required to be filed by us pursuant to Section 15(d) of the Securities Exchange Act of 1934. Our inability to timely file the required reports is due to, among other things, the fact that management s time and attention have been consumed by the auditing and re-auditing of our financial statements for the years ended December 31, 2000, 2001, 2002 and 2003, and the resulting restatements, by the development and implementation of improvements to our internal controls and financial reporting processes, and by the internal and external investigations into the accounting and other matters described in Item 1 Recent Developments and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations.

Since March 2003, management has implemented and continues to implement significant changes in organization, policies and procedures designed to enhance our disclosure controls and procedures and the related internal controls. These include, among other measures: new restrictions and guidelines governing sales personnel, terms and conditions of sale and revenue recognition; new and more stringent credit approval policies; new policies governing approval, review and recording of expenditures and other legal and financial transactions; new procedures governing documentation and approval of options and warrants issued in connection with legal and financial transactions; and new internal reporting procedures. Nevertheless, during much of 2003, many of these enhancements to our disclosure controls and procedures and the related internal controls were not yet in place, or were only partially in place. For this reason, management has undertaken an extensive and substantive review and evaluation of all financial transactions that, individually or collectively, could have a material impact on the information contained in this Form 10-K. These review procedures, in combination with the changes in internal control that have been implemented as of the end of the period covered by this report, form the basis for our determination that the financial statements and other information contained in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the years ended December 31, 2001, 2002 and 2003.

(b) *Changes in Internal Controls.* Except as described above in subsection (a) of this Item 9A, there was no change in our internal control over financial reporting during our fourth fiscal quarter for 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this Item 10 is incorporated by reference to the Definitive Proxy Statement relating to our 2004 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of our fiscal year ended December 31, 2003.

Item 11. ***Executive Compensation***

The information required by this Item 11 is incorporated by reference to the Definitive Proxy Statement relating to our 2004 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of our fiscal year ended December 31, 2003.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this Item 12 is incorporated by reference to the Definitive Proxy Statement relating to our 2004 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of our fiscal year ended December 31, 2003.

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Item 13. ***Certain Relationships and Related Transactions***

The information required by this Item 13 is incorporated by reference to the Definitive Proxy Statement relating to our 2004 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of our fiscal year ended December 31, 2003.

Item 14. ***Principal Accounting Fees and Services***

The information required by this Item 14 is incorporated by reference to the Definitive Proxy Statement relating to our 2004 Annual Meeting of Stockholders, which is to be filed within 120 days after the end of our fiscal year ended December 31, 2003.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules and Reports on Form 8-K***

(a)(1) *Financial Statements:*

The consolidated financial statements of Endocare, Inc. are included in a separate section of this Annual Report on Form 10-K commencing on the pages referenced below:

(2) *Financial Statement Schedules:*

Schedule II Valuation and Qualifying Accounts for the years ended December 31, 2001, 2002 and 2003 is included in the consolidated financial statements at page F-38. All other schedules have been omitted because they are not applicable, not required or the information is included in the consolidated financial statements or the notes thereto.

(3) *Exhibits:*

Exhibit No.	Description
2.1(1)	Agreement and Plan of Reorganization, dated February 21, 2002, by and among the Company, Timm Medical 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. 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.

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Exhibit No.	Description
2.3(3)	Asset Purchase Agreement, dated February 6, 2002, by and between the Company and Gary M. Onik, M.D. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.4(3)	Asset Purchase Agreement, dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among the Company and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. 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.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of September 30, 2002, by and among the Company, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
2.7(6)	Agreement of Purchase and Sale, dated as of April 7, 2003, by and among American Medical Systems, Inc., the Company and Timm Medical Technologies, Inc.
2.8(7)	Asset Purchase and Technology License Agreement, dated as of April 29, 2003, by and between the Company and CryoCath Technologies Inc.
2.9(8)	Agreement of Purchase and Sale, dated as of October 15, 2003, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
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	Amended and Restated Bylaws of the Company.
10.3(2)	Promissory Note, dated November 2, 1999, by Jerry Anderson in favor of the Company.
10.10(9)	Lease Agreement, dated November 26, 2001 by and between the Company and the Irvine Company.
10.11(9)	Form of Indemnification Agreement by and between the Company and its directors.
10.12(9)	Form of Indemnification Agreement by and between the Company and its executive officers.
10.13(10)	1995 Director Option Plan (as amended and restated through March 2, 1999).
10.14(12)	1995 Stock Plan (as amended and restated through April 16, 2002).
10.15(13)	2002 Supplemental Stock Plan.
10.16(4)	Promissory Note, dated July 15, 2002, issued by U.S. Medical Development, Inc. to the Company.
10.17(5)	First Amended and Restated Promissory Note, dated September 30, 2002, issued by U.S. Medical Development, Inc. to the Company.
10.18(11)	Registration Rights Agreement, dated as of February 21, 2002, by and among the Company and the parties listed on Schedule A thereto.
10.19(13)	Registration Rights Agreement, dated as of May 28, 2002, by and between the Company and Cryomedical Sciences, Inc.
10.20(13)	Letter Agreement, dated June 11, 1999, by and between the Company and Jerry Anderson
10.21(13)	Blanket Purchase Agreement, effective April 1, 2002, by and between Timm Medical Technologies, Inc. and the U.S. Department of Veterans Affairs.
10.22(13)	2002 Executive Separation Benefits Plan.
10.23(14)	Employment Agreement, dated as of March 3, 2003, by and between the Company and William J. Nydam.

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Exhibit No.	Description
10.24(14)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Katherine Greenberg.
10.25	Employment Agreement, dated as of March 25, 2003, by and between the Company and Kevin Quilty.
10.26	First Amendment to Employment Agreement, dated as of September 14, 2003, by and between the Company and Katherine Greenberg.
10.27	Consulting Agreement, dated as of August 27, 2003, by and between the Company and Craig T. Davenport.
10.28(15)	Employment Agreement, dated as of December 15, 2003, by and between the Company and Craig T. Davenport.
21.1	Subsidiaries of Registrant.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney, included on signature pages.
31.1	Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
31.2	Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Katherine Greenberg.
32.1	Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
32.2	Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Katherine Greenberg.

* We have requested confidential treatment with respect to certain portions of these documents.

Management contract or compensatory plan or arrangement

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

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

(3) Previously filed on Form 10-Q for the quarter ended June 30, 2002.

(4) Previously filed on Form 8-K on August 16, 2002.

(5) Previously filed on Form 8-K on October 15, 2002.

(6) Previously filed on Form 8-K on April 22, 2003.

(7) Previously filed on Form 8-K on April 29, 2003.

(8) Previously filed on Form 8-K on October 20, 2003.

(9) Previously filed on Form 10-K for the year ended December 31, 2001.

(10) Previously filed with our Registration Statement on Form S-8 filed on June 2, 1999.

(11) Previously filed with our Registration Statement on Form S-3 filed on May 15, 2002.

(12) Previously filed with our definitive proxy statement for the 2002 annual meeting filed on April 30, 2002.

(13) Previously filed on Form 10-K for the year ended December 31, 2002.

(14) Previously filed on Form 8-K on March 27, 2003.

(15) Previously filed on Form 8-K on December 16, 2003.

(b) *Reports on Form 8-K*

We filed a Form 8-K under Item 5 on October 20, 2003, announcing that: (i) we had sold our urodynamics and urinary incontinence product lines to SRS Medical Corp; and (ii) a Delaware Court of Chancery had ruled that we must pay Biolife Solutions, Inc., formerly Cryomedical Sciences (BioLife), $1.6 million in damages plus accrued interest and legal fees to settle a dispute that resulted from our acquisition of the cryosurgical technology and assets of BioLife.

We filed a Form 8-K under Item 5 on December 16, 2003, announcing the appointment of Craig T. Davenport as our new Chief Executive Officer, effective December 15, 2003.

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Supplemental Information

We have not sent an annual report or proxy materials to our stockholders as of the date of this Annual Report on Form 10-K. We intend to provide our stockholders with an annual report and proxy materials after the filing of this Annual Report on Form 10-K, and we will furnish the annual report to the SEC at that time.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENDOCARE, INC.

Date: March 15, 2004

By: /s/ CRAIG T. DAVENPORT

Craig T. Davenport

Chief Executive Officer

POWER OF ATTORNEY

Know all men by these present, that each person whose signature appears below constitutes and appoints Craig T. Davenport and Katherine Greenberg, and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agent, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CRAIG T. DAVENPORT Craig T. Davenport	Chairman and Chief Executive Officer (principal executive officer)	March 15, 2004
/s/ KATHERINE GREENBERG Katherine Greenberg	Senior Vice President and Chief Financial Officer (principal financial and accounting officer)	March 15, 2004
/s/ ROBERT F. BYRNES Robert F. Byrnes	Director	March 15, 2004
/s/ JOHN R. DANIELS, M.D. John R. Daniels, M.D.	Director	March 15, 2004
/s/ RONALD A. MATRICARIA Ronald A. Matricaria	Director (lead director)	March 15, 2004
/s/ TERRENCE A. NOONAN Terrence A. Noonan	Director	March 15, 2004

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Signature	Title	Date
/s/ MICHAEL J. STRAUSS, M.D. Michael J. Strauss, M.D.	Director	March 15, 2004
/s/ THOMAS R. TESTMAN Thomas R. Testman	Director	March 15, 2004

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

To the Board of Directors

Endocare, Inc.

We have audited the accompanying consolidated balance sheets of Endocare, Inc. (the Company) and subsidiaries as of December 31, 2002 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Endocare, Inc. and subsidiaries at December 31, 2002 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

Los Angeles, California
March 10, 2004

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31		
	2001	2002	2003
Total revenues	$ 13,036,566	$ 30,916,425	$ 30,497,177
Costs and expenses:			
Cost of revenues	6,208,258	16,484,396	16,057,526
Research and development	2,543,557	2,899,866	1,257,620
Selling, general and administrative	15,728,183	33,769,442	47,189,348
Goodwill impairment and other charges		20,311,293	
Total costs and expenses	24,479,998	73,464,997	64,504,494
Loss from operations	(11,443,432)	(42,548,572)	(34,007,317)
Gain on divestitures, net			8,630,890
Loss on minority investment	(250,000)		
Interest income	771,982	1,013,343	587,556
Interest expense	(531,028)	(6,839)	(39,531)
Loss before minority interests	(11,452,478)	(41,542,068)	(24,828,402)
Minority interests		(443,678)	(618,900)
Net loss	$(11,452,478)	$(41,985,746)	$(25,447,302)
Net loss per share of common stock basic and diluted	$ (0.68)	$ (1.76)	$ (1.05)
Weighted-average shares of common stock outstanding	16,741,000	23,822,000	24,162,090

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

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31	
	2002	2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,177,825	$ 23,976,539
Available-for-sale securities	22,183,160	
Accounts receivable less allowances for doubtful accounts and sales returns of $2,226,432 and $2,431,835 at December 31, 2002 and 2003, respectively	4,604,576	3,822,570
Inventories	4,491,642	2,609,046
Prepaid expenses and other current assets	640,758	4,432,578
Total current assets	50,097,961	34,840,733
Property and equipment, net	8,244,693	5,638,579
Goodwill	17,538,224	17,538,224
Intangibles, net	15,763,323	11,745,778
Investments and other assets	983,754	2,233,601
Total assets	$ 92,627,955	$ 71,996,915
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,932,439	$ 3,035,242
Accrued compensation	2,816,320	3,858,527
Other accrued liabilities	7,327,703	8,942,830
Total current liabilities	13,076,462	15,836,599
Minority interests	928,741	839,029
Stockholders equity:		
Preferred stock, $.001 par value; 1,000,000 shares authorized; none issued and outstanding		
Common stock, $.001 par value; 50,000,000 shares authorized; 24,148,254 and 24,183,254 shares issued and outstanding at December 31, 2002 and 2003, respectively	24,350	24,390
Additional paid-in capital	169,935,487	171,875,434
Accumulated deficit	(88,931,583)	(114,378,885)
Receivable from stockholder	(214,292)	
Accumulated other comprehensive income, net of tax	12,466	
Deferred compensation	(132,045)	(107,271)
Treasury stock at cost, 201,200 and 206,200 shares at December 31, 2002 and 2003, respectively	(2,071,631)	(2,092,381)
Total stockholders equity	78,622,752	55,321,287
Total liabilities and stockholders equity	$ 92,627,955	$ 71,996,915

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

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIENCY)

	Common Stock		Additional	Accumulated	Receivable From	Accumulated Other Comprehensive Income, Net	Deferred		Total Stockholders Equity
	Shares	Capital	Paid-In Capital	Deficit	Stockholder	of Tax	Compensation	Treasury Stock	(Deficiency)
Balance at December 31, 2000	14,991,649	$15,019	$ 52,139,306	$(35,493,359)	$(728,292)	$	$	$(61,410)	$ 15,871,264
Net loss				(11,452,478)					(11,452,478)
Secondary offering of common stock, net	4,600,000	4,600	72,573,737						72,578,337
Conversion of convertible debentures and accrued interest, net	1,128,733	1,129	7,240,512						7,241,641
Common stock issued in exchange for investment	213,010	213	2,837,080						2,837,293
Common stock issued for patents	20,921	21	149,979						150,000
Common stock issued, other	20,883	21	73,144						73,165
Stock options and warrants exercised	1,076,630	1,076	2,550,241						2,551,317
Compensation related to issuance of options and warrants to consultants for services			773,027						773,027
Forgiveness of receivable from stockholder					257,000				257,000
Balance at December 31, 2001	22,051,826	22,079	138,337,026	(46,945,837)	(471,292)			(61,410)	90,880,566
Comprehensive income (loss):									
Net loss				(41,985,746)					(41,985,746)
Unrealized gain on available-for-sale securities, net						12,466			12,466
Comprehensive income (loss)				(41,985,746)		12,466			(41,973,280)
Common stock issued and options assumed in Timm Medical acquisition	1,620,530	1,621	25,739,507				(165,114)		25,576,014
Common stock issued for patents and covenant not to compete	220,022	220	3,256,919						3,257,139
Stock options and warrants exercised	430,076	430	2,033,128						2,033,558
							33,069		33,069

Amortization of options issued to employees			
Compensation related to issuance of options and warrants to consultants for services	568,907		568,907

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIENCY) (Continued)

	Common Stock		Additional	Accumulated	Receivable From	Accumulated Other Comprehensive Income, Net	Deferred		Total Stockholders Equity
	Shares	Capital	Paid-In Capital	Deficit	Stockholder	of Tax	Compensation	Treasury Stock	(Deficiency)
Repurchase of treasury stock	(174,200)							(2,010,221)	(2,010,221)
Forgiveness of receivable from stockholder					257,000				257,000
Balance at December 31, 2002	24,148,254	24,350	169,935,487	(88,931,583)	(214,292)	12,466	(132,045)	(2,071,631)	78,622,752
Comprehensive income (loss)									
Net loss				(25,447,302)					(25,447,302)
Unrealized gain on available for-sale securities, net						(12,466)			(12,466)
Comprehensive loss:				(25,447,302)		(12,466)			(25,459,768)
Stock options exercised	35,000	35	22,777						22,812
Issuance of restricted stock	5,000	5	19,995						20,000
Compensation related to issuance of options to employees			1,780,322				24,774		1,805,096
Compensation related to issuance of options and warrants to consultants for services			116,853						116,853
Treasury stock received as repayment of loan previously forgiven	(5,000)							(20,750)	(20,750)
Forgiveness of receivable from stockholder					(214,292)				214,292
Balance at December 31, 2003	24,183,254	$24,390	$171,875,434	$(114,378,885)	$	$	$(107,271)	$(2,092,381)	$ 55,321,287

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

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31		
	2001	2002	2003
Cash flows from operating activities:			
Net loss	$(11,452,478)	$(41,985,746)	$(25,447,302)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	716,336	3,095,472	4,668,701
Gain on sale of marketable securities			(12,466)
Gain on divestitures, net			(8,630,890)
Compensation expense related to issuance of options, warrants and restricted stock	773,027	601,976	1,941,949
Treasury stock received as repayment of loan previously forgiven			(20,750)
Goodwill impairment and other charges		20,311,293	
Loss on minority investment	250,000		
Minority interests		443,678	618,900
Forgiveness of receivable from stockholder	257,000	257,000	214,292
Amortization of deferred financing costs	229,847		
Common stock issued for interest payable	143,337		
Changes in operating assets and liabilities, net of effects from purchases and divestitures:			
Accounts receivable	(2,770,285)	1,366,069	932,006
Inventories	(808,885)	(3,508,305)	643,752
Prepaid expenses and other current assets	(163,842)	(198,366)	(1,291,873)
Accounts payable	(437,547)	76,123	102,803
Accrued compensation	(88,961)	422,608	1,042,207
Other accrued liabilities	58,758	4,255,072	1,615,127
Net cash used in operating activities	(13,293,693)	(14,863,126)	(23,623,544)
Cash flows from investing activities:			
Acquisitions, net of cash acquired		(24,092,497)	
Purchases of property and equipment	(672,738)	(2,075,575)	(276,385)
Intangibles	(50,339)		(28,924)
Loan made to investee	(250,000)		
Repayment of loan made to investee	250,000		
Partnership distributions to minority interests		(776,532)	(708,558)
Sale (purchase) of available-for-sale securities		(22,170,694)	22,183,160
Other assets	(241,428)	246,111	(1,249,847)
Net cash (used in) provided by investing activities	(964,505)	(48,869,187)	19,919,446

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ENDOCARE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	For the Years Ended December 31		
	2001	**2002**	**2003**
Cash flows from financing activities:			
Payments made on credit facility and other debt	(1,074,268)		
Proceeds from secondary offering	72,578,337		
Proceeds from other issuance of common stock	73,165		
Stock options and warrants exercised	2,551,317	2,033,558	22,812
Repurchase of treasury stock		(2,010,221)	
Proceeds from divestitures			9,480,000
Net cash provided by financing activities	74,128,551	23,337	9,502,812
Net increase (decrease) in cash and cash equivalents	59,870,353	(63,708,976)	5,798,714
Cash and cash equivalents, beginning of year	22,016,448	81,886,801	18,177,825
Cash and cash equivalents, end of year	$81,886,801	$ 18,177,825	$23,976,539
Noncash activities:			
Convertible debentures and accrued interest converted to common stock, net of unamortized deferred financing costs of $458,694 at December 31, 2001	$ 7,241,641	$	$
Transfer of inventory to property and equipment for placement at customer sites	10,251	2,902,184	505,454
Common stock exchanged for investment in U.S. Medical Development, Inc.	2,837,293		
Common stock issued and options assumed in the acquisition of Timm Medical		25,741,128	
Common stock issued for patents and covenant not to compete	150,000	3,257,139	
Change in unrealized gain on available-for-sale securities		12,466	
Other supplemental information:			
Interest paid	776,055		39,530
Income taxes paid	1,600	1,600	1,600

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

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Operations of the Company

Endocare, Inc. (Endocare or the Company) is a medical device company focused on developing, manufacturing and selling cryosurgical products with the potential to improve the treatment of cancer and other tumors, and on manufacturing and marketing vacuum technology as a non-pharmacological option for treatment of erectile dysfunction. The Company was formed in 1990 as a research and development division of Medstone International, Inc., a manufacturer of shockwave lythotripsy equipment for the treatment of kidney stones. Following its incorporation under the laws of the state of Delaware in 1994, the Company became an independent, publicly owned corporation upon Medstone s distribution of the Company s stock to the existing stockholders on January 1, 1996.

The Company initially concentrated on developing devices for the treatment of prostate cancer. The Company commenced sales of its Food and Drug Administration, or FDA-approved Cryocare Surgical System (System) in the United States in 1999. Because of the Company s initial concentration on prostate cancer, a majority of its sales and marketing resources are directed towards the promotion of its cryoablation technology to urologists for the treatment of prostate and renal cancer. The Company is also expanding its focus across a number of surgical markets, including the ablation of tumors in the kidney, lung and liver, as well as for pain management in patients with metastatic bone cancer. Accordingly, Endocare recently formed a new sales and marketing group to focus on the radiology market where its products can be used to treat these other cancer sites.

Endocare primarily markets and sells its cryosurgical products and services directly to hospitals and other providers of healthcare services. Internationally, the Company markets its products through distributors and other third parties. Endocare also contracts with third-party payors in the United States for the use of its Cryocare Surgical Systems in cryoablation treatments for prostate diseases on a per-procedure fee basis.

In addition, the Company offers the ErecAid line of vacuum therapy systems, which include the ErecAid Classic system, and ErecAid Esteem system for non-pharmaceutical treatment of erectile dysfunction. The Company acquired these product lines in the first quarter of 2002 through the acquisition of Timm Medical Technologies, Inc. (Timm Medical), a provider of a variety of urological products. Several of these product lines were divested during 2003, including the urological prostheses product line and certain products used in the diagnosis and treatment of erectile dysfunction, urinary incontinence and benign prostatic hyperplasia (BPH). This acquisition has allowed the Company to expand its sales and marketing organization and to increase market access to urologists for its cryoablation and penile rehabilitation technologies (see Note 4).

Recent Operating Results and Liquidity

The Company s 2003 operating results included divestiture of non-core lines of business allowing it to better concentrate on its core businesses. At the same time, divestiture of these lines reduced or eliminated some sources of revenue and gross profit for the Company. In addition, while the Company lowered research and development costs in 2003, and consolidated functions formerly performed by subsidiaries at the Company s Irvine, California headquarters, the Company also incurred significant one-time charges associated with the ongoing investigations related to its historical accounting and financial reporting. The net result of the Company s activities in 2003 was a $25,447,000 loss. Significant factors contributing to the 2003 operating results were as follows:

Costs of $14,255,000 incurred in connection with on-going regulatory investigations of our historical accounting and financial reporting, including $5,057,000 in attorney s fees and settlement costs, $4,000,000 in accounting and audit fees for re-audits and restatements of the 2000, 2001 and audit of 2002 financial statements, $1,630,000 in financial consulting and staffing support and $3,568,000 in severance payments mainly due to the former CEO and CFO;

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Incremental sales and marketing investments to gain market share in the urology market and to advance the use of our cryosurgical technology in the interventional radiology market;

Net gains on divestitures of $8,631,000 in connection with sales of the intellectual property and inventory related to the SurgiFrost cardiac arrhythmia products, the Dura II penile prosthesis and the urinary incontinence line which partially reduced the 2003 loss.

Since inception, the Company has incurred losses from operations and has reported negative cash flows. As of December 31, 2003, the Company had an accumulated deficit of $114,379,000, and cash and cash equivalents of $23,977,000. The Company has no long-term debt and no other material financial commitments other than those under operating lease agreements and purchase commitments for raw materials used in manufacturing its products. Management anticipates further growth in procedure revenues in 2004 (42.3% growth was experienced in 2003 as compared to 2002). However, the Company expects to record another loss in 2004. The Company will continue to invest in sales and marketing activities to increase market penetration, and research and development to improve its existing products and develop new ones. The Company also faces potentially large costs related to directors and officers liability insurance, delinquent state and local taxes, as well as expenditures needed to bring the Company into compliance with SEC rules and regulations, including with Section 404 of Sarbanes-Oxley Act of 2002, and efforts to regain its listing on Nasdaq.

In addition to the cash needed to fund the Company s ongoing operations, there have been and will continue to be substantial demands on cash related to ongoing investigations of the Company s historical accounting and financial reporting. There may also be material cash payments required in connection with resolving a class action and a derivative lawsuit (see Note 12). The Company may be required to pay judgments or settlements and to incur expenses in defending against these claims that could exceed the Company s directors and officers liability insurance coverage. Regulators may fine the Company when the investigations are complete.

The Company will continue to use cash reserves, which it believes to be adequate, to finance its projected 2004 cash flow deficit. If the Company is unable to generate cash flow from operations, it may need to raise additional capital to fund its operations through the sale of equity securities to private or public investors, debt, further divestiture of product lines and licensure of its cryoablation technology for applications other than the treatment of prostate, liver, lung and kidney diseases and bone pain management. Additional capital, if needed, might not be available on terms acceptable to the Company, or at all. If additional capital were raised through the issuance of equity securities, the percentage of the Company s stock owned by its then-current stockholders would be reduced.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all majority owned and controlled subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates. Principal areas requiring the use of estimates include: determination of allowances for uncollectible accounts and sales returns, warranty obligations, reserves for excess and obsolete inventory, valuation allowances for investments and deferred tax assets, impairment of

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

long-lived and intangible assets, determination of stock-based compensation to employees and consultants, and reserves for litigation. The Company cannot predict what effect, if any, that these or other events or circumstances may have on its financial position, results of operations and cash flows.

Revenue Recognition

Revenues from sales of Cryocare Surgical Systems, disposable cryoprobes and other urological products are recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, and collectibility is reasonably assured. The Company also contracts with medical facilities and healthcare payors for the use of the Cryocare Surgical Systems in cryoablation treatments for which the Company charges a per-procedure fee. The fee typically includes a procedure kit containing cryoprobes and other disposables needed to perform a cryoablation procedure, in addition to a service component. The service component of the procedure generally consists of rental and transport of a Cryocare Surgical System as well as the services of a technician to assist the physician with the set-up, use and monitoring of the equipment. The medical facilities and healthcare payors are billed for procedures performed using Cryocare Surgical Systems owned either by the Company or by third parties who perform the service component of the procedure. The Company receives procedure fee revenue from the payors and, where a third-party service provider is involved, remits a portion of the fee to the service provider. The fee is recorded as revenue in the period when the procedure is performed and, where applicable, a service fee paid for the Cryocare Surgical System owned by a third party is included in cost of revenues. The cost of revenues for the bundled services includes depreciation related to Company owned Cryocare Surgical Systems over an estimated useful life of three years.

The Company has deferred the recognition of certain Cryocare Surgical System revenues where it has granted future minimum procedure fee guarantees. Deferred revenues are adjusted in future periods when the minimum procedure fee guarantees have been met. Deferred revenue at December 31, 2001, 2002, and 2003, totaled $119,000, $1,082,000 and $459,000, respectively (included in other accrued liabilities).

In 2001, sales to U.S.M.D., Ltd. accounted for 31.5% of total revenues. No other customers accounted for more than 10% of total revenues in 2001 and no individual customer accounted for more than 10% of total revenues in 2002 and 2003. The Company derived approximately 88% from sales in the United States during this three-year period. See Notes 4, 5 and 11.

The Company routinely assesses the financial strength of its customers and, as a consequence, believes that its accounts receivable credit risk exposure is limited. Accounts receivable are carried at original invoice amount less an estimate for doubtful accounts and sales returns based on a periodic review of outstanding receivables. International shipments are billed and collected by the Company in U.S. dollars. Allowances are provided for known and anticipated credit losses as determined by management in the course of regularly evaluating individual customer receivables. This evaluation takes into consideration a customer s financial condition and credit history as well as current economic conditions. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Inventories

Inventories, consisting of raw materials, work-in-process and finished goods, are stated at the lower of cost or market, with cost determined by the first-in, first-out method. Reserves for slow-moving and obsolete inventories are provided based on historical experience and product demand. The Company evaluates the adequacy of these reserves periodically.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Long-Lived Assets, including Intangible Assets Subject to Amortization

The Company reviews long-lived assets and asset groups for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. The Company considers assets to be impaired and writes them down to fair value if estimated cash flows associated with those assets are less than their carrying amounts. Fair value is based upon the present value of the associated cash flows. The Company has determined that no long-lived assets were impaired at December 31, 2003.

Property and Equipment

Property and equipment are stated at cost and are depreciated on a straight-line basis over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the related lease term. Cryosurgical equipment placed at customer sites for use with the Company s disposable cryoprobes is depreciated into cost of revenues over estimated useful lives of three years. Repair and maintenance costs are expensed as incurred. Depreciation expense was $428,169, $1,893,939 and $3,372,221 in 2001, 2002 and 2003, respectively.

Goodwill and Intangible Assets

The excess of the purchase price over the fair value of net assets acquired has been allocated to goodwill and identifiable intangible assets. The Company had no reported goodwill prior to January 1, 2002. The Company does not amortize goodwill which is consistent with the provisions of Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and other Intangible Assets.* Intangible assets that are deemed to have finite useful lives are recorded at cost and amortized using the straight-line method over the estimated useful lives of the assets. Estimated useful lives of such intangible assets are as follows:

Trade name	15 years
Domain name	5 years
Covenant not to compete	3 to 5 years
Developed technology	15 years
Patents	3 to 15 years

Changes in circumstances (for example, changes in laws or regulations to which we are subject, technological advances or changes in the Company s strategies) may result in changes to the useful lives from initial estimates. Factors such as changes in the planned use of intangibles may result from changes in customer base, contractual agreements, or regulatory requirements and may result in shorter useful lives. In such circumstances, the Company will revise the useful life of the long-lived asset and amortize the remaining net book value over the adjusted remaining useful life. There were no changes in estimated useful lives during 2001, 2002 and 2003. In the fourth quarter of 2002, the Company recorded a $17,984,000 impairment charge relating to the goodwill arising from the Timm Medical acquisition. There was no impairment change recorded for the year ended December 31, 2003.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Amortization expense for each of the years ending December 31 will consist of the following amounts:

2004	$ 1,212,753
2005	1,111,615
2006	1,037,115
2007	972,490
2008	966,615
Thereafter	6,445,190
	$11,745,778

Amortization expense totaled $288,167, $1,201,533 and $1,296,480 in 2001, 2002 and 2003, respectively.

Available-for-Sale Securities

During 2002 and 2003, the Company invested its funds in a diversified portfolio of marketable debt securities, which consisted of corporate bonds, government agencies securities and commercial paper. Available-for-sale securities are classified as available-for-sale securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* Fair values of marketable securities are based on quoted prices in active markets. Unrealized gains or losses, net of applicable income taxes, are recorded as a component of accumulated other comprehensive income in stockholders equity. Investments are periodically evaluated to determine if an other-than-temporary decline in value has occurred. Such evaluation is dependent on specific facts and circumstances and includes factors, such as the market value of the security in relation to its cost basis, the financial condition of the subject investment and the intent and ability to hold the investment for a sufficient period of time to allow for recovery in market value. Realized gains and losses and unrealized losses judged to be other-than-temporary are included in the determination of net income. The cost of securities sold is determined using the specific-identification method. Since these securities are available for use in current operations, they are classified as current assets without regard to the securities contractual maturity dates. During 2003, the Company sold its available-for-sale securities and reinvested the proceeds in highly liquid instruments such as money market funds. Realized gains on sale were not significant.

Following is a summary of available-for-sale securities (gross unrealized gains and losses are not presented as they are immaterial):

	Amortized Cost	Estimated Fair Value
December 31, 2002		
U.S. government and federal agency securities	$ 3,000,000	$ 3,009,390
Municipal bonds	15,100,000	15,100,000
Corporate bonds	1,000,000	1,080,820
Commercial paper	3,000,000	2,992,950
Total	$22,100,000	$22,183,160

Other Investments

Other investments primarily consist of strategic investments of less than 20% equity interest in certain companies acquired in conjunction with various strategic alliances. These represent minority interests in start-up technology companies and mobile medical service providers. The Company does not have the ability to exercise significant influence over any of these companies; therefore, they are recorded at cost and

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accounted for under the cost method of accounting. Realized gains and losses are recorded in interest and other income when related investments are sold. Investments in privately held companies are regularly assessed for impairment through review of operations and indicators of continued viability. Reviews of operations to assess the carrying values include evaluation of operating performance, financing status, liquidity prospects and cash flow forecasts. Impairment losses are recorded when events and circumstances indicate that such assets might be impaired and the decline in value is other-than-temporary. These investments are included in investments and other assets.

Product Warranties

Certain of the Company s products are covered by warranties against defects in material and workmanship for periods up to two years after the sale date, except for the erectile dysfunction products, which are subject to a limited lifetime warranty. The estimated warranty cost is recorded at the time of sale and is adjusted periodically to reflect actual experience. Factors that affect the Company s warranty liability include the number of units sold, historical and anticipated rates of warranty claims, and cost per claim. The Company s warranty costs and liability (included in other accrued liabilities) were not significant.

Research and Development

Research and development expenditures primarily include personnel, clinical studies, and material expenses incurred to design, create, and test prototypes. These expenditures are charged to operations as incurred until technological feasibility has been established.

Advertising

Amounts incurred for advertising costs are included in selling, general and administrative expenses as incurred and totaled $424,402, $1,591,009 and $581,163 for the years ended December 31, 2001, 2002 and 2003, respectively.

Cash and Cash Equivalents

All highly liquid investments purchased with an original maturity of three months or less are considered to be cash equivalents. Cash and cash equivalents include money market funds and various deposit accounts.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, primarily consist of cash and cash equivalents, available-for-sale securities, and accounts receivable. The Company from time to time may be exposed to credit risk with its bank deposits in excess of the FDIC insurance limits. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash and cash equivalents. Available-for-sale securities are invested under the direction of the Board of Directors. The Company s receivables are derived primarily from sales of Cryocare Surgical Systems, disposable CryoProbes and other urological products to medical facilities, medical groups, urologists and direct consumers, and procedure fees generated from medical facilities that are not considered high credit risk. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. Reserves are maintained for potential credit losses.

Fair Value of Financial Instruments

The primary objective of the Company s investment activities is to preserve principal while at the same time maximizing the income the Company receives from its invested cash without significantly increasing risk of loss. The Company s consolidated balance sheets include the following financial instruments: cash and cash

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

equivalents, available-for-sale securities, accounts receivable, minority investments, accounts payable and accrued liabilities. The carrying amounts of current assets and liabilities approximate their fair values because of the relatively short period of time between the origination of these instruments and their expected realization.

Risks and Uncertainties

The Company s profitability depends in large part on increasing its revenue base and effectively managing costs of sales, customer acquisition costs and administrative overhead. The Company continually reviews its pricing and cost structure in an effort to select the optimal revenue and distribution models. Several factors could adversely affect revenues and costs, such as changes in health care practices, payor reimbursement, inflation, new technologies, competition and product liability litigation, which are beyond any company s control and could adversely affect the Company s ability to accurately predict revenues and effectively control costs. Many purchasers of the Company s products and services rely upon reimbursement from third-party payors, including Medicare, Medicaid and other government or private organizations. These factors could have a material adverse effect on the Company s financial condition, results of operations or cash flows.

Segment Information

The Company presents segment information externally the same way management uses financial data internally to make operating decisions and assess performance. Each of the Company s subsidiaries manufactures, markets and sells urological products and services to insurers and health care providers. They share similar characteristics in the customers they serve, the nature of products and services provided and the methods by which the products and services are distributed. The subsidiaries are also subject to similar regulatory environment and long-term economic prospects. As such, the Company has one reportable segment.

Off-Balance Sheet Financings and Liabilities

Other than lease commitments, legal contingencies incurred in the normal course of business, and employment contracts, the Company does not have any off-balance sheet financing arrangements or liabilities. In addition, the Company s policy is not to enter into derivative instruments, futures or forward contracts. The Company s business is transacted solely in U.S. dollars and, while future fluctuations of the U.S. dollar may affect the price competitiveness of the Company s products, there is no known significant direct foreign currency exchange rate risk. Finally, the Company does not have any majority-owned subsidiaries or any interests in, or relationships with, any material special-purpose entities that are not included in the consolidated financial statements.

Stock-Based Compensation

The Company has four stock-based employee compensation plans, which are described more fully in Note 9. The Company accounts for the plans under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Compensation cost for stock options granted to employees is reflected in net income (loss) and is measured as the excess of the market price of the Company s stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost for fixed awards subject to vesting is recognized pro rata over the vesting period.

The Company has adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. The following table illustrates the effect on net loss and

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loss per share if the Company had applied the fair value recognition provisions to stock-based employee compensation.

	Year Ended December 31		
	2001	2002	2003
Net loss, as reported(a)	$(11,452,478)	$(41,985,746)	$(25,447,302)
Reconciling items (net of related tax effects):			
Add: Stock-based employee compensation expense determined under the intrinsic-value-based method for all awards(b)		33,069	24,774
Less: Stock-based compensation expense determined under the fair-value-based method for all awards expense	(2,020,142)	(4,075,475)	(2,312,996)
Net adjustment	(2,020,142)	(4,042,406)	(2,288,222)
Net loss, as adjusted	$(13,472,620)	$(46,028,152)	$(27,735,524)
Basic and diluted loss per share:			
As reported	$ (0.68)	$ (1.76)	$ (1.05)
As adjusted	(0.80)	(1.93)	(1.15)

(a) The Company issues stock options and warrants to consultants for services performed. Compensation expense for the fair value of these options is determined by the Black-Scholes option-pricing model and is charged to operations over the service period or as the performance goals are achieved. Such expense is included in net loss as reported. In addition, the net loss for 2003 included compensation expense totaling $1,780,000 relating to option settlements with two former employees in conjunction with their separation arrangements in accordance with the fair value method of accounting under SFAS No. 123, *Accounting for Stock Based Compensation* (see Note 9).

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

Net Loss Per Share

Basic loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted loss per share adjusts basic loss per share for the effects of convertible securities, stock options, warrants and other potentially dilutive securities. Dilutive loss per share for each of the three years in the period ended December 31, 2003 is calculated using only the weighted-average number of common shares outstanding during the periods, as the inclusion of stock options and warrants would have been antidilutive. Accordingly, diluted loss per share equals basic loss per share for each of the three years in the period ended December 31, 2003.

Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company s assets and liabilities along with net operating loss and credit carryforwards, if it is more likely than not that the tax benefits will be realized. To the extent a deferred tax asset cannot be recognized under the preceding criteria, allowances must be established. The impact on deferred taxes of changes in tax rates and laws, if any, are applied to the years during which

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temporary differences are expected to be settled and reflected in the financial statements in the period of enactment.

The Company is also subject to other taxes, including capital taxes, sales and use taxes, and various other state and local taxes, which are assessed on a basis other than taxable income. These taxes totaled $512,000, $1,074,000 and $685,000 during 2001, 2002 and 2003, respectively, and are included in selling, general and administrative expenses. Taxes payable at December 31, 2002 and 2003 were $2,194,000 and $2,579,000, respectively (included in other accrued liabilities).

3. Goodwill Impairment

The Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets*, with respect to amortization for acquisitions after June 2001 and, with respect to impairment, as of January 1, 2002. Under SFAS No. 142, goodwill and indefinite-lived intangible assets are no longer amortized but instead are reviewed annually for impairment and on an interim basis if events or changes in circumstances between annual tests indicate that an asset might be impaired. Indefinite-lived intangible assets are tested for impairment by comparing their fair values to their carrying values under a two-step process. The first step requires the Company to compare the fair value of its reporting units to the carrying value of the net assets of the respective reporting units, including goodwill. If the fair value of the reporting unit is less than the carrying value, goodwill of the reporting unit is potentially impaired and the Company then completes Step 2 to measure the impairment loss, if any. The second step requires the calculation of the implied fair value of goodwill by deducting the fair value of all tangible and intangible net assets of the reporting unit from the fair value of the reporting unit. If the implied fair value of goodwill is less then the carrying amount of goodwill, an impairment loss is recognized equal to the difference.

In accordance with SFAS No. 142, the Company completed its annual goodwill impairment test on October 1, 2002 and 2003 for all of its reporting units. The Company utilized an independent third-party appraiser to assess the fair values of each reporting unit. The Company then compared the fair values of the reporting units to their carrying values. Based on this assessment, a goodwill impairment charge of $17,984,000 was recorded in the fourth quarter of 2002 to reduce the carrying value of the goodwill acquired in the Timm Medical acquisition. The impairment resulted from the termination or abandonment of three of the acquired distribution agreements for urological products following the acquisition due to performance and market acceptance issues and concern over the financial viability of their manufacturers. At the time of the acquisition, these arrangements were expected to account for 60% of Timm Medical s annual revenue growth. The Company completed its annual goodwill impairment test for all reporting units as of October 1, 2003, and determined that the remaining goodwill was not impaired.

In the fourth quarter of 2002, the Company also recorded a $2,327,000 other-than-temporary loss in the value of the Company s investment in U.S. Medical Development, Inc. acquired in June 2001 (see Note 11). The loss was based on management s assessment that the investee is unable to sustain an earnings capacity, which would justify the carrying amount of the investment.

4. Acquisitions

Business Acquisitions

Timm Medical Technologies, Inc.

On February 21, 2002, the Company entered into an agreement and plan of reorganization to acquire Timm Medical for total consideration of $36,512,000 and $838,000 in legal, accounting and other acquisition related costs. In connection with the merger, all outstanding shares of the capital stock of Timm Medical were exchanged for $10,770,000 in cash and 1,620,530 shares of the Company s common stock valued at $23,806,000 (of which 63,412 shares were held in escrow, of which all but 2,841 were released after six

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months). In addition, the Company assumed certain outstanding options of Timm Medical, which were exercisable into 168,162 shares of Endocare common stock at $7.25 per share. These options were valued at $1,935,000 using the Black-Scholes option pricing model, of which $1,770,000 related to vested options and $165,000 related to unvested options. Except for the adjustment in the number of exercisable shares and the corresponding exercise price per share based on the conversion ratio as defined in the purchase agreement, all other option terms and vesting periods remain unchanged. The value of the unvested options was recorded as deferred compensation on the acquisition date to be amortized over the remaining vesting period.

This transaction was accounted for under the purchase method of accounting and the consolidated financial statements of the Company include the financial results of Timm Medical from February 21, 2002. The total purchase price of $37,350,000 (including transaction costs and the amount recorded as deferred compensation) was allocated to the tangible and intangible assets acquired based on their respective fair value as follows:

Total purchase consideration and related costs	$ 37,350,000
Fair value of tangible net assets acquired	(1,041,000)
Fair value of amortizable intangibles:	
Developed technology	(10,000,000)
Trademark	(500,000)
Unearned compensation	(165,000)
Goodwill (non-tax deductible)	$ 25,644,000

Factors contributing to the origination of goodwill include the enhancement of the product line and projected growth in urology sales through collaborative distribution agreements with other medical device companies and the sales force which the Company believed are valuable assets as the Company divests non-core product lines and redeploys existing resources in the area of tumor ablation. Subsequent to the acquisition, the Company recorded a goodwill impairment charge of $17,984,000 in the fourth quarter of 2002 (see Note 3).

Net cash paid in the acquisition is as follows:

Total purchase consideration and related costs	$ 37,350,000
Fair value of common stock issued	(23,806,000)
Fair value of options assumed	(1,935,000)
Cash paid	11,609,000
Cash acquired	(1,127,000)
Net cash paid	$ 10,482,000

Subsequent to the acquisition date, the Company decided to divest certain non-core product lines, including the Dura II penile implants line sold in April 2003, and the urinary incontinence and urodynamics lines sold in October 2003 (see Note 5).

Mobile Prostate Treatment Businesses

On September 30, 2002, the Company completed the acquisition of certain general and limited equity interests in the mobile prostate and BPH treatment businesses (Mobile Businesses) of U.S. Medical Development, Inc. (formerly U.S. Therapies, LLC), a privately held urology services company based in Dallas, Texas, and its affiliates, U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. (collectively, USMD). USMD is a customer

and was the exclusive distributor of the Company s Cryocare Surgical Systems and cryoprobes in

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

certain states (see Note 11). The purchase included equity interests held by USMD ranging from 1% to 100% in 13 partnerships and limited liability companies for total consideration of $11,185,000 as follows: $3,300,000 in cash, $185,000 in assumption of debt, forgiveness of a $6,800,000 loan previously made by the Company to USMD, and application of a $900,000 earnest money deposit made by the Company in April 2002 upon the execution of a letter of intent.

The $6,800,000 note was a non-recourse loan made to USMD in July 2002 to fund the acquisition of certain business interests by USMD. Interest was at prime rate plus one percent with a scheduled maturity on September 30, 2002. The note was secured by the business interests acquired by USMD. Upon the acquisition in September 2002, the loan was converted to a full recourse unsecured note and was amended to reduce the interest rate to the lowest federal applicable rate in effect with maturity extended to March 30, 2006.

Pursuant to the original terms of the purchase agreement, the Company agreed to forgive the $7,700,000 principal balance of the note and the earnest deposit (the Indebtedness) upon the achievement of $12,000,000 in gross revenues by the Mobile Businesses during the period October 1, 2002 to December 31, 2005 (the Forgiveness Period). The purchase agreement was amended February 2004 to extend the Forgiveness Period to December 31, 2008. In addition, effective January 1, 2004, the Company reduced the service fee it pays to one of the partnerships for the use of their Cryocare Surgical Systems from $2,500 to $2,000 per procedure, representing an adjustment to a market rate. As a result, the reduction in service fee does not require a reallocation of goodwill.

Management believes that the $7,700,000 will be forgiven and has treated the note as additional purchase price allocation as follows:

Total purchase consideration (includes $549,000 in acquisition-related costs)	$11,734,000
Fair value of tangible net assets acquired (primarily property and equipment)	(1,616,000)
Covenant not to compete	(240,000)
Goodwill (non-tax deductible)	$ 9,878,000

The goodwill is primarily related to the distribution network provided by the Mobile Businesses, which allows the Company to further penetrate desired markets. Since investors in the Mobile Businesses are comprised of urologists, the acquisition facilitates the continued promotion of cryosurgery as the preferred treatment for prostate cancer. In addition, USMD exited the cryosurgical and BPH operations upon the sale and terminated its exclusive distribution agreement with Endocare. This allows the Company to market directly to urologists previously served by USMD and to competitors of USMD who were precluded from purchasing from the Company under the previous distribution relationship. No sales have been made to USMD since the September 30, 2002 acquisition was completed.

The tangible assets acquired include 11 Cryocare Surgical Systems previously purchased from the Company by USMD and resold to the partnerships. These systems are recorded at fair value of $2,109,000 on the acquisition date, which approximated the carrying value recorded by USMD, and are depreciated over their remaining useful lives not to exceed three years. The covenant not to compete is amortized over three years.

Net cash paid in the acquisition is as follows:	
Total purchase consideration and related costs	$11,734,000
Cash acquired	(396,000)
Net cash paid	$11,338,000

Endocare is the general partner or member in each of the Mobile Businesses and generally holds over 20% in combined general and limited equity interests. The Company has sole responsibility for the

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management of the Mobile Businesses and exercises exclusive control over their operations. Other equity holders have limited participation rights, which are protective in nature. As such, the Mobile Businesses have been consolidated with the Company s operations since September 30, 2002.

Pro Forma Results of Operations

The following table presents unaudited pro forma results of operations for the year ended December 31, 2002 assuming the Timm Medical and Mobile Business acquisitions occurred as of January 1, 2002:

Revenues	$ 34,876,000
Net loss	$(43,773,000)
Net loss per share basic and diluted	$ (1.82)
Weighted average shares outstanding	24,053,000

The pro forma results of operations reflect adjustments for additional amortization expense for intangible assets acquired, reduction in interest income due to net cash paid in acquisitions and stock compensation expense related to employee options assumed, and increased weighted average shares outstanding to reflect the issuance of common stock in the Timm Medical acquisition.

Asset Purchases

The Company has acquired intangible assets from time to time, including patents and intellectual property as follows:

On May 28, 2002, pursuant to an asset purchase agreement, the Company agreed to acquire the cryosurgical assets of Cryomedical Sciences, Inc., now known as BioLife Solutions, Inc. (BioLife), consisting primarily of a portfolio of patents central to the cryoablation technology, for $2,200,000 in cash and 120,022 shares of the Company s common stock valued at $1,847,000. This transaction was accounted for under the purchase method of accounting. The total purchase consideration of $4,119,000 (including $72,000 in acquisition-related costs) was allocated to the patents since other assets acquired had de minimus value. Pursuant to a Registration Rights Agreement, the Company was required to file a registration statement with the SEC to register the shares issued to BioLife. In November 2002, BioLife filed suit against the Company for failing to register the shares in a timely manner, seeking damages for breach of contract. See Note 12.

In February 2002, the Company entered into an asset purchase agreement with a cryosurgeon inventor of certain technologies related to the Company s business, to acquire certain patents and a covenant not to compete for 100,000 shares of the Company s common stock valued at $1,410,000. Of this amount, $1,058,000 (75,000 shares) was allocated to the patent and is amortized over 15 years and the remaining $352,000 (25,000 shares) was allocated to the covenant not to compete and is amortized over five years. The agreement also requires the seller to provide certain consulting services over 15 years for the consideration received. No

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consideration was allocated to the consulting agreement since the value of such services could not be accurately determined. In January 2003, the Company extended a $344,000 loan to the seller to finance tax payments related to the gain on the sale (see Note 13).

In April 2001, the Company entered into an assignment agreement to acquire the rights to a patent related to the cryoguide system in exchange for $50,000 in cash and 20,921 shares of Company s common shares with a fair value of $150,000 as of the purchase date. In addition, the Company is obligated to make royalty payments equal to 3.5% of net revenues (as defined) related to the cryoguide system through the patent expiration date. The total purchase price of $200,000 was allocated to patents and is amortized over the remaining useful life of 12 years.

5. Dispositions and Restructuring Activities

In 2003, the Company embarked on a strategy to refocus its core technological competence and primary market emphasis on the development of minimally invasive technologies for tissue and cancer ablation. Part of this strategy entails divestiture of certain product lines that are unrelated to the Company s focus. The Company also undertook a review of its strategic plans and operational infrastructure in order to maximize efficiency and promote optimal use of resources. In addition to the divestiture of a Florida billing and contracting subsidiary in December 2002, which reduced headcount by 12 employees, the Company downsized its Eden Praire, Minnesota, operations in June 2003, consolidating many administrative functions at its Irvine, California, headquarters and reducing headcount by 26 employees. The Company s Board of Directors also approved the divestiture of certain non-core product lines and assets in the first quarter of 2003, including the sale of the Dura II penile implants, the cardiac-related product manufacturing operations and license of related technology, and the urinary incontinence and urodynamics product lines. These related assets were classified as held and used at December 31, 2002.

Advanced Medical Procedures, LLC (AMP)

Effective December 31, 2002, the Company divested certain assets held by AMP, a Florida limited liability company originally acquired in June 1999 through a pooling-of-interests transaction. AMP operated a mobile cryosurgery business, which provided cryosurgical equipment for the treatment of prostate and liver cancer on a procedural basis. AMP also performed payor and reimbursement contracting, billing and collection services for the Company and certain third parties. To consolidate its operations, the Company centralized AMP s former operations in its Irvine, California, headquarters. AMP s office facility, leases and third-party billing contracts were transferred to the former employees under a newly incorporated entity for no consideration. The asset divestiture resulted in a loss of $115,000 in the fourth quarter of 2002 (included in selling, general and administrative expenses), which was primarily related to property and equipment transferred to the former employees.

Dura II Penile Implants

On April 7, 2003, Timm Medical sold certain assets related to the Dura II positionable urological prostheses product line to American Medical Systems, Inc. for approximately $2,150,000 in cash. Assets sold include developed technology, intellectual property, customer lists, production equipment and Dura II inventory. The sale resulted in a loss of $35,000 in the second quarter of 2003 (included in gain on divestitures, net).

Cryosurgical Products for Cardiac Applications

On April 14, 2003, the Company sold its cardiac-related product manufacturing operations and licensed the related intellectual property to CryoCath for $10,000,000. CryoCath was the exclusive distributor for cryoprobes and consoles in connection with the SurgiFrost™ system, a cryoablation system designed to treat

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

cardiac arrhythmias. The Company transferred all of its manufacturing assets and inventory related to the cardiac product line to CryoCath, including technical know-how, vendor lists, production equipment and inventory. In addition, CryoCath received an exclusive worldwide perpetual license for cardiac uses to the Company s proprietary argon gas based technology associated with the product and will make payments to the Company under a nine-year descending royalty stream based on net sales of products incorporating the licensed technology. The Company also agreed to a 12-year worldwide covenant not to compete in the cardiac field. Upon the consummation of the sale, the Company terminated its pre-existing distribution agreement with CryoCath. The Company is also required to attend quarterly and annual technical update meetings through 2014. Since the technology was internally developed and the tangible assets sold had de minimus value, the sale resulted in a 2003 second quarter gain of $9,980,000. The royalty stream decreases from 10% to 3% of net sales from the SurgiFrost™ system during the period 2004 to 2012. The royalty payments will be recorded in the periods earned. At December 31, 2003, the Company had collected $7,480,000 of the total sale proceeds. The remaining $2,500,000, included in prepaid expenses and other current assets at December 31, 2003, was collected in January 2004.

Minnesota Facility

Subsequent to the acquisition of Timm Medical, the Company undertook a review of the Company s operational and financial infrastructure. To maximize operational efficiency and resource utilization, the Board of Directors approved a plan in the first quarter of 2003 to close Timm Medical s former manufacturing facility in Minnesota after the sale of the Dura II and urinary incontinence product lines. With the exception of certain marketing and financial functions, all operations were transferred to the Company s Irvine, California, headquarters in June 2003 or were outsourced. The cost of the restructuring totaled $386,000, which included $266,000 in severance payments and $120,000 in lease losses for vacating the unused leased space. These losses are recorded in the second quarter of 2003 upon the communication of the separation terms to the affected employees. In addition, Timm Medical had $465,000 in property and equipment, a portion of which may be abandoned or sold for salvage value at a future date. These assets are classified as held and used until they are disposed or abandoned. In the first quarter of 2003, management has adjusted the useful life of the assets to be abandoned to amortize their carrying value, less estimated salvage, through the scheduled abandonment date of April 2004.

Urinary Incontinence and Urodynamics

On October 15, 2003, Timm Medical agreed to sell the manufacturing assets related to its urodynamics and urinary incontinence product lines to SRS Medical Corp. (SRS) for a $2,742,000 note. These assets include certain patents and trademarks related to the urodynamics and urinary incontinence products, inventory, customer lists and technical know-how. The note bears interest at 7.5% and is secured by the assets sold. Quarterly payments will begin on March 31, 2004, equal to the higher of (a) minimum quarterly payments as defined or (b) 15% of the net revenues related to the urinary incontinence assets acquired and 15% of the net revenues related to SRS existing urodynamics business, including the urodynamics assets acquired. The minimum quarterly payments will commence at $112,500 for the quarter ended March 31, 2004, and increase to $298,406 for the quarter ended March 31, 2007. Amounts which remain outstanding at March 31, 2007 will be payable at $250,000 per quarter thereafter until fully paid. The carrying values of the urodynamics and urinary incontinence related assets were $1,314,000 on the date of sale. Management concluded that collection of the note from SRS was not reasonably assured. As a result, a loss of $1,314,000 was recorded in the fourth quarter of 2003 equal to the carrying value of the assets sold. Collections on the note, if any, will be reported as gain in the period received.

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Mobile Prostate Treatment Businesses

In late 2003, the Company initiated the dissolution of four of the 13 partnerships acquired from USMD, one of which was engaged in BPH treatment and three of which were engaged in cryosurgical procedures for prostate cancer. The BPH partnership discontinued operations beginning in the first quarter of 2003 due to significant reduction in payor reimbursements and the Company s desire to exit the non-core BPH business. The Company elected to terminate the cryosurgical partnerships due to decisions by certain of the limited partner physicians to withdraw from these partnerships. After the dissolution, the Cryocare Surgical Systems held by these partnerships will be redeployed to other markets as placement units.

Since the Company will continue to receive license fees from CryoCath and may receive installment purchase price payments from SRS (to be recognized as revenue when received) after the sales, the revenues and related costs of the CryoCath and the urinary incontinence product lines have been included in continuing operations for each of the three years in the period ended December 31, 2003. The revenues and cost of revenues for the Dura II product line are not significant and are not presented as discontinued operations.

The combined revenues and costs of revenues related to the divested product lines for each of the years ended December 31 are as follows:

	2002	2003
Revenues	$5,375,435	$1,972,017
Cost of Revenues	2,337,258	948,776
Gross Margin	$3,038,177	$1,023,241

Incremental selling, general and administrative expenses attributable to these product lines were not significant.

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6. Balance Sheet Supplemental Information

	December 31	
	2002	2003
Inventories:		
Raw materials	$ 1,391,161	$ 859,886
Work in process	176,011	272,606
Finished goods	2,924,470	1,476,554
Total inventories	$ 4,491,642	$ 2,609,046
Prepaid expenses and other current assets:		
Prepaid insurance	$ 262,922	$ 212,593
Restricted cash held in escrow (see Note 12)		1,366,775
Receivable from CryoCath (see Note 5)		2,500,000
Other	377,836	353,210
Prepaid expenses and other current assets	$ 640,758	$ 4,432,578
Property and equipment:		
Equipment	$ 5,498,473	$ 4,940,757
Cryosurgical systems placed at customer sites	4,260,653	3,825,115
Furniture and fixtures	1,118,852	1,072,827
Leasehold improvements	487,812	372,194
Total property and equipment, at cost	11,365,790	10,210,893
Accumulated depreciation and amortization	(3,121,097)	(4,572,314)
Property and equipment, net	$ 8,244,693	$ 5,638,579
Intangibles:		
Trade name	$ 500,000	$ 500,000
Domain name	435,000	435,000
Covenant not to compete	592,500	592,500
Patents	5,734,733	5,450,025
Developed technology	10,000,000	7,000,000
Total intangibles	17,262,233	13,977,525
Accumulated amortization	(1,498,910)	(2,231,747)
Intangibles, net	$ 15,763,323	$ 11,745,778
Other accrued liabilities:		
Professional fees	$ 277,617	$ 2,966,436
State and local taxes	2,193,548	2,578,679
Litigation accrual (see Note 12)	1,500,000	1,500,000
Deferred revenue	1,081,566	465,320

Warranty reserves	431,947	274,847
Discounts payable to distributor	557,890	
Other	1,285,135	1,157,548
Total other accrued liabilities	$ 7,327,703	$ 8,942,830

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Debt

Convertible Debentures

In June and July 1999, the Company received $8,000,000 from the sale to institutional investors of 7% convertible debentures due in three years from the date of issuance. Interest was payable annually in cash or, at the Company s option, in common stock at a price per share based on recent bid prices. The debentures were convertible into common shares at $5.125 to $6 per share. During the second quarter of 2000, these debentures were converted into 1,475,610 shares of the Company s common stock.

On May 5, 2000, the Company received a total of $8,000,000 from the sale of additional 7% convertible debentures, of which $500,000 of these debentures were converted into 74,074 shares of the Company s common stock during the fourth quarter of 2000, $1,000,000 of these debentures were converted into 148,148 shares of the Company s common stock during the first quarter of 2001, $4,200,000 of these debentures were converted into 622,222 shares of the Company s common stock during the second quarter of

2001, and the final $2,300,000 of these debentures were converted into 340,741 shares of the Company s common stock in July 2001. Of the debentures converted in 2000 and 2001, an additional $549,098 or 38,861 shares and $200,335 or 17,622 shares, respectively, were issued as interest at a rate of 7%.

Under the financing agreements, the purchasers had a call option exercisable at any time through July 29, 2002, to require the Company to sell to the purchasers an additional $8,000,000 in convertible debentures, which mature in three years, bear interest at 7% per annum and are convertible at $6.75 per share. The Company also had a put option to require the investors to acquire an additional $8,000,000 in convertible debentures if the closing bid price for the common stock as listed was more than $9 to $10 per share for (i) 20 trading days in a consecutive 30 trading day period, and (ii) on the date the Company elected to exercise the put option, and (iii) if certain other conditions were met. The fair value of the investor s two call options described above totaling $1,600,000 was estimated using the Black-Scholes pricing model and was recorded in deferred financing costs. This amount was amortized into interest expense over the original lives of the call options. The net unamortized balance of $1,156,863 was reclassified to additional paid in capital upon conversion of the original $8,000,000 of convertible debentures into common stock in 2000.

Credit Facility

On July 29, 1999, the Company entered into a Loan and Security Agreement with a lender, which originally provided for a revolving credit line plus up to an additional amount based on eligible accounts receivable of the Company (the Loan). The balance available under the revolving portion of the credit facility was $4,000,000 with an additional $1,000,000 available based on eligible accounts receivable of the Company. The Loan accrued interest at the highest prime or equivalent rate announced by certain designated banks, plus 2% for the portion of the loan based on eligible accounts receivable or 3.5%. The Loan was secured by a first priority lien on all of the assets of the Company, except for intellectual property, was fully guaranteed by AMP, a wholly owned subsidiary of the Company, and contained certain restrictive covenants. The loan was repaid upon maturity on July 31, 2001, and the Loan and Security Agreement was canceled on the same date.

8. Stockholders Equity

Secondary Offering

On November 21, 2001, the Company completed a public offering of 4,000,000 shares of its common stock at a price of $17.00 per share. On December 4, 2001, the Company sold an additional 600,000 shares of its common stock at the public offering price of $17.00 per share upon exercise of the over-allotment granted

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

to the underwriters in the public offering. The Company raised $78,200,000 in proceeds through the public offering before deducting commissions and offering expenses of $5,600,000.

9. Equity Incentive Plans

Stock Options

At December 31, 2003, Endocare had four stock-based compensation plans. The 1995 Stock Plan authorizes the Board or one or more committees designated by the Board (the Committee) to grant options and rights to purchase common stock to employees and certain consultants and distributors. Options granted under the 1995 Stock Plan may be either incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended, nonstatutory stock options or other equity instruments, as determined by the Board or the Committee. The exercise price of options granted under the 1995 Stock Plan is equal to the fair market value of Endocare common stock on the date of grant. Options generally vest 25% on the one-year anniversary date, with the remaining 75% vesting monthly over the following three years. Options are exercisable for 10 years. Through December 31, 2003, 5,330,083 shares of common stock have been reserved for issuance under the 1995 Stock Plan. On the first trading day of each calendar year, the number of shares available for issuance automatically increases by 3% of the total number of outstanding common shares at the end of the preceding calendar year, up to a maximum of 1,000,000 shares. As of December 31, 2003, options to purchase 2,738,752 shares of the Company s common stock are outstanding and 472,354 options are available for grant.

The 1995 Director Option Plan (the Director Plan) was adopted by the Board of Directors in October 1995 and approved by the shareholders in November 1995. It provides automatic, non-discretionary grants of options to Endocare s non-employee directors (Outside Directors). The Director Plan provides that each Outside Director is granted an option to purchase 20,000 shares of Endocare common stock vested over a two-year period upon his or her initial election or appointment as an Outside Director. Subsequently, each Outside Director who has served for at least six months will be granted an additional option (Subsequent Option) to purchase 5,000 shares of Endocare common stock, on January 1 of each year, or the first trading day thereafter, so long as he or she remains an Outside Director. The exercise price of options granted to Outside Directors must be the fair market value of Endocare common stock on the date of grant. Options granted to Outside Directors have 10-year terms, subject to an Outside Director s continued service as a director. The Subsequent Options granted to the Outside Directors become fully exercisable on the first anniversary of the date of grant. 275,000 shares of common stock have been reserved for issuance under the Director Plan. As of December 31, 2003, options to purchase 265,000 common shares have been granted; 75,000 have been exercised; 10,000 were forfeited and are available for reissuance; and 180,000 are outstanding.

The Company adopted the 2002 Supplemental Stock Plan (2002 Plan) effective June 25, 2002. Under the 2002 Plan, non-statutory options may be granted to employees, consultants and outside directors with an exercise price equal to at least 85% of the fair market value per share of the Company s common stock on the date of grant. The 2002 Plan expires June 24, 2012, unless earlier terminated in accordance with plan provisions. The 2002 Plan also terminates automatically upon certain extraordinary events, such as the sale of substantially all of the Company s assets, a merger in which the Company is not the surviving entity or acquisition of 50% or more of the beneficial ownership in the Company s common stock by other parties. Upon such an event, all options become fully exercisable. Through December 31, 2003, 435,000 shares of common stock have been reserved for issuance, all of which have been granted; 235,000 options have been forfeited and are available for reissuance; and 200,000 are outstanding.

In addition to the option plans described above, on June 25, 2001, the Company granted to its then Chief Financial Officer and Chief Operating Officer (the former CFO) options to purchase 300,000 shares of the Company s common stock at $13.75 per share. 62,500 of the shares vested on June 25, 2002, and

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

187,500 shares were to vest on a monthly basis over 36 months thereafter. The remaining 50,000 shares were to vest upon the earlier of (i) the former CFO s continuation in service through June 25, 2006, or (ii) his attainment of a performance-based objective. This option was canceled on March 3, 2003 as discussed in Note 12 Employment and Severance Agreements.

On March 3, 2003, the Company granted 750,000 and 250,000 options to purchase common stock to the current President and Chief Operating Officer and the Chief Financial Officer, respectively. The options were granted at $2.25 per share; 250,000 of the President s options are available for accelerated vesting based on the attainment of certain milestones and objectives or five years, whichever comes first. 25% of the remaining 750,000 options vest on the first anniversary with the balance ratably over three years.

On December 15, 2003, the Company granted 1,000,000 options to purchase common stock to the Chief Executive Officer. The options were granted at 4.27 per share; 100,000 of these options are available for accelerated vesting based on the attainment of certain milestones and objectives or five years, whichever comes first. 25% of the remaining options vest immediately with the balance vesting ratably over three years.

All options granted pursuant to the Company s stock-based compensation plans are subject to immediate vesting upon a change in control as defined.

The following tables summarize Endocare s option activity under the three plans:

	Year Ended December 31					
	2001		2002		2003	
	Number of Options	Weighted-Avg. Exercise Price Per Option	Number of Options	Weighted-Avg. Exercise Price Per Option	Number of Options	Weighted-Avg. Exercise Price Per Option
Outstanding, beginning of year	2,743,293	$ 3.37	2,700,057	$ 6.70	3,153,427	$ 8.50
Granted	1,041,000	11.45	1,145,507	11.90	2,893,000	3.42
Cancelled	(136,282)	6.43	(272,649)	10.99	(892,675)	11.96
Exercised	(947,954)	2.28	(419,488)	4.52	(35,000)	3.73
Outstanding, end of year	2,700,057	$ 6.70	3,153,427	$ 8.50	5,118,752	$ 5.06

	Options Outstanding			Options Exercisable	
Range Of Exercise Price	Number Outstanding at December 31, 2003	Weighted-Avg. Remaining Contractual Life (Number of Years)	Weighted-Avg. Exercise Price	Number Exercisable at December 31, 2003	Weighted-Avg. Exercise Price
$ 0.18 - 2.00	468,834	2.34	$ .45	469,834	$ .45
2.03 - 4.00	1,726,810	7.98	2.40	447,810	2.66
4.50 - 6.19	1,940,949	9.40	4.44	876,552	4.61
6.93 - 9.00	122,161	6.31	8.60	106,599	8.71
11.75 - 13.88	526,145	8.06	12.17	261,145	12.32
14.00 - 21.30	332,853	7.85	16.50	202,460	16.50
0.18 - 21.30	5,118,752	7.96	$ 5.06	2,364,400	$ 5.47

The weighted average fair value of the Company s options at the grant date was approximately $7.58 in 2001, $9.54 in 2002 and $3.02 in 2003.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model, with the following assumptions:

	2001	2002	2003
Stock volatility	.8	1.14	1.57
Risk-free interest rate	4.8%	4.3%	3.4%
Expected life in years	5 years	5 years	5 years
Stock dividend yield			

During 2001, 2002 and 2003, the Company incurred employment taxes associated with the exercise of employee stock options and loan forgiveness totaling $182,000, $870,000 and $121,000, respectively. Employment related taxes payable at December 31, 2002 and 2003 were $1,169,000 and $1,290,000, respectively (included in accrued compensation).

Warrants

The Company has issued warrants in conjunction with debt financing transactions, underwriting agreements, patent licenses and service contracts between 1996 and 2000 Warrants have a contractual term of five years and vest over a one- to five-year period. Warrant exercise prices range from $2.31 to $15.40 per share. As of December 31, 2003, the Company had warrants outstanding to purchase 75,000 shares of the Company s common stock, of which 65,000 are exercisable. During 2001 and 2002, warrants to purchase 106,896 and 30,000 shares of common stock, respectively, were exercised. No warrants to purchase shares were exercised in 2003.

The Company also issued detachable warrants to investors to purchase 188,680 shares of the Company s common stock in conjunction with the November 2000 private placement (see Note 8). These warrants have a five-year term and are immediately exercisable at $13.91 per share. 12,500 shares were exercised in 2001 with 176,180 outstanding at December 31, 2003.

The Company estimates the fair value of each warrant on the date of grant using the Black-Scholes option pricing model, with the assumptions similar to option grants above. Warrants granted in connection with the issuance of equity and debt and asset purchase transactions are recorded to additional paid-in capital. Warrants issued for services are amortized to expense over the related service periods.

Stockholder Rights Plan

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

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Income Taxes

The Company reported no income tax expense for each of the three years in the period ended December 31, 2003 due to its operating losses. The following table summarizes the tax effects of temporary differences, which give rise to significant portions of the deferred tax assets at December 31:

	2002	2003
Deferred tax assets (liabilities):		
Investment valuation reserves	$ 1,074,000	$ 1,074,000
Basis difference in intangible assets	(1,314,000)	(146,000)
Property and equipment allowances and depreciation	570,000	(320,000)
Inventory obsolescence and related allowances	1,087,000	1,135,000
Accounts receivable allowances and revenue deferrals	2,951,000	1,049,000
Note receivable allowances		1,040,000
Installment sales		(849,000)
Other accrued liabilities	2,462,000	2,105,000
Accrued compensation	654,000	1,397,000
Net operating loss and credit carryforwards	23,274,000	33,808,000
	30,758,000	40,293,000
Valuation allowance	(30,758,000)	(40,293,000)
Net deferred tax assets	$	$

Due to continuing operating losses, the valuation allowance increased by $8,877,000 and $9,535,000 during the years ended December 31, 2002 and 2003, respectively. In addition, the valuation allowance increased by an additional $4,118,000 during 2002 due to the transfer of fully reserved deferred tax assets obtained in connection with the Timm Medical acquisition. Due to the Company s history of operating losses, management has not determined that it is more likely than not that the Company s deferred tax assets will be realized through future earnings. Accordingly, valuation allowances have been recorded to fully reserve the Company s deferred tax assets as of December 31, 2002 and 2003.

In February 2002, the Company entered into a definitive agreement to acquire Timm Medical in a nontaxable stock transaction. As of the acquisition date, Timm Medical had $4,118,000 of deferred tax assets (net of deferred tax liabilities) consisting principally of $12,156,000 of federal net operating loss carryforwards and $156,000 of federal research and experimentation credit carryforwards. Due to the uncertainty over the realization of these assets, a valuation reserve has been recorded against the deferred tax assets acquired. Subsequent tax benefits resulting from realization of these deferred tax assets will be applied to reduce the valuation allowance and goodwill related to the Timm Medical acquisition. Additionally, as the acquisition resulted in an ownership change for Timm Medical, the annual utilization of the net operating loss and research and experimentation credit carryforwards of Timm Medical will be limited for tax purposes under Internal Revenue Code (IRC) Sections 382 and 383.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Actual income tax expense differs from amounts computed by applying the U.S. federal income tax rate of 34% to pretax loss as a result of the following:

	Years Ended December 31,		
	2001	2002	2003
Computed expected tax benefit	$(3,894,000)	$(14,275,000)	$(8,442,000)
Nondeductible expenses	177,000	244,000	302,000
Goodwill impairment		6,115,000	
Increase in valuation allowance	3,655,000	7,916,000	8,140,000
Other	62,000		
Actual tax expense	$	$	$

As of December 31, 2003, the Company has federal and state net operating loss carryforwards of $85,411,000 and $53,740,000, respectively. The federal net operating loss carryforwards begin to expire in 2011 and the state net operating loss carryforwards begin to expire in 2006. In addition, the Company has federal and state research and experimentation credit carryforwards of $436,000 and $253,000, respectively. The federal research and experimentation credit carryforwards begin to expire in 2011 and the state research and experimentation credit carryforwards do not expire.

IRC Sections 382 and 383 limit the annual utilization of net operating loss and tax credit carryforwards existing prior to a change in control. Based upon prior equity transaction activity, some or all of the Company s existing net operating loss and tax credit carryforwards may be subject to annual limitations under IRC Sections 382 and 383. The Company has not performed an analysis to determine whether such change in control has occurred for tax reporting purposes and if so, the specific limitations that may result.

11. Collaborative and Other Agreements

Sanarus Medical Inc.

In October 1999, the Company entered into a strategic alliance with Sanarus Medical, Inc. (Sanarus), a privately held medical device company. The Company received 200,041 Series A voting convertible Preferred Shares or 6.8% of the total outstanding voting securities at the investment date in exchange for $300,000. The Company also received a warrant to acquire 3,166,000 common shares (approximately 52.0% of Sanarus voting stock on an as-converted, fully-diluted basis at that time) for $.01 per share in consideration for entering into a manufacturing, supply and license agreement (the 1999 Agreement). The 1999 Agreement provided Sanarus an exclusive, royalty-free, worldwide non-sublicensable right to develop, manufacture and sell products using cryoablation technology developed by Endocare for use in the field of gynecology and breast diseases. The 1999 Agreement expires at the earlier of the 30th anniversary, expiration of the patents underlying the licensed technology or a change in control event (as defined) at Sanarus. The warrant is exercisable at any time through October 12, 2009. In June 2001, the Company and Sanarus entered into a license agreement (the 2001 Agreement) amending the terms and conditions of the 1999 Agreement to provide for, among other things: (i) the termination of Sanarus exclusive, royalty-free, worldwide non-sublicensable right under the 1999 Agreement; (ii) Sanarus grant to Endocare of an exclusive (even as to Sanarus), worldwide, irrevocable, fully paid-up right to develop, manufacture and sell products using certain Sanarus technology for use in the diagnosis, prevention and treatment of prostrate, kidney and liver diseases, disorders and conditions; and (iii) Endocare s grant to Sanarus of an exclusive (even as to Endocare), worldwide, irrevocable, fully paid-up right to develop, manufacture and sell products using certain Endocare technology for use in the diagnosis, prevention and treatment of gynecological and breast diseases, disorders and conditions.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2001, the Company provided a bridge loan to Sanarus in the amount of $250,000 and received a warrant to purchase 36,210 shares of Series B voting Preferred Stock. The loan was repaid in July 2001 upon receipt of additional equity funding by Sanarus. In April 2003, the Company and other investors entered into a second bridge loan financing in which Sanarus issued to the Company a convertible promissory note in the aggregate amount of $600,000 and a warrant to purchase equity shares in Sanarus with an aggregate exercise price of up to $300,000. Upon completion of a $19,100,000 equity financing by Sanarus in October 2003, the $600,000 bridge loan and warrant were canceled in exchange for 908,025 shares of Series C voting Preferred Stock and a warrant to purchase 308,823 Series C shares at $.68 per share. This and other financings changed the Company s current voting percentage from 1.8% on an as converted, basis (20% on an as converted, fully diluted basis) at December 31, 2002 to 2.7% on an as converted basis (7.9% on an as converted, fully diluted basis) at December 31, 2003.

Under the 1999 and 2001 Agreements, the Company manufactured customized cryoprobes for the treatment of breast diseases for Sanarus at cost plus a profit margin. Certain proprietary components were purchased directly from Sanarus and were included in cost of revenues. These revenues and cost of revenues were not significant. Effective December 31, 2002, the Company no longer supplied or manufactured products for Sanarus.

The Company s former Chief Executive Officer and Chairman of the Board was a member of Sanarus Board of Directors through October 22, 2003. A former member of the Company s Board of Directors is also a member of Sanarus Board of Directors, and is an officer and partner in a venture fund that in the aggregate beneficially owns more than 10% of the outstanding Series A Preferred Stock of Sanarus. Total investment in Sanarus of $300,000 and $917,000 at December 31, 2002 and 2003, respectively, is included in investments and other assets. The investment is recorded at cost since the Company does not have significant influence over the operations of Sanarus.

U.S. Medical Development, Inc.

On June 30, 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 U.S. Medical Development, Inc., formerly U.S. Therapies, LLC, in the form of 1,134,922 Class A units. The investment represents approximately 9% of the total issued and outstanding Class A Units of U.S. Medical Development, Inc. and approximately 5% of the Class A Units on a fully diluted basis. U.S. Medical Development, Inc. is a privately held national urology services company based in Dallas, Texas, 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, Inc, was appointed a distributor and given exclusive sales rights to the Company s Cryocare Surgical System and associated disposable products in 16 states. U.S.M.D., Ltd. also had the exclusive right to distribute the Cryocare Surgical System to HealthTronics Surgical Services, Inc. and its affiliates, a publicly held company that provides urologic and orthopedic services to patients in 35 states through physician partnerships. The investment in U.S. Medical Development, Inc. is included in investments and other assets and is carried using the cost method of accounting as the Company does not have significant influence over the operations of U.S. Medical Development, Inc. The Company has recorded sales of Cryocare Surgical Systems and cryoprobes to U.S.M.D., Ltd. totaling $4,105,000 and $2,257,000 in 2001 and 2002, respectively. As discussed in Note 4, the distributor agreement was terminated upon the Company s acquisition of certain Mobile Businesses from USMD on September 30, 2002. No amounts were due from U.S.M.D., Ltd. at December 31, 2002 or 2003.

As discussed in Note 3, the Company recorded an other-than-temporary loss of $2,327,000 in its investment in U.S. Medical Development, Inc. during the fourth quarter of 2002. The carrying value of the investment at December 31, 2002 and 2003 was $510,000.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

CryoCath

In September 2001, the Company entered into a strategic alliance with CryoCath pursuant to an exclusive global market access and supply agreement, whereby CryoCath and the Company would co-develop a new, advanced line of surgical probe systems to treat cardiac arrhythmias. CryoCath would purchase the newly developed systems from Endocare and market them on a global basis under the CryoCath trademark, SurgiFrost™. CryoCath paid the Company $125,000 in license fees upon execution of the agreement. Additional fees were due upon the availability of a malleable cryoprobe and for the sale of a fixed number of cryo-consoles. However, these amounts were never received since the performance targets had not been met. The agreement also provided volume purchase discounts to CryoCath to be determined annually on a retrospective basis. The agreement had an initial term of five years and with renewals for two additional three-year periods if certain conditions were met. As discussed in Note 5, the distribution agreement was terminated in April 2003 (Note 5) upon the sale of the cardiac product line and related assets to CryoCath. Purchase discounts due to CryoCath of $558,000 at December 31, 2002 (included in other accrued liabilities) were settled as part of the sale of the cardiac product line to CryoCath in April 2003.

Qualigen, Inc.

In June 2001, the Company entered into an exclusive original equipment manufacturer agreement with Qualigen, Inc. (Qualigen), to distribute Qualigen s 15-minute PSA test known as the FastPack™ System as part of the Company s diagnostic workstation for urology. The agreement had a term of five years and included one year of exclusivity with the option for 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 to sell Qualigen s FDA-cleared 15-minute total prostate-specific antigen test directly to urology practices as a stand-alone product on a non-exclusive basis. These agreements were terminated as of December 31, 2002. The Company purchased $150,000 in products from Qualigen during 2001.

Patent, Licensing, Royalty and Distribution Agreements

The Company has entered into other patent, licensing and royalty agreements with third parties, some of whom also have proctoring and other consulting agreements with the Company and are owners of or affiliated with entities which have purchased Cryocare Surgical Systems and cryoprobes from the Company. These agreements generally provide for purchase consideration in the form of cash, common shares, warrants or options and royalties based on a percentage of sales related to the licensed technology, subject to a minimum amount per year. The patents and licensing rights acquired are recorded based on the fair value of the consideration paid. Options and warrants issued are valued using the Black-Scholes option pricing model. These assets are amortized over their respective estimated useful lives. Royalty payments are expensed as incurred.

In addition to the U.S.M.D., Ltd. and CryoCath agreements, the Company has entered into distribution agreements with third parties. These agreements govern all terms of sale, including shipping terms, pricing, discounts and minimum purchase quotas, if applicable. Pricing is fixed and determinable and the distributors contractual obligation to pay is not contingent on other events, such as final sale to the end-user. The Company generally does not grant a right of return except for defective products in accordance with its warranty policy, and in some cases for unsold inventory within a limited time period upon the termination of the distribution agreement.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Commitments and Contingencies

Leases

The Company leases office space and equipment under operating leases, which expire at various dates through 2007. Some of these leases contain renewal options and rent escalation clauses. Future minimum lease payments by year and in the aggregate under all noncancelable operating leases consist of the following:

Year ending December 31	
2004	$ 663,231
2005	497,676
2006	472,214
2007	76,910
	$1,710,031

Employment and Severance Agreements

The Company has entered into employment agreements with certain executives which provide for annual base salaries and cash bonuses of up to 45% of base salary subject to attainment of corporate goals and objectives, and in addition to stock options. The agreements provide for severance payments if the executive is terminated other than for cause or terminates for good reason as each is defined. The agreements generally also provide that should a change in control occur, the executives will receive benefits under the Company s 2002 Separation Benefits Plan and the severance payments provided in their respective employment agreements will be reduced dollar-for-dollar. The options vest over specified time periods with accelerated vesting upon attainment of performance targets in certain instances.

Former Officers

Former Chief Executive Officer and Chairman of the Board

The Company has entered into a Separation Agreement and a one-year Consulting Agreement with the Company s former Chief Executive Officer and Chairman of the Board (the former CEO), each effective as of July 31, 2003. Under the Separation Agreement, the former CEO is entitled to receive a $375,000 severance payment, in addition to accrued and unpaid wages and unused vacation time. The former CEO waived all rights to which he is or may be entitled under the Company s 2002 Separation Benefits Plan. In exchange for an additional $375,000 upfront payment, under the provisions of the Consulting Agreement, as amended, the former CEO has agreed to a one-year covenant not to compete and during its term, he is required to provide consulting services at the direction of management for a minimum of eight hours per quarter. Consulting services in excess of eight hours per quarter will be compensated at $2,000 per day. The former CEO will continue to participate in the Company s benefit plans for 24 months. Of the former CEO s outstanding vested stock options, 565,000 will continue to remain outstanding as permitted under the 1995 Stock Plan, and 200,000 of his outstanding stock options were terminated. The Company recorded a charge of $775,500 in the third quarter of 2003 for the severance and related benefits. The Separation Agreement and Consulting Agreement further provide that the former CEO is required to repay the severance payment and consulting fees received upon either (i) his conviction in a court of law, or entering into a plea of guilt or no contest to, any crime directly relating to his activities on behalf of the Company during his employment, or (ii) successful prosecution of an enforcement action by the Securities and Exchange Commission (SEC) against him. The total severance payment due of $750,000 was deposited into an escrow account held by the Company. The restricted cash was included in prepaid expenses and other current assets and the severance liability was included in accrued compensation at December 31, 2003. In March 2004, all amounts due under the Separation Agreement to the former CEO were released from the escrow account.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Former Chief Financial Officer

The Company entered into an employment agreement, dated March 3, 2003 (the Employment Agreement), with the former CFO. Under the agreement, the Company is required to pay the former CFO a base salary of $220,000 and cash bonus of up to $88,000 per year. The Employment Agreement also provides that all of the former CFO s options to purchase outstanding common stock (385,000 shares) would be cancelled and replaced by immediately exercisable options to be granted between September 4, 2003 and November 3, 2003. The replacement options were issued on October 30, 2003 at an exercise price of $4.50 per share, which is equal to the fair market value of the common stock on the date of grant.

The Employment Agreement also provides that upon any Qualified Termination (as defined), the former CFO will be entitled to a cash payment of $616,000, continued participation in the Company s benefit plans for 24 months, a $50,000 relocation allowance and an additional payment to cover the tax liabilities relating to the allowance. In addition, the exercise period of the replacement options will be extended until the second anniversary of the termination date. Effective July 31, 2003, the Company terminated the former CFO s employment other than for cause. The Company recorded a third quarter charge for $731,000 for severance, medical, and relocation benefits due under the Qualified Termination provisions. In addition, the Company recorded a third quarter charge for $1,715,000 for the fair value of the 385,000 replacement options determined using the Black-Scholes option pricing model.

Under the Employment Agreement, the former CFO is required to repay all amounts received in a Qualified Termination upon (i) the former CFO s conviction in a court of law, or entering into a plea of guilt or no contest to, any crime directly relating to his activities on behalf of the Company during his employment, or (ii) successful prosecution of an enforcement action by the SEC against the former CFO. The total severance payments due of $616,000 were deposited into an escrow account held by the Company. The restricted cash was included in prepaid expenses and other current assets and the severance liability was included in accrued compensation at December 31, 2003. In March 2004, all amounts due under the Separation Agreement to the former CFO were released from the escrow account.

2002 Executive Separation Benefits Plan

Effective July 17, 2002, the Company adopted the 2002 Executive Separation Benefits Plan (Separation Plan) to provide separation benefits to certain designated employees. The Separation Plan provides that, in the case of any Covered Termination, the participants will receive from six months to two years of their base salary plus the maximum bonus, as defined. Covered Terminations include termination by the employee for good reason after a change in control, by the employee for any or no reason during the 30-day period immediately following the six-month anniversary of a change in control, or voluntarily by the Company or its successor after a change in control for a reason other than cause, death or disability. Participants are also entitled to continued eligibility for the Company s benefit program for a period equal to the number of months of base pay to be received.

Employee Benefit Plans

The Company has a 401(k) savings plan covering substantially all employees. The Plan currently provides for a discretionary match of amounts contributed by each participant as approved by the Compensation Committee of the Board of Directors. Prior to the acquisition, Timm Medical also sponsored a 401(k) savings plan for its employees (the Timm Medical Plan). Management combined the two plans effective September 30, 2003. Employer matching contributions to the Endocare s Plan totaled approximately $153,846 for the year ended December 31, 2001. No matching contributions were made in 2002 or 2003.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Legal Matters

In November 2002, the Company was sued in an action filed by BioLife in the Delaware Court of Chancery. BioLife sought damages for alleged breaches of contract stemming from the Company s acquisition of the tangible and intangible assets related to BioLife s cryosurgical business (see Note 4). BioLife alleged that the Company failed to timely register 120,022 shares of the Company s common stock provided to BioLife as partial consideration for the asset acquisition, in violation of a registration rights agreement relating to the shares issued to BioLife. On October 1, 2003, BioLife was awarded $1,648,000 plus prejudgment interest and costs (including legal fees) and BioLife was required to surrender the 120,022 shares to the Company. As a result of this decision, the Company recorded a 2002 fourth quarter charge of $1,500,000 (included in other accrued liabilities), representing the difference between the court s award to BioLife and the estimated fair value of the shares to be surrendered. That ruling became an appealable final order and judgment on October 10, 2003 and the Company filed a notice of appeal. On February 20, 2004, the Company agreed to abandon the appeal in exchange for a cash payment of $1,887,474 to Biolife, which represented a discount of $150,000 from the total judgment amount (including accrued interest and costs) and return of the 120,022 common shares. The shares were recorded as treasury stock in March 2004 based on the fair value of $492,000 at that date and the balance of $1,395,000 was applied against a litigation accrual previously recorded in 2002 and included in other accrued liabilities at December 31, 2003.

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

On December 6, 2002, Frederick Venables filed a purported derivative action against the Company and certain former officers and certain current and former board members in the California Superior Court for the County of Orange alleging breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment. On April 17, 2003, the court issued an order staying the action until resolution of the anticipated motion to dismiss the consolidated complaint in the federal securities action pending in the Central District of California. Pursuant to this order, no deadline is currently set for our response to the complaint. The complaint seeks unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding our revenues and expenses in press releases and SEC filings.

Plaintiffs in the two lawsuits discussed in the preceding paragraphs are seeking compensatory damages, including interest, costs and expenses, attorneys fees, and other relief. The Company intends to defend these cases vigorously.

The SEC is currently conducting an investigation to determine whether any federal securities laws were violated in connection with the filing of the Company s financial statements for 2001 and the first two quarters of 2002, including investigation into allegations that the Company and certain of its current and former officers and directors issued or caused to be issued false and misleading statements regarding the Company s revenues and expenses in those SEC filings. The Company is cooperating fully with this investigation.

The Department of Justice is currently conducting an investigation into allegations that the Company and certain of its current and former officers and directors intentionally issued or caused to be issued false and

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

misleading statements regarding the Company s revenues and expenses in SEC filings. The Company is cooperating fully with this investigation.

In December 2002, the Company filed a demand for arbitration before the American Arbitration Association in Minnesota against a former employee. The complaint included various claims in response to which the employee made several counterclaims. In March 2003, the Company was notified by the United States Department of Labor that counsel for the employee had presented a letter of complaint alleging that the Company, its former Chairman and Chief Executive Officer and former Chief Financial Officer violated 18 U.S.C. § 1514A by improperly retaliating against the employee. In December 2003, the Company and the employee agreed to settle all claims on mutually acceptable terms without the admission of liability by any party for an amount that is not significant. Pursuant to the settlement, the employee withdrew his letter of complaint, and the Department of Labor has indicated that it considers this matter closed.

In June 2003, the Company was awarded a favorable judgment for $351,000 in a litigation matter previously initiated by Timm Medical against a third party. Since collection is not assured, this amount of this settlement will be recorded in the period when it is actually paid to the Company.

In addition, the Company, in the normal course of business, is subject to various other legal matters, which management believes will not individually or collectively have a material adverse effect on the Company s results of operations or cash flows of a future period. The results of litigation and claims cannot be predicted with certainty, and the Company cannot provide assurance that the outcome of various legal matters, including a class action and a derivative lawsuit, will not have a material adverse effect on its consolidated financial condition, results of operations or cash flows. At December 31, 2003, except as indicated above, the Company has not established a liability for these contingencies in the consolidated balance sheets since the likelihood of loss and the potential liability cannot be reasonably estimated at this time. Management s evaluation of the likelihood of an unfavorable outcome with respect to these actions could change in the future. The Company has purchased directors and officers liability and other insurance which may fund certain losses, including defense costs, related to the above litigation matters. These recoveries will be recorded when the amounts are determined to be recoverable from the insurance carriers.

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

13. Related Party Transactions

Loans to Officers

The Company has extended loans to certain employees and related parties. Loans made that are other than for the purchase of common stock are included in Investments and Other Assets in the accompanying consolidated balance sheets.

In November 1999, the Company received a full recourse promissory note for $1,028,125 in connection with the sale of 175,000 common shares at fair value to the Company s then-Senior Vice President, Sales and Marketing. The four-year note bore interest at 5.99% per annum, payable annually, and was recorded as a reduction in stockholders equity. The Company agreed to forgive the principal on the note ratably over four years subject to that individual remaining an employee. At December 31, 2003, the full value of the note has been forgiven. Principal forgiven totaled $257,000 in 2001 and 2002, and $214,292 in 2003. The Company recorded the annual forgiveness as compensation expense (included in selling, general and administrative expense). No interest income has been recorded on the note. In August 2003, the Company terminated the

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

individual s employment and is currently negotiating with this individual regarding repayment of the loan. Recoveries, if any, will be recorded when received.

In March 2001, the Company received full recourse promissory notes from three officers totaling $128,000 due at the earlier of the second anniversary or the employment termination date. These notes bear interest at 4.8% per annum and were extended to facilitate the employees acquisition of Company s common shares in the open market. At December 31, 2002, the Company wrote off $140,000 representing the outstanding principal and unpaid interest on these notes (included in selling, general and administrative expense).

In January 2003, the Company extended a $344,000 non-recourse loan to an individual who is a shareholder and consultant. The Company previously entered into an asset purchase agreement with the shareholder in February 2002. The Company extended the loan to the shareholder to assist with the payment of related federal income taxes arising from the 2002 purchase transaction. The loan is secured by the shares issued, bears interest at 1.8% and is due at the earlier of January 2005 or 30 days after the borrower ceases to be a consultant to the Company.

14. Other Investments

Material equity investments in companies acquired through collaboration agreements not previously disclosed earlier in the footnotes include the following:

a. 833,333 common shares (approximately 14% interest) in Medical Resource Management, Inc. (MRM), a publicly traded company that provides mobile surgical equipment rental, certified technician, training and support services to hospitals and medical facilities on a fee per procedure basis (acquired September 2000 for cash of $250,000). MRM specializes in laser surgery, cryosurgery, brachytherapy and other capital-intensive medical equipment. In June 2001, Emergent Group, Inc. acquired the outstanding stock of MRM in a share exchange. The Company wrote off the $250,000 carrying value of this investment as a loss on minority investment in the second quarter of 2001 since the shares received in exchange have de-minimus value.

b. 33,945 common shares in Matritech, Inc., a publicly traded company that develops proteomics-based diagnostic products for early detection of cancer (acquired February 2001 for cash of $150,000). Timm Medical was the exclusive United States distributor of bladder cancer diagnostic test kits manufactured by Matritech, Inc. The distribution agreement was terminated in June 2002. Purchases from Matritech, Inc. were immaterial. The carrying value of the investment at December 31, 2002 and 2003 was $72,000 and $64,000, respectively.

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ENDOCARE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. Quarterly Results of Operations (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2003 and 2002.

	Quarter Ended March 31, 2003	Quarter Ended June 30, 2003	Quarter Ended September 30, 2003	Quarter Ended December 31, 2003
Revenues	$ 7,661,784	$ 7,490,367	$ 8,041,119	$ 7,303,907
Cost of revenues	$ 3,996,046	$ 3,469,503	$ 4,093,747	$ 4,498,230
Gain on divestitures, net	$	$ 9,944,424	$	$ (1,313,534)
Net income (loss)	$ (6,087,898)	$ 1,661,452	$ (11,112,845)	$ (9,908,011)
Net income (loss) per share of common stock:				
Basic	$ (.25)	$ .07	$ (.46)	$ (.41)
Diluted	$ (.25)	$ .07	$ (.46)	$ (.41)
Weighted average shares of common stock outstanding:				
Basic	24,151,962	24,155,740	24,182,004	24,183,254
Diluted	24,151,962	25,287,911	24,182,004	24,183,254

	Quarter Ended March 31, 2002	Quarter Ended June 30, 2002	Quarter Ended September 30, 2002	Quarter Ended December 31, 2002
Revenues	$ 6,640,026	$ 8,785,887	$ 8,381,793	$ 7,108,719
Cost of revenues	$ 3,304,736	$ 4,188,170	$ 4,525,786	$ 4,465,704
Goodwill impairment and other charges				20,311,293
Net loss	$ (3,473,281)	$ (5,205,052)	$ (4,724,897)	$ (28,582,516)
Net loss per share of common stock:				
Basic	$ (0.15)	$ (0.22)	$ (0.19)	$ (1.18)
Diluted	$ (0.15)	$ (0.22)	$ (0.19)	$ (1.18)
Weighted average shares of common stock outstanding:				
Basic	22,808,000	24,000,000	24,279,000	24,297,000
Diluted	22,808,000	24,000,000	24,279,000	24,297,000

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ENDOCARE, INC. AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

	Balance at the Beginning of the Period	Additions		Deductions	Balance at the End of the Period
		Charges to Operations	(a) Other		
2001					
Allowance for Doubtful Receivables and Sales Returns	$ 406,639	$ 897,450	$	$(636,537)	$ 667,552
2002					
Allowance for Doubtful Receivables and Sales Returns	$ 667,552	$1,233,039	$538,000	$(212,159)	$2,226,432
2003					
Allowance for Doubtful Receivables and Sales Returns	$2,226,432	$ 650,961	$	$(445,558)	$2,431,835

(a) Other additions of $538,000 in 2002 represents the allowance for doubtful receivables and sales returns related to Timm Medical as of the acquisition date.

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EXHIBIT INDEX

Exhibit No.	Description
2.1(1)	Agreement and Plan of Reorganization, dated February 21, 2002, by and among the Company, Timm Medical 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. Schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.3(3)	Asset Purchase Agreement, dated February 6, 2002, by and between the Company and Gary M. Onik, M.D. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.4(3)	Asset Purchase Agreement, dated May 28, 2002, by and among the Company and Cryomedical Sciences, Inc. Certain schedules and other attachments to this exhibit were omitted. We agree to furnish supplementally a copy of any omitted schedules or attachments to the Commission upon request.
2.5(4)	Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of August 12, 2002, by and among the Company and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C. 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.
2.6(5)	Amendment No. 1 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of September 30, 2002, by and among the Company, Inc. and U.S. Medical Development, Inc., U.S.M.D., Ltd. and U.S.M.D. I, L.L.C.
2.7(6)	Agreement of Purchase and Sale, dated as of April 7, 2003, by and among American Medical Systems, Inc., the Company and Timm Medical Technologies, Inc.
2.8(7)	Asset Purchase and Technology License Agreement, dated as of April 29, 2003, by and between the Company and CryoCath Technologies Inc.
2.9(8)	Agreement of Purchase and Sale, dated as of October 15, 2003, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
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	Amended and Restated Bylaws of the Company.
10.3(2)	Promissory Note, dated November 2, 1999, by Jerry Anderson in favor of the Company.
10.10(9)	Lease Agreement, dated November 26, 2001 by and between the Company and the Irvine Company.
10.11(9)	Form of Indemnification Agreement by and between the Company and its directors.
10.12(9)	Form of Indemnification Agreement by and between the Company and its executive officers.
10.13(10)	1995 Director Option Plan (as amended and restated through March 2, 1999).
10.14(12)	1995 Stock Plan (as amended and restated through April 16, 2002).
10.15(13)	2002 Supplemental Stock Plan.
10.16(4)	Promissory Note, dated July 15, 2002, issued by U.S. Medical Development, Inc. to the Company.
10.17(5)	First Amended and Restated Promissory Note, dated September 30, 2002, issued by U.S. Medical Development, Inc. to the Company.
10.18(11)	Registration Rights Agreement, dated as of February 21, 2002, by and among the Company and the parties listed on Schedule A thereto.

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Exhibit No.	Description
10.19(13)	Registration Rights Agreement, dated as of May 28, 2002, by and between the Company and Cryomedical Sciences, Inc.
10.20(13)	Letter Agreement, dated June 11, 1999, by and between the Company and Jerry Anderson
10.21(13)	Blanket Purchase Agreement, effective April 1, 2002, by and between Timm Medical Technologies, Inc. and the U.S. Department of Veterans Affairs.
10.22(13)	2002 Executive Separation Benefits Plan.
10.23(14)	Employment Agreement, dated as of March 3, 2003, by and between the Company and William J. Nydam.
10.24(14)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Katherine Greenberg.
10.25	Employment Agreement, dated as of March 25, 2003, by and between the Company and Kevin Quilty.
10.26	First Amendment to Employment Agreement, dated as of September 14, 2003, by and between the Company and Katherine Greenberg.
10.27	Consulting Agreement, dated as of August 27, 2003, by and between the Company and Craig T. Davenport.
10.28(15)	Employment Agreement, dated as of December 15, 2003, by and between the Company and Craig T. Davenport.
21.1	Subsidiaries of Registrant.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24.1	Power of Attorney, included on signature pages.
31.1	Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
31.2	Certification under Section 302 of the Sarbanes-Oxley Act of 2002 for Katherine Greenberg.
32.1	Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Craig T. Davenport.
32.2	Certification under Section 906 of the Sarbanes-Oxley Act of 2002 for Katherine Greenberg.

* We have requested confidential treatment with respect to certain portions of these documents.

Management contract or compensatory plan or arrangement

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

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

(3) Previously filed on Form 10-Q for the quarter ended June 30, 2002.

(4) Previously filed on Form 8-K on August 16, 2002.

(5) Previously filed on Form 8-K on October 15, 2002.

(6) Previously filed on Form 8-K on April 22, 2003.

(7) Previously filed on Form 8-K on April 29, 2003.

(8) Previously filed on Form 8-K on October 20, 2003.

(9) Previously filed on Form 10-K for the year ended December 31, 2001.

(10) Previously filed with our Registration Statement on Form S-8 filed on June 2, 1999.

(11) Previously filed with our Registration Statement on Form S-3 filed on May 15, 2002.

(12) Previously filed with our definitive proxy statement for the 2002 annual meeting filed on April 30, 2002.

(13) Previously filed on Form 10-K for the year ended December 31, 2002.

(14) Previously filed on Form 8-K on March 27, 2003.

(15) Previously filed on Form 8-K on December 16, 2003.