ENDOCARE INC
Form 10-K
March 16, 2005

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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, 2004; 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 þ No o (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, 2004 was approximately $51,977,890 (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 percent 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 24,352,378 shares of the Registrant s common stock issued and outstanding as of March 1, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Definitive Proxy Statement related to the Registrant s 2005 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, 2004, 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
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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, plans, planned and words of similar import. Our act 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.

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 and renal cancer markets, further developing and increasing the acceptance of our technology in the interventional radiology and oncology markets for treatment of liver and lung cancers and management of pain from bone metastases, while achieving penetration across additional markets with our proprietary cryosurgical technology and maintaining our leading position in vacuum technology for erectile dysfunction.

Today, our FDA-cleared Cryocare Surgical System occupies a growing position in the urological market for treatment of prostate and renal cancer. Because of our initial concentration on prostate and renal cancer, the majority of our sales and marketing resources are directed toward 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 and liver, and the management of bone pain caused by tumors. To that end, we employ a dedicated sales and marketing team focused on marketing percutaneous cryoablation procedures related to kidney, liver, lung and bone cancer to interventional radiology physicians throughout the United States. We intend to continue to invest in resources to continue to penetrate the interventional radiology and oncology markets and develop new markets for our cryosurgical products and technologies, particularly in the area of tumor ablation.

Through our Timm Medical subsidiary, we market 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, and are a leader in 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.

We were incorporated under the laws of the State of Delaware in May 1994. We maintain our executive offices at 201 Technology Drive, Irvine, California 92618, and our telephone number at that address is

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(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.

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 in the United States. The American Cancer Society estimated there would be approximately 232,000 new cases of prostate cancer diagnosed and approximately 30,000 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 percent of men diagnosed with prostate cancer are over the age of 65. Rates of occurrence are more than twice as high among African American men as Caucasian men. In addition to age and race, other risk factors are linked to prostate cancer, such as genetics, diet and exposure to environmental toxins such as Agent Orange.

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 to detect any lumps in the prostate. 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.

Due to variations in screening protocols, it is difficult to determine the percentage of newly diagnosed prostate cancer patients who have localized tumors, which offer the greatest potential for cure. Estimates range from 60 percent to 90 percent of cancer patients have localized tumors. Based on these percentages we estimate that between approximately 139,000 and 209,000 newly diagnosed patients may be appropriate candidates for our cryosurgical treatment in 2005. Furthermore, we estimate that at least 18,000 patients in the United States each year are diagnosed with recurrent prostate cancer following previous radiation therapy. With the increasing utilization of radiation therapy, primarily brachytherapy, for initial treatment in prostate cancer, we believe that this number will increase. For recurrent tumors that are detected while still localized, we believe cryoablation is an appropriate procedure with fewer side effects than salvage radical prostatectomy and can be performed at a substantially lower cost to the medical facility.

Non-Cryosurgical Treatment Options

Therapeutic alternatives for patients with prostate cancer have been limited and these treatments can significantly impact the patient s quality of life. Current treatment options include radical surgery, radiation therapy, hormone or other therapies, watchful waiting, and cryosurgery. 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. Radical prostatectomy often requires a three- to five-day hospital stay for patient recovery and therefore a higher cost to the medical facility than cryoablation.

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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 cryosurgery 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

Newly published ten-year data suggest that prostate 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.

Endocare Cryosurgery Technology Development

We have sought to continually develop our technology to increase the safety and efficacy of our products. In 1996, we developed our first generation eight-probe argon based cryosurgical system. Argon allows for room temperature gas to safely pass through the cryoprobe to create a highly sculpted repeatable ice ball. In 1997, we incorporated temperature-monitoring software to allow for continual feedback from the thermocouple tips. In 1998, we launched our CryoGuide intraoperative planning software, which allowed physicians better planning and targeting technology for use during a procedure. In 2000, we launched our 2.4 mm Direct Access cryoprobe and CryoGrid which we believe shortened the time necessary to perform a procedure and added to the safety and ease of the procedure. In 2002 we developed and launched Autofreeze, our innovative software technology that provides computer-controlled automated freeze/thaw cycles. In 2003, we launched our second generation Cryocare Surgical System, which we refer to as Cryocare CS, which integrated all the past and latest technology, including an on-board, integrated ultrasound device, into one complete system. We believe these advancements will further shorten the time required to perform the procedure, which could result in

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physicians having the potential to earn more revenue by being able to perform a greater number of procedures in the same amount of time.

Our System Solution: Cryocare CS

In April 2003 we unveiled our Cryocare CS System. We believe Cryocare CS is the most sophisticated cryosurgery system currently available and combines the latest technology to make our FDA-cleared TCAP (Targeted Cryoablation of the Prostate) procedure simple, fast, safe and effective. Exclusive features of the Cryocare CS include an on-board training module, integrated color Doppler ultrasound designed specifically for the needs of prostate cryosurgery, CryoGuide our patented intraoperative planning module and AutoFreeze our patented treatment software that provides computer-controlled automated freeze/thaw cycles based upon target endpoint temperatures and continual feedback from the thermocouple tips.

The argon gas-based Cryocare CS accommodates up to eight independently operated cryoprobes and six thermocouples to allow physicians to monitor temperatures of tissue adjacent to the prostate in real-time. Our proprietary suite of cryoprobes is engineered to consistently produce sculpted ice conforming to the unique anatomy of the prostate. Our vacuum-insulated DirectAccess[tm] CryoProbes help deliver lethal ice in a controllable and repeatable fashion. Our CryoGrid[tm], which is similar to a brachytherapy grid, is affixed to the ultrasound stepper and 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 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.

Key Clinical Advantages of Our Cryocare CS System

Cryocare CS 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 using our Cryocare CS 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 to be in excess of $2.0 billion annually. Although estimates vary depending upon the epidemiologic methods used, studies indicate that up to 30 million American men, including approximately 52 percent of those aged 40 to 70 years, have erectile dysfunction. Current pharmacotherapy for erectile dysfunction includes oral, transurethral and injectable intracavernosal treatments. The non-oral erectile dysfunction market was estimated as $85 million worldwide in 2003, with $45 million sales in Europe and $32 million in the United States. 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

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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. The National Ambulatory Medical Care Survey indicated that in 1999, for every 1,000 men in the United States, 22.3 physician office visits were made for erectile dysfunction. While treatment choices range from pharmaceutical (oral or injectable) to mechanical (vacuum erection devices) to prosthetic (implant), a recent report suggested that approximately one in three men who achieve a satisfactory erection with either a vacuum erectile device or pharmaceutical treatment will prefer to continue with the vacuum erectile device. 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

We hold a leading market position in vacuum therapy systems, with 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. We believe the vacuum erectile device is widely considered to be the least invasive erectile dysfunction therapy, and has been reported to have 80 percent to 90 percent efficacy rates.

Even with the success of oral drug therapies, our vacuum therapy 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.

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-sales to hospitals and distributor sales of these systems to service entities who would provide systems and technicians to hospitals where cryosurgical procedures were performed.

In 2003, we redirected our strategy for cryosurgical products toward our primary emphasis of increasing acceptance of our technology platform to many different organs throughout the body and increasing utilization among physicians currently performing cryosurgery. This led to a reduced emphasis on attempting to drive acceptance of cryoablation through sales of capital equipment into the urology market. 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 and renal cancers. In 2003 and 2004, we derived a significant percentage of our revenues from recurring sales of disposable supplies used with the Cryocare Surgical System.

A cryosurgical procedure requires the necessary disposable devices usually provided in the form of a kit. In addition to the disposable devices, there is 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 cryosurgical procedure. In addition to the use of a Cryocare Surgical System, an ultrasound device is needed for visual monitoring of the prostate and ice formation, unless our new Cryocare CS unit is used, since it includes an on-board, integrated ultrasound unit. 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 by an independent third party.

We sell the disposable devices to hospitals either as part of a procedure fee or separately, that is, without the service component. We also continue to sell our Cryocare Surgical Systems both to hospitals and service

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partners, although we will often place a system with a new customer under our placement program for purposes of generating additional procedure fees.

An important challenge we face in the prostate cancer market is to overcome initial reluctance on the part of urologists to embrace cryosurgery and to educate physicians so that they are able to incorporate cryosurgery into their primary treatment regimen. 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 compete 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 prostatectomy for prostate cancer. There are 20 years of clinical data supporting use of various forms of radiation treatment options such as brachytherapy and beam radiation treatments, which 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 the current most popular forms of treatment. While there are long-term clinical data available on radical prostatectomy, this treatment approach, typical of surgery in general, is 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. We also believe that cryosurgery has significant economic benefits for medical facilities and physicians. These benefits include shorter hospital stays for recovery and the reduced time a cryosurgery procedure takes to perform as compared to radical prostatectomy and many forms of nuclear medicine.

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 major 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 which is another important component of the urology market for cryosurgery;

Creating a significant number of new practicing cryosurgeons each year through our physician education program;

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 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. 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.

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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 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 benign prostate hyperplasia, also known as BPH or prostate enlargement.

Erectile Dysfunction Products

Our product line of vacuum therapy systems, including the ErecAid Esteem and ErecAid Classic systems, for the non-pharmacological treatment of erectile dysfunction holds a leading position among products using vacuum technology in treating this condition.

In April 2003, we sold the intangibles and inventory associated with our penile prosthesis product line 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.

Products

We currently market the following products:

Prostate and Renal Cancer:

Cryocare Surgical System A cryosurgical system with eight cryoprobe capability.

Cryocare CS System A cryosurgical system with onboard ultrasound.

CryoGuide A computerized cryoprobe placement, simulation and guidance system for cryosurgery.

Cryoprobes Disposable probes used with the Cryocare Surgical System.

FasTrac Percutaneous access device that allows one step insertion of cryoprobes.

Additional Cryosurgical Markets:

Cryocare Surgical System A cryosurgical system with eight cryoprobe capability specially configured for interventional radiology and oncology.

Erectile Dysfunction:

RigiScan Monitor A diagnostic tool for erectile dysfunction.

ErecAid Esteem System A vacuum therapy system.

ErecAid Classic System A vacuum therapy system.

Raw Materials

We rely on third party suppliers to provide certain critical components for all of our product lines. In certain cases, the 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 which contain other terms and conditions protecting us against unforeseen interruptions in their production. We maintain adequate stock levels at our own locations to ensure an uninterrupted source of supply. Wherever possible, we seek to

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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 2004, we have rights to 37 issued United States patents relating to cryosurgical ablative technology. Included within these 37 issued United States patents are 5 patents in which we have licensed-in rights. The remainder of the patents are 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 Unites States patent applications relative to cryosurgical ablative technology. Additionally, we have 28 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.

We own 21 issued United States patents relating to our erectile dysfunction product line. Additionally, we have 12 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. In the past, 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.

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 that dramatically improves patient outcomes. Our primary focus is on developing devices for the treatment of prostate, kidney, lung and liver tumors and the pain associated with bone metastases. To that end, we plan to develop innovations that improve the speed and efficacy of our Cryocare Surgical System, as well as to explore new applications for use of our technology platform in the body.

We spent approximately $2.9 million, $1.3 million and $1.6 million for the years ended 2002, 2003 and 2004 respectively, on research and development activities.

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Sales

We sell our products primarily to physicians, hospitals and third party service providers and have both domestic and international customers. None of our customers accounted for in excess of 10 percent of our net revenues in 2004. The following products and services account for 15 percent or more of total revenues for each of the years ended December 31:

	2002	2003	2004
Cryoablation and urological products:			
Cryocare Surgical Systems	*	*	*
Cryoprobes, disposables and procedures	41%	59%	68%
Cardiac products (CryoCath)	*	*	*
Urological products (Timm Medical)	41%	36%	26%

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

We currently sell our cryosurgical products domestically through our direct sales force, which, as of December 31, 2004 consisted of 29 people, including 22 sales representatives and sales managers and 7 cryosurgical field technicians. Our strategy is to continue to introduce the clinical benefits of cryosurgery to new physicians as well as educating physicians already performing cryosurgery so that they are able to increasingly incorporate cryosurgery into their primary treatment plans. We also intend to create patient demand by providing education regarding the benefits of cryosurgical therapy versus alternative treatment options and by using national advertising and other programs targeted directly at prostate disease patients.

Internationally, our cryosurgical products are sold primarily through independent distributors. Our international sales represented approximately 14.7 percent, 10.6 percent and 9.4 percent of our consolidated revenue in 2002, 2003 and 2004, 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 19 sales representatives as of December 31, 2004. 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):

	2002	2003	2004
		(In thousands)	
United States	$ 26,369	$ 27,257	$ 29,601
International:			
China	402	469	557
Canada	2,104	331	818
Other	2,041	2,440	1,709
Total international	4,547	3,240	3,084
Total revenues	$ 30,916	$ 30,497	$ 32,685

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, the majority of 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.

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

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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.

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. As of December 31, 2004, no such codes were in place.

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, 2004, we had no 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 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. The Department of Veterans Affairs can terminate this contract on 30 days notice. In 2004 Timm Medical recognized approximately $1.5 million in revenues under this contract. We are currently engaged in a bidding process which may lead to a renewal of our contract with the Veterans Affairs network. We can give no assurance that we will be selected to renew our agreement or that, if selected, the terms and conditions of the renewed agreement will not be less profitable than our current agreement terms. If we are not selected to renew our agreement, our revenues, results of operations and cash flows will be impacted.

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Manufacturing

We manufacture our Cryocare Surgical System and related disposables at our facilities in Irvine, California. Our 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 most recently in June 2004, and also in February and March 2003 and September 2002. These audits have been 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 packaged and shipped at our Minneapolis facility. Injection molding and assembly of the devices 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 FD&C 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.

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 FD&C 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 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.

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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 in Europe and approval for distribution 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.

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 requirements that could be applicable to our business. Complying with these regulatory requirements 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

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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.

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, 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.

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).

Regulations implementing the HIPAA security standards have a compliance date of April 20, 2005. In general, the security standards require covered entities (such as Timm Medical) to implement reasonable technical, physical and administrative security measures to safeguard protected health information maintained, used and disclosed in electronic form. To date, we are in the process of determining the additional policies and procedures and monitoring mechanisms necessary in order to achieve full compliance by the April 2005 deadline.

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 receive 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.

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Competition

The medical device industry is subject to intense competition. Significant competitors in the area of prostate cancer therapies include ONCURA, CR Bard, Inc., Mentor Corporation, 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 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, 2004, we had a total of 153 employees. Of these employees, 6 are engaged directly in research and development activities, 10 in regulatory affairs/quality assurance, 25 in manufacturing, 79 in sales, marketing, clinical support and customer service and 33 in general and administrative positions. We expect to increase the number of people employed in sales and marketing to increase revenue and grow market share, measured in terms of procedures. 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 typically 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. 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.

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

As previously reported, 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. 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.

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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 are generally obliged, to the extent permitted by law, to indemnify our directors and officers who are named defendants in legal proceedings related to their service.

We may be unable to satisfy the requirements of Sarbanes 404, or we or our auditors may identify significant deficiencies or material weaknesses in our internal controls.

Pursuant to Sarbanes 404, we are required to furnish a report of our management s assessment of the effectiveness of our internal controls over financial reporting and our auditors are required to provide an attestation report on management s assessment. We have omitted the internal control report and related attestation report from this Annual Report on Form 10-K in reliance on the SEC s November 30, 2004 exemptive order, which grants certain smaller accelerated filers an additional 45 days in which to furnish the internal control report and related attestation report. We have identified control deficiencies in our system of internal controls. During the 45-day extension period, we expect to evaluate these control deficiencies and to assess whether or not they rise to the level of significant deficiencies or material weaknesses. We have prepared an internal plan of action for compliance, and we are in the process of assessing our internal controls to provide the basis for our internal control report. We expect to be able to furnish the internal control report and related attestation report within the required 45-day period. However, we may be unable to satisfy the requirements of Sarbanes 404, or our internal control report or the related attestation report may identify significant deficiencies or material weaknesses in our internal controls, either of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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 in Part I Item 3 Legal Proceedings, our 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.

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

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

We have incurred annual operating losses each year since our inception. For the fiscal years ended December 31, 2002, 2003 and 2004, we had losses from operations of approximately $42.5 million, $34.0 million and $36.6 million, respectively. As of December 31, 2004, our accumulated deficit was approximately $152.0 million. It is possible that we will not generate sufficient revenues from product sales and service revenues to achieve profitability. Even if we do achieve significant revenues from our product sales

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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:

- 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.

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 intend to seek to have our common stock relisted on a national stock exchange, 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 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.

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.

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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.

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.

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.

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 believe that our current structure and business and our contemplated future operations comply and will comply with the federal anti-kickback law. However, certain of our business practices do not fit or will not 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 material adverse effect on us.

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

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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 our company. 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 our company. 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 litigation or to protect our other intellectual property rights. It could result in the rejection or invalidation of our existing and future patents. Any adverse outcome in litigation relating to the validity of our patents, or any failure to pursue litigation or otherwise to protect our patent position, could 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 United States 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

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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 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.

We face risks relating to compliance with new federal requirements regarding the transmission and retention of health information.

We and the health care providers that we interact with face new federal requirements that mandate major changes in the transmission and retention of health information. HIPAA and related regulations impose expanded protection of the privacy and security of personal medical data, including standards for the exchange of electronic health information. There are many uncertainties remaining about how HIPAA applies to the

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medical device industry, 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 receive medical information for other purposes as well. In addition, because Timm Medical is a covered entity for HIPAA purposes, failure of Timm Medical to comply with HIPAA could result in civil and criminal fines and penalties that 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 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.

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

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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 material adverse effect on us.

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

Our business exposes us to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. While we believe that we are reasonably insured against these risks, we may not be able to maintain insurance in amounts or scope sufficient to provide us with adequate coverage. 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 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 prostatectomy, 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 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:

- 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;
- timing of regulatory approvals for new products;
- outcomes of clinical studies by us or our competitors;
- competition from other treatment modalities;

physician and patient acceptance of cryosurgery; and

ability to obtain reimbursement for procedures in lung and liver cancer, and pain related to bone metasteses.

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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.

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 investigations 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;

introduction of new competing technologies;

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

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impairment test as of October 1, 2002, 2003 and 2004 for all of our reporting units. We utilized an independent 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 $18.0 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. For 2004, we recorded an additional $15.8 million impairment charge related to Timm Medical to further reduce the carrying value of the goodwill and intangibles acquired in the purchase of Timm Medical, and to write-off goodwill and intangibles related to our ownership interests in certain mobile prostate treatment businesses (See Note 5 of the Notes to Consolidated Financial Statements).

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 and intangible assets. 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.

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.

We also lease 8,900 square feet of office and warehouse space in our Eden Prairie, Minnesota, facility which houses our erectile dysfunction operations. The lease for this facility expires in 2009.

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

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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 asserted 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 sought class certification and unspecified damages from us, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order denying our motion to dismiss the consolidated complaint. On November 8, 2004, we executed a settlement agreement with the lead plaintiffs and their counsel. Under the agreement, in exchange for a release of all claims, we and certain individuals will pay a total of $8.95 million in cash. Our directors and officers liability insurance carriers agreed to fund the total amount of $8.95 million, subject to reservations of rights by the carriers. On February 7, 2005, the Court issued a final order approving the agreement and dismissing the class-action lawsuit.

On December 6, 2002, Frederick Venables filed a purported derivative action against us and certain former officers, certain former board members and one current board member 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. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint was stayed until 2005. The complaint sought 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. On December 6, 2004, we executed a settlement agreement with the plaintiff and his counsel. On December 8, 2004, the Court issued a final order approving the agreement and dismissing the derivative lawsuit. The agreement provides that, in exchange for the plaintiff s release of all claims, we would pay a total of $500,000 in cash to cover the fees and expenses of the plaintiff s counsel. The agreement also requires us to maintain various corporate governance measures for a period of at least two years, unless a modification is necessary in the good faith business judgment of our Board of Directors.

We have been in settlement discussions with the staff of the SEC regarding the terms of a settlement of the previously announced investigation by the SEC. The proposed settlement currently under discussion, which must be agreed upon by the staff and will then be subject both to final approval by the SEC and court approval, includes the following principal terms:

- we would pay a total of $750,001, consisting of $1 in disgorgement and $750,000 in civil penalties;
- we would agree to a stipulated judgment enjoining future violations of securities laws; and
- we would agree to maintain various improvements in our internal controls that have previously been implemented.

If approved, the proposed settlement would resolve all claims against us relating to the formal investigation that the SEC commenced in January 2003.

As previously announced, the Department of Justice also currently is 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. The Department of Justice s investigation is ongoing and is not affected by the proposed settlement with the SEC described above.

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

Not applicable.

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

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 followed by the delisting of our common stock.

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, 2004		
First Quarter	$ 4.40	$ 2.95
Second Quarter	4.00	2.49
Third Quarter	3.24	2.10
Fourth Quarter	2.95	2.25
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

Holders

As of March 1, 2005, there were 264 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.

Recent Sales of Unregistered Securities

None, except as previously reported in a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

Issuer Purchases of Equity Securities

Not applicable.

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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 Operations 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, 2000 and 2001, was previously 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.

	2000	2001	2002	2003	2004
			(In thousands, except per share data)		
Revenues:	$ 6,568	$ 13,037	$ 30,916	$ 30,497	$ 32,685
Costs and expenses:					
Cost of revenues	3,757	6,208	16,484	16,058	16,916
Research and development	2,371	2,544	2,900	1,257	1,608
Selling, general and administrative	13,436	15,728	33,770	47,189	34,961
Goodwill impairment and other charges			20,311		15,810
Total costs and expenses	19,564	24,480	73,465	64,504	69,295
Loss from operations	(12,996)	(11,443)	(42,549)	(34,007)	(36,610)
Gain(loss) on divestitures, net				8,631	(711)
Net loss	$ (13,828)	$ (11,452)	$ (41,986)	$ (25,447)	$ (37,619)
Net loss per share of common stock basic and diluted	$ (1.08)	$ (0.68)	$ (1.76)	$ (1.05)	$ (1.55)
Weighted-average shares of common stock outstanding	12,757	16,741	23,822	24,162	24,263
Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	$ 22,016	$ 81,887	$ 40,361	$ 23,375	$ 7,830
Working capital	20,885	84,999	37,021	19,924	9,235
Total assets	29,183	95,094	92,628	71,997	34,374
Long-term obligations(1)	8,574				
Total stockholders equity	15,871	90,881	78,623	55,321	17,426

(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.

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Overview

We are an innovative medical device company focused on the development of minimally invasive technologies for tissue and tumor ablation through cryoablation. We develop and manufacture devices for the treatment of prostate and renal cancer and we believe that our proprietary technologies have broad applications across a number of markets, including the ablation of tumors in the lung and liver and pain resulting from bone metasteses.

In addition to our cryosurgery products, we sell other products we acquired when we purchased Timm Medical in the first quarter of 2002. The primary products are our ErecAid vacuum therapy systems. In 2003 we either divested or discontinued certain non-strategic urological product lines acquired in the Timm Medical purchase. The reduction in year-over-year sales of our Timm Medical products is largely attributable to these divestitures.

Today, our FDA-cleared Cryocare Surgical System occupies a growing position in the urological market for treatment of prostate and renal cancer. Because of our initial concentration on prostate and renal cancer, the majority of our sales and marketing resources are directed toward 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. In November 2003, we formed a dedicated sales and marketing team focused on marketing percutaneous cryoablation procedures related to liver and lung cancer and pain resulting from bone metasteses to interventional 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.

Strategy and Key Metrics

Our strategy is to achieve a dominant position in the prostate and renal cancer markets, and further develop and increase the acceptance of our technology in the interventional radiology and oncology markets for treatment of liver and lung cancers and management of pain from bone metastases. At the same time, we seek to achieve penetration across additional markets with our proprietary cryosurgical technology, while maintaining our leading position in vacuum technology for erectile dysfunction.

Our primary objective for our cryosurgical business is to grow market share, measured in terms of the number of procedures performed with our Cryocare Surgical System. Accordingly, procedure growth is an important metric to which we refer in order to measure the success of our strategy. In the past several years, we have been successful in increasing the number of procedures on a year-over-year basis. Most recently, in 2004 procedures increased 34.5 percent to 4,713 from 3,504 in 2003. In 2005, our objective is to increase the number of procedures at a significant rate which is comparable to growth rates we have achieved historically.

In addition to being a key business metric, procedure growth is an important driver of revenue growth, because a significant percentage of our revenues consists of sales of the disposable supplies used in procedures performed with the Cryocare Surgical System, as shown below under Results of Operations. In 2003 we redirected our strategy for our cryosurgical business away from emphasizing sales of Cryocare Surgical Systems and instead towards seeking to increase recurring sales of disposable supplies.

The factors driving interest in and utilization of cryoablation by urologists include increased awareness and acceptance of cryoablation by industry thought leaders, continued publication of clinical follow up data on the effectiveness of cryoablation, including recently published 10-year data, increased awareness among patients of cryoablation and its preferred outcomes as compared to other modalities the efforts of our dedicated cryoablation sales force and our continued expenditure of funds on patient education and advocacy.

Our erectile dysfunction business was categorized as an asset for sale in our financial statements in 2004. We have had discussions with several potential acquirors, but we cannot be sure we will be able to consummate an acceptable transaction. We intend to operate this business so as to provide positive cash flow. The sale of this business will have a material impact on our Results of Operations discussed below. We believe the application of our erectile dysfunction device for penile rehabilitation may have the ability to assist our cryoablation sales force with accessing potential patients a urologist might have for cryoablation.

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Results of Operations

Revenues and cost of revenues related to the following products and services for the three-year period ended December 31, 2004 are as follows:

	Year Ended December 31,		
	2002	2003	2004
	(In thousands)		
Revenues:			
Cryocare Surgical Systems	$ 3,422	$ 1,283	$ 1,403
Cryoprobes, disposables and bundled procedure fees	12,601	17,930	22,100
Cardiac products (CryoCath)	2,104	331	629
Urological products (Timm Medical)	12,789	10,953	8,553
	$ 30,916	$ 30,497	$ 32,685
Cost of Revenues:			
Cryocare Surgical Systems	$ 1,480	$ 466	$ 255
Cryoprobes, disposables and bundled procedure fees	8,111	10,626	13,330
Cardiac products (CryoCath)	1,539	399	
Urological products (Timm Medical)	5,354	4,567	3,331
	$ 16,484	$ 16,058	$ 16,916

We recognize revenues from sales of Cryocare Surgical Systems, disposable cryoprobes and other urological products when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable, and collectibility is reasonably assured. We also contract with medical facilities for the use of the Cryocare Surgical Systems in cryoablation treatments for which we charge 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.

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 system 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.

Research and development expenses include expenses associated with the design and development of new products as well as significant enhancements to existing products. 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.

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.

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Costs, expenses and other results of operations for the three-year period ended December 31, 2004 are as follows:

	Year Ended December 31,		
	2002	2003	2004
	(In thousands)		
Cost of revenues	$ 16,484	$ 16,058	$ 16,916
Research and development	2,900	1,257	1,608
Selling, general and administrative	33,770	47,189	34,961
Goodwill impairment and other charges	20,311		15,810
Total costs and expenses	$ 73,465	$ 64,504	$ 69,295
Gain (loss) on divestitures		8,631	(711)
Interest income, net	1,007	548	286
Minority interests	(444)	(619)	(584)

Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

Revenues. Revenues for the year ended December 31, 2004 increased $2.2 million to $32.7 million from $30.5 million in 2003 representing an increase of 7.2 percent. The increase in revenues was primarily attributable to growth in sales of disposables and procedure fees related to our cryosurgical business, partially offset by lower revenues from Timm Medical.

The number of cryosurgical procedures performed, and related sales of disposable products used in these procedures, grew significantly in 2004 compared to in 2003. Procedures increased 34.5 percent to 4,713 in 2004 from 3,504 in 2003, while the related revenues increased 23.5 percent to $22.1 million in 2004 from $17.9 million in 2003. Contributing to growth in sales of cryosurgical products was an increase in procedures performed by interventional radiologists, treating tumors in lung and liver cancers and pain resulting from bone metastases. These procedures generally have a lower average selling price than procedures performed by urologists on prostate and renal cancer, although cost of revenues are also lower.

Sales of our Timm Medical product lines decreased 21.8 percent to $8.6 million in 2004 from $11.0 million for 2003. This was primarily due to a $1.6 million decrease from the divestiture of the Dura II line of implantable penile prostheses and the divestiture of the urinary incontinence product lines in the second and fourth quarter of 2003, respectively.

Cost of Revenues. Cost of revenues for 2004 increased 5.0 percent to $16.9 million compared to $16.1 million for 2003. The increase in cost of revenues resulted primarily from growth in sales of cryosurgical probes and procedures, offset by elimination of costs related to the Dura II and urinary incontinence product lines and costs related to CryoCath royalty revenue. Cost of revenues related to our cryosurgical probes and procedures increased 25.5 percent to $13.3 million for 2004 from $10.6 million in 2003. The cost of revenues increase was also partly driven by an increase in the percentage of cryosurgical procedures for which we subcontract a portion of the service to third party service providers at an additional cost.

Gross Margins. Gross margins on revenues increased to 48.2 percent for 2004 compared to 47.3 percent for 2003 due to the elimination of costs on royalty revenue from CryoCath and higher margins on our sales of Cryocare Surgical Systems. Gross margin from sales of Cryocare Surgical Systems increased to 81.8 percent in 2004 compared to 63.7 percent in 2003, primarily resulting from payments received during 2004 for systems which had been excluded from revenues in prior years under our revenue recognition policy and amortization of deferred systems revenues. The associated cost of revenues from these prior year sales were recorded at the time of sale. To a lesser extent the increase in gross margin resulted from sales of Cryocare Surgical Systems that were formerly placement units, which generally

had a lower net book value at the time of sale.

Research and Development Expenses. Research and development expenses for 2004 increased 23.1 percent to $1.6 million compared to $1.3 million for 2003. The increase was primarily attributable to increased costs associated with several new development projects that we have undertaken in our efforts to reduce the

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manufacturing costs of the disposable components used in cryoablation surgical procedures. As a percentage of revenues, research and development expenses increased to 4.9 percent in 2004 from 4.1 percent for 2003.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for 2004 decreased 25.9 percent to $35.0 million compared to $47.2 million for 2003. Legal and accounting costs incurred in connection with investigations into our historical accounting and financial reporting were $14.3 million in 2003. This included $3.6 million for severance and stock compensation expense (of which $1.8 million was a non-cash charge for equity based compensation) related primarily to the termination of our then chief executive and chief financial officers. Those same legal and accounting costs declined to $7.1 million for 2004. Included in the $7.1 million were $2.3 million of costs related to our efforts to comply with Sarbanes-Oxley requirements.

The remaining $5.0 million decrease reflects a $1.1 million reduction in bad debt expense and a $2.4 million reduction primarily from our June 2004 cost reduction program. We consolidated certain sales functions and territories, streamlined our corporate organizational structure, reduced staff, eliminated certain marketing activities and restructured our sales and marketing programs.

Goodwill Impairment and Other Charges. During the year ended 2004, we recorded $15.8 million in impairment charges to write down the goodwill and amortizable intangibles in conjunction with Timm Medical and our ownership interests in certain mobile prostate treatment businesses. The charge represents the excess of the carrying value of these entities compared to their fair value, less estimated costs to sell. Fair value for the mobile prostate treatment businesses was based on a proposed purchase offer. Fair value for Timm Medical was based on an independent appraisal using a weighted combination of the publicly-traded peer group company valuations and discounted cash flow analyses.

Interest Income, Net. Interest income, net, for 2004 was $0.3 million compared to $0.5 million for 2003. The decrease in net interest income in 2004 compared to 2003 resulted from a decline in our average cash balance. Approximately $0.2 million of the $0.3 million earned in 2004 relates to interest payments received on the SRS note. (See Note 7).

Minority Interests. Minority interests represent earnings attributable to minority investors in the mobile prostate treatment businesses we acquired in 2002. The amounts recorded for minority interests were $0.6 million for 2004 and 2003. Revenues and earnings from these businesses remained consistent with our overall operations. We sold our interests in these mobile prostate treatment businesses effective December 31, 2004.

Gain (Loss) on Divestitures, Net. In 2004 we recorded a net loss of $0.7 million related to the divestiture of our ownership interests in certain mobile prostate businesses (the Partnerships). In 2003 we recorded a net gain of $8.6 million related to the divestiture of several product lines and related assets. 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 2004 was $37.6 million or $1.55 per basic and diluted share on 24,262,868 weighted average shares outstanding, compared to a net loss of $25.4 million, or $1.05 per basic and diluted share on 24,162,090 weighted average shares outstanding for 2003.

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

Revenues. 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 percent. 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, led to 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 or 61.8 percent from $3.4 million in 2002 to $1.3 million in 2003 due to a shift in our strategy to focus on

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procedural growth rather than driving adoption of cryosurgical technology through sales of capital equipment. Revenues from ongoing product lines, excluding Cryocare Surgical Systems and the divested product lines, were up $5.1 million in 2003 over 2002.

Growth in sales of cryoprobes, other disposables and bundled procedure fees increased $5.3 million or 42.1 percent from $12.6 million in 2002 to $17.9 million in 2003. The number of procedures performed domestically 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 percent from $4,500 per procedure in 2002 to $4,700 in 2003. Sales of other urology products related to our Timm Medical business were 14.1 percent lower in 2003 than in 2002, falling $1.8 million from $12.8 million to $11.0 million. 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 $3.3 million and $1.6 million in combined revenues during 2002 and 2003, respectively.

Approximately $1.8 million of the year over year change in revenue is due to the reduction in sales of cardiac products in 2003 compared to 2002 from our sale of certain rights and assets related to the SurgiFrost product line to CryoCath. Throughout 2002 we sold these products under a pre-existing distribution agreement, whereas we discontinued sales of this product in April 2003 following the divestiture.

Cost of Revenues. Cost of revenues decreased $0.4 million or 2.4 percent 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 percent in 2002 to 36.3 percent 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 percent in 2002 to 59.2 percent 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.

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

Research and Development Expenses. Research and development expenses for the year ended December 31, 2003 decreased $1.6 million or 55.2 percent from $2.9 million 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 and 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 increased $13.4 million or approximately 39.6 percent to $47.2 million for the year ended December 31, 2003 compared to $33.8 million for the year ended December 31, 2002. The primary cause of the increase was 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. Through December 31, 2003 costs related to these investigations amounted to $16.5 million of which $14.3 million was recorded in 2003. Included in the 2003 expenses was $3.6 million related to severance agreements with various executives, including $3.2 million for our former CEO and CFO/COO. Approxi-

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mately $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 our former CFO/COO and another employee.

Also a factor was a one-time charge of $1.5 million taken in 2002 for a judgment entered against us in October 2003 in the matter of Biolife Solutions, Inc. v. Endocare, Inc.

Also in June 2003, we consolidated a number of general and administrative functions into our Irvine, California headquarters. In addition, 2002 selling, general and administrative expenses included only 10 months of the post-acquisition operations for Timm Medical.

Goodwill Impairment and Other Charges. We took a charge of $18.0 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 $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 million 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 interest rates.

Minority Interests. Minority interests represent earnings attributable to minority investors in the mobile prostate treatment businesses we acquired on September 30, 2002. Minority interests increased 50 percent from $0.4 million in 2002 to $0.6 million in 2003. The increase is due to results for 2002 including only the three post-acquisition months, while in 2003 minority interest represents 12 months of earnings.

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 costs related to accounting investigations were partially offset by the net gain on divestitures.

Liquidity and Capital Resources

Since inception, we have incurred losses from operations and have reported negative cash flows. As of December 31, 2004, we had an accumulated deficit of approximately $152.0 million and cash and cash equivalents of approximately $7.8 million.

We do not expect to reach break-even or cash flow positive in 2005, and we expect to continue to generate losses from operations for the foreseeable future. These losses, which are expected to decline, have resulted primarily from our continued investment to gain acceptance of our technology. Cryoprobes, disposables and bundled procedure fees, representing 68% of total revenues in 2004 compared to 41% of total revenues in 2002, increased 75% from $12.6 million in 2002 to $22.1 million in 2004, providing evidence that our strategy is working. We also continue to incur significant costs associated with ongoing investigations and other matters related to historical accounting and financial reporting, including obligations to indemnify our former officers and directors in connection with those investigations. These costs, primarily legal, audit and accounting support fees, totaled $7.1 million, and $14.3 million (net of insurance reimbursement) for the year 2004 and 2003, respectively. For the year ended December 31, 2004, $2.3 million of these costs also related to our efforts to achieve compliance with Sarbanes 404. We also face large cash expenditures in the future related to past due state and local tax obligations, which we estimate amounted to $3.3 million as of December 31, 2004, as

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well as additional investment needed to bring us into compliance with Sarbanes 404. We are in the process of negotiating resolutions of the past due state and local tax obligations with the applicable tax authorities.

On March 11, 2005, we issued 5,635,378 shares of our common stock, warrants to purchase an additional 1,972,374 shares of common stock at $3.50 per share and warrants to purchase an additional 1,972,374 shares of common stock at $4.00 per share for an aggregate cash purchase price of $15.6 million ($2.77 per share), in a private placement to a syndicate of institutional investors as well as our Chief Executive Officer, our President and a non-employee director.

We intend to continue investing in our sales and marketing efforts to physicians in order to raise awareness and gain further acceptance of our technology. This investment is required in order to increase the physician s usage of our technology in the treatment of prostate and renal cancers, lung and liver cancers and in the management of pain from bone metastases. Such costs will be reported as current period charges under generally accepted accounting principles. We will use existing cash reserves and the net proceeds from the $15.6 million private placement of our common stock described above to finance our projected operating and cash flow needs along with continued expense management efforts.

Contractual Obligations

In the table below, we set forth our contractual obligations as of December 31, 2004. 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	2005	2006-2007	2008-2009
	(In thousands)			
Non-cancelable operating leases(1)	$ 1,580	$ 640	$ 810	$ 130
Purchase commitments(2)	1,286	1,286		
	$ 2,866	$ 1,926	$ 810	$ 130

(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 foregoing 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 U.S. generally accepted accounting

principles. 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 Risks 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.

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Revenue Recognition. We follow the provisions of Staff Accounting Bulletin 104, Revenue Recognition in Financial Statements (SAB 104), for revenue recognition. Under SAB 104, 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 medical facility and retain the entire procedure 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 medical facility 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 products and the portion related to providing mobile Cryocare Surgical Systems to customers. Providing loaner equipment to customers is a strategy aimed at promoting broader acceptance of our technology and driving sales of disposable products 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 we own 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. Medical Development, Inc. and its affiliates 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 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.

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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 none at December 2004, and represented 19 percent and 24 percent 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 percent, 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. In 2004, we recognized impairment charges of $3.1 million and $9.9 million to reduce the carrying value of the goodwill acquired in the Timm Medical acquisition and equity interests in the mobile prostate treatment businesses, respectively. Included in the 2004 impairment charge was $0.7 million of estimated costs to sell these entities.

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 concluded that a write down for impairment of any of our long-lived assets was not required. In 2004, we recognized impairment charges of $2.1 million and $80,000 to reduce the carrying value of intangible assets acquired in the Timm Medical acquisition and equity interests in the mobile prostate treatment businesses, respectively.

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 a 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 Method of Accounting of Investments in Common Stock,* which set forth factors to be evaluated in

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determining whether a loss in value should be recognized. Factors include the investee s operational performance, indicators of continued viability, financing status, liquidity prospects and cash flow forecasts. We also consider our ability to hold the investment until we recover our cost, 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, 2004 we have established a valuation allowance of $54.2 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. As of December 31, 2004, 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 schedules, 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 August 6, 2004. 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.* We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports pursuant to the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures,

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management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level.

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, and to achieve compliance with Sarbanes 404. Pursuant to Sarbanes 404, we are required to furnish a report of our management s assessment of the effectiveness of our internal controls over financial reporting and our auditors are required to provide an attestation report on management s assessment. We have omitted the internal control report and related attestation report from this Annual Report on Form 10-K in reliance on the SEC s November 30, 2004 exemptive order, which grants certain smaller accelerated filers an additional 45 days in which to furnish the internal control report and related attestation report. We have identified control deficiencies in our system of internal controls. During the 45-day extension period, we expect to evaluate these control deficiencies and to assess whether or not they rise to the level of significant deficiencies or material weaknesses. We have prepared an internal plan of action for compliance, and we are in the process of assessing our internal controls to provide the basis for our internal control report. We expect to be able to furnish the internal control report and related attestation report within the required 45-day period. However, we may be unable to satisfy the requirements of Sarbanes 404, or our internal control report or the related attestation report may identify significant deficiencies or material weaknesses in our internal controls, either of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

(b) *Management s Annual Report on Internal Control Over Financial Reporting.* Omitted in reliance on the SEC s November 30, 2004 exemptive order, which grants certain smaller accelerated filers an additional 45 days in which to furnish the internal control report and related attestation report required by Sarbanes 404.

(c) *Attestation Report of Registered Public Accounting Firm.* Omitted in reliance on the SEC s November 30, 2004 exemptive order, which grants certain smaller accelerated filers an additional 45 days in which to furnish the internal control report and related attestation report required by Sarbanes 404.

(d) *Changes in Internal Controls.* Except as described above in this Item 9A, there was no change in our internal control over financial reporting during our fourth fiscal quarter for 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2005 Annual Meeting of Stockholders, which we expect to file within 120 days after the end of our fiscal year ended December 31, 2004.

Item 11. ***Executive Compensation***

The information required by this Item 11 is incorporated by reference to the Definitive Proxy Statement relating to our 2005 Annual Meeting of Stockholders, which we expect to file within 120 days after the end of our fiscal year ended December 31, 2004.

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

The information required by this Item 12 is incorporated by reference to the Definitive Proxy Statement relating to our 2005 Annual Meeting of Stockholders, which we expect to file within 120 days after the end of our fiscal year ended December 31, 2004

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 2005 Annual Meeting of Stockholders, which we expect to file within 120 days after the end of our fiscal year ended December 31, 2004.

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 2005 Annual Meeting of Stockholders, which we expect to file within 120 days after the end of our fiscal year ended December 31, 2004.

PART IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a)(1) *Financial Statements:*

The Consolidated Financial Statements of the Company 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, 2002, 2003 and 2004 is included in the Consolidated Financial Statements at page F-35. 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) *Exhibit:*

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.
2.10(9)	Amendment No. 2 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of February 27, 2004, 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
2.11(9)	Service Fee Agreement, dated as of February 26, 2004, by and among the Company and the Limited Partners of Mid-America Cryotherapy, L.P.
2.12(9)	First Amendment to Agreement of Purchase and Sale, dated as of March 25, 2004, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.13(10)	First Amendment to Asset Purchase Agreement, dated as of August 18, 2004, by and between the Company and Gary Onik, M.D.
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(11)	Amended and Restated Bylaws of the Company.
10.1(12)	Lease Agreement, dated November 26, 2001 by and between the Company and the Irvine Company.
10.11(12)	Form of Indemnification Agreement by and between the Company and its directors.
10.12(12)	Form of Indemnification Agreement by and between the Company and its executive officers.
10.13(13)	1995 Director Option Plan (as amended and restated through March 2, 1999).
10.14(14)	1995 Stock Plan (as amended and restated through December 30, 2003).
10.15(15)	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(16)	Registration Rights Agreement, dated as of February 21, 2002, by and among the Company and the parties listed on Schedule A thereto.
10.19(15)	Registration Rights Agreement, dated as of May 28, 2002, by and between the Company and Cryomedical Sciences, Inc.
10.20(15)	Letter Agreement, dated June 11, 1999, by and between the Company and Jerry Anderson.

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Exhibit No.	Description
10.21(15)	Blanket Purchase Agreement, effective April 1, 2002, by and between Timm Medical Technologies, Inc. and the U.S. Department of Veterans Affairs.
10.22(15)	2002 Executive Separation Benefits Plan.
10.23(17)	Employment Agreement, dated as of March 3, 2003, by and between the Company and William J. Nydam.
10.24(17)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Katherine Greenberg.
10.25(11)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Kevin Quilty.
10.26(11)	First Amendment to Employment Agreement, dated as of September 14, 2003, by and between the Company and Katherine Greenberg.
10.27(11)	Consulting Agreement, dated as of August 27, 2003, by and between the Company and Craig T. Davenport.
10.28(18)	Employment Agreement, dated as of December 15, 2003, by and between the Company and Craig T. Davenport.
10.31(19)	Letter Agreement, dated as of June 9, 2004, by and between the Company and Katherine Greenberg.
10.32(20)	Employment Agreement, dated as of August 11, 2004, by and between the Company and Michael R. Rodriguez.
10.33(21)	General Release of All Claims, dated as of August 10, 2004, by and between the Company and Katherine Greenberg.
10.33(22)	2004 Stock Incentive Plan.
10.34	2004 Non-Employee Director Option Program under 2004 Stock Incentive Plan.
10.35	Form of Award Agreement Under 2004 Stock Incentive Plan.
10.36	Stipulation of Settlement, dated as of November 1, 2004, relating to securities class action lawsuit.
10.37	Description of Craig Davenport salary adjustment, effective December 2004.
10.38	Confidential Settlement Agreement and Release, dated as of December 14, 2004, by and between the Company and certain Underwriters at Lloyd s, London.
10.39	Release and Settlement Agreement, dated as of December 16, 2004, by and between the Company and National Union Fire Insurance Company.
10.40(23)	Partnership Interest Purchase Agreement, dated as of December 30, 2004, by and between the Company and Advanced Medical Partners, Inc.
21.1	Subsidiaries of Registrant
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney, included on signature page.
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 Michael R. Rodriguez.
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 Michael R. Rodriguez.

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

Management contract or compensatory plan or arrangement

(1) Previously filed as an exhibit to our Form 8-K filed on March 5, 2002.

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

(3) Previously filed as an exhibit to our Form 10-Q filed on August 14, 2002.

(4) Previously filed as an exhibit to our Form 8-K filed on August 16, 2002.

(5) Previously filed as an exhibit to our Form 8-K filed on October 15, 2002.

(6) Previously filed as an exhibit to our Form 8-K filed on April 22, 2003.

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(7) Previously filed as an exhibit to our Form 8-K filed on April 29, 2003.

(8) Previously filed as an exhibit to our Form 8-K filed on October 20, 2003.

(9) Previously filed as an exhibit to our Form 10-Q filed on May 10, 2004.

(10) Previously filed as an exhibit to our Form 10-Q filed on November 9, 2004.

(11) Previously filed as an exhibit to our Form 10-K filed on March 15, 2004.

(12) Previously filed as an exhibit to our Form 10-K filed on March 29, 2002.

(13) Previously filed as an exhibit to our Registration Statement on Form S-8 filed on June 2, 1999.

(14) Previously filed as an appendix to our Definitive Proxy Statement filed on December 3, 2003.

(15) Previously filed as an exhibit to our Form 10-K filed on December 3, 2003.

(16) Previously filed as an exhibit to our Registration Statement on Form S-3 filed on May 15, 2002.

(17) Previously filed as an exhibit to our Form 8-K filed on March 27, 2003.

(18) Previously filed as an exhibit to our Form 8-K filed on December 16, 2003.

(19) Previously filed as an exhibit to our Form 10-Q filed on August 9, 2004.

(20) Previously filed as an exhibit to our Form 8-K filed on August 12, 2004.

(21) Previously filed as an exhibit to our Form 8-K filed on September 1, 2004.

(22) Previously filed as an appendix to our Definitive Proxy Statement filed on August 6, 2004.

(23) Previously filed as an exhibit to our Form 8-K filed on January 6, 2005.

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, 2005

By: /s/ Craig T. Davenport

Craig T. Davenport
Chairman and 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 Michael R. Rodriguez, 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, 2005
/s/ Michael R. Rodriguez Michael R. Rodriguez	Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer)	March 15, 2005
/s/ John R. Daniels, M.D. John R. Daniels, M.D.	Director	March 15, 2005
/s/ Eric S. Kentor Eric S. Kentor	Director	March 15, 2005
/s/ Terrence A. Noonan Terrence A. Noonan	Director	March 15, 2005
/s/ Michael J. Strauss, M.D. Michael J. Strauss, M.D.	Director	March 15, 2005

/s/ Thomas R. Testman Thomas R. Testman	Director	March 15, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2003 and 2004, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. 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 the standards of the Public Company Accounting Oversight Board (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, 2003 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. 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 4, 2005, except for Note 14, as
to which the date is March 11, 2005

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ENDOCARE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31		
	2002	2003	2004
	(In thousands, except per share data)		
Total revenues	$ 30,916	$ 30,497	$ 32,685
Costs and expenses:			
Cost of revenues	16,484	16,058	16,916
Research and development	2,900	1,257	1,608
Selling, general and administrative	33,770	47,189	34,961
Goodwill impairment and other charges	20,311		15,810
Total costs and expenses	73,465	64,504	69,295
Loss from operations	(42,549)	(34,007)	(36,610)
Gain (loss) on divestitures, net		8,631	(711)
Interest income, net	1,007	548	286
Loss before minority interests	(41,542)	(24,828)	(37,035)
Minority interests	(444)	(619)	(584)
Net loss	$ (41,986)	$ (25,447)	$ (37,619)
Net loss per share of common stock basic and diluted	$ (1.76)	$ (1.05)	$ (1.55)
Weighted-average shares of common stock outstanding	23,822	24,162	24,263

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	
	2003	2004
	(In thousands, except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,375	$ 7,830
Accounts receivable less allowances for doubtful accounts and sales returns of $1,078 and $74 at December 31, 2003 and 2004, respectively	2,974	3,319
Inventories	2,019	2,828
Prepaid expenses and other current assets	4,331	1,533
Assets held for sale	3,654	10,459
Total current assets	36,353	25,969
Property and equipment, net	3,661	2,672
Goodwill	9,878	
Intangibles, net	5,162	4,390
Investments and other assets	1,853	1,343
Assets held for sale	15,090	
Total assets	$ 71,997	$ 34,374
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,568	$ 2,294
Accrued compensation	3,719	3,396
Other accrued liabilities	6,971	7,668
Liabilities held for sale	3,181	3,376
Total current liabilities	16,439	16,734
Minority interests	237	214
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; 24,183,254 and 24,342,482 shares issued and outstanding at December 31, 2003 and 2004, respectively	24	24
Additional paid-in capital	171,875	169,400
Accumulated deficit	(114,379)	(151,998)
Deferred compensation	(107)	
Treasury stock at cost, 206,200 shares at December 31, 2003	(2,092)	
Total stockholders equity	55,321	17,426

Total liabilities and stockholders equity	$ 71,997	$ 34,374

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)
(In thousands)

	Common Stock		Additional	Accumulated	Receivable From	Accumulated Other Comprehensive Income, Net	Deferred		Total Stockholders
	Shares	Amount	Paid-In Capital	Deficit	Stockholder	of Tax	Compensation	Treasury Stock	Equity
Balance at December 31, 2001	22,052	22	138,337	(46,946)	(471)			(61)	90,881
Comprehensive income (loss):									
Net loss				(41,986)					(41,986)
Unrealized gain on available-for-sale securities, net						13			13
Comprehensive income (loss)				(41,986)		13			(41,973)
Common stock issued and options assumed in Timm Medical acquisition	1,620	2	25,739				(165)		25,576
Common stock issued for patents and covenant not to compete	220		3,257						3,257
Stock options and warrants exercised	430		2,033						2,033
Amortization of options issued to employees							33		33
Compensation related to issuance of options and warrants to consultants for services			569						569
Repurchase of treasury stock	(174)							(2,010)	(2,010)
Forgiveness of receivable from					257				257

stockholder

Balance at December 31, 2002	24,148	24	169,935	(88,932)	(214)	13	(132)	(2,071)	78,623
Comprehensive income (loss)									
Net loss				(25,447)					(25,447)
Unrealized gain on available for-sale securities, net						(13)			(13)
Comprehensive loss:				(25,447)		(13)			(25,460)
Stock options exercised	35		23						23
Issuance of restricted stock	5		20						20
Compensation related to issuance of options to employees			1,780				25		1,805
Compensation related to issuance of options and warrants to consultants for services			117						117

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ENDOCARE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIENCY) (Continued)
(In thousands)

	Common Stock		Additional	Accumulated	Receivable	Accumulated Other Comprehensive Income,			Total Stockholders
	Shares	Amount	Paid-In Capital	Deficit	From Stockholder	Net of Tax	Deferred Compensation	Treasury Stock	Equity
Treasury stock received as repayment of loan previously forgiven	(5)							(21)	(21)
Forgiveness of receivable from stockholder					214				214
Balance at December 31, 2003	24,183	$ 24	$ 171,875	$ (114,379)	$	$	$ (107)	$ (2,092)	$ 55,321
Net loss:				(37,619)					(37,619)
Stock options exercised	350		92						92
Compensation related to issuance of options and warrants			123				13		136
Treasury stock retired			(2,596)					2,596	
Purchase of treasury stock	(191)							(504)	(504)
Deferred compensation on options forfeited			(94)				94		
Balance at December 31, 2004	24,342	$ 24	$ 169,400	$ (151,998)	$	$	$	$	$ 17,426

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,		
	2002	2003	2004
	(In thousands)		
Net loss	$ (41,986)	$ (25,447)	$ (37,619)
Cash flows from operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,095	4,669	3,481
Gain on sale of marketable securities		(12)	
Gain (loss) on divestitures, net		(8,631)	711
Compensation expense related to issuance of options, warrants and restricted stock	602	1,942	136
Treasury stock received as repayment of loan previously forgiven		(21)	
Goodwill impairment and other charges	20,311		15,810
Loss on disposal of fixed assets			139
Minority interests	444	619	584
Forgiveness of receivable from stockholder	257	214	
Changes in operating assets and liabilities, net of effects from purchases and divestitures:			
Accounts receivable	1,366	932	(248)
Inventories	(3,508)	644	(1,516)
Prepaid expenses and other current assets	(198)	(1,292)	1,132
Accounts payable	76	103	(394)
Accrued compensation	423	1,042	(150)
Other accrued liabilities	4,255	1,615	846
Net cash used in operating activities	(14,863)	(23,623)	(17,088)
Cash flows from investing activities:			
Acquisitions, net of cash acquired	(24,092)		
Purchases of property and equipment	(2,076)	(276)	(456)
Intangibles		(29)	
Partnership distributions to minority interests	(776)	(709)	(739)
Sale (purchase) of available-for-sale securities	(22,171)	22,183	
Proceeds from divestitures		9,480	2,388
Other assets	246	(1,250)	315
Net cash (used in) provided by investing activities	(48,869)	29,399	1,508
Cash flows from financing activities:			
Stock options and warrants exercised	2,033	23	92
Repurchase of treasury stock	(2,010)		(504)

Net cash provided by financing activities	23	23	(412)
Net increase (decrease) in cash and cash equivalents	(63,709)	5,799	(15,992)
Cash and cash equivalents, beginning of year	81,887	18,178	23,977
Less: Cash transferred to assets held for sale		(602)	(155)
Cash and cash equivalents, end of year	$ 18,178	$ 23,375	$ 7,830

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ENDOCARE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	For the Years Ended December 31,		
	2002	2003	2004
	(In thousands)		
Non cash activities:			
Transfer of inventory to property and equipment for placement at customer sites	$ 2,902	$ 505	$ 951
Common stock issued and options assumed in the acquisition of Timm Medical	25,741		
Common stock issued for patents and covenant not to compete	3,257		
Change in unrealized gain on available-for-sale securities	12		
Other supplemental information:			
Interest paid		40	8
Income taxes paid	2	2	2

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
(Tabular numbers in thousands, except per share data)

1. Organization and Operations of the Company

Endocare, Inc. (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. In addition, the Company offers vacuum therapy systems for non-pharmaceutical treatment of erectile dysfunction. The Company was formed in 1990 as a research and development division of Medstone International, Inc. (Medstone), a manufacturer of shockwave lithotripsy 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.

2. Recent Operating Results and Liquidity

Since inception, the Company has incurred losses from operations and has reported negative cash flows. As of December 31, 2004, the Company had an accumulated deficit of approximately $152.0 million and cash and cash equivalents of approximately $7.8 million.

The Company expects to continue to generate losses from operations for the foreseeable future. These losses, which are expected to decline, have resulted primarily from our continued investment to gain acceptance of our technology. Cryoprobes, disposables and bundled procedure fees, representing 68% of total revenues in 2004 compared to 41% of total revenues in 2002, increased 75% from $12.6 million in 2002 to $22.1 million in 2004, providing evidence that our strategy is effective. The Company continues to incur significant costs associated with ongoing investigations and other matters related to historical accounting and financial reporting, including obligations to indemnify former officers and directors in connection with such investigations. These costs, primarily legal, audit and accounting support fees, totaled $7.1 million, and $14.3 million (net of insurance reimbursement) for the twelve months ended 2004 and 2003, respectively. For the year ended December 31, 2004, $2.3 million of these costs also related to the Company s efforts to achieve compliance with section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes 404). The Company also faces large cash expenditures in the future related to delinquent state and local tax obligations, as well as additional investment needed to bring the Company into compliance with Sarbanes 404.

On March 11, 2005, the Company issued 5,635,378 shares of common stock, warrants to purchase an additional 1,972,374 shares of common stock at $3.50 per share and warrants to purchase an additional 1,972,374 shares of common stock at $4.00 per share for an aggregate cash purchase price of $15.6 million ($2.77 per share) in a private placement to a syndicate of institutional investors as well as the Company s Chief Executive Officer, President and a non-employee director. See Note 14.

The Company intends to continue investing in its sales and marketing efforts to physicians in order to raise awareness and acceptance of the Company s technology. Such investment is required in order to increase the physician s usage of the Company s technology in the treatment of prostate and renal cancers, lung and liver cancers and in the management of pain from bone metastases. Such costs are reported as current period charges under generally accepted accounting principles. The Company will use existing cash reserves and the net proceeds from the $15.6 million private placement of Common Stock described above to finance its projected operating and cash flow needs along with continued expense management efforts.

3. Summary of Significant Accounting Policies

Principles of Consolidation

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

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles 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 long-lived and intangible assets, determination of stock-based compensation to employees and consultants, and reserves for litigation and other legal and regulatory matters, among others.

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 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 setup, use and monitoring of the equipment. The medical facilities 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 medical facilities 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 as of December 31, 2002, 2003, and 2004, totaled $1.1 million, $0.4 million and $0.1 million, respectively (included in other accrued liabilities). The Company settled all minimum guarantee obligations during 2004.

No individual customer accounted for more than 10 percent of total revenues in 2002, 2003 and 2004. The Company derived 85.3 percent, 89.4 percent and 90.6 percent of revenues from sales in the United States during this three-year period.

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

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

inventories are provided based on historical experience and product demand. The Company evaluates the adequacy of these reserves periodically.

The following is a summary of inventory (excluding assets held for sale):

	December 31,	
	2003	2004
	(In thousands)	
Raw materials	$ 1,978	$ 1,727
Work in process	265	443
Finished goods	1,173	1,036
Total inventories	3,416	3,206
Less inventory reserve	(1,397)	(378)
Inventories, net	$ 2,019	$ 2,828

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 $1.9 million, $3.4 million and $2.5 million in 2002, 2003 and 2004, respectively.

The following is a summary of property and equipment (excluding assets held for sale):

	December 31,	
	2003	2004
	(In thousands)	
Equipment and computers	$ 1,641	$ 1,504
Cryosurgical systems placed at customer sites	5,904	5,778
Furniture and fixtures	797	834
Leasehold improvements	321	321
Total property and equipment, at cost	8,663	8,437
Accumulated depreciation and amortization	(5,002)	(5,765)
Property and equipment, net	$ 3,661	$ 2,672

Long-Lived Assets, Goodwill and Intangible Assets Subject to Amortization

The Company acquires goodwill and amortizable intangible assets in business combinations and asset purchases (see Note 6). The excess of the purchase price over the fair value of net assets acquired are allocated to goodwill and

identifiable intangibles. 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* as more fully described in Note 5. Goodwill and indefinite lived assets are reviewed annually for impairment and on an interim basis if events or changes in circumstances indicate that the asset might be impaired.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Intangible assets that are deemed to have finite useful lives are recorded at cost and amortized using the straight-line method over their estimated useful lives, as follows:

Trade names	15 years
Domain names	5 years
Covenants not to compete	3 to 5 years
Developed technology	15 years
Patents	3 to 15 years

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. We consider assets to be impaired and write 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. Changes in circumstances (for example, changes in laws or regulations, technological advances or changes in the Company s strategies) may also reduce the useful lives from initial estimates. Changes in the planned use of intangibles may result from changes in customer base, contractual agreements, or regulatory requirements. 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 2002, 2003 and 2004. In the fourth quarter of 2002 and the third quarter of 2004, the Company recorded an $18.0 million and a $15.8 million impairment charge, respectively, relating to the goodwill and amortizable intangibles from Timm Medical and the mobile prostate treatment partnerships. (See Notes 5 and 7). No impairment charge was recorded in 2003.

Amortization expense for each of the years ending December 31 will consist of the following amounts (excluding assets held for sale):

2005	$ 550
2006	537
2007	472
2008	467
2009	467
Thereafter	1,897
	$ 4,390

Amortization expense totaled $1.2 million, $1.3 million and $1.0 million in 2002, 2003 and 2004, respectively.

The following is a summary of intangible assets (excluding assets held for sale):

	December 31,	
	2003	2004
	(In thousands)	
Domain name	$ 435	$ 435
Covenant not to compete	592	352
Patents	6,113	5,875

Total intangibles	7,140	6,662
Accumulated amortization	(1,978)	(2,272)
Intangibles, net	$ 5,162	$ 4,390

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ENDOCARE, INC. AND SUBSIDIARIES
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Investments

During 2002 and 2003, the Company invested in a diversified portfolio of marketable debt securities, including corporate bonds, government agency securities and commercial papers. These securities were sold in 2003 for an insignificant gain. The Company also holds other investments which primarily consist of strategic investments of less than 20 percent equity interest in certain companies acquired in conjunction with various strategic alliances. These represent minority interests in start-up technology companies. The Company does not have the ability to exercise significant influence over the financial or operational policies or administration of any of these companies; therefore, they are accounted for under the cost method. Realized gains and losses are recorded when related investments are sold. Investments in privately-held companies are regularly assessed for impairment through review of operations and indicators of continued viability, including 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 $1.6 million, $0.6 million and $1.8 million for 2002, 2003 and 2004, 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, 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. 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. Procedure fees are generated from medical facilities. The Company has a diversified customer base and no single payor is considered a 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.

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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 equivalents, 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 the 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.

Reclassification

Certain previously reported amounts have been reclassified to conform with the current presentation.

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 a 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.

Capital Stock and Earnings Per Share

During the first quarter of 2004, the Company retired 326,222 of its common shares held in treasury, including 120,022 shares purchased from BioLife Solutions, Inc. (BioLife) for approximately $0.5 million in February 2004, in connection with settlement of its litigation with BioLife (See Note 12).

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the respective periods. Diluted loss per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options and warrants that were outstanding during the respective periods presented. For periods when the Company

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reported a net loss, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were antidilutive.

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 temporary differences are expected to be settled and reflected in the financial statements in the period of enactment. The Company estimates that as of December 31, 2003 and 2004 it owes $2.6 million and $3.3 million, respectively, in state and local taxes, primarily sales and use taxes in various jurisdictions in the United States.

Stock-Based Compensation

As of December 31, 2004, the Company had four stock-based compensation plans, including the 2004 Stock Incentive Plan approved by the Company s shareholders on September 10, 2004. 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 loss and is measured as the excess of the market price of the Company s stock at the date of grant over the exercise price. Compensation costs for fixed awards that are subject to vesting are recognized over the vesting period. In practice, the Company has only awarded stock options to its employees with exercise prices equal to the fair market value of the stock at the date of grant.

The Company has adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation Translation and Disclosure.* The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions to stock-based employee compensation.

	Year Ended December 31,		
	2002	2003	2004
	(In thousands)		
Net loss, as reported(a)(c)	$ (41,986)	$ (25,447)	$ (37,619)
Reconciling items:			
Add: Stock-based employee compensation expense determined under the intrinsic-value-based method for all awards(b)	33	25	136
Less: Stock-based compensation expense determined under the fair-value-based method for all awards expense(c)	(4,075)	(2,313)	(3,875)
Net adjustment	(4,042)	(2,288)	(3,739)
Net loss, as adjusted	$ (46,028)	$ (27,735)	$ (41,358)
Basic and diluted loss per share:			
As reported	$ (1.76)	$ (1.05)	$ (1.55)
As adjusted	$ (1.93)	$ (1.15)	$ (1.70)

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ENDOCARE, INC. AND SUBSIDIARIES
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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:

	2002	2003	2004
Stock volatility	1.14	1.57	88.6
Risk-free interest rate	4.3%	3.4%	3.6%
Expected life in years	5 years	5 years	5 years
Stock dividend yield			

(a) In the past, the Company had issued stock options and warrants to consultants for services performed. Compensation expense for the fair value of these options was determined by the Black-Scholes option-pricing model and was charged to operations over the service period or as performance goals were achieved. Such expense was included in net loss as reported.

(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 Company s 2002 acquisition of Timm Medical and amortized over the remaining vesting period. The 2004 amounts include a $0.1 million charge related to options held by the Company s former CFO, which will continue to vest for one year after separation in August 2004.

(c) Pursuant to APB No. 25, the reported net loss for 2003 included $1.8 million in compensation expense relating to option settlements with two former executives in conjunction with their separation agreements (including a $1.7 million charge for replacement options recorded upon termination of the former CFO/ COO on July 31, 2003). Pursuant to SFAS No. 123/148, the fair value of the replacement options would have been recorded between the option modification date of March 3, 2003 and termination date. The $2.3 million expense for 2003 represents stock-based compensation determined under SFAS No. 123/148, less the $1.8 million recorded charge.

In December 2004, SFAS No. 123R, Share-Based Payment was issued. SFAS No. 123R is a revision of SFAS No. 123, Accounting for Stock Based Compensation , and supersedes APB 25. Among other items, SFAS 123R eliminates the use of APB 25 and the intrinsic value method of accounting, and requires companies to recognize the cost of employee services received in exchange for awards of equity instruments, based on the grant date fair value of those awards, in the financial statements. The effective date of SFAS 123R is the first reporting period beginning after June 15, 2005, which is third quarter 2005 for calendar year companies, although early adoption is allowed. SFAS 123R permits companies to adopt its requirements using either a modified prospective method, or a modified retrospective method. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS 123R for all share-based payments granted after that date, and based on the requirements of SFAS 123 for all unvested awards granted prior to the effective date of SFAS 123R. Under the modified retrospective method, the requirements are the same as under the modified prospective method, but also permits entities to restate financial statements of previous periods based on proforma disclosures made in accordance with SFAS 123.

We currently utilize the Black-Scholes standard option pricing model to measure the fair value of stock options granted to employees. While SFAS 123R permits us to continue to use such a model, the standard also permits the use of a lattice model. We have not yet determined which model we will use to measure the fair value of employee stock options upon the adoption of SFAS 123R.

SFAS 123R also requires that the benefits associated with the tax deductions in excess of recognized compensation cost be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after the effective date. These future amounts cannot be estimated, because they depend on, among

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other things, when employees exercise stock options. Also, we have not recognized the benefits for excess tax deductions in our operating cash flows in prior periods due to the uncertainty of when we will generating taxable income to realize such benefits.

We currently expect to adopt SFAS 123R effective July 1, 2005; however, we have not yet determined which of the aforementioned adoption methods we will use. The adoption of SFAS No. 123R s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position and cash flows. The impact of adoption of SFAS No. 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS No. 123R in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share in the table above. See Note 9 for further information on our stock-based compensation plans.

4. New Accounting Pronouncements

In November 2004, SFAS 151, Inventory Costs-an amendment of ARB No. 43, Chapter 4, was issued. This Statement amends the guidance in Accounting Research Bulletin (ARB) No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not expect adoption of this standard to have a material impact on its consolidated financial statements.

5. Asset Impairment

Under SFAS No. 142, *Goodwill and Other Intangible Assets,* goodwill and indefinite-lived intangible assets are not 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. Goodwill is tested for impairment by comparing its fair value to its carrying value 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 two 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 of each year for all of its reporting units. The Company used an independent third-party appraiser to assess the fair values of each reporting unit based on a weighted combination of (i) the guideline company method that utilizes revenue multiples for comparable publicly-traded companies, and (ii) a discounted cash flow 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. The Company then determined the implied fair value of the goodwill and amortizable intangibles. Based on this analysis, the Company recorded:

a) A fourth quarter of 2002 impairment charge of $18.0 million to reduce the carrying value of goodwill for Timm Medical. The impairment resulted from the termination or abandonment of three of the acquired distribution agreements for urological products following the acquisition of Timm Medical 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 approximately 60% of Timm Medical s annual revenue growth.

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b) A third quarter of 2004 impairment charge of $5.9 million to reduce the carrying value of Timm Medical s goodwill ($3.1 million) and developed technology ($2.1 million) to fair value and an additional charge of approximately $.7 million for the estimated cost to sell Timm Medical. The interim impairment analysis in the third quarter of 2004 was required based on the Company s decision to actively market Timm Medical to potential buyers in July 2004 (see Note 7), as well as declining revenues, turnover in sales force, and below average growth as compared to general industry trends. The Company updated our impairment analysis effective October 1, 2004 and concluded no further impairment had occurred.

c) A third quarter of 2004 impairment charge of $9.9 million to write-off the carrying value of goodwill ($9.8 million) and covenant not to compete ($.1 million) with respect to the pending divestiture of the mobile prostate treatment businesses (the Partnerships) based on a preliminary purchase offer (see Note 7). The goodwill primarily related to the distribution network provided by the Partnerships, which allowed the Company to further penetrate desired markets. Since investors in the mobile treatment businesses are comprised of urologists, the Partnerships facilitated the continued promotion of cryosurgery as the preferred treatment for prostate cancer. In addition, upon the Company s purchase of the Partnerships in September 2002, the seller (USMD) exited the cryosurgical operations and terminated its exclusive distribution agreement with the Company, allowing the Company to access a previously restricted market. After the Company sold the Partnerships in December 2004, the Company still expected to, and did, retain access to the service and distribution network through the Company s existing contracts and continue to benefit from the strategic value of a non-exclusive distribution arrangement with the buyer. However, since this economic benefit could not be quantified with reasonable accuracy, the Company recorded the $9.9 million charge to write off the excess of the carrying value of the Partnerships net assets over the preliminary purchase offer, less selling costs. See Note 7 for the loss recorded upon final sale in the fourth quarter of 2004.

In the fourth quarter of 2002, the Company also recorded a $2.3 million other-than-temporary loss in the value of our investment in U.S. Medical Development, Inc. (formerly U.S. Therapies, LLC.) acquired in June 2001. The loss was based on management s assessment that the investee was unable to sustain an earnings capacity, that would justify the carrying amount of the investment.

6. Acquisitions

Business Combinations

On February 21, 2002, the Company acquired the outstanding common stock and assumed certain employee stock options of Timm Medical for total consideration of $37.3 million $10.8 million in cash, 1.6 million shares of the Company s Common s common stock valued at $23.8 million, assumption of employee stock options valued at $1.9 million and $0.8 million in transaction costs.

On September 30, 2002, the Company acquired certain controlling general and limited equity interests in 13 mobile prorate treatment businesses (the Partnerships) from a group of companies collectively known as USMD for $11.7 million $4.2 million in cash, $0.2 million in assumption of debt, $6.8 million in loan forgiveness and $0.5 million in acquisition costs. The Company s equity interests ranged from 1 percent to 100 percent in each partnership and limited liability company. USMD was an exclusive distributor of the Company s cryosurgical products in 16 states and operated the mobile businesses to provide support services for cryoblation procedures to the Company, including cryosurgical system rental, logistics and coordination, transport and technician services. Under service agreements with each Partnership, the Company pays a fixed fee per procedure equal to the fair value of such services. These fees are eliminated in consolidation, such that only the actual costs of the services incurred by the Partnerships are included in the Company s operating costs.

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The purchase price of Timm Medical and the Partnerships was allocated as follows:

	Timm Medical	Partnerships
	(In thousands)	
Purchase consideration	$ 37,350	$ 11,734
Fair value of tangible assets acquired	(1,041)	(1,616)
Fair value of amortizable intangibles:		
Developed technology	(10,000)	
Trademark	(500)	
Covenant not to compete		(240)
Deferred compensation	(165)	
Goodwill (non-tax deductible)	$ 25,644	$ 9,878
Purchase consideration	$ 37,350	$ 11,734
Fair value of common stock issued	(23,806)	
Fair value of options assumed	(1,935)	
Cash paid	11,609	11,734
Cash acquired	(1,127)	(396)
Net cash paid	$ 10,482	$ 11,338

The goodwill from Timm Medical primarily related to enhancement of the Company s product line and projected growth in urology sales through collaborative distribution agreements with other medical device companies and the sales force which we believed were valuable assets to be re-deployed to promote tumor ablation. As discussed in Note 5, in the fourth quarter of 2002 and third quarter of 2004, the Company recorded a charge of $18.0 million and $5.9 million, respectively, to reduce the carrying value of the goodwill and intangibles related to Timm Medical. The goodwill from the mobile prostate businesses is primarily related to the distribution network provided by the partnerships and the Company s ability to access a market previously restricted under an exclusive distribution agreement with USMD. As discussed in Note 5, in the third quarter of 2004, the Company recorded a charge of $9.9 million to write off the value of the goodwill and intangibles based on a proposed offer by a third party to purchase these partnerships. The sale was consummated in December 2004 (see Note 7).

Asset Purchases

On May 28, 2002, the Company agreed to acquire a portfolio of patents central to the cryoablation technology from Cryomedical Sciences, Inc. (now known as BioLife Solutions, Inc. or Biolife) for $2.2 million in cash and 120,022 shares of the Company s common stock valued at $1.8 million. The total purchase consideration of $4.1 million (including $0.1 million in acquisition-related costs) was allocated to patents since other assets acquired had de minimus value. In November 2002, BioLife filed suit against us for failing to register the shares issued in a timely manner as required under an asset purchase and registration rights agreement. (See Note 12).

In February 2002, The Company purchased the patents to certain cryosurgical technologies and a covenant not to compete from a cryosurgeon inventor for 100,000 shares of the Company s common stock valued at $1.4 million, of which $1.1 million (75,000 shares) was allocated to the patent to be amortized over 15 years and the remaining $0.3 million (25,000 shares) was allocated to the covenant to be amortized over 5 years. The agreement also requires

the seller to perform certain consulting services over 15 years for the consideration received. No consideration was allocated to the consulting agreement since its value could not be accurately measured. In January 2003, the Company extended a $344,000 loan to the seller to finance tax payments related to the gain on sale (see Note 13).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Dispositions and Assets Held for Sale

Divestitures of Non-Core Product Lines 2003

In 2003, the Company embarked on a strategy to refocus the Company s 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 non core product lines 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.

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 $2.2 million 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 Technologies, Inc. (CryoCath) for $10.0 million. CryoCath was the exclusive distributor for cryoprobes and consoles in connection with the SurgiFrost^{tm} system, a cryoablation system designed to treat cardiac arrhythmias. The Company transferred all of the Company s 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 required to attend quarterly and annual technical update meetings through 2014. Since the technology was internally developed and the tangible assets sold had minimal value, the sale resulted in a 2003 second quarter gain of $10.0 million. The royalty stream decreases from 10 percent to 3 percent of net sales from the SurgiFrost^{tm} 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 $7.5 million of the total sale proceeds. The remaining $2.5 million, included in prepaid expenses and other current assets at December 31, 2003, was collected in January 2004. Royalty income was $0.6 million in 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 $2.7 million 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 percent and is secured by the assets sold. As amended in March 2004, the note requires quarterly payments of $45,000 beginning March 31, 2004, increasing to $60,000 for the quarter ended December 31, 2005. Amounts which remain outstanding at December 31, 2005 will be payable at $60,000 per quarter until the outstanding principal and accrued interest are paid in full. The carrying values of the urodynamics and urinary incontinence related assets were $1.3 million on the date of sale. Management concluded that collection of the note from SRS was not reasonably assured. As a result, a loss of $1.3 million was recorded in the fourth quarter of 2003 equal to the carrying value of the assets sold and collections on the note, if any, will be reported as gain in the period

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

received. Collections during 2004 were $0.2 million and have been applied to accrued interest (included in interest income in the consolidated statements of operations).

The combined revenues, costs of revenues and gross profit related to the divested product lines are $2.0 million, $1.0 million and $1.0 million, respectively, for 2003, and $5.4 million, $2.3 million and $3.1 million for 2004, respectively.

Incremental selling, general and administrative expenses attributable to these product lines were not significant. The revenues and cost of revenues for the divested product lines are not significant and are not presented as discontinued operations.

Assets Held for Sale 2004

In July 2004, the Company began actively marketing Timm Medical and the Company s equity interests in the mobile prostate treatment businesses to potential buyers. In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, the assets and liabilities of Timm Medical and the Partnerships (collectively the Disposal Group) were reclassified as assets held for sale in the consolidated balance sheets as of December 31, 2003 and 2004.

Mobile Prostate Treatment Businesses (Partnerships)

On December 30, 2004, the Company entered into a Partnership Interest Purchase Agreement (the Purchase Agreement) with Advanced Medical Partners, Inc. (AMPI). Pursuant to the Purchase Agreement, the Company agreed to sell to AMPI the Company s interests in nine partnerships and the Company s minority investment in U.S. Therapies, LLC (a national urology services company) acquired in June 2001 for $0.9 million. The Purchase Agreement provides that if AMPI were to sell the minority investment within one year for proceeds in excess of $0.2 million, the Company would receive 50 percent of such excess, up to $0.5 million. Such proceeds, if any, will be recorded in the period received. As a result of the sale, the Company recorded a loss on divestiture of $0.7 million in the 2004 fourth quarter. The loss comprises $0.9 million in proceeds less selling costs of approximately $63,000 and $1.5 million of the net tangible assets sold. The proceeds were received in February 2005 and were included in prepaid expenses and other current assets at December 31, 2004. After the sale, the Company will continue to pay the Partnerships, similar to other service providers, the contracted fee for mobile support services. As such, the Partnerships are not presented as discontinued operations. The four remaining mobile treatment businesses have ceased operations or are pending dissolution.

Timm Medical

The Company is in preliminary discussions with several parties regarding the sale of Timm Medical. Assuming the Company is able to negotiate acceptable terms and conditions, the Company expects to complete the sale within 12 months and have classified Timm Medical s assets and liabilities as current at December 31, 2004. In accordance with SFAS No. 144, these assets and liabilities have been adjusted to fair value less estimated cost to sell. Depreciation of fixed assets and amortization of intangibles has also been suspended as of July 31, 2004. Revenues for Timm Medical were $11.0 million and $8.5 million in 2003 and 2004, respectively. Net income (loss) was $(0.5) million and $0.3 million, respectively, excluding the impairment charge. The operations of Timm Medical will be classified as discontinued operations upon its sale or earlier if the Company can reasonably determine that its operations and cash flows will be eliminated and that the Company will not have any significant continuing involvement after the disposal transaction.

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Assets held for sale as of December 31, include the following:

	2003	2004
	(In thousands)	
Assets:		
Cash, inventories and other current assets	$ 2,143	$ 1,204
Property and equipment, net	1,977	467
Goodwill, net	7,660	4,552
Intangibles, net	6,583	4,170
Other assets	381	66
Total assets	$ 18,744	$ 10,459
Liabilities:		
Accounts payable and other current liabilities	$ 607	$ 654
Other accrued liabilities	2,574	2,042
Costs to sell		680
Total liabilities	3,181	3,376
Net assets held for sale	$ 15,563	$ 7,083

8. Stock-Based Compensation Plans

As of December 31, 2004, the Company had four stock-based compensation plans. On September 10, 2004, the Company s stockholders approved the 2004 Stock Incentive Plan. 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 loss and is measured as the excess of the market price of the Company s stock at the date of grant over the exercise price. Compensation costs for fixed awards that are subject to vesting are recognized pro rata over the vesting period. In practice, the Company has only awarded stock options to its employees with exercise prices equal to the fair market value of the stock at the date of grant.

The following tables summarize the Company s option activities:

	Year Ended December 31,					
	2002		2003		2004	
	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
	2,700,057	$ 6.70	3,153,427	$ 8.50	5,118,752	$ 5.06

Outstanding, beginning of year						
Granted	1,145,507	11.90	2,893,000	3.42	1,397,500	2.94
Cancelled	(272,649)	10.99	(892,675)	11.96	(804,570)	5.32
Exercised	(419,488)	4.52	(35,000)	3.73	(350,000)	0.26
Outstanding, end of year	3,153,427	8.50	5,118,752	5.06	5,361,682	4.72

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Range Of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding at December 31, 2004	Weighted-Avg. Remaining Contractual Life (Number of Years)	Weighted-Avg. Exercise Price	Number Exercisable at December 31, 2004	Weighted-Avg. Exercise Price
$ 0.18 - 2.03	139,000	2.61	$ 1.17	139,000	$ 1.17
2.06 - 4.00	2,403,206	8.59	2.47	636,127	2.44
4.02 - 6.19	2,036,907	8.53	4.41	980,101	4.60
6.94 - 9.00	101,769	5.25	8.64	99,611	8.68
10.19 - 13.88	445,333	7.06	12.21	331,675	12.29
14.35 - 21.23	235,467	6.90	16.63	186,189	16.70
0.18 - 21.23	5,361,682	8.15	$ 4.72	2,372,703	$ 6.01

The weighted average fair value of the Company s options at the grant date was approximately $9.54 in 2002, $3.02 in 2003 and $2.22 in 2004.

During 2002 and 2003, the Company incurred employment taxes associated with the exercise of employee stock options and loan forgiveness totaling $0.9 million and $0.1 million, respectively. There were none incurred in 2004. Employment related taxes payable at December 31, 2003 and 2004 were $1.3 million and $1.2 million, respectively (included in accrued compensation).

9. Equity Incentive Plans

Stock Options

As of December 31, 2004, the Company had options outstanding under four stock-based compensation plans, as follows:

2004 Stock Incentive Plan. The 2004 Stock Incentive Plan adopted in September 2004 authorizes the Board or one or more committees designated by the Board (the Plan Administrator) to grant options and rights to purchase common stock to employees, directors and consultants. Options may be either incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended, non-statutory stock options or other equity instruments. The 2004 Stock Incentive Plan replaced the 1995 Stock Plan and 1995 Director Plan described below. The exercise price is equal to the fair market value of the Company s common stock on the date of grant (or 110 percent of such fair market value, in the case of options granted to any participant who owns stock representing more than 10 percent of the Company s combined voting power). Options generally vest 25 percent on the one-year anniversary date, with the remaining 75 percent vesting monthly over the following three years and are exercisable for 10 years. As of December 31, 2004, 1,500,000 shares of common stock have been reserved for issuance under the 2004 Stock Incentive Plan. On the first trading day of each calendar year beginning in 2005, shares available for issuance will automatically increase by 3 percent 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. In addition, the maximum aggregate number of shares which may be issued under the 2004 Stock Incentive Plan will be increased by any shares (up to a maximum of 2,800,000 shares) awarded under the 1995 Stock Plan and 1995 Director Plan that are forfeited, expire or are cancelled. Options become fully vested if an employee is terminated without cause within 12 months of a change in

control as defined. Upon a corporate transaction as defined, options not assumed or replaced will vest immediately. Options assumed or replaced will vest if the employee is terminated without cause within 12 months. As of December 31, 2004, there were outstanding under the 2004 Stock Incentive Plan options to purchase 709,000 shares of the Company s common stock and 1,110,090 options were available for grant.

1995 Stock Plan. The 1995 Stock Plan authorized the Board or one or more committees designated by the Board (such committee, 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

incentive stock options as defined in Section 422 of the Internal Revenue Code of 1986, as amended, non-statutory 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 was required to equal the fair market value of the Company s common stock on the date of grant. Options generally vest 25 percent on the one-year anniversary date, with the remaining 75 percent vesting monthly over the following three years. Options are exercisable for 10 years. The 1995 Stock Plan was replaced by the 2004 Stock Incentive Plan on September 10, 2004. As of December 31, 2004, there were outstanding under the 1995 Stock Plan options to purchase 2,329,349 shares of the Company s common stock and no options were available for grant.

1995 Director Option Plan. The 1995 Director Option Plan (the Director Plan) provided automatic, non-discretionary grants of options to the Company s non-employee directors (Outside Directors). The Director Plan provided that each Outside Director is granted an option to purchase 20,000 shares of the Company s 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 had served for at least six months was granted an additional option (Subsequent Option) to purchase 5,000 shares of the Company s common stock, on January 1 of each year, or the first trading day thereafter, so long as he or she remained an Outside Director. The exercise price of options granted to Outside Directors was required to be the fair market value of the Company s 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. The 1995 Director Option Plan was replaced by the 2004 Stock Incentive Plan on September 10, 2004. As of December 31, 2004, there were outstanding under the 1995 Director Option Plan options to purchase 140,000 shares of the Company s common stock and no options were available for grant.

2002 Supplemental Stock Plan. 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 percent 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 percent 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, 2004, there were outstanding under the 2002 Plan options to purchase 183,333 shares of the Company s common stock and 251,667 options were available for grant.

Option Arrangements Outside of Plans. 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/COO) 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 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/COO 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 then-current 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. Twenty-five percent 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

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comes first. Twenty-five percent of the remaining options vest immediately with the balance vesting ratably over three years.

Except for the 2004 Stock Incentive Plan, all options granted pursuant to the Company s stock-based compensation plans are subject to immediate vesting upon a change in control as defined.

Warrants

The Company occasionally has issued warrants in conjunction with debt financing transactions, underwriting agreements, patent licenses and service contracts. Warrants generally have a contractual term of five years and vest over a one- to five-year period. As of December 31, 2004, the Company had warrants outstanding to purchase 25,000 shares of the Company s common stock at an exercise price of $9.00 per share. These warrants expired on January 3, 2005, and none were exercised prior to their expiration. No warrants to purchase shares were exercised in 2003 or 2004.

The Company also issued detachable warrants to investors to purchase 188,680 shares of the Company s common stock in conjunction with a November 2000 private placement. These warrants have a five-year term and were immediately exercisable at $13.91 per share. As of December 31, 2004, 176,180 remain outstanding.

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 percent 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 percent 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 percent 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. The rights will expire at the close of business on April 15, 2009 (the Final Expiration Date), unless the Final Expiration Date is extended or unless the rights are earlier redeemed or exchanged by the Company.

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10. Income Taxes

The Company reported no income tax expense for each of the three years in the period ended December 31, 2004 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:

	2003	2004
	(In thousands)	
Deferred tax assets (liabilities):		
Investment valuation reserves	$ 1,074	$
Basis difference in intangible assets	(146)	778
Property and equipment allowances and depreciation	(320)	267
Inventory obsolescence and related allowances	1,135	396
Accounts receivable allowances and revenue deferrals	1,049	226
Note receivable allowances	1,040	1,040
Installment sales	(849)	(849)
Other accrued liabilities	2,105	2,448
Accrued compensation	1,397	1,511
Net operating loss and credit carryforwards	33,808	43,094
Capital loss on carryforwards		5,279
	40,293	54,190
Valuation allowance	(40,293)	(54,190)
Net deferred tax assets	$	$

Due to continuing operating losses, the valuation allowance increased by $9.5 million and $13.9 million during the years ended December 31, 2003 and 2004, respectively. 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, 2003 and 2004.

Actual income tax expense differs from amounts computed by applying the United States federal income tax rate of 34 percent to pretax loss as a result of the following:

	Years Ended December 31,		
	2002	2003	2004
		(In thousands)	
Computed expected tax benefit	$ (14,275)	$ (8,442)	$ (12,479)
Nondeductible expenses	244	302	102
Goodwill impairment	6,115		1,057
Increase in valuation allowance	8,877	9,535	13,897
State taxes	(1,369)	(1,395)	(2,003)
Other	408		(574)

Actual tax expense	$	$	$

As of December 31, 2004, the Company has federal and state net operating loss carryforwards of $109.0 million and $77.3 million, 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 $0.8 million and $0.3 million, respectively. The federal research and experimentation credit carryforwards begin to expire in 2011 and the state research and experimentation credit carryforwards do not expire.

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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. This includes $4.1 million in net deferred tax assets related to pre-acquisition losses from Timm Medical consisting principally of $12.2 million of federal net operating loss (NOL) carryforwards and $0.2 million of federal research and experimentation credit carryforwards. These deferred tax assets were fully reserved on the acquisition date due to uncertainty that benefits will be realized. Subsequent tax benefits realized from these deferred tax assets will be applied to reduce the valuation allowance and goodwill related to the Timm Medical acquisition. 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 percent of the total outstanding voting securities at the investment date in exchange for $0.3 million. The Company also received a warrant to acquire 3,166,000 common shares (approximately 52 percent of Sanarus voting stock on an as-converted, fully-diluted basis at that time) for $0.01 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 the Company 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 the Company 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 prostate, kidney and liver diseases, disorders and conditions; and (iii) The Company s grant to Sanarus of an exclusive (even as to the Company), worldwide, irrevocable, fully paid-up right to develop, manufacture and sell products using certain of the Company s technology for use in the diagnosis, prevention and treatment of gynecological and breast diseases, disorders and conditions.

In June 2001, the Company provided a bridge loan to Sanarus in the amount of $0.3 million 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 $0.6 million and a warrant to purchase equity shares in Sanarus with an aggregate exercise price of up to $0.3 million. Upon completion of an equity financing by Sanarus in October 2003, the 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 $0.68 per share. This and other financings changed the Company s current voting percentage from 1.8 percent on an as converted, basis (20 percent on an as converted, fully diluted basis) at December 31, 2002 to 2.7 percent on an as converted basis (7.9 percent 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

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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 percent of the outstanding Series A Preferred Stock of Sanarus. Total investment in Sanarus of $0.9 million as of December 31, 2003 and 2004, is included in investments and other assets. The investment is recorded at cost since the Company does not exercise significant influence over the operations of Sanarus.

CryoFluor Therapeutics

Effective December 21, 2004, the Company and CryoFluor Therapeutics, L.L.C. (CryoFluor) entered into a Services Agreement and First Amendment to CryoFluor s Operating Agreement. Under the Services Agreement, the Company will provide to CryoFluor certain product design and development services, which consist of both preclinical stage services and clinical stage services.

In exchange for the preclinical stage services, CryoFluor issued 500,000 ownership units to the Company on December 21, 2004, which are subject to vesting as described below. In exchange for the clinical stage services, the Services Agreement provides that on December 30, 2004 or at such other date as the Company and the managers of CryoFluor shall agree (the Second Tranche Date), CryoFluor will issue to the Company an additional 445,000 ownership units subject to completion of the preclinical services and compliance with all of the Company s obligations to be performed by the Second Tranche Date. Each ownership unit has an ascribed value of $1.00.

The ownership units are subject to vesting as follows: (i) 50,000 of the units vested on December 21, 2004, constituting approximately 1.3 percent of CryoFluor s outstanding ownership interests at such date; (ii) 44,500 units upon the Second Tranche Date; (iii) 450,000 units upon completion of the preclinical services and CryoFluor s acceptance of the Company s report relating to the preclinical services; and (iv) the remaining 400,500 units upon completion of the clinical services and CryoFluor s acceptance of the Company s report relating to the clinical services. In the event of a termination of the Services Agreement for any reason, all ownership units that have not vested as of the termination date will be forfeited.

Pursuant to the First Amendment to the Operating Agreement, the Company was admitted as a member of CryoFluor on December 21, 2004. Under the First Amendment to the Operating Agreement, each other member of CryoFluor granted to the Company a limited right of first negotiation with respect to the sale of ownership units held by such member. In addition, CryoFluor granted to the Company a limited right of first negotiation with respect to the sale, assignment, license or other transfer of the technology owned by CryoFluor that is the subject of the development program under the Services Agreement. Through December 31, 2004, the Company has received 500,000 ownership units, of which 50,000 units have vested. Since CryoFluor is a development stage company and the fair value of the Company s contracted services could not be accurately determined, the Company has recorded a valuation allowance against the ascribed value of its minority interest investment in CryoFluor.

As of December 31, 2003 and 2004, the Sanarus and CryoFluor investments are accounted for using the cost method as the Company does not exercise significant influence over their operations. As the Company receives additional vested units from CryoFluor, allowing it to exercise significant influence, the Company may use the equity method of accounting at that time.

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 consulting agreements with the Company and are owners of or affiliated with entities which

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have purchased products 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 minimum amounts 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.

The Company has entered into additional 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 distributor s contractual obligation to pay is not contingent on other events, such as final sale to an 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.

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 non-cancelable operating leases consist of the following (in thousands):

Year ending December 31, 2005	$ 640
2006	614
2007	196
2008	88
2009	42
	$ 1,580

Employment and Severance Agreements

The Company has entered into employment agreements with certain executives which provide for annual base salaries and cash incentive payments of up to 45 percent of base salary subject to attainment of corporate goals and objectives pursuant to incentive compensation programs approved by the Company s board of directors, and stock options. The agreements provide for severance payments if the executive is terminated other than for cause or terminates for good reason as defined. 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 was entitled to receive a $0.4 million 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 $0.4 million upfront payment, under the provisions of the Consulting Agreement, as amended, the former CEO agreed to a one-year covenant not to compete and during its term, he was required to provide consulting services at the direction of management for a minimum of eight hours per quarter. 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

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

recorded a charge of $0.8 million 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 $0.8 million was deposited into an escrow account and was released from the escrow account in March 2004. In the third quarter of 2004, the former CEO exercised options to purchase 325,000 shares at $0.18 per share. Options for the remaining 240,000 shares expired unexercised.

Former Chief Financial and Operating Officer

The Company entered into an employment agreement, dated March 3, 2003 (the Employment Agreement), with the Company s former Chief Financial and Operating Officer (the former CFO/ COO). Under the agreement, the Company is required to pay the former CFO/ COO a base salary of $0.2 million and cash bonus of up to $88,000 per year. The Employment Agreement also provides that all of the former CFO/ COO s options to purchase 385,000 shares of common stock 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/ COO will be entitled to a cash payment of $0.6 million, 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/ COO s employment other than for cause. The Company recorded a third quarter charge for $0.7 million for severance, medical, and relocation benefits due under the Qualified Termination provisions. In addition, the Company recorded a third quarter charge for $1.7 million 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/ COO is required to repay all amounts received in a Qualified Termination upon (i) the former CFO/ COO 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/ COO. The total severance payments due of $0.6 million were deposited into an escrow account and were released from the escrow account in March 2004. The replacement options remain outstanding as of December 31, 2004.

Former Chief Financial Officer

On August 27, 2004, the Company executed a General Release of All Claims (the General Release) with its former Chief Financial Officer (the former CFO), which is effective as of August 10, 2004. Pursuant to the terms of the General Release, the Company agreed to continue to pay the former CFO her current base salary of $0.2 million per year via semi-monthly salary continuation payments for a period of 12 months and continuation of her health benefits pursuant to COBRA for one year. Finally, the Company has agreed to permit the former CFO to continue to vest in all stock options previously granted by the Company through July 31, 2005 and recorded stock-based compensation expense of $0.1 million.

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 provided that, in

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the case of any Covered Termination, the participants would receive from six months to two years of their base salary plus the maximum bonus, as defined. Covered Terminations included 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 were 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. Effective July 2004, the Company terminated the Separation Plan.

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). The Company combined the two plans effective September 30, 2003. No matching contributions were made in 2002, 2003 or 2004.

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. 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 $1.6 million 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 $1.5 million, representing the difference between the court s award to BioLife and the estimated fair value of the shares to be surrendered. On October 10, 2003 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 $1.9 million to Biolife and return of the 120,022 common shares. The shares were recorded as treasury stock in March 2004 based on the fair value of $0.5 million at that date and the balance of $1.4 million 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 ordering plaintiffs to file a consolidated complaint, which was filed on October 31, 2003. The consolidated complaint asserted 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 the Company s revenues and expenses in press releases and SEC filings. Plaintiffs sought class certification and unspecified damages from the Company, as well as forfeiture and reimbursement of bonus compensation received by two of the individual defendants. On April 26, 2004, the court issued an order denying the Company s motion to dismiss the consolidated complaint. On November 8, 2004, the Company executed a settlement agreement with the lead plaintiffs and their counsel. The court has granted preliminary approval of this agreement and authorized the parties to provide notice of its terms to class members. Under the agreement, in exchange for a release of all claims, the Company and certain individuals would pay a total of $8.95 million in cash. The Company s directors and officers liability insurance carriers funded the total amount of $8.95 million prior to December 31, 2004, subject to reservations of rights by the carriers (see below). On February 7, 2005, the Court issued a final order approving the agreement and dismissing the class-action lawsuit.

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On December 6, 2002, Frederick Venables filed a purported derivative action against the Company and certain former officers, certain former board members and one current board member 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. Pursuant to a stipulation filed on or about April 23, 2004 and approved by the court, the deadline to respond to the complaint was stayed until 2005. The complaint sought unspecified monetary damages, equitable relief and injunctive relief based upon allegations that the defendants issued false and misleading statements regarding the Company s revenues and expenses in press releases and SEC filings. On December 6, 2004, the Company executed a settlement agreement with the plaintiff and his counsel. On December 8, 2004, the Court issued a final order approving the agreement and dismissing the derivative lawsuit. Under the agreement, in exchange for the plaintiff s release of all claims, the Company paid a total of $0.5 million in cash prior to December 31, 2004 to cover the fees and expenses of the plaintiff s counsel. The agreement also requires the Company to maintain various corporate governance measures for a period of at least two years, unless a modification is necessary in the good faith business judgment of our Board of Directors.

The Company carries $20 million of directors and officers liability insurance coverage under four policies with limits of $5 million each. The primary carrier reimbursed the Company s defense costs up to the limits of its $5 million policy. However, the three excess carriers, representing $15 million of the $20 million of coverage, filed arbitration complaints seeking rescission of the policies. In December 2004 and February 2005, the Company reached settlement with two of the three excess carriers to reimburse the Company for current and future legal defense and litigation settlement costs. The Company is currently engaged in settlement discussions with the remaining carrier in an effort to resolve this matter, but the Company cannot assure you that this matter will be resolved in its favor.

The Company has been in settlement discussions with the staff of the SEC regarding the terms of a settlement of the previously announced investigation by the SEC. The proposed settlement currently under discussion, which must be agreed upon by the staff and will then be subject both to final approval by the SEC and court approval, includes the following principal terms: (i) the Company would pay a total of $750,001, consisting of $1 in disgorgement and $750,000 in civil penalties (which has been accrued as of December 31, 2004); (ii) the Company would agree to a stipulated judgment enjoining future violations of securities laws; and (iii) the Company would agree to maintain various improvements in its internal controls that have previously been implemented. If approved, the proposed settlement would resolve all claims against the Company relating to the formal investigation that the SEC commenced in January 2003.

As previously announced, the Department of Justice also currently is conducting an investigation into allegations that the Company and certain of its current and former officers and directors intentionally issued, or caused to issued, false and misleading statements. The Department of Justice s investigation is ongoing and is not affected by the proposed settlement with the SEC described above.

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 CEO and former CFO/ COO 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.

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2003, the Company was awarded a favorable judgment for $0.4 million 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 will not have a material adverse effect on its consolidated financial condition, results of operations or cash flows. As of December 31, 2004, except for the matters indicated above for which the Company has accrued $2.2 million, the Company has not established a liability for 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

From time to time, 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 $1.0 million 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 percent 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. As of December 31, 2003, the full value of the note has been forgiven. Principal forgiven totaled $0.3 million in 2002 and $0.2 million 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 individual s employment.

In March 2001, the Company received full recourse promissory notes from three officers totaling $0.1 million due at the earlier of the second anniversary or the employment termination date. These notes bear interest at 4.8 percent 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 $0.1 million representing the outstanding principal and unpaid interest on these notes (included in selling, general and administrative expense).

In January 2003, we extended a $344,000 non-recourse note to an individual who is a stockholder and consultant to the Company. The Company previously entered into an asset purchase agreement with the stockholder in February 2002. The Company extended the loan to assist with the stockholder s payment of related federal income taxes arising from the 2002 asset sale. The loan is secured by the shares issued, bears interest at 1.8% and is due January 2006.

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. Subsequent Events

On March 11, 2005 the Company issued 5,635,378 shares of common stock, warrants to purchase an additional 1,972,374 shares of common stock at $3.50 per share and warrants to purchase an additional 1,972,374 shares of common stock at $4.00 per share for an aggregate cash purchase price of $15.6 million ($2.77 per share), in a private placement to a syndicate of institutional investors. In addition to the syndicate of institutional investors, an aggregate of 355,595 shares were purchased by the Company s Chief Executive Officer, President and a non-employee director on the same terms for a total of $1.0 million. The securities issued in the private placement were issued in reliance on an exemption from the registration requirements of the Securities Act and may not be offered or sold absent registration or an applicable exemption from the registration requirements of the Securities Act.

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ENDOCARE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. Quarterly Results of Operations (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2004 and 2003 (in thousands, except per share date).

	Quarter Ended March 31, 2004	Quarter Ended June 30, 2004	Quarter Ended September 30, 2004	Quarter Ended December 31, 2004
Revenues	$ 7,382	$ 8,312	$ 8,365	$ 8,626
Cost of revenues	$ 4,234	$ 4,313	$ 4,274	$ 4,095
Gain on divestitures, net	$	$ 50	$ 54	$ (815)
Net loss	$ (8,623)	$ (5,620)	$ (19,257)	$ (4,119)
Net loss per share of common stock:				
Basic	$ (0.36)	$ (0.23)	$ (0.80)	$ (0.17)
Diluted	$ (0.36)	$ (0.23)	$ (0.80)	$ (0.17)
Weighted average shares of common stock outstanding:				
Basic	24,088	24,000	24,175	24,342
Diluted	24,088	24,000	24,175	24,342

	Quarter Ended March 31, 2003	Quarter Ended June 30, 2003	Quarter Ended September 30, 2003	Quarter Ended December 31, 2003
Revenues	$ 7,662	$ 7,490	$ 8,041	$ 7,304
Cost of revenues	$ 3,996	$ 3,470	$ 4,094	$ 4,498
Gain on divestitures, net	$	$ 9,944	$	$ (1,313)
Net income (loss)	$ (6,088)	$ 1,662	$ (11,113)	$ (9,908)
Net income (loss) per share of common stock:				
Basic	$ (0.25)	$ 0.07	$ (0.46)	$ (0.41)
Diluted	$ (0.25)	$ 0.07	$ (0.46)	$ (0.41)
Weighted average shares of common stock outstanding:				

Basic	24,152	24,156	24,182	24,183
Diluted	24,152	25,288	24,182	24,183

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ENDOCARE, INC. AND SUBSIDIARIES
SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

	Balance at the Beginning of the Period	Additions: Charges to Operations	Additions: Other	Deductions	Balance at the End of the Period
		(In thousands)			
2002					
Allowance for Doubtful Receivables and Sales Returns	$ 668	$ 1,156	$	$ (200)	$ 1,624
2003					
Allowance for Doubtful Receivables and Sales Returns	$ 1,624	$ 658	$	$ (296)	$ 1,986
2004					
Allowance for Doubtful Receivables and Sales Returns	$ 1,986	$ (726)	$	$ (1,186)	$ 74

Amounts exclude assets held for sale.

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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.
2.10(9)	Amendment No. 2 to Partnership and Limited Liability Company Membership Interest Purchase Agreement, dated as of February 27, 2004, 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
2.11(9)	Service Fee Agreement, dated as of February 26, 2004, by and among the Company and the Limited Partners of Mid-America Cryotherapy, L.P.
2.12(9)	First Amendment to Agreement of Purchase and Sale, dated as of March 25, 2004, by and between SRS Medical Corp. and Timm Medical Technologies, Inc.
2.13(10)	First Amendment to Asset Purchase Agreement, dated as of August 18, 2004, by and between the Company and Gary Onik, M.D.
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(11)	Amended and Restated Bylaws of the Company.
10.1(12)	Lease Agreement, dated November 26, 2001 by and between the Company and the Irvine Company.
10.11(12)	Form of Indemnification Agreement by and between the Company and its directors.
10.12(12)	Form of Indemnification Agreement by and between the Company and its executive officers.
10.13(13)	1995 Director Option Plan (as amended and restated through March 2, 1999).
10.14(14)	1995 Stock Plan (as amended and restated through December 30, 2003).
10.15(15)	2002 Supplemental Stock Plan

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Exhibit No.	Description
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(16)	Registration Rights Agreement, dated as of February 21, 2002, by and among the Company and the parties listed on Schedule A thereto.
10.19(15)	Registration Rights Agreement, dated as of May 28, 2002, by and between the Company and Cryomedical Sciences, Inc.
10.20(15)	Letter Agreement, dated June 11, 1999, by and between the Company and Jerry Anderson.
10.21(15)	Blanket Purchase Agreement, effective April 1, 2002, by and between Timm Medical Technologies, Inc. and the U.S. Department of Veterans Affairs.
10.22(15)	2002 Executive Separation Benefits Plan.
10.23(17)	Employment Agreement, dated as of March 3, 2003, by and between the Company and William J. Nydam.
10.24(17)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Katherine Greenberg.
10.25(11)	Employment Agreement, dated as of March 25, 2003, by and between the Company and Kevin Quilty.
10.26(11)	First Amendment to Employment Agreement, dated as of September 14, 2003, by and between the Company and Katherine Greenberg.
10.27(11)	Consulting Agreement, dated as of August 27, 2003, by and between the Company and Craig T. Davenport.
10.28(18)	Employment Agreement, dated as of December 15, 2003, by and between the Company and Craig T. Davenport.
10.31(19)	Letter Agreement, dated as of June 9, 2004, by and between the Company and Katherine Greenberg.
10.32(20)	Employment Agreement, dated as of August 11, 2004, by and between the Company and Michael R. Rodriguez.
10.33(21)	General Release of All Claims, dated as of August 10, 2004, by and between the Company and Katherine Greenberg.
10.33(22)	2004 Stock Incentive Plan.
10.34	2004 Non-Employee Director Option Program under 2004 Stock Incentive Plan.
10.35	Form of Award Agreement Under 2004 Stock Incentive Plan.
10.36	Stipulation of Settlement, dated as of November 1, 2004, relating to securities class action lawsuit.
10.37	Description of Craig Davenport salary adjustment, effective December 2004.
10.38	Confidential Settlement Agreement and Release, dated as of December 14, 2004, by and between the Company and certain Underwriters at Lloyd s, London.
10.39	Release and Settlement Agreement, dated as of December 16, 2004, by and between the Company and National Union Fire Insurance Company.
10.40(23)	Partnership Interest Purchase Agreement, dated as of December 30, 2004, by and between the Company and Advanced Medical Partners, Inc.
21.1	Subsidiaries of Registrant
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney, included on signature page.

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 Michael R. Rodriguez.
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 Michael R. Rodriguez.

* We have requested confidential treatment with respect to certain portions of these documents.
Management contract or compensatory plan or arrangement

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(1) Previously filed as an exhibit to our Form 8-K filed on March 5, 2002.

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

(3) Previously filed as an exhibit to our Form 10-Q filed on August 14, 2002.

(4) Previously filed as an exhibit to our Form 8-K filed on August 16, 2002.

(5) Previously filed as an exhibit to our Form 8-K filed on October 15, 2002.

(6) Previously filed as an exhibit to our Form 8-K filed on April 22, 2003.

(7) Previously filed as an exhibit to our Form 8-K filed on April 29, 2003.

(8) Previously filed as an exhibit to our Form 8-K filed on October 20, 2003.

(9) Previously filed as an exhibit to our Form 10-Q filed on May 10, 2004.

(10) Previously filed as an exhibit to our Form 10-Q filed on November 9, 2004.

(11) Previously filed as an exhibit to our Form 10-K filed on March 15, 2004.

(12) Previously filed as an exhibit to our Form 10-K filed on March 29, 2002.

(13) Previously filed as an exhibit to our Registration Statement on Form S-8 filed on June 2, 1999.

(14) Previously filed as an appendix to our Definitive Proxy Statement filed on December 3, 2003.

(15) Previously filed as an exhibit to our Form 10-K filed on December 3, 2003.

(16) Previously filed as an exhibit to our Registration Statement on Form S-3 filed on May 15, 2002.

(17) Previously filed as an exhibit to our Form 8-K filed on March 27, 2003.

(18) Previously filed as an exhibit to our Form 8-K filed on December 16, 2003.

(19) Previously filed as an exhibit to our Form 10-Q filed on August 9, 2004.

(20) Previously filed as an exhibit to our Form 8-K filed on August 12, 2004.

(21) Previously filed as an exhibit to our Form 8-K filed on September 1, 2004.

(22) Previously filed as an appendix to our Definitive Proxy Statement filed on August 6, 2004.

(23) Previously filed as an exhibit to our Form 8-K filed on January 6, 2005.