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**Theragenics™**  
Fighting Cancer

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THOMSON FINANCIAL

Theragenics Corporation®  
Annual Report  
2004

**Fighting Cancer: To help raise awareness about prostate cancer, Theragenics™ has launched an educational campaign featuring bull-riding champions Owen Washburn and Lee Akin as our national spokesmen.**



**M. Christine Jacobs,**  
Chairman, President and CEO

## **To Our Shareholders:**

2004 was a challenging year for Theragenics™ and for others in our industry. Yet we made significant progress – in direct sales initiatives, a new and imaginative marketing campaign, our presence in D.C., and ongoing diversification efforts (both internal and external).

Our sales force is making positive inroads. Direct sales are up to levels we have not seen since the summer of 2003, and inactive accounts have been reduced. Further, our partnership with International Urology Network (IUN), a 3,500-member GPO, provides a new sales channel for our products. To educate prospective patients, we gave our patient website, [www.theraseed.com](http://www.theraseed.com), a facelift. In the first three months, the site had a 74 percent increase in traffic, leading to an increase in calls to our cancer information center.

On the direct-to-consumer front, we kicked off a unique "Heartland" campaign. This region of the U.S. includes millions of men, many of them farmers and ranchers, who can't afford weeks away from work to recuperate from prostate surgery. Research indicated that patients in this part of the U.S. were not being provided full information about treatment options. Results from our campaign using professional bull riders to get the word out about TheraSeed® have been so impressive that we're expanding the program in 2005.

In Washington, D.C., as a follow-up initiative to our participation in the Medicare Reform Act, we worked with members of the U.S. House of Representatives and U.S. Senate to pass a "Sense of Congress" related to prostate cancer. Although not a binding law, it encourages doctors to provide information about all proven treatment options to their prostate cancer patients. Our aim is to have this translated into positive press, patient awareness and educational focus. More than 20 media articles were published about this historic resolution.

Our prostate brachytherapy business is our core, however, and we are very much aware that we need product diversification. Our robust balance sheet affords us this opportunity, and we made progress here, too. We treated the first patients in a trial of our TheraSight™ device, a product designed to treat the wet form of age-related macular degeneration, the leading cause of blindness in the United States. Another trial, this one of our TheraSource® device, was completed during the year. Also in 2004, we began selling two radiochemicals manufactured on our cyclotrons. In Oak Ridge, we continued to look into non-medical uses of the plasma separation process (PSP), such as homeland security and energy storage.

As for external diversification, we did not slow down the hunt for a suitable acquisition candidate, screening and evaluating approximately 80 companies during 2004. We know that this has been a long process, but we don't want to squander shareholders' resources on a poor fit, or on an acquisition that does not match our corporate criteria.

In short, we believe we spent wisely in 2004, in ways that will provide value to our shareholders in the long run. And we're pretty excited to begin 2005 with signs that these investments are starting to pay off. We appreciate your trust.

Sincerely,

A handwritten signature in black ink that reads "M. Christine Jacobs". The signature is fluid and cursive, with a large initial "M" and a long, sweeping underline.

M. Christine Jacobs,  
Chairman, President and CEO

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

FORM 10-K

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

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NO. 0-15443

**THERAGENICS CORPORATION®**  
(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

58-1528626  
(I.R.S. Employer Identification Number)

5203 Bristol Industrial Way Buford, Georgia  
(Address of principal executive offices)

30518  
(Zip Code)

Registrant's telephone number, including area code:  
(770) 271-0233

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common stock, \$.01 par value, Together with associated Common Stock Purchase Rights	New York Stock Exchange

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  No

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 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act)

YES  No

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant, as determined by reference to the closing price of the Common Stock as reported on the New York Stock Exchange on July 2, 2004, the last business day of the registrant's most recently completed second fiscal quarter, was \$133,875,461.

As of March 7, 2005 the number of shares of Common Stock, \$.01 par value, outstanding was 30,023,202.

Documents incorporated by reference: Proxy Statement for the registrant's 2005 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2004, is incorporated by reference in Part III herein.

## Part I

### Item 1. BUSINESS

#### General

Theragenics Corporation® (“Theragenics™” or the “Company”), incorporated under Delaware law in 1981, is the manufacturer of TheraSeed®, a rice-sized, FDA-cleared device used to treat solid localized tumors, primarily prostate cancer, with a one-time, minimally invasive procedure. Theragenics™ is the world’s largest producer of palladium-103, the radioactive isotope that supplies the therapeutic radiation for its TheraSeed® device. Physicians, hospitals and other healthcare providers, primarily located in the United States, utilize the TheraSeed® device. The TheraSeed® device has also been approved for marketing throughout the member countries of the European Union by obtaining its CE Mark. Sales of the TheraSeed® device in Europe have not been significant. The majority of sales are channeled through third-party distributors. The Company also sells its TheraSeed® devices directly to physicians.

The Company’s website address is <http://www.theragenics.com>. The Company’s annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports are available free of charge through its website by clicking on the “Investor Relations” page and selecting “SEC Filings.” These reports will be available as soon as reasonably practicable after such material has been electronically filed with, or furnished to, the SEC. These reports are also available through the SEC’s website at <http://www.sec.gov>. The information on these websites and the information contained therein or connected thereto are not intended to be incorporated by reference into this Form 10-K.

Early in 2003 the Company diversified its product line with the purchase of the U.S. iodine-125 prostate brachytherapy business of BEBIG Isotopen-und Medizintechnik GmbH (BEBIG), formerly distributed by Isotope Products Laboratories (both subsidiaries of a publicly traded German company, Eckert & Ziegler AG). The purchase gives Theragenics™ exclusive U.S. manufacturing and distribution rights to an FDA-cleared iodine-125-based medical device for the treatment of prostate cancer. Theragenics™ began distribution of the iodine-125-based medical device early in 2003, and subsequently began to produce I-Seed (the Theragenics™ iodine-125-based medical device) early in 2004, utilizing the automated production equipment procured in the business acquisition. The Company sells the I-Seed device directly to physicians, hospitals and other healthcare providers. The non-exclusive distributors of the TheraSeed® device have no distribution rights for the I-Seed device. Non-exclusive rights to distribute the TheraSeed® device in Europe were granted to BEBIG as part of the transaction. The Company believes that the ability to provide both TheraSeed® and I-Seed devices enhances the Company’s ability to market to direct customers who seek a single source for both palladium-103 and iodine-125 brachytherapy seeds. The product line and equipment purchase will not affect the Company’s existing non-exclusive distribution agreements for the TheraSeed® device.

From May 1997 to August 2000, substantially all TheraSeed® devices were sold through an exclusive distributor. Notice of termination of that exclusive distribution agreement was received in August 2000, ending Theragenics™ contractual requirement to use an exclusive distributor. The contract was subsequently terminated in January 2001. The Company currently sells its TheraSeed® devices directly to physicians and through two non-exclusive third party distributors, a reduction from the four in place at the beginning of 2003. During 2003, one of the non-exclusive distributors of the TheraSeed® device acquired two of the other three non-exclusive distributors of the TheraSeed® device. One of the remaining two distributors has exercised its option to extend its distribution agreement with the Company through December 2006. The domestic and international distribution agreements with the other distributor allow each party the right to give notice of non-renewal of the agreements at the end of December 2004, which would be effective December 31, 2005. During December 2004, the Company was notified by this distributor that it would not be renewing its distribution agreements, and accordingly such agreements would terminate effective December 31, 2005.

In 1998 the Company received regulatory approval for the marketing of the TheraSeed<sup>®</sup> device throughout the member countries of the European Union by obtaining its CE Mark. Sales of the TheraSeed<sup>®</sup> device in Europe were not significant in any of the three years in the period ended December 31, 2004.

The U.S. Department of Energy (DOE) has granted Theragenics<sup>™</sup> access to unique DOE technology, known as plasma separation process or PSP, for use in production of isotopes, including palladium-102 (the "PSP Operation"). The Company has constructed a facility in Oak Ridge, Tennessee to house the equipment, infrastructure and work force necessary to support the production of isotopes, including palladium-102, using this DOE technology. The building and the PSP became operational during the latter half of 2002. The Company also has access to and has made investments in other unique DOE resources.

In connection with the Company's ongoing program targeted at diversifying its future revenue stream, the Company continues to explore new applications for PSP technology. Among other things, the PSP technology enables the Company to conduct feasibility runs designed to validate isotope usage in various diverse industries and potential markets. The Company is active in the Federal budget process, and is working to ensure that the PSP's capabilities are known to Federal agencies such as the Departments of Defense and Energy.

During 2004 the Company's Oak Ridge operations enriched palladium-102, which can be activated in a nuclear reactor to produce palladium-103. The enriched palladium-102, along with access to specialized reactor and related capabilities, could potentially supply the palladium-103 radioisotope to support TheraSeed<sup>®</sup> production, if necessary. In addition, the production of palladium-102 allowed the Company to study the PSP and its interaction with palladium-102 in order to calibrate the PSP and determine predictable yields generated by the PSP.

The Company's diversification program also includes a clinical trial using a palladium-103 device, called the TheraSource<sup>®</sup> Intravascular Brachytherapy System, designed to prevent restenosis or renarrowing of arteries following treatment of peripheral vascular disease by percutaneous transluminal angioplasty. Following the approval of the Investigational Device Exemption granted by the U. S. Food and Drug Administration (FDA) in August 2002 to initiate the TheraP clinical trial, Theragenics<sup>™</sup> began a clinical trial using a palladium-103 device (patent pending) early in 2003. Theragenics<sup>™</sup> closed enrollment in the TheraP trial early in the second quarter of 2004 at 20 patients. Eighteen patients have progressed to the six-month endpoint and two patients have elected to discontinue follow-up in the trial. None of the twenty patients treated with the TheraSource<sup>®</sup> device has experienced a device-related adverse event. The Company is currently assessing the results of the trial to determine the most appropriate course of action going forward.

During the second quarter of 2004, the Company filed an Investigational Device Exemption (IDE) with the FDA to begin a human clinical trial for the TheraSight<sup>®</sup> Ocular Brachytherapy System, a device intended to treat exudative (wet) age-related macular degeneration (AMD), a disease that leads to loss of eyesight and in some cases complete blindness. The IDE was approved by the FDA on July 29, 2004, and enrollment commenced in the fourth quarter of 2004 to test the safety and feasibility of the TheraSight<sup>®</sup> device. The Company has patents pending on the TheraSight<sup>®</sup> device and plans to run the trial at six separate clinical sites and expects to treat approximately 30 patients. The first three patients were treated in the TheraSight<sup>®</sup> Trial at Emory Eye Center in Atlanta, Georgia.

The Company has also identified potential opportunities, utilizing its cyclotrons, for production of radiochemical products, which are typically used in medical nuclear imaging procedures. During 2004, the Company began regular shipments to customers of two radiochemicals, produced on the Company's cyclotrons. The Company has received a Drug Master File for these products from the FDA, which will potentially allow access to a wider range of customers. The Company also continues to assess the markets for other radiochemicals it is able to produce using the existing cyclotrons.

The Company is also searching for, reviewing and evaluating external opportunities for diversification in the form of joint ventures, partnerships, and/or acquisitions of technologies, products and companies.

## **Industry Overview**

### *Prostate Cancer*

Excluding skin cancer, prostate cancer is the most common form of cancer, and the second leading cause of cancer deaths, in men. The American Cancer Society estimates there will be about 232,090 new cases of prostate cancer diagnosed and an estimated 30,350 deaths associated with the disease in the United States during 2005.

Prostate cancer incidence and mortality increase with age. Prostate cancer is found most often in men who are over the age of 50. More than seven out of ten men diagnosed with prostate cancer are over the age of 65. According to the American Cancer Society, approximately one man in six will be diagnosed with prostate cancer during his lifetime, although only one man in thirty-three will die of this disease.

Weak or interrupted urine flow, an inability to urinate, frequent urination and pain during urination can all be signs of prostate cancer. Additional symptoms can include blood in the urine, continual lower back pain in the pelvis or pain in the upper thighs. However, it should be noted that these symptoms are nonspecific and can be caused from non-malignant conditions.

According to the American Cancer Society, approximately 86% of all prostate cancers are found in the local and regional stages (local means it is still confined to the prostate; regional means it has spread from the prostate to nearby areas, but not to distant sites such as other organs). The 5-year survival rate for men with prostate cancers found in the local and regional stages is nearly 100%. According to the American Cancer Society, the survival rate for all stages of prostate cancer combined has increased from 67% to 97% over the past 20 years.

In addition to age, other risk factors are linked to prostate cancer, such as genetics. Men who have relatives that have been affected, especially if the relatives were young at diagnosis, have an even higher risk of contracting the disease. Researchers have discovered changes in certain genes, influenced by DNA mutations inherited from a parent, may cause some men to be more inclined to develop prostate cancer. It has also been suggested that environmental factors such as exposure to cancer-causing chemicals or radiation may cause DNA mutations in many organs, but this theory has not been confirmed.

Another factor that may contribute to prostate cancer is diet. A diet high in fat may play a part in causing prostate cancer. The American Cancer Society suggests that Lycopenes, found in vegetables and certain fruits such as tomatoes, grapefruit and watermelon, and the mineral selenium found in fish, meat, poultry, cereals and vegetables such as mushrooms and asparagus, seem to lower prostate cancer risk. An increase in prostate cancer may also be related to a diet high in calcium and low in fructose (fruit sugar).

The prostate is a walnut-sized gland surrounding the male urethra, located below the bladder and adjacent to the rectum. The two most prevalent prostate diseases are benign prostatic hyperplasia (BPH) and prostate cancer. BPH is a non-cancerous enlargement of the innermost part of the prostate. Prostate cancer is a malignant tumor that begins 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.

The American Cancer Society recommends that men without symptoms, risk factors and who have a life expectancy of at least ten years, should begin regular annual medical exams at the age of 50, and believes that health care providers should offer as part of the exam the prostate-specific antigen (PSA) blood test and a digital rectal examination (DRE). 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 either prostatitis (a noncancerous 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.

A tumor found by a prostate biopsy is usually assigned a grade by a pathologist. The most common prostate cancer grading system is called the Gleason grading system. A Gleason score, which ranges from 2 to 10, usually is used to estimate the tumor's growth rate. Typically, the lower the score, the slower the cancer grows. Most localized cancers of the prostate gland are associated with an intermediate score ranging from Gleason scores 4 through 6.

Staging is the process of determining how far the cancer has spread. The treatment and recovery outlook depend on the stage of the cancer. The TNM system is the staging process used most often. The TNM system describes the extent of the primary tumor (T stage), whether the cancer has spread to nearby lymph nodes (N stage), and the absence or presence of distant metastasis (M stage). The TNM descriptions can be grouped together with stages labeled 0 through IV (0-4). The higher the number, the further the cancer has spread. The following table summarizes the various stages of prostate cancer.

Stages

T1 or T2

T3 or T4

N+ or M+

Characteristics of prostate cancer

Localized in the prostate

Locally advanced

Spread to pelvic lymph nodes (N+) or distant organs (M+)

*Treatment Options*

In addition to brachytherapy, treatment options for localized prostate cancer include radical prostatectomy (RP), external beam radiation therapy (EBRT) which includes intensity modulated radiation therapy (IMRT), cryosurgery, hormone therapy, watchful waiting, and finasteride, a drug commonly prescribed to treat benign enlargement of the prostate and male baldness. Some of these therapies may be combined to address a specific cancer stage or patient need. For example, the TheraSeed® device has been used in combination with EBRT to treat some locally advanced cases of prostate cancer. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas. The following is a summary of treatment options for prostate cancer other than seeding.

*Radical Prostatectomy* is the most common surgical procedure. Radical Prostatectomy (RP) involves the complete removal of the prostate gland and has been used for over 30 years in treating early-stage, localized tumors. RP typically requires a three-day average hospital stay and a lengthy recovery period (generally three to five weeks). Possible side effects include impotence and incontinence.



*External Beam Radiation Therapy (EBRT)* involves directing a beam of radiation at the prostate gland from outside the body to destroy tumorous tissue and has been a common technique for treating many kinds of cancer since the 1950s. EBRT has typically been reserved for early-stage prostate cancer in locally advanced cases where the patient is an inappropriate surgical risk. Patients are usually treated five days per week in an outpatient center over a period of six to eight weeks. Rectal complications resulting from damage to the rectal wall caused by the radiation beam as it travels to the prostate are the most common side effects. Other possible side effects also include incontinence and impotence, but these side effects generally occur with less frequency than they do following RP.

Newer forms of external beam radiation include three-dimensional conformal radiation therapy (3DCRT), Intensity Modulated Radiation Therapy (IMRT) and conformal proton beam radiation. Three-dimensional conformal radiation utilizes computerized mapping and a fitted plastic body mold to keep the patient still so the radiation can be aimed more accurately at the prostate. The objective of 3DCRT is to minimize the risk of damage to healthy tissue caused by radiation. However, long-term results are needed to confirm this theory. Intensity Modulated Radiation Therapy (IMRT) is an advanced form of 3D therapy. In addition to aiming beams from several directions, the intensity (or strength) of the beams can be adjusted to decrease the dose of radiation reaching the sensitive normal tissues while delivering a uniformly high dose to the cancer. Conformal proton radiation therapy uses a similar approach, but instead of using x-rays, this technique focuses proton beams on the cancer. Protons typically cause little damage to tissues and may be able to deliver more radiation to the prostate. While preliminary results are promising, proton beam radiation is expensive and there are very few proton beam devices in the U.S. at this time.

*Cryosurgery* involves placing several hollow probes (needles) into the prostate using transrectal ultrasound and killing the cancer by freezing the entire prostate. Patients usually remain in the hospital for one to two days. There will be some bruising and soreness of the area where the probe was inserted. Side effects of cryosurgery may include damage to nerves near the prostate that may cause impotence and incontinence, damage to bladder and intestines, and a fistula (an abnormal opening) between the rectum and bladder. Current techniques using ultrasound guidance have only been available for a few years and outcomes of long-term (10- to 15-year) follow-up must still be collected and analyzed. For this reason, according to the American Cancer Society, most doctors do not include cryosurgery among the options they routinely consider for initial treatment of prostate cancer.

*Ancillary 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. Ancillary therapies are often used during advanced stages of the disease to extend life and relieve symptoms. Side effects of hormonal drug therapy include increased development of breasts, impotence and decreased libido. In addition, many hormone pharmaceuticals artificially lower PSA levels in patients, which can interfere with staging 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*, while not a treatment, is recommended by some physicians in certain circumstances based on the severity and growth rate of the disease, as well as on 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 requires periodic physician visits and PSA monitoring.

In addition to the treatment options described above, other forms of treatment and prevention may be developed and tested in clinical settings.

## The Theragenics™ Solution

Theragenics™ produces TheraSeed®, an FDA-cleared device for treatment of all solid localized tumors and currently used principally for the treatment of prostate cancer. In the prostate application, TheraSeed® devices are implanted throughout the prostate gland in a minimally invasive surgical technique, with transrectal ultrasound guidance. The radiation emitted by the seeds is contained within the immediate prostate area for the purpose of killing the tumor while attempting to spare surrounding organs of significant radiation exposure. The seeds, whose capsules are biocompatible, remain in the prostate after delivering their radiation dose. The TheraSeed® device is best suited for solid localized tumors.

Management believes the TheraSeed® device offers significant advantages over RP and EBRT. Recent multi-year clinical studies indicate that seeding offers success rates for early-stage prostate cancer that are comparable to or better than those of RP or EBRT and is associated with reduced complication rates. In addition, the TheraSeed® treatment is a one-time outpatient procedure with a typical two to three day recovery period. By comparison, RP is an inpatient procedure typically accompanied by an average three day hospital stay and a three to five week recovery period, and EBRT involves six to eight weeks of daily radiation treatments.

The TheraSeed® device is a radioactive "seed" approximately 4.5 millimeters long and 0.8 millimeters wide, or roughly the size of a grain of rice. Each seed consists of biocompatible titanium that encapsulates the radioactive substance palladium-103. The half-life of palladium-103, or the time required to reduce the emitted radiation to one-half of its initial level, is 17 days. The half-life characteristics result in the loss of almost all radioactivity in less than four months.

The Company also offers the I-Seed device. This iodine-based device was acquired as part of the purchase of the U.S. iodine-125 prostate brachytherapy business from BEBIG during 2003. While Management believes that palladium-103 continues to have certain advantages over iodine-125, including (i) higher dose rates; (ii) a shorter half life, which shortens the duration of some radiation induced side effects by two-thirds; and (iii) reduced radiation exposure to medical personnel in treatment follow-up, the purchase of the iodine product line enables the Company to compete more effectively for those direct customers who prefer to buy both seeds from a single source. The non-exclusive distributors of the TheraSeed® device have no distribution rights for the I-Seed device.

The I-Seed device is also a radioactive "seed" approximately 4.5 millimeters long and 0.8 millimeters wide, or roughly the size of a grain of rice. Each seed consists of biocompatible titanium that encapsulates a ceramic substrate containing the radioactive substance iodine-125. The half-life of iodine-125, or the time required to reduce the emitted radiation to one-half of its initial level, is approximately 60 days. The half-life characteristics result in the loss of almost all radioactivity in approximately 20 months.

### *Treatment Protocol*

Prostate cancer patients electing seed therapy first undergo a transrectal ultrasound test or CT scan, which generates a two-dimensional image of the prostate. With the assistance of a computer program, a three-dimensional treatment plan is created that calculates the number and placement of the seeds required for the best possible distribution of radiation to the prostate.

Once the implant model has been constructed, the procedure is scheduled and the seeds are ordered. The number of seeds implanted normally ranges from 50 to 150, but the number of seeds varies with the size of the prostate. The procedure is usually performed under local anesthesia in an outpatient setting. A transrectal ultrasound probe is first positioned in the rectum to guide needle placement and seed location. Correct needle placement is facilitated by a template, or grid, that covers the perineum (the area between the scrotum and rectum through which the needles are inserted). This template is attached to the transrectal ultrasound probe. Implant needles loaded with seeds are assigned to the appropriate template holes as indicated in the treatment plan. Each needle is guided through the template and then through the perineum to its predetermined position within the prostate under direct transrectal ultrasound visualization. The seeds are implanted as the needle is withdrawn from the prostate. When all seeds have been inserted, seed placement is verified through a transrectal ultrasound image, CT scan, fluoroscope or MRI. An experienced practitioner typically performs the procedure in approximately 45 minutes, with the patient often returning home the same day.

Seeding has been used as a treatment for prostate cancer for more than 20 years. Twenty years ago, seeds containing the radioactive isotope iodine-125 were implanted in prostate tumors under open surgery. However, this technique fell into disfavor because the seeds were often haphazardly arranged resulting in radiation not reaching all of the targeted cancerous prostate tissue. Compounding this was the fact that often an unintended radiation dose was delivered to healthy surrounding tissues, particularly the urethra and rectum. Clinical results indicate that the computer modeling, advanced imaging and other techniques used in seeding today have significantly ameliorated these drawbacks.

### *Clinical Results*

*Strong Efficacy Results.* Clinical data indicates that seeding offers success rates for early-stage prostate cancer treatment that are comparable to or better than those of radical prostatectomy (RP) or external beam radiation therapy (EBRT). A number of published studies on the use of seeding in the treatment of early-stage prostate cancer have been very positive.

A twelve-year study published in the Volume 4, Issue 1 (2005) edition of the journal *Brachytherapy*, revealed that high-risk prostate cancer patients treated with brachytherapy using palladium-103 experienced greater success than patients treated with radical prostatectomy. The study was conducted by Dr. Jerrold Sharkey of the Urology Health Center in New Port Richey, Florida, Dr. Alan Cantor, et al and retrospectively reviewed 1,707 prostate cancer patients, treated from 1992 to 2004, 80% of whom were treated with brachytherapy and 20% of whom were treated with surgery. The study reported that high-risk patients treated with seeding showed an 88% cure rate compared to a 43% cure rate obtained from surgery at 12 years. The results for intermediate-risk patients reflected a success rate of 89% with seed therapy compared to a 58% success rate with surgery at 12 years and for low-risk patients the success rate for seeding was 99% compared to a 97% success rate with surgery at 10 years.

A twelve-year clinical study published in the 2004 Supplement of *International Journal of Radiation Oncology, Biology and Physics*, reported that the relative survival rate is 84% for low risk cancer patients, 78% for intermediate risk cancer patients and 68% for high risk cancer patients. The study was conducted by Dr. Lou Potters, et al. of the New York Prostate Institute and included 1,504 patients treated with brachytherapy between 1992 and 2000.

A study published in the January 2004 issue of *International Journal of Radiation Oncology, Biology and Physics*, reported that brachytherapy, radical prostatectomy, high-dose external beam radiation therapy and combined therapies produced similar cure rates. The study was conducted by Dr. Patrick Kupelian, Dr. Louis Potters, et al. and included 2,991 patients with Stage T1 or T2 prostate cancer. Of these patients, 35% of patients underwent surgery, 16% received low-dose EBRT, 10% received high-dose EBRT, 7% received combination therapy and 32% received brachytherapy. After five years, the biochemical relapse-free survival rate was 83% for brachytherapy, 81% for radical prostatectomy, 81% for high-dose EBRT, 77% for combination therapy and 51% for low-dose EBRT.

In the June 2002 issue of *Current Science, Inc.*, a study by Dr. Jerrold Sharkey, Dr. Alan Cantor, et al. compared the effectiveness of brachytherapy and radical prostatectomy in 1,305 men with stage T1 and T2 prostate cancer. From 1993 to 2002, data from the treated patients were reviewed and classified by initial PSA level and Gleason scores. According to the publication, "The results failed to show any superiority of prostatectomy over brachytherapy with palladium-103 (the TheraSeed® device) with respect to time until relapse indicated by PSA level increase. In fact, any differences between treatments favor brachytherapy, particularly for intermediate and high-risk groups."

A nine-year clinical study published in the March 2000 issue of *International Journal of Radiation Oncology, Biology and Physics*, reported that 83.5% of the patients treated with the TheraSeed® device were cancer-free at nine years. The study was conducted by Dr. John Blasko of the Seattle Prostate Institute and included 230 patients with clinical stage T1 and T2 prostate cancer. Only 3% experienced cancer recurrence in the prostate.

Seeding treatment in combination with EBRT has also recorded impressive results in the treatment of higher risk prostate cancer patients.

An eight-year clinical study published in the January 2005 issue of *International Journal of Radiation Oncology, Biology and Physics*, reported biochemical progression-free survival rates of 98.2%, 98.4% and 88.2% for low-, intermediate-, and high-risk patients, respectively, who underwent brachytherapy using either palladium-103 or iodine-125 and supplemental EBRT or androgen deprivation therapy (ADT). The study was conducted by Dr. Gregory Merrick, et al., of the Schiffler Cancer Center and included 668 patients who underwent brachytherapy between April 1995 and January 2001 followed by EBRT and/or ADT.

Results from a 10-year study conducted by Dr. Datolli and Dr. Wallner published in the *International Journal of Radiation Oncology, Biology and Physics* in September 2002, were presented at the October 2002 American Society of Therapeutic Radiology and Oncology (ASTRO) conference confirming the effectiveness of the TheraSeed® device in patients with aggressive cancer who previously were considered poor candidates for seeding. The 10-year study was comprised of 175 patients with Stage T2a-T3 prostate cancer treated from 1991 through 1995. Of these patients 79 percent remained completely free of cancer without the use of hormonal therapy or chemotherapy.

In their paper published for the *Seminars in Surgical Oncology 1997*, Drs. Blasko, Ragde, Grimm, et al. presented an eight-year actuarial local and distal disease-free rate of 91% and 83%, respectively for 231 patients who were considered to represent higher risks of locally advanced prostate cancer and were treated with a combination of palladium-103 or iodine-125 seeding and a modified dose of EBRT.

A study by Dr. Michael Dattoli of University Community Hospital, Tampa, Florida, and Dr. Kent Wallner of Memorial Sloan-Kettering Cancer Center, New York, New York, published in the *International Journal of Radiation Oncology, Biology and Physics* in July 1996 found a three-year actuarial freedom from biochemical failure (based on PSA scores) of 79% among 73 patients with clinically localized, high risk prostate cancer who were treated with EBRT in combination with palladium-103. This compares favorably to results reported for patients treated with conventional dose EBRT alone. These locally advanced cases are significant because typical RP protocols would not classify them as suitable for surgical treatment.

*Reduced Incidence of Side Effects.* Because the TheraSeed® device delivers a highly concentrated and confined dose of radiation directly to the prostate, healthy surrounding tissues and organs are typically spared excessive radiation exposure. This typically results in fewer and less severe side effects and complications than may be incurred with other conventional therapies.

A five-year study, using either palladium-103 or iodine-125 seed devices, published in the August 2001 edition of *International Journal of Radiation Oncology, Biology and Physics* promotes brachytherapy treatment for early-stage prostate cancer in men under 65 while indicating lower incidence of side effects such as incontinence and impotence. According to Dr. Gregory Merrick of Schiffler Cancer Center in Wheeling, West Virginia, the findings from the study involving 76 patients ranging in ages between 48 and 62 years who received seed implants between the period of 1995 to 1999 are encouraging "because it shows younger men that they can survive cancer with a significantly lower incidence of side effects."

Doctors Gregory S. Merrick, Kent E. Wallner and Wayne M. Butler, in their paper "Permanent Interstitial Brachytherapy for the Management of Carcinoma of the Prostate Gland", published in the *Journal of Urology* in May 2003, summarized the permanent prostate brachytherapy literature, including biochemical outcomes, quality of life parameters and areas of controversy. The result of this study included the statement that "Using various planning and intraoperative techniques the majority of the brachytherapy literature demonstrates durable biochemical outcomes for patients with low, intermediate and high risk features." The paper concluded that continued refinements in brachytherapy planning and implementation techniques, post implantation evaluation and continued elucidation of the etiology of urinary, bowel and sexual dysfunction should result in further improvements in biochemical and quality of life outcomes.

*Lower Treatment Cost.* The total one-time cost of seeding is typically lower than the cost of RP, which usually requires a three-day average hospital stay, and EBRT, which requires a six-to-eight week course of treatment.

## **Production**

With the exception of rhodium-103 (Rh-103), all raw materials used in the production of the TheraSeed® and I-Seed devices are relatively inexpensive and readily available from third party suppliers. Rhodium-103 is readily available on the open market.

Palladium-103 is a radioactive isotope that can be produced by neutron bombardment of palladium-102 in a nuclear reactor, or by proton bombardment of Rh-103 in a cyclotron. Following the production of palladium-103 from Rh-103 in a cyclotron, the palladium-103 is harvested from the cyclotron and moved through a number of proprietary production processes until it reaches its final seed form.

The Company has produced palladium-103 using Company-owned cyclotrons since 1993. The Company currently has fourteen cyclotrons in production, and has no current plans to purchase additional cyclotrons. The Company's cyclotrons were designed, built, installed and tested by a company specializing in the construction of such equipment.

Cyclotron operations constitute only one component of the TheraSeed® device manufacturing process. Because the production of the TheraSeed® device is highly sensitive and labor intensive, Management has been focusing attention and effort on automating and otherwise improving aspects of the Company's manufacturing process. Certain portions of the Company's production processes were automated during the past seven years. Through automation, Management believes it can continue to improve efficiency, further reduce radiation exposure to personnel and provide additional production capacity for the TheraSeed® and I-Seed devices.

The Company began production of the I-Seed product early in 2004. The automated production equipment was acquired as part of the purchase of the U.S. iodine-125 prostate brachytherapy business from BEBIG during 2003.

Since 1997, the Company's quality control system related to its medical device manufacturing has been certified as meeting all the requirements of the International Organization for Standards' ISO 9001/EN46001 Quality System Standard.

The Company constructed a facility in the Oak Ridge, Tennessee area to house the equipment, infrastructure and work force necessary to support the production of isotopes, including palladium-103, using unique plasma separation process (PSP) technology being leased from the U.S. Department of Energy. PSP technology is a method of separating relatively large quantities of specific non-radioactive isotopes from specific elements. The PSP technology enables current and future feasibility runs designed to validate isotope usage in various diverse markets and industries. Although the PSP technology was initially acquired to allow for increased manufacturing capacity of palladium-103 to support TheraSeed® production and other R&D activities using palladium-103, the technology may allow for expanded use of palladium-103 or other isotopes in other applications.

## **Marketing**

From May 1997 until August 2000, Indigo Medical, Inc. (Indigo), a Johnson and Johnson Company, held the exclusive worldwide rights to market and sell the TheraSeed® device for prostate cancer under a Sales and Marketing Agreement with Theragenics™ (the "Agreement"). Under the Agreement, Indigo had the responsibility for the exclusive marketing and training related to the TheraSeed® device. In August 2000 Indigo exercised its option and gave notice of termination of the Agreement. As a result of Indigo's notice of termination, Theragenics regained the right to directly market and distribute its TheraSeed® device for the treatment of prostate cancer to physicians and third-party distributors. Subsequent to Indigo's notice of termination, the Company executed non-exclusive distribution agreements with four companies for the distribution of the TheraSeed® device. The non-exclusive distribution agreements for the distribution of the TheraSeed® device gave each distributor the right to distribute the TheraSeed® device in the U.S., Canada and Puerto Rico for the treatment of prostate cancer and other solid localized cancerous tumors. Two of these non-exclusive agreements gave the distributors the option to distribute the TheraSeed® device internationally.

Currently, the Company has non-exclusive distribution agreements in place with two companies for the distribution of the TheraSeed® device, a reduction from the four distributors in place at the beginning of 2003. The Company's current two distributors for TheraSeed® are C.R. Bard and Medi-Physics, Inc. (formerly d/b/a Nycomed Amersham and now part of Oncura, a company formed by a merger of the brachytherapy business of Amersham plc and Galil Medical Ltd. and referred to herein as "Oncura"). During 2003, C.R. Bard acquired two of the other three non-exclusive distributors of the TheraSeed® device. Total sales to the two existing and the two previous non-exclusive distributors represented approximately 81%, 81% and 83% of product revenue for the years ended December 31, 2004, 2003 and 2002, respectively, with sales to two of the four non-exclusive distributors each exceeding 10% of total revenue for each year. C.R. Bard, which accounts for the majority of distributor sales, has exercised its option to extend its distribution agreement with the Company through December 2006. The domestic and international distribution agreements with Oncura allow each party the right to give notice of non-renewal of the agreements at the end of December 2004, which would be effective December 31, 2005. During December 2004, the Company was notified by Oncura that it would not be renewing its distribution agreements, and accordingly such agreements would terminate effective December 31, 2005.

Beginning in 2002, the Company engaged marketing and advertising specialists with experience in healthcare and direct-to-consumer marketing, and expects direct-to-consumer activity to continue during 2005. The Company also expects to continue other activities in an attempt to support its brand name and increase demand for the TheraSeed® device, including advertising to physicians, clinical studies aimed at showing the advantages of the TheraSeed® device in the treatment of prostate cancer, technical field support to TheraSeed® customers, and other customer service and patient information activities. During 2002, a small direct sales force comprising brachytherapy specialists was formed to promote and support the TheraSeed® brand. This sales force was expanded during 2003 and 2004 and will continue to be utilized during 2005.

During 2004, the Company entered into a three-year exclusive strategic alliance with International Urology Network (IUN). This will provide group purchasing services to over 3,500 of IUN's community-based urologists for the Company's TheraSeed® and I-Seed devices. IUN is a diversified physician services organization specializing in the support of community-based practices, offering its members a variety of value-added services that enable practices to remain efficient, effective, and to continue to deliver quality patient care.

#### **Patents and Licenses; Trade Secrets**

The Company holds nine United States patents directed to radiation delivery devices for therapeutic uses, including palladium and iodine delivery devices, processes for making such devices, and containers for storing and shipping such devices, and has several additional United States patent applications pending that also relate to this subject matter. The Company also has some corresponding issued patents in Australia, Canada, Mexico and New Zealand, as well as some corresponding pending patent applications in Australia, Canada, Japan, the European Patent Office (representing up to 24 European Countries), New Zealand, and South Africa, as well as one pending Patent Cooperation Treaty patent application currently designating more than 120 countries. The Company also has an issued United States patent relating to the use of isotopes and isotopic compositions for secure identification of various articles of commerce, as well as corresponding pending patent applications in Canada and the European Patent Office. In addition, the Company has six pending United States patent applications relating to other new products and services related to the business of the Company. The Company considers the ownership of patents important, but not necessarily essential, to its operations. The Company also uses a strategy of confidentiality agreements and trade secret treatment to provide primary protection to a number of proprietary design modifications in the cyclotrons, as well as various production processes.

The Company also holds a worldwide exclusive license from the University of Missouri for the use of technology required for producing the TheraSphere® device. Theragenics™ holds the rights to all improvements developed by the University of Missouri on this technology. The Company, in turn, sublicenses exclusive worldwide rights to this technology and all improvements to Nordion International, Inc. Pursuant to its licensing agreement with the University of Missouri, the Company is obligated to pay the University the greater of a fixed annual amount or a percentage of the gross sales amount derived from sales of the TheraSphere® device.

The Company holds an exclusive license to patents for technology concerning methods for delivery of the TheraSphere® device in several countries, including the United States, Canada, Australia, Argentina, South Africa and the countries of the European Patent Convention, and has an exclusive license to some additional patent applications on file in other countries, including Japan. The Company exclusively sub-licenses this technology to Nordion International, Inc. for worldwide use.

The Company also relies to a significant degree on trade secrets, proprietary know-how and technological advances that are either not patentable or which the Company chooses not to patent. In particular, the Company has designed certain modifications to its cyclotrons as well as various production processes that it deems to be proprietary. The Company seeks to protect non-patented proprietary information, in part, by confidentiality agreements with suppliers, employees and consultants.

#### **Seasonality**

Although effects from seasonality cannot be identified in relation to a specific quarter or quarters, Management believes that holidays, major medical conventions and vacations taken by physicians, patients and patients' families, may have a seasonal impact on sales for the TheraSeed® and I-Seed devices.

## Research and Development

Research and development (R&D) expenses were \$9.6 million, \$7.5 million, and \$6.5 million in 2004, 2003 and 2002, respectively. R&D expenses have related primarily to the peripheral vascular and macular degeneration programs, as well as development efforts to improve the Company's proprietary production processes, and include the cost of palladium-103 utilized in R&D initiatives (see Item 7 - "*Management's Discussion and Analysis of Financial Condition and Results of Operations, 2004 compared to 2003 and 2003 compared to 2002*").

## Competition

The Company competes in a market characterized by technological innovation, extensive research efforts and significant competition. In general, the TheraSeed<sup>®</sup> and I-Seed devices compete with conventional methods of treating localized cancer, including, but not limited to, radical prostatectomy (RP) and external beam radiation therapy (EBRT) which includes intensity modulated radiation therapy (IMRT), as well as competing permanent devices. RP currently represents the most common medical treatment for early-stage, localized prostate cancer. EBRT is also a well-established method of treatment and is widely accepted for patients who represent a poor surgical risk or whose prostate cancer has advanced beyond the stage for which surgical treatment is indicated. Management believes that if general conversion from these treatment options (or other established or conventional procedures) to brachytherapy treatment does occur, such conversion will likely be the result of a combination of equivalent or better efficacy, reduced incidence of side effects and complications, lower cost, other quality of life issues and pressure by health care providers and patients. In addition, a third-party study commissioned by the Company indicated the direct historical correlation between fair reimbursement for brachytherapy and the number of brachytherapy procedures performed (see also Item 7 "*Management's Discussion and Analysis of Financial Condition and Results of Operations, Medicare Developments*").

Several companies produce and distribute palladium-103 and iodine-125 seeds, which compete directly with the TheraSeed<sup>®</sup> and I-Seed devices. Management believes that Theragenics<sup>™</sup> has competitive advantages over these companies including, but not limited to: (i) its proprietary production processes that have been developed and patented; (ii) its record of reliability and safety in its manufacturing operations; (iii) the time and resources required for competitors' production capabilities to ramp up to commercial production on a scale comparable to Theragenics<sup>™</sup>; (iv) outsourcing of the Company's cancer information center to healthcare specialist, Telerx, a subsidiary of Merck Pharmaceutical and (v) its direct sales force, the non-exclusive distribution agreements that the Company currently has in place, and the strategic alliance with International Urology Network, which allow it to leverage multiple distribution channels and access multiple marketing approaches and philosophies.

At any point in time, Management of Theragenics<sup>™</sup> and/or its non-exclusive distributors may change their respective pricing policies for the TheraSeed<sup>®</sup> or I-Seed (in the case of Theragenics<sup>™</sup>) device in order to take advantage of market opportunities or respond to competitive situations. Responding to market opportunities and competitive situations, including but not limited to competitor selling tactics, could have an adverse effect on the prices of the TheraSeed<sup>®</sup> or I-Seed device and/or could have a favorable effect on market share and volumes, while failure to do so could adversely affect market share and volumes although per unit pricing could possibly be maintained.



In addition to the competition from the procedures and companies noted above, many companies, both public and private, are researching new and innovative methods of preventing and treating cancer. In addition, many companies, including many large, well-known pharmaceutical, medical device and chemical companies that have significant resources available to them, are engaged in radiological pharmaceutical and device research. These companies are located in the United States, Europe and throughout the world. Significant developments by any of these companies could have a material adverse effect on the demand for Theragenics'™ products.

#### **Government Regulation**

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by the FDA. The Company is also subject to regulation by other governmental agencies, including the Occupational Safety and Health Administration, the Environmental Protection Agency, the Nuclear Regulatory Commission, and other federal and state agencies. As a result of receiving its CE Mark during 1998, the Company must also comply with the regulations of the Competent Authorities of the European Union for any TheraSeed® device sold in the member nations of the European Union.

The Company is also required to adhere to applicable FDA regulations for Quality System Regulation (previously known as Good Manufacturing Practices), including extensive record keeping and periodic inspections of manufacturing facilities.

The Company obtained FDA 510(k) clearance in 1986 to market the TheraSeed® device for, in general, the treatment of localized solid tumors. A new 510(k) clearance would be required for any modifications in the device or its labeling that could significantly affect the safety or effectiveness of the original product.

The Company's manufacturing, distribution and security of radioactive materials are governed by the State of Georgia in agreement with the Nuclear Regulatory Commission (NRC). The users of the TheraSeed® device are also required to possess licenses issued either by the states in which they reside or the NRC (depending upon the state involved and the production process used). The Company's expansion plans required the Company to secure additional permits and licenses from a number of environmental, health and safety regulatory agencies. To date, the Company has not experienced delays in licensing any of its facilities or cyclotrons.

The Company is required under its radioactive materials license to maintain radiation control and radiation safety personnel, procedures, equipment and processes, and to monitor its facilities and its employees and contractors. The Company is also required to provide financial assurance that adequate funding will exist for end-of-life radiological decommissioning of its cyclotrons and other areas of its property where radioactive materials are handled. The Company's decommissioning obligations will increase if production capacity is expanded.

The Company is also subject to federal, state and local environmental regulations ensuring the general protection of the environment. During 2003, the Company became aware of the need for an Industrial Process Waste Water Permit from the city of Buford, Georgia. The Company has taken all the required steps to obtain this permit and expects to obtain this permit, but has also requested a determination of non-applicability. The Company has been authorized by the City to discharge industrial process waste water to the municipal sewage system while the City considers its final decision.

The Company transfers low-level radioactive waste to licensed commercial radioactive waste treatment or disposal facilities for incineration or land disposal. The Company provides training and monitoring of its personnel to facilitate the proper handling of all materials.

The U.S. Department of Energy has granted Theragenics™ access to unique DOE technology, known as the PSP, for use in production of isotopes. U.S. Government Export Control Laws and Regulations, and classification restrictions, govern the export of certain products which can be produced in the PSP and the disclosure and export of certain technology and capabilities associated with the PSP. As a result of the sensitive nature of the PSP equipment and the specialized technology involved, the DOE is able to terminate the Company's access in the event of national emergency or in the interest of national defense, or require the Company to perform programmatic work involving use of the technology for the DOE in connection with carrying out its governmental mission. The Company would be entitled to compensation in the event of termination in connection with national emergency or defense or for programmatic use of the technology for the DOE.

## **Employees**

As of December 31, 2004, the Company had 178 full time employees (including full time temporary employees and executive personnel). Of this total, 138 were engaged in the development and production of the Company's products. The remainder of the employees were engaged in sales, marketing and general corporate activities. The Company's employees are not represented by a union or a collective bargaining agreement, and Management considers employee relations to be good.

## **Item 2. Properties**

The Company owns two manufacturing facilities located in Buford, Georgia. One facility houses cyclotrons, raw material processing, assembly and shipping operations. The second facility, which is adjacent to the first facility, houses additional cyclotrons as well as research and development activities of the Company. The Company also owns an administrative facility adjacent to its production facilities in Buford.

The Company owns approximately 32 acres in Buford Georgia on which its two manufacturing facilities and administration facilities are located. Land remains available for future development adjacent to its current Buford location. Management intends to use this land for long term expansion of its manufacturing and support operations, if such expansion is required.

The Company leases 21 acres of land in the Oak Ridge, Tennessee area, on which it has constructed a facility to house the equipment, infrastructure and workforce necessary to support operations using technology leased from the U.S. Department of Energy (see *Item 7- "Management's Discussion and Analysis of Financial Condition and Results of Operations"*).

## **Item 3. Legal Proceedings**

In January 1999, the Company and certain of its officers and directors were named as defendants in certain securities actions alleging violations of the federal securities laws, including Sections 10(b), 20(a) and Rule 10b-5 of the Securities and Exchange Act of 1934, as amended. These actions were consolidated into a single action in the U.S. District Court for the Northern District of Georgia. The complaint, as amended, purported to represent a class of investors who purchased or sold securities during the time period from January 29, 1998 to January 11, 1999. The amended complaint generally alleged that the defendants made certain misrepresentations and omissions in connection with the performance of the Company during the class period and sought unspecified damages. On May 14, 1999 a stockholder of the Company filed a derivative complaint in the Delaware Court of Chancery purportedly on behalf of the Company, alleging that certain directors breached their fiduciary duties by engaging in the conduct that was alleged in the consolidated federal class action complaint. The derivative action was stayed by the agreement of the parties. On July 19, 2000, the Court granted the Company's motion to dismiss the consolidated federal class action complaint for failure to state a claim against the Company, and granted the plaintiffs leave to amend their complaint. On August 21, 2000, the plaintiffs filed a second amended complaint and on March 30, 2001, the Court denied the defendant's motion to dismiss the plaintiffs' second amended complaint. The Court also denied the Company's motion for reconsideration. Subsequently, the Court certified the class and the parties commenced discovery. Discovery was completed, and the Company filed a motion for summary judgment on September 30, 2003.

On July 1, 2004, while the summary judgment motion was pending, the Company, the Company's directors and officers' liability insurance carrier, and the plaintiffs' counsel reached an agreement to settle the consolidated federal class action for an amount within the remaining limits of the Company's directors and officers' liability insurance. The plaintiffs dismissed their lawsuit against the defendants and, on behalf of the settling class, released defendants from any and all liability arising from the incidents alleged in the second amended complaint. The Company was not required to make any financial contribution toward the settlement. On September 29, 2004, the Court gave final approval to the settlement, with no objectors and no requests for exclusion. The final approval allowed the right to appeal the final order until November 1, 2004. No appeals were made to the final order and the case was officially over as of that date. The derivative lawsuit is still pending. Its status is currently being reevaluated in light of the settlement of the securities class action lawsuit.

The Company and one of its distributors, Oncura, are currently arbitrating claims arising in connection with the Company's non-exclusive distribution agreement with Oncura. Oncura claims that the Company has not addressed Oncura's concerns about pricing by renegotiating pricing in good faith. Oncura is seeking a change in the pricing terms of the distribution agreement through the arbitration proceeding, and has indicated that it will seek to recover a portion of payments previously made. The Company filed a counterclaim against Oncura alleging that Oncura breached its obligations under the distribution agreement concerning marketing brachytherapy products and the use of the Company's trademarks. The arbitrators have been appointed and the parties are conducting discovery. Management believes that Oncura's claims are without merit and is opposing them vigorously. Management believes the Company has meritorious counter-claims against Oncura.

From time to time the Company may be a party to claims that arise in the ordinary course of business, none of which, in the view of Management, is expected to have a material adverse effect on the consolidated financial position or results of operations of the Company.

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

The Company did not submit any matter to a vote of its security holders during the fourth quarter of calendar year 2004.

## **PART II**

#### **Item 5. Market for Registrant's Common Equity and Related Stockholder Matters**

The Company's Common Stock, \$.01 par value, (Common Stock) is traded on the New York Stock Exchange (NYSE) under the symbol "TGX". The high and low prices for the Company's Common Stock as reported on the NYSE for each quarterly period in 2004 and 2003 are as follows:

	<u>High</u>	<u>Low</u>
<b>2004</b>		
First Quarter	\$6.20	\$ 5.00
Second Quarter	5.42	4.20
Third Quarter	4.60	3.53
Fourth Quarter	4.35	3.50
<b>2003</b>		
First Quarter	\$4.71	\$ 3.12
Second Quarter	4.81	3.55
Third Quarter	6.02	4.05
Fourth Quarter	6.20	4.31

As of March 7, 2005, the closing price of the Company's Common Stock was \$3.28 per share. Also, as of that date, there were approximately 530 holders of record of the Company's Common Stock. The number of record holders does not reflect the number of beneficial owners of the Company's Common Stock for whom shares are held by depository trust companies, brokerage firms and others.

The Company has a Stockholder Rights Plan (the "Rights Plan"), which contains provisions designed to protect the Company's stockholders. Pursuant to the Rights Plan, each share of the Company's Common Stock contains a share purchase right (a "Right"). The Rights expire in February 2007, and do not become exercisable unless certain events occur; including, the acquisition of, or commencement of a tender offer for, 15% or more of the outstanding Common Stock. In the event certain triggering events occur, including the acquisition of 20% or more of the outstanding Common Stock, each Right that is not held by the 20% or more stockholders will entitle its holder to purchase additional shares of Common Stock at a substantial discount to then current market prices. The Rights Plan and the terms of the Rights, which are set forth in a Rights Agreement between the Company and SunTrust Bank, Atlanta, as Rights Agent, could add substantially to the cost of acquiring the Company, and consequently could delay or prevent a change in control of the Company.

#### **Dividend Policy**

The Company has never declared or paid a cash dividend on its Common Stock. It is the present policy of the Board of Directors to retain all earnings to support operations and to finance expansion. Consequently, the Board of Directors does not anticipate declaring or paying cash dividends on the Common Stock in the foreseeable future. In addition, the Company's current credit facility prohibits the payment of dividends.

#### **Item 6. Selected Financial Data**

The selected financial data set forth below as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004, have been derived from the financial statements of the Company included elsewhere herein, which have been audited by Grant Thornton LLP, independent registered public accountants. The selected financial data as of December 31, 2002, 2001 and 2000, and for each of the two years in the period ended December 31, 2001, have been derived from the financial statements of the Company, which have been audited by Grant Thornton LLP but are not included herein. The selected financial data set forth below should be read in conjunction with the financial statements of the Company and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere herein.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
<b>(Amounts in thousands, except per share data)</b>					
<b>Statement of Earnings Data:</b>					
Product sales	\$ 33,030	\$ 35,393	\$ 41,512	\$ 49,667	\$ 43,898
Licensing fees	308	187	352	333	106
Total revenue	<u>33,338</u>	<u>35,580</u>	<u>41,864</u>	<u>50,000</u>	<u>44,004</u>
Cost of product sales	<u>14,122</u>	<u>15,628</u>	<u>14,677</u>	<u>14,641</u>	<u>13,578</u>
Gross profit	19,216	19,952	27,187	35,359	30,426
Selling, general and administrative	17,619	13,788	12,845	10,448	6,872
Research and development	<u>9,583</u>	<u>7,467</u>	<u>6,538</u>	<u>2,671</u>	<u>2,108</u>
Operating profit (loss)	<u>(7,986)</u>	<u>(1,303)</u>	<u>7,804</u>	<u>22,240</u>	<u>21,446</u>
Other income	<u>1,134</u>	<u>894</u>	<u>897</u>	<u>1,408</u>	<u>7,253</u>
Net earnings (loss) before income tax and cumulative effect of change in accounting principle	(6,852)	(409)	8,701	23,648	28,699
Income tax expense (benefit)	<u>(2,542)</u>	<u>(319)</u>	<u>3,145</u>	<u>8,514</u>	<u>10,019</u>
Earnings (loss) before cumulative effect of change in accounting principle	(4,310)	(90)	5,556	15,134	18,680
Cumulative effect of change in accounting principle	-	(222)	-	-	-
Net earnings (loss)	<u>\$ (4,310)</u>	<u>\$ (312)</u>	<u>\$ 5,556</u>	<u>\$ 15,134</u>	<u>\$ 18,680</u>
Earnings (loss) per common share					
Basic:					
Earnings (loss) before cumulative effect of change in accounting principle	\$ (0.14)	\$ (0.00)	\$ 0.19	\$ 0.51	\$ 0.63
Cumulative effect of change in accounting principle	-	(0.01)	-	-	-
Net earnings (loss)	<u>\$ (0.14)</u>	<u>\$ (0.01)</u>	<u>\$ 0.19</u>	<u>\$ 0.51</u>	<u>\$ 0.63</u>
Diluted:					
Earnings (loss) before cumulative effect of change in accounting principle	\$ (0.14)	\$ (0.00)	\$ 0.19	\$ 0.50	\$ 0.62
Cumulative effect of change in accounting principle	-	(0.01)	-	-	-
Net earnings (loss)	<u>\$ (0.14)</u>	<u>\$ (0.01)</u>	<u>\$ 0.19</u>	<u>\$ 0.50</u>	<u>\$ 0.62</u>
Weighted average common shares					
Basic	29,971	29,902	29,746	29,627	29,534
Diluted	29,971	29,902	29,994	30,029	29,962

	December 31,				
	2004	2003	2002	2001	2000
<b>(In thousands)</b>					
<b>Balance Sheet Data:</b>					
Cash and short-term investments	\$ 28,450	\$ 45,104	\$ 56,344	\$ 45,373	\$ 29,722
Marketable securities	33,811	21,327	11,977	10,852	15,459
Property, plant and equipment, net	70,215	73,372	74,050	76,830	75,632
Total assets	<u>148,678</u>	<u>152,789</u>	<u>151,395</u>	<u>144,007</u>	<u>130,700</u>
Long-term debt, including current installments	-	-	-	-	-
Shareholders' equity	<u>\$ 138,060</u>	<u>\$ 142,326</u>	<u>\$ 142,090</u>	<u>\$ 136,007</u>	<u>\$ 120,163</u>

## THERAGENICS CORPORATION®

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

#### *Overview*

Theragenics Corporation® is the manufacturer of TheraSeed®, a rice-sized, FDA-cleared device used to treat solid localized tumors, primarily prostate cancer, with a one-time, minimally invasive procedure. Theragenics™ is the world's largest producer of palladium-103, the radioactive isotope that supplies the therapeutic radiation for its TheraSeed® device. Physicians, hospitals and other healthcare providers, primarily located in the United States, utilize the TheraSeed® device. The TheraSeed® device has also been approved for marketing throughout the member countries of the European Union by obtaining its CE Mark. Sales of the TheraSeed® device in Europe have not been significant. The majority of sales are channeled through two third-party distributors. The Company also sells its TheraSeed® devices directly to physicians.

Early in 2003 the Company diversified its product line with the purchase of the U.S. iodine-125 prostate brachytherapy business of BEBIG Isotopen-und Medizintechnik GmbH (BEBIG), formerly distributed by Isotope Products Laboratories (both subsidiaries of a publicly traded German company, Eckert & Ziegler AG). The purchase gives Theragenics™ exclusive U.S. manufacturing and distribution rights to an FDA-cleared iodine-125-based medical device for the treatment of prostate cancer. Theragenics™ began distribution of the iodine-125-based medical device early in 2003, and subsequently began to produce I-Seed (the Theragenics™ iodine-125-based medical device) early in 2004, utilizing the automated production equipment procured in the business acquisition. The Company sells the I-Seed device directly to physicians, hospitals and other healthcare providers. The non-exclusive distributors of the TheraSeed® device have no distribution rights for the I-Seed device. Non-exclusive rights to distribute the TheraSeed® device in Europe were granted to BEBIG as part of the transaction. The Company believes that the ability to provide both TheraSeed® and I-Seed devices enhances the Company's ability to market to direct customers who seek a single source for both palladium-103 and iodine-125 brachytherapy seeds. The product line and equipment purchase will not affect the Company's existing non-exclusive distribution agreements for the TheraSeed® device.

The U.S. Department of Energy (DOE) has granted Theragenics™ access to unique DOE technology, known as plasma separation process or PSP, for use in production of isotopes, including palladium-102 (the "PSP Operation"). The Company has constructed a facility in Oak Ridge, Tennessee to house the equipment, infrastructure and work force necessary to support the production of isotopes, including palladium-102, using this DOE technology. The building and the PSP became operational during the latter half of 2002. The Company also has access to and has made investments in other unique DOE resources. Additional equipment in the amount of \$1.7 million, which is physically located within DOE facilities in Oak Ridge, has not yet been placed in service and is recorded as construction-in-progress on the accompanying balance sheets. Due to delays by the DOE's primary contractor in Oak Ridge, the Company currently anticipates that this additional equipment will become operational during the first half of 2005. As a result of the sensitive nature of the PSP equipment and other unique DOE resources and facilities, the specialized technology involved and the restrictions on access to unique DOE-operated facilities, the Company has contracted with the DOE's primary contractor for its Oak Ridge facilities to handle certain technical and operational services that are critical to the operation, including designing and fabricating new parts and modifications to the equipment and DOE facilities, operating and providing ongoing access to DOE facilities, and providing access to other DOE resources. The success of the PSP Operation is, in part, dependent on the continued cooperation of the DOE and its primary contractor, which could be adversely affected by future changes in governmental program priorities and funding. If there are problems with the operation or modification of the DOE-operated facilities, problems with access to other DOE resources, or if unforeseen challenges arise, the PSP Operation may not be successful or the costs or availability associated with the PSP Operation could be adversely affected. Additionally, as a result of the sensitive nature of the PSP equipment and the specialized technology involved, the DOE is able to terminate the Company's access in the event of national emergency or in the interest of national defense, or require the Company to perform programmatic work involving use of the technology for the DOE in connection with carrying out its governmental mission. The Company would be entitled to compensation in the event of termination in connection with national emergency or defense or for programmatic use of the technology for the DOE. Use of the PSP by Theragenics™ is also subject to classification and export control restrictions imposed by the DOE and the U.S. government.

In connection with the Company's ongoing program targeted at diversifying its future revenue stream, the Company continues to explore new applications for PSP technology. Among other things, the PSP technology enables the Company to conduct feasibility runs designed to validate isotope usage in various diverse industries and potential markets. The Company is actively looking at other opportunities for utilization of the PSP, including, but not limited to, being active in the Federal budget process, and working to ensure that the PSP's capabilities are known to Federal agencies such as the Departments of Defense and Energy.

In the first quarter of 2004 the Company's Oak Ridge operations began to enrich palladium-102, which can be activated in a nuclear reactor to produce palladium-103. The enriched palladium-102, along with access to specialized reactor and related capabilities, could potentially supply the palladium-103 radioisotope to support TheraSeed® production, if necessary. In addition, the production of palladium-102 allowed the Company to study the PSP and its interaction with palladium-102 in order to calibrate the PSP and determine predictable yields generated by the PSP. The Company completed PSP production of palladium-102 at the Oak Ridge facility during October 2004, and completed chemical recovery and processing in December 2004. The Company sold the excess palladium metal remaining after the production of palladium-102 for approximately \$431,000 in November 2004, which reduced the carrying value of inventory by this amount. As a result of the cessation of production of palladium-102 at the Oak Ridge facility, in 2005 the Company will cease capitalization of all of the palladium-102 production costs.

The Company's diversification program also includes a clinical trial using a palladium-103 device, called the TheraSource® Intravascular Brachytherapy System, designed to prevent restenosis or renarrowing of arteries following treatment of peripheral vascular disease by percutaneous transluminal angioplasty. Following the approval of the Investigational Device Exemption granted by the U. S. Food and Drug Administration (FDA) in August 2002 to initiate the TheraP clinical trial, Theragenics™ began a clinical trial using a palladium-103 device (patent pending) early in 2003. Theragenics™ closed enrollment in the TheraP trial early in the second quarter of 2004 at 20 patients. Eighteen patients have progressed to the six-month endpoint and two patients have elected to discontinue follow-up in the trial. None of the twenty patients treated with the TheraSource® device has experienced a device-related adverse event. The Company is currently assessing the results of the trial to determine the most appropriate course of action going forward.

During the second quarter of 2004, the Company filed an Investigational Device Exemption (IDE) with the FDA to begin a human clinical trial for the TheraSight® Ocular Brachytherapy System, a device intended to treat exudative (wet) age-related macular degeneration (AMD), a disease that leads to loss of eyesight and in some cases complete blindness. The IDE was approved by the FDA on July 29, 2004, and enrollment commenced in the fourth quarter of 2004 to test the safety and feasibility of the TheraSight® device. The Company has patents pending on the TheraSight® device and plans to run the trial at six separate clinical sites and expects to treat approximately 30 patients. The first three patients were treated in the TheraSight® Trial at Emory Eye Center in Atlanta, Georgia. The Company continues to be mindful of the potential competition in this market, including but not limited to, existing treatments and other on-going clinical trials in this area. Research and development expenditures are likely to continue as our diversification initiatives are pursued.

The Company has also identified potential opportunities, utilizing its cyclotrons, for production of radiochemical products, which are typically used in medical nuclear imaging procedures. During 2004, the Company began regular shipments to customers of two radiochemicals, produced on the Company's cyclotrons. The revenue recognized during the twelve months ended December 31, 2004 was not material. The Company has received a Drug Master File for these products from the FDA, which will potentially allow access to a wider range of customers. The Company also continues to assess the markets for other radiochemicals it is able to produce using the existing cyclotrons. These developments could, if pursued, increase research and development expenses. Radiochemical product sales are not expected to have a material impact on revenue during 2005.

The Company is also searching for, reviewing and evaluating external opportunities for diversification in the form of joint ventures, partnerships, and/or acquisitions of technologies, products and companies.

### ***Results of Operations***

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

Total revenue was \$33.3 million in 2004 compared to \$35.6 million in 2003, a decrease of \$2.3 million, or 6.3%. The decline in revenue was primarily due to an 8.0% decrease in unit sales of the TheraSeed® device, partially offset by \$852,000 of revenue recognized during 2004 for ancillary services to one distributor. I-Seed unit sales represented approximately 4% of total unit sales in both 2004 and 2003. The average selling price of the TheraSeed® device was consistent during 2004 when compared to the average selling price during 2003.

During 2004, the Company sold approximately 17.0% of total unit sales of the Company's palladium-103 (TheraSeed®) device and iodine-125 (I-Seed) device directly to customers compared to 16.3% of total unit sales (TheraSeed® and I-Seed) directly to customers during 2003. Total revenue from sales to direct customers (TheraSeed® and I-Seed) was 18.9% of total product revenue during 2004 compared to 19.2% of total product revenue during 2003. Revenue from distributors, including the \$852,000 of revenue generated from ancillary services, decreased approximately 6.2% during 2004 compared to 2003.

Currently, the Company has non-exclusive distribution agreements in place with two companies for the distribution of the TheraSeed® device, a reduction from the four distributors in place at the beginning of 2003. During 2003, C.R. Bard acquired two of the other three non-exclusive distributors of the TheraSeed® device. Comparing unit sales to C.R. Bard during 2004 to the same three distributor's unit sales during 2003 on a combined basis shows a 1.2% increase for the twelve months ended December 31, 2004 compared to the corresponding period of 2003. C.R. Bard has exercised its option to extend its distribution agreement with the Company through December 2006.

The domestic and international distribution agreements with the other distributor, Oncura, allow each party the right to give notice of non-renewal of the agreements at the end of December 2004, which would be effective December 31, 2005. During December 2004, the Company was notified by Oncura that it would not be renewing its distribution agreements effective December 31, 2005. Sales to Oncura during 2004 declined by 28.4% compared to the corresponding period of 2003. The Company believes that sales through Oncura have been adversely affected by the distributor's efforts to market prostate cancer treatments other than the TheraSeed® device or brachytherapy.



The Company and Oncura are currently arbitrating claims arising in connection with the Company's non-exclusive distribution agreement with Oncura. Oncura claims that the Company has not addressed Oncura's concerns about pricing by renegotiating pricing in good faith. Oncura is seeking a change in the pricing terms of the distribution agreement through the arbitration proceeding, and has indicated that it will seek to recover a portion of payments previously made. The Company filed a counterclaim against Oncura alleging that Oncura breached its obligations under the distribution agreement concerning marketing brachytherapy products and the use of the Company's trademarks. The arbitrators have been appointed and the parties are conducting discovery. Management believes that Oncura's claims are without merit and is opposing them vigorously. Management believes the Company has meritorious counter-claims against Oncura.

In addition to the impact of disappointing performance by one of the two distributors of TheraSeed<sup>®</sup>, Management believes that the brachytherapy industry continues to be affected by competition from alternative therapies, changes in medicare reimbursement, declining prices for iodine-125 and palladium-103 seeds, competitors' selling tactics and the effects of consolidation in the industry. At any point in time, Theragenics<sup>™</sup> and/or its non-exclusive distributors may change their respective pricing policies for the TheraSeed<sup>®</sup> or I-Seed (in the case of Theragenics<sup>™</sup>) device in order to take advantage of market opportunities or respond to competitive situations. Responding to market opportunities and competitive situations could have an adverse effect on the prices of the TheraSeed<sup>®</sup> or I-Seed device and could have a favorable effect or prevent an unfavorable effect on market share and volumes. Conversely, the Company and its non-exclusive distributors could individually and independently decide to maintain per unit pricing under certain competitive situations that could adversely affect current or potential market share and volumes.

The Company's licensing fees revenue represents licensing payments for the Company's TheraSphere<sup>®</sup> technology. Such licensing fees are not expected to become material in the foreseeable future.

Cost of sales was \$14.1 million during 2004 compared to \$15.6 million in 2003. Gross profit was approximately 57.6% of revenue in 2004, compared to 56.1% in 2003. The increase in gross profit percentage in 2004 compared to 2003 was largely due to the capitalization of costs associated with the first production of palladium-102 material using the PSP technology at the Company's Oak Ridge, Tennessee facility. Total production costs capitalized were approximately \$1.3 million during 2004. The total cost of the inventory, including the material and production costs capitalized, is \$1.5 million and is included in work-in-process inventory in the accompanying December 31, 2004 balance sheet. The Company completed PSP production of palladium-102 at the Oak Ridge facility during October 2004, and completed chemical recovery and processing in December 2004. The Company sold the excess palladium metal remaining after the production of palladium-102 for approximately \$431,000 in November 2004, which reduced the carrying value of inventory by this amount. As a result of the cessation of production of palladium-102 at the Oak Ridge facility, in 2005 the Company will cease capitalization of all of the palladium-102 production costs. The gross margin in 2004 was also favorably impacted by \$852,000 of revenue from ancillary services to one distributor during the twelve months ended December 31, 2004. Gross margin during 2004 was negatively impacted by the considerable fixed cost component of Theragenics<sup>™</sup> operations in combination with lower revenue during the twelve months ended December 31, 2004 compared to the corresponding period of 2003.

Selling, general and administrative (SG&A) expenses were \$17.6 million in 2004, compared to \$13.8 million in 2003, an increase of \$3.8 million, or 27.8%. The increase in 2004, compared to 2003, was due primarily to costs incurred to comply with Section 404 of the Sarbanes-Oxley Act of 2002, an increase in professional fees for assistance in various key strategic initiatives, an increase in marketing and advertising costs and an increase in compensation and related expenses due primarily to the expansion of the direct sales force.

R&D expenses increased to \$9.6 million, or 28.7% of revenue in 2004, from \$7.5 million, or 21.0% of revenue in 2003. The increase in research and development expense during 2004 was primarily attributable to an increase in costs to support the Company's peripheral vascular and macular degeneration programs and include the cost of palladium-103 produced for use in R&D initiatives (see "Overview" above).

Other income, primarily comprising interest income, was \$1.1 million in 2004 compared to \$894,000 in 2003. The increase during 2004 is primarily the result of better returns on the Company's investments as a result of higher interest rates in 2004. The Company's investments consist primarily of short-term cash investments and high-credit quality corporate and municipal obligations, in accordance with the Company's investment policies. Funds available for investment have and will continue to be utilized for the Company's current and future expansion programs, R&D activities, and strategic opportunities for growth and diversification. As funds continue to be used for these programs and activities, and as interest rates continue to change, Management expects other income to fluctuate accordingly.

The Company's effective income tax rate was a benefit of 37.1% during the twelve months ended December 31, 2004 compared to a benefit of 78.0% during the twelve months ended December 31, 2003. The Company's income tax rate in each period differed from statutory rates primarily due to the recognition of tax credits generated by the Company's investments in its expansion projects, research activities and tax-exempt interest income.

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

Total revenue was \$35.6 million in 2003 compared to \$41.9 million in 2002, a decrease of \$6.3 million, or 15.0%. The decline in revenue was primarily due to a 17% decrease in unit sales of the TheraSeed® device. TheraSeed® sales direct to customers and to third party distributors remained comparable as a percentage of total TheraSeed® sales in 2003 and 2002. Although the average selling price of TheraSeed® remained steady in 2003 when compared to 2002, the overall decrease in revenues is the direct result of the decrease in total unit sales, both direct and to third-party distributors.

The Company has non-exclusive distribution agreements in place with two companies for the distribution of the TheraSeed® device, a reduction from the four distributors in place at the beginning of 2003. During 2003, one of the non-exclusive distributors of the TheraSeed® device acquired two of the other three non-exclusive distributors of the TheraSeed® device. Sales to this acquiring distributor, combined with sales to the distributors it acquired, decreased approximately 24% in 2003 as compared to 2002.

The Company believes that the decrease in unit sales throughout the year was a combination of several factors including disappointing sales by the Company's non-exclusive distribution partners; consolidation and ownership changes in the brachytherapy market; continued deep discounting in the market by many competitors, including iodine seeds throughout the year and palladium seeds in the latter part of the year; and uncertainty related to changing rules for Medicare reimbursement (see "*Medicare Developments*" below).

The Company diversified its product line in 2003 with the introduction of I-Seed, an iodine-based brachytherapy device (see "Overview" above). The Company believes the ability to provide both devices, i.e., TheraSeed® and I-Seed, will allow access to direct customers otherwise not available. I-Seed sales represented approximately 4% of total brachytherapy product sales during 2003. The non-exclusive distributors of the TheraSeed® device have no distribution rights for the I-Seed device.

The Company's licensing fees revenue represents licensing payments for the Company's TheraSphere® technology. Such licensing fees are not expected to become material in the foreseeable future.

At any point in time, Theragenics™ and/or its non-exclusive distributors may change their respective pricing policies for the TheraSeed® device in order to take advantage of market opportunities or to respond to competitive situations. Responding to market opportunities and competitive situations could have an adverse effect on the prices of the TheraSeed® device and could have a favorable effect or prevent an unfavorable effect on market share and volumes. Failure to respond to market opportunities and competitive situations in order to maintain per unit pricing could adversely affect current or potential market share and volumes and/or result in a decrease in margins.

Cost of sales was \$15.6 million during 2003 compared to \$14.7 million in 2002. Gross profit was approximately 56.1% of revenue in 2003, compared to 64.9% in 2002. The decrease in gross profit percentage in 2003 compared to 2002 was largely due to the considerable fixed cost component of Theragenics'™ operations, partially offset by the transfer of material and resources to support research and development initiatives and the completion of depreciation, early in 2003, of the first cyclotron placed in service. Approximately \$3.6 million of operating expenses related to the PSP facility, including approximately \$1.2 million of depreciation, were recognized in cost of sales during 2003 compared to \$2.0 million during the second half of 2002. In addition, as a result of the purchase of the U.S. iodine-125 prostate brachytherapy business of BEBIG early in 2003 (see "Overview" above), approximately \$860,000 of operating expenses were included in cost of sales during 2003 for direct costs related to the I-Seed device. The I-Seed production line at the Company's Buford facility became operational early in 2004. As a result, depreciation and costs incurred to support this production line will be included in cost of sales during 2004.

Selling, general and administrative (SG&A) expenses were \$13.8 million in 2003, compared to \$12.8 million in 2002, an increase of \$1.0 million, or 7.8%. The increase in 2003, compared to 2002, was due primarily to an increase in headcount and expenses associated with the direct sales force as a result of hiring brachytherapy specialists to promote the TheraSeed® brand. SG&A expenses were also higher during 2003 as a result of outsourcing the Company's cancer information center to healthcare specialist, Telerx, a subsidiary of Merck Pharmaceutical, and a significant increase in Directors and Officers liability insurance premiums. These increases were partially offset by a reduction in the start-up expenses related to the PSP facility, which became operational in the second half of 2002. (see "Overview" above and "Liquidity and Capital Resources" below).

R&D expenses increased to \$7.5 million, or 21.0% of revenue in 2003, from \$6.5 million, or 15.6% of revenue in 2002. The increase in R&D expenses in 2003 was a result of the Company's diversification initiatives geared to expand the application of palladium-103 to other oncological and non-oncological uses, and to explore options for using the Company's expertise and capabilities in other areas. The bulk of these expenses were associated with the Company's peripheral vascular and macular degeneration programs and include the cost of palladium-103 produced for use in R&D initiatives (see "Overview" above).

Other income, primarily comprising interest income, was \$894,000 in 2003 compared to \$897,000 in 2002. The Company's investments consist primarily of short-term cash investments and high-credit quality municipal obligations, in accordance with the Company's investment policies. Funds available for investment have been and will continue to be utilized for the Company's current and future expansion programs and R&D activities, and may be used for the acquisition of technologies, products or companies consistent with the goals of Theragenics™. As funds continue to be used for these programs and activities, and as interest rates continue to change, Management expects other income to fluctuate accordingly.

The Company's effective income tax rate was a benefit of 78% in 2003, primarily due to permanent differences related to tax-exempt interest income on municipal and government securities, compared to an expense of 36% in 2002. The Company's income tax rate in each period differed from statutory rates primarily due to the recognition of tax credits generated by the Company's investments in its expansion projects, research activities, and tax-exempt interest income.

### ***Critical Accounting Policies***

The financial statements of Theragenics Corporation® are prepared in conformity with accounting principles generally accepted in the United States of America. Management is required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the periods presented. The significant accounting policies which we believe are the most critical to aid in fully understanding and evaluating our reported financial results include the following:

*Property, plant and equipment.* Property, plant and equipment are recorded at cost and depreciated on a straight-line basis over the estimated useful lives of such assets. The Company's estimates can result in differences from the actual useful lives of certain assets. The Company currently owns and operates 14 cyclotrons, the first of which entered service in 1993. Each of the Company's cyclotrons is depreciated using an estimated 10-year life. Management's estimate of the useful life of these cyclotrons is based on the Company's experience to date with these cyclotrons. Based on experience gained relative to the operation, refurbishment, and maintenance of the cyclotrons, Management believes there is a substantive basis for the current depreciable lives of the cyclotrons. Although the older cyclotrons require increased maintenance, all the cyclotrons remain in service, including fully depreciated cyclotrons, because the material produced by each machine is required for ongoing operations and the Company's current research and development initiatives.

The PSP equipment was placed in service during the second half of 2002 and is depreciated using an estimated fifteen-year life. The PSP equipment utilizes specialized, unique technology.

Management will continue to periodically examine estimates used for depreciation for reasonableness. If the Company should determine that the useful life of property, plant or equipment should be shortened or lengthened, depreciation expense would be adjusted accordingly for the remaining useful life/(lives) of the identified asset/(s).

A significant portion of the Company's depreciable assets is utilized in the production of its product. Management assesses the impairment of its depreciable assets whenever events or circumstances indicate that such assets might be impaired. In the event the expected undiscounted future cash flow attributable to the asset is less than the carrying value of the asset, an impairment loss equal to the excess of the asset's carrying value over its fair value is recorded. Management believes that no impairment of depreciable assets exists as of December 31, 2004. It is possible, however, that Management's estimates concerning the realizability of the Company's depreciable assets could change in the future.

*Goodwill.* Early in 2003 the Company entered into an agreement to purchase the brachytherapy business of BEBIG Isotopen-und Medizintechnik GmbH (BEBIG), a subsidiary company of Eckert & Ziegler AG. A total of approximately \$6.3 million was paid in connection with the acquisition and the payments were allocated between the fair value of the assets in the amount of \$3.7 million and \$2.6 million to goodwill. The equipment became operational during the first quarter of 2004. The Company has determined that the production line will be amortized over a fifteen-year life.

The Company accounts for goodwill and other intangible assets in accordance with the provisions of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ("SFAS 142"). Under SFAS 142, goodwill and intangible assets with indefinite lives are not amortized to expense and must be reviewed for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. The first step of the impairment test, used to identify potential impairment, compares the fair value of a reporting unit with its carrying amount, including goodwill and intangible assets with indefinite lives. The Company operates as one reporting unit and therefore compares its book value to market value (market capitalization plus a control premium). If fair value exceeds book value, goodwill is considered not impaired, and the second step of the impairment test is unnecessary. If book value exceeds market value, the second step of the impairment test is performed to measure the amount of impairment loss, if any. For this step the implied fair value of the goodwill is compared with the book value of the goodwill. If the carrying amount of the goodwill exceeds the implied fair value of the goodwill, an impairment loss would be recognized in an amount equal to that excess. Any loss recognized cannot exceed the carrying amount of goodwill. After an impairment loss is recognized, the adjusted carrying amount of goodwill is its new accounting basis. Subsequent reversal of a previously recognized impairment loss is prohibited once the measurement of that loss is completed. The Company completed its annual goodwill impairment assessment as of November 28, 2004 and determined that goodwill was not impaired and no impairment charge was recorded.

Intangible assets with definite lives are being amortized and this amortization is included in the accompanying statements of operations.

*Allowance for doubtful accounts.* Management judgments and estimates are made and used in connection with establishing an allowance for the possibility that portions of our accounts receivable balances may become uncollectable. Accounts receivable are reduced by this allowance. Specifically, Management analyzes accounts receivable in relation to current economic trends and changes in our customer payment history in establishing this allowance. The accounts receivable balance, net of the provision for trade accounts receivables allowance of \$177,000, was approximately \$5.8 million as of December 31, 2004.

*Stock-based compensation.* The Company has granted performance restricted stock rights. The number of shares issuable upon vesting of the performance restricted stock rights will vary based on total shareholder return or TSR over the vesting period as compared to an industry peer group, as further described in Note H of the Notes to Financial Statements. Each quarter the Company estimates TSR and records compensation expense based on TSR experienced to date. To the extent that TSR varies significantly from period to period, the Company may record additional compensation expense or adjust previously recorded compensation expense to reflect the current estimate of TSR over the vesting period.

## Commitments and Other Contractual Obligations

The principal commitments of the Company include land leases, rental space and office equipment under operating, non-cancelable leases that expire at various dates through April 2029, and asset purchase obligations. Approximate minimum payments of these obligations are as follows:

Obligation	Payments due by period						
	Total	2005	2006	2007	2008	2009	Thereafter
Land lease (1)	\$ 3,321,500	\$ 136,500	\$ 136,500	\$ 136,500	\$ 136,500	\$ 136,500	\$ 2,639,000
Rental space, equipment and automobile	<u>882,305</u>	<u>204,327</u>	<u>195,598</u>	<u>182,380</u>	<u>180,000</u>	<u>120,000</u>	<u>-</u>
Total operating leases	4,203,805	340,827	332,098	318,880	316,500	256,500	2,639,000
Purchase obligations (2)	<u>456,000</u>	<u>456,000</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Total obligations	<u>\$ 4,659,805</u>	<u>\$ 796,827</u>	<u>\$ 332,098</u>	<u>\$ 318,880</u>	<u>\$ 316,500</u>	<u>\$ 256,500</u>	<u>\$ 2,639,000</u>

(1) Land lease payments are subject to adjustments for increases in the Consumer Price Index, January 1, 2005 and every five years thereafter.

(2) In June 2004 the Company entered into an asset purchase agreement with a contractor for the design and manufacture of certain equipment. The capital asset purchase agreement in the amount of \$570,000 is expected to be completed in early 2005. At year-end 2004, progress payments in the amount of approximately \$114,000 had been paid in relation to the purchase agreement.

The Company has issued standby letters of credit from time to time as security for certain liabilities. At December 31, 2004, total outstanding letters of credit, under the Credit Agreement, approximated \$933,000. These letters of credit are related to asset retirement liabilities of long-lived assets, as well as a utility deposit to the City of Oak Ridge, Tennessee.

### *Liquidity and Capital Resources*

The Company had cash, short-term investments and marketable securities of \$62.3 million at December 31, 2004, compared to \$66.4 million at December 31, 2003. Cash and short-term investments were \$28.5 million at December 31, 2004 compared to \$45.1 million at December 31, 2003. Marketable securities were \$33.8 million at December 31, 2004 compared to \$21.3 million at December 31, 2003. Marketable securities consist primarily of short-term cash investments and high-credit quality corporate and municipal obligations, in accordance with the Company's investment policies. The aggregate decrease in cash, short-term investments and marketable securities was primarily a result of capital expenditures. Working capital was \$72.6 million at December 31, 2004, compared to \$74.0 million at December 31, 2003. The Company also has a Credit Agreement with a financial institution that provides for revolving borrowings of up to \$40.0 million, including a \$5.0 million sub-limit for letters of credit, through a credit facility with a three-year term. No borrowings were outstanding under the Credit Agreement as of December 31, 2004. Letters of credit totaling \$933,000 were outstanding under the Credit Agreement as of December 31, 2004. These letters of credit represent decommission funding required by the Georgia Department of Natural Resources and a utility deposit to the City of Oak Ridge, Tennessee in connection with the PSP facility.

Cash generated by operations was \$126,000 and \$5.4 million in 2004 and 2003, respectively. Cash used by or generated from operations consists of net earnings/(loss) plus non-cash expenses such as depreciation, amortization, and changes in balance sheet items such as accounts receivable, inventories, prepaid expenses and payables. Accounts receivable increased approximately \$2.0 million during 2004 as a result of increased revenue in the fourth quarter of 2004 as compared to the fourth quarter of 2003 and the timing of payments received from the Company's distributors. Inventories increased \$1.1 million during 2004 primarily as a result of the capitalization of \$1.3 million of costs associated with the first production of palladium-102 material using the PSP technology at the Company's Oak Ridge, Tennessee facility, partially offset by the sale of the excess palladium metal for \$431,000 during the fourth quarter of 2004. The excess palladium metal remained after completion of production of palladium-102 during the fourth quarter of 2004. Prepaid expenses and other current assets decreased \$539,000 during 2004 primarily as a result of a reduction of prepayments under the Company's advertising program and group health insurance programs during 2004 compared to 2003. Trade accounts payable decreased \$267,000 during 2004 due primarily to the payment of liabilities associated with the Company's I-Seed acquisition during the first quarter of 2004 and the timing of payments for other accounts payable. Other current liabilities increased \$269,000 during 2004 primarily as a result of costs associated with the internal controls requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Capital expenditures totaled \$3.3 million and \$2.5 million during 2004 and 2003, respectively. In addition, the Company made payments of \$1.0 million and \$5.2 million during 2004 and 2003, respectively, as part of the Company's purchase of the U. S. iodine-125 prostate brachytherapy business of BEBIG (see "*Overview*" above). The Company procured an automated production line as part of the agreement that became operational during the first quarter of 2004. The \$1.0 million payment during the first quarter of 2004 was the last payment required under the agreement.

The Company expects that R&D spending will decline during 2005 as compared to the level of R&D spending during 2004 (see "*Results of Operations*" above). Cash could be used in 2005 for increased marketing and TheraSeed® support activities and in the pursuit of diversification efforts such as the purchase of technologies, products or companies.

In addition to capital expenditures, cash used for investing activities during 2004 included \$27.6 million used to purchase marketable securities, offset by maturities of other investments amounting to \$15.0 million. Marketable securities, consisting primarily of short-term cash investments and high-credit quality corporate and municipal obligations, are purchased in accordance with the Company's investment policies. The Company expects to continue to invest cash as available.

Cash provided by financing activities was \$108,000 and \$505,000 during 2004 and 2003, respectively, consisting of cash proceeds from the exercise of stock options and the Company's Employee Stock Purchase Plan.

The Company believes that current cash and investment balances and cash from future operations and credit facilities will be sufficient to meet its current anticipated working capital and capital expenditure requirements. In the event additional financing becomes necessary, Management may choose to raise those funds through other means of financing as appropriate.

During the fourth quarter of 2003, the Company executed a Credit Agreement with a financial institution. The Credit Agreement, which expires October 29, 2006 (subject to earlier termination by the lender upon the occurrence of certain events of default), provides for revolving borrowings of up to \$40.0 million at any time outstanding, including a \$5.0 million sub-limit for letters of credit. Interest on outstanding borrowings is payable at the rate of interest periodically designated by the financial institution as its base rate, or, at the option of the Company, interest may accrue at a LIBOR based rate, plus an applicable margin which is subject to quarterly adjustment. Interest on base rate loans is payable monthly, while interest on LIBOR loans is payable on the last day of the applicable one, two or three month interest period. As of December 31, 2004 no borrowings were outstanding under the Credit Agreement. We have issued standby letters of credit from time to time as security for certain liabilities. At December 31, 2004, total outstanding letters of credit, under the Credit Agreement, approximated \$933,000. These letters of credit are related to asset retirement liabilities of long-lived assets, as well as a utility deposit to the City of Oak Ridge, Tennessee.

The Credit Agreement is unsecured, but provides for a "springing lien" to be established on substantially all of the assets of the Company (subject to certain exceptions) in the event certain events of default occur under the Credit Agreement. The Credit Agreement contains representations and warranties, as well as affirmative, reporting and negative covenants, customary for financings of this type. Among other things, certain provisions of the Credit Agreement limit the incurrence of additional debt and require the maintenance of certain financial ratios.

The Credit Agreement replaced the August 1999 unsecured credit agreement with the Company's previous lender, which would have expired on October 31, 2003. The prior unsecured credit agreement provided for a \$40.0 million revolving loan and letter of credit commitment, and an additional uncommitted \$10.0 million line of credit.

### ***Medicare Developments***

Previously, Theragenics™ TheraSeed® device and other brachytherapy seeds fell within various "transitional pass-through codes," which were separate from the procedure payment codes that comprise much of Medicare's Outpatient Prospective Payment System (OPPS). On April 1, 2002, the Centers for Medicare and Medicaid Services (CMS) implemented changes in hospital payments for brachytherapy and other services provided under Medicare's OPPS for the remainder of 2002. Through December 31, 2002, CMS bundled a portion of pass-through reimbursement for all brachytherapy seeds and other devices with the associated procedure codes, thereby effectively sheltering seeds from "pro rata reductions" that would otherwise have applied under Medicare Law. To the extent that these pass-through device costs exceeded the bundled amount, the remaining cost was subject to a 63.6% pro-rated reduction in reimbursement.

During 2003, CMS further revised its policies by bundling the costs of the prostate brachytherapy procedure, as well as the costs for catheters, needles and all seeds, into two new codes for prostate brachytherapy (one for palladium-103 and one for iodine-125). By creating two codes and setting separate reimbursement amounts for palladium-103 seed brachytherapy (including the TheraSeed® device) and iodine-125 seed brachytherapy (including the I-Seed device), CMS made an important, positive change in its final rule for 2003 compared to its initial proposal published on August 9, 2002. Specifically, the per-patient reimbursement amount under the 2003 final rule for palladium-103 prostate brachytherapy exceeded the original payment amount proposed in August 2002 for both palladium-103 and iodine-125. The final 2003 per-patient amount for palladium-103 prostate brachytherapy also exceeded the 2003 payment amount for iodine-125 prostate brachytherapy. To the extent that the brachytherapy costs for either seed, for an individual patient exceeded the bundled payment amount during 2003, the remaining costs could not be submitted for additional reimbursement.

On December 8, 2003, the President signed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 into law that provides for improved reimbursement and coding policies in 2004 and beyond for brachytherapy seeds/sources under Medicare's OPPS. To reflect the changes in the statute, CMS revised its November 7, 2003 final rule by publishing a new interim final rule for 2004 on January 6, 2004.



The brachytherapy provisions in the 2003 Medicare legislation, which went into effect on January 1, 2004, require Medicare to unbundle the cost of the seeds from the costs of the brachytherapy procedure, catheters and needles under the OPPS. More specifically, the 2003 Medicare legislation requires Medicare to reimburse hospitals for each brachytherapy seed/source furnished between January 1, 2004 to December 31, 2006 based on the hospital's costs for each patient (calculated from the hospital's charges adjusted by the hospital's specific cost-to-charge ratio). This means that hospital reimbursement is no longer limited to or dictated by the reimbursement amounts assigned to the brachytherapy codes, which CMS used in 2003.

With respect to coding, the legislation requires the Medicare program to create and use coding that classifies brachytherapy seeds/sources separately from all the other services and items reimbursed under the OPPS. These separate codes for brachytherapy seeds/sources must be used in a manner that reflects the type of radioactive isotope (for example, palladium-103), the radioactive intensity and the number of brachytherapy seeds/sources used to treat each patient.

Depending on the number of seeds needed to treat each prostate cancer patient, the total reimbursement (for the combination of the unbundled procedure codes and seeds) for the payment methodology in place until at least December 31, 2006 may be higher than the 2003 bundled payment amounts. The legislation enacted in 2003 also directs the U.S. General Accounting Office (GAO) to conduct a study examining future payment policies for brachytherapy seeds.

The Company believes its efforts in assisting policymakers in formulating and revising Medicare policies to recognize the unique aspects of classification and reimbursement that apply to brachytherapy devices such as TheraSeed<sup>®</sup> were pivotal to the enactment of the improved 2003 Medicare legislation for brachytherapy seeds/sources. The Company plans to continue working to assist policymakers regarding these important issues in the future.

The Company believes that the significant number of proposed and actual changes in Medicare coding and reimbursement policy in the years preceding and during 2003, created confusion for hospitals and doctors, which may have had a detrimental impact on sales in 2004 and 2003 (see "*Results of Operations*" above). In addition, due to the fact that the Medicare rules governing coding of brachytherapy seeds/sources have undergone significant change during the past few years, the Company believes that Medicare reimbursement may continue to create confusion for hospitals and doctors going forward. In that regard, Management continues to closely monitor any effects of the reimbursement structure on the brachytherapy market as it continues to evaluate pricing, marketing and distribution strategies. The Company continues to engage a consulting firm specializing in reimbursement practices to help communicate brachytherapy reimbursement guidelines to customers.

#### ***Forward Looking and Cautionary Statements***

This document contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding sales, marketing and distribution efforts, the Company's direct sales organization, including, but not limited to, its growth and effectiveness, third-party reimbursement, CMS policy, sales mix, effectiveness and continuation of non-exclusive distribution agreements, pricing for the TheraSeed<sup>®</sup> and I-Seed devices, future cost of sales, R&D efforts and expenses, inventory investment, SG&A expenses, other income, timing and ultimate outcome of the Company's activities in peripheral vascular and macular degeneration programs and other diversification efforts, potential new products and opportunities, the PSP-related operations, the development of new markets and technologies, the capabilities of the PSP to produce enriched isotopes, opportunities for isotopes produced by Theragenics<sup>™</sup>, including, but not limited to, stable isotopes and radiochemical products, the identification and development of new markets and applications for isotopes, Theragenics<sup>™</sup> plans and

strategies for diversification, and the sufficiency of the Company's liquidity and capital resources. From time to time, the Company may also make other forward-looking statements relating to such matters as well as statements relating to anticipated financial performance, business prospects, technological developments, other research and development activities and similar matters. These forward-looking statements are subject to certain risks, uncertainties and other factors which could cause actual results to differ materially from those anticipated, including risks associated with research and development activities, including animal studies and clinical trials related to new products, risks associated with new product development cycles, effectiveness and execution of marketing and sales programs of Theragenics™ and its non-exclusive distributors, risks associated with customer distribution concentration and consolidation among non-exclusive distributors and potential changes in distributor relationships, potential costs and delays in capacity expansion and start-up, potential costs and delays in PSP-related operations, effect of palladium-103 demand on cyclotron and PSP capacity and investment in inventory, the iodine-125 product line, actual or potential changes in product pricing, competitive conditions and selling tactics of the Company's competitors, continued acceptance of TheraSeed® or the I-Seed devices by the market, management of growth, acceptance and efficacy of palladium-103 for other applications, adverse changes in governmental program priorities and budgetary funding by the relevant governmental authorities, continuing access to unique DOE technology, the DOE's ability to require the Company to use DOE technology for governmental purposes or terminate the Company's use in the event of a national emergency or for national defense, government regulation of the therapeutic radiological pharmaceutical and device business, potential changes in third-party reimbursement, risks associated with market development activities, potential inability of the PSP to produce isotopes suited for a particular application, potential inability to produce selected isotopes at costs competitive to other options or potential inability to produce selected isotopes at costs to make applications economically feasible, risks associated with governmental regulations and related export controls and security requirements for PSP technology and products. All forward looking statements and cautionary statements included in this document are made as of the date hereby based on information available to the Company as of the date hereof, and the Company assumes no obligation to update any forward looking statement or cautionary statement.

### ***Quarterly Results***

The following table sets forth certain statement of operations data for each of the Company's last eight quarters. This unaudited quarterly information has been prepared on the same basis as the annual audited information presented elsewhere in this Form 10-K, reflects all adjustments (consisting only of normal, recurring adjustments) which are, in Management's opinion, necessary for a fair presentation of the information for the periods covered and should be read in conjunction with the financial statements and notes thereto. The operating results for any quarter are not necessarily indicative of results for any future period. Quarterly data presented may not reconcile to totals for full year results due to rounding.

	2004				2003			
	First Qtr	Second Qtr	Third Qtr	Fourth Qtr	First Qtr	Second Qtr	Third Qtr	Fourth Qtr
	(Amounts in thousands, except per share data)							
Total revenue	\$ 7,953	\$ 8,646	\$ 8,283	\$ 8,456	\$ 11,102	\$ 8,949	\$ 8,519	\$ 7,010
Cost of product sales	3,398	3,467	3,282	3,975	4,537	3,959	3,614	3,518
Gross profit	4,555	5,179	5,001	4,481	6,565	4,990	4,905	3,492
Selling, general and administrative	4,072	4,470	4,463	4,616	3,391	3,230	3,404	3,763
Research and development	2,278	2,308	2,749	2,248	1,501	1,612	2,348	2,006
Other income	173	257	355	349	228	225	225	216
Net earnings (loss) before income taxes and cumulative effect of change in accounting principle	(1,622)	(1,342)	(1,856)	(2,034)	1,901	373	(622)	(2,061)
Income tax expense (benefit)	(656)	(408)	(734)	(745)	682	107	(234)	(874)
Net earnings (loss) before cumulative effect of change in accounting principle	(966)	(934)	(1,122)	(1,289)	1,219	266	(388)	(1,187)
Cumulative effect of change in accounting principle	-	-	-	-	(222)	-	-	-
Net earnings (loss)	<u>\$ (966)</u>	<u>\$ (934)</u>	<u>\$ (1,122)</u>	<u>\$ (1,289)</u>	<u>\$ 997</u>	<u>\$ 266</u>	<u>\$ (388)</u>	<u>\$ (1,187)</u>
Earnings per common share:								
Basic								
Net earnings (loss) before cumulative effect of change in accounting principle	\$ (0.03)	\$ (0.03)	\$ (0.04)	\$ (0.04)	\$ 0.04	\$ 0.01	\$ (0.01)	\$ (0.04)
Cumulative effect of change in accounting principle	-	-	-	-	(0.01)	-	-	-
Net earnings (loss)	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ 0.03</u>	<u>\$ 0.01</u>	<u>\$ (0.01)</u>	<u>\$ (0.04)</u>
Diluted								
Net earnings (loss) before cumulative effect of change in accounting principle	\$ (0.03)	\$ (0.03)	\$ (0.04)	\$ (0.04)	\$ 0.04	\$ 0.01	\$ (0.01)	\$ (0.04)
Cumulative effect of change in accounting principle	-	-	-	-	(0.01)	-	-	-
Net earnings (loss)	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ 0.03</u>	<u>\$ 0.01</u>	<u>\$ (0.01)</u>	<u>\$ (0.04)</u>
Weighted average shares outstanding:								
Basic:	29,957	29,969	29,974	29,983	29,829	29,908	29,932	29,940
Diluted:	29,957	29,969	29,974	29,983	29,925	29,996	29,932	29,940

**Inflation**

Management does not believe that the relatively moderate levels of inflation, which have been experienced in the United States in recent years, have had a significant effect on the Company's results of operations.

**Item 7A. Quantitative and Qualitative Disclosure About Market Risk**

The Company's market risk exposure, related to market risk sensitive financial instruments, is not material. Letters of credit totaling approximately \$933,000 were outstanding under the terms of the Credit Agreement as of December 31, 2004. No borrowings were outstanding under the Credit Agreement as of December 31, 2004. (See *Liquidity and Capital Resources* above).

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

See index to Financial Statements (Page 40) and following pages.

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

None

**Item 9A. Controls and Procedures****Evaluation of Disclosure Controls and Procedures**

The Company's Chief Executive Officer and Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures as of December 31, 2004 and, based on that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these controls and procedures were effective as of December 31, 2004.

Disclosure controls and procedures are the controls and other procedures designed to ensure that information that the Company is required to disclose in its reports under the Exchange Act is recorded, processed, summarized and reported within the time periods required. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information the Company is required to disclose in the reports that it files under the Exchange Act is accumulated and communicated to Management of the Company, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

### **Design and Evaluation of Internal Control Over Financial Reporting**

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, the Company has included a report of Management's assessment of the design and effectiveness of its internal controls as part of this Annual Report on Form 10-K for the fiscal year ended December 31, 2004. The Company's independent registered public accounting firm also attested to, and reported on, Management's assessment of the effectiveness of internal control over financial reporting. Management's report and the independent registered public accounting firm's attestation report are included in the Company's 2004 financial statements under the captions entitled "Management's Report on Internal Control Over Financial Reporting" and "Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting" and are incorporated herein by reference.

### **Changes in Internal Control Over Financial Reporting**

No changes in our internal control over financial reporting were identified as having occurred in the fiscal quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Item 9B. Other Information**

None.

## **PART III**

### **Item 10. Directors and Officers of Registrant\***

The Company has adopted a Code of Ethics for the Chief Executive Officer and Senior Financial Officers and a Code of Conduct for all employees. These codes are available on the Company's website at <http://www.theragenics.com>. These codes are also available without charge upon request directed to Investor Relations, Theragenics Corporation®, 5203 Bristol Industrial Way, Buford, Georgia 30518. The Company intends to disclose amendments or waivers of these codes with respect to the Chief Executive Officer, Senior Financial Officers or Directors required to be disclosed by posting such information on its website.

The Company's Chief Executive Officer is required to certify to the New York Stock Exchange each year that she was not aware of any violation by the Company of the Exchange's corporate governance listing standards. The Chief Executive Officer made her annual certification to that effect to the New York Stock Exchange as of June 3, 2004. The Company's Form 10-K on file with the Securities and Exchange Commission includes the certifications of the Company's Chief Executive Officer and Chief Financial Officer required by Rule 13a-14 and Section 302 of the Sarbanes-Oxley Act of 2002.

### **Item 11. Executive Compensation\***

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

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

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

- \* Except as set forth above, the information called for by Items 10, 11, 12, 13 and 14 is omitted from this Report and is incorporated by reference to the definitive Proxy Statement to be filed by the Company not later than 120 days after December 31, 2004, the close of its fiscal year.

## **PART IV**

### **Item 15. Exhibits and Financial Statement Schedules**

#### **a) The following documents are filed as part of this Report.**

- 1. Financial Statements**  
See index to financial statements on page 40.
- 2. Financial Schedules**  
See index to financial statements on page 40.
- 3. Exhibits**  
See index to exhibits on page 73.

- 3.1 Certificate of Incorporation as amended through July 29, 1998 (incorporated by reference to Exhibit 3.1 of the Company's report on Form 10-Q for the quarterly period ended June 30, 1998)
- 3.2 By-Laws (incorporated by reference to Exhibit 3.4 of the Company's registration statement on Form S-1, File No. 33-7097, and post-effective amendments thereto)
- 4.1 See Exhibits 3.1 - 3.2 for provisions in the Company's Certificate of Incorporation and By-Laws defining the rights of holders of the Company's Common Stock
- 10.1 License Agreement with University of Missouri, as amended (incorporated by reference to Exhibit 10.3 of the Company's registration statement on Form S-1, File No. 33-7097, and post-effective amendments thereto)
- 10.2 Reassignment and Release Agreement among the Company, John L. Russell, Jr., and Georgia Tech Research Institute (incorporated by reference to Exhibit 10.8 of the Company's registration statement on Form S-1, File No. 33-7097, and post-effective amendments thereto)
- 10.3 Agreement with Nordion International Inc. (incorporated by reference to the Company's report on Form 8-K dated March 23, 1995)
- 10.4 Rights Agreement dated as of February 17, 1997 between the Company and SunTrust Bank, Atlanta (incorporated by reference to Exhibit 99.1 of the Company's registration statement on Form 8-A filed February 27, 1997)
- 10.5 Sublease dated March 25, 1999 between Theragenics Corporation® and Community Reuse Organization of East Tennessee+ (incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the quarterly period ended March 31, 1999)
- 10.6 Work for Others Agreement dated March 25, 1999 between Theragenics Corporation® and Lockheed Martin Energy Research Corporation+ (incorporated by reference to Exhibit 10.2 of the Company's report on Form 10-Q for the quarterly period ended March 31, 1999)
- 10.7 Credit Agreement dated October 29, 2003 between Theragenics Corporation® and SouthTrust Bank (incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the quarterly period ended September 30, 2003)
- 10.8 1986 Incentive and Non-Incentive Stock Option Plan\* (incorporated by reference to Exhibit 10.11 of the Company's registration statement on Form S-1, File No. 33-7097, and post-effective amendments thereto)
- 10.9 1990 Incentive and Non-Incentive Stock Option Plan\* (incorporated by reference to Exhibit 10.10 of the Company's report on Form 10-K for the year ended December 31, 1990)
- 10.10 Theragenics Corporation® 1995 Stock Option Plan\* (incorporated by reference to Exhibit 10.1 of the Company's common stock registration statement on Form S-8, file no. 333-15313)
- 10.11 1997 Stock Incentive Plan\* (incorporated by reference to appendix B of the Company's Proxy Statement for its 1997 Annual Meeting of Stockholders filed on Schedule 14A)
- 10.12 Theragenics Corporation® Employee Stock Purchase Plan\* (incorporated by reference to appendix A of the Company's Proxy Statement for its 1998 Annual Meeting of Stockholders filed on Schedule 14A)
- 10.13 Theragenics Corporation® 2000 Stock Incentive Plan\* (incorporated by reference to Exhibit 10.16 of the Company's report on Form 10-K for the year ended December 31, 1999)
- 10.14 Employment Agreement of M. Christine Jacobs\* (incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the quarterly period ended March 31, 2000)

- 10.14A First Amendment to Executive Employment Agreement for M. Christine Jacobs\* (incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the quarterly period ended June 30, 2003)
- 10.15 Employment Agreement of Bruce W. Smith\* (incorporated by reference to Exhibit 10.22 of the Company's report on Form 10-K for the year ended December 31, 1998)
- 10.15A Amendment to Executive Employment Agreement for Bruce W. Smith\* (incorporated by reference to Exhibit 10.18 of the Company's report on Form 10-K for year ended December 31, 2002)
- 10.15B Second Amendment to Executive Employment Agreement for Bruce W. Smith\* (incorporated by reference to Exhibit 10.19 of the Company's report on Form 10-K for year ended December 31, 2002)
- 10.15C Third Amendment to Executive Employment Agreement for Bruce W. Smith\* (incorporated by reference to Exhibit 10.20 of the Company's report on Form 10-K for year ended December 31, 2002)
- 10.15D Fourth Amendment to Executive Employment Agreement for Bruce W. Smith\* (incorporated by reference to Exhibit 10.2 of the Company's report on Form 10-Q for the quarterly period ended June 30, 2003)
- 10.16 Employment Agreement of James A. MacLennan\* (incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the quarterly period ended September 30, 2002)
- 10.17 Amended Employee Employment Agreement for Tracy M. Culver\* (incorporated by reference to Exhibit 10.25 of the Company's report on Form 10-K for the year ended December 31, 2003)
- 10.18 Employee Employment Agreement for Michael O'Bannon\* (incorporated by reference to Exhibit 10.26 of the Company's report on Form 10-K for the year ended December 31, 2003)
- 10.18A Amendment to Employee Employment Agreement for Michael O'Bannon\* (incorporated by reference to Exhibit 10.27 of the Company's report on Form 10-K for the year ended December 31, 2003)
- 10.19 Additional Compensation Information\*
- 10.20 Short-Term Incentives\*
- 10.21 Long-Term Incentives\*
- 10.22 Forms of Option Award\*
- 10.23 Form of Restricted Stock Award\*
- 10.24 Advisor to the President Agreement with John Herndon\* (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed February 14, 2005)
- 10.25 Form of Directors and Officers Indemnification Agreement\* (incorporated by reference to Exhibit 10.28 of the Company's report on Form 10-K for the year ended December 31, 2003)
- 24.1 Consent of Independent Registered Public Accounting Firm for Incorporation by Reference of Audit Report into Registration Statements
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Chief Executive Officer pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Chief Financial Officer pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Management contract or compensatory plan.

+ Confidential treatment has been requested for portions of this document.



## 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.

### THE RAGENICS CORPORATION (Registrant)

By: /s/ M. Christine Jacobs  
M. Christine Jacobs  
Chief Executive Officer

Dated: March 15, 2005  
Buford, Georgia

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.

Name	Title	Date
<u>/s/ M. Christine Jacobs</u> M. Christine Jacobs	Chief Executive Officer (Principal Executive Officer), President, and Chairman	3/15/05
<u>/s/ James A. MacLennan</u> James A. MacLennan	Chief Financial Officer (Principal Financial and Accounting Officer) and Treasurer	3/15/05
<u>/s/ Otis W. Brawley, M.D.</u> Otis W. Brawley, M.D.	Director	3/15/05
<u>/s/ Orwin L. Carter</u> Orwin L. Carter	Director	3/15/05
<u>/s/ Earnest W. Deavenport, Jr.</u> Earnest W. Deavenport, Jr.	Director	3/15/05
<u>/s/ Patrick L. Flinn</u> Patrick L. Flinn	Director	3/15/05
<u>/s/ John V. Herndon</u> John V. Herndon	Director	3/15/05
<u>/s/ Philip A. Incarnati</u> Philip A. Incarnati	Director	3/15/05
<u>/s/ Peter A. A. Saunders</u> Peter A. A. Saunders	Director	3/15/05

**THERAGENICS CORPORATION®**

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## Management's Report on Internal Control Over Financial Reporting

The Management of Theragenics Corporation® is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theragenics™ have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

The Company's Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, Management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on our assessment we believe that, as of December 31, 2004, our internal control over financial reporting is effective based on those criteria.

Our independent auditors have issued an audit report on Management's assessment of the Company's internal control over financial reporting, which follows this report.

Report of Independent Registered Public Accountants

Board of Directors  
Theragenics Corporation®

We have audited the balance sheets of Theragenics Corporation® (a Delaware corporation) as of December 31, 2004 and 2003, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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 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 financial position of Theragenics Corporation® as of December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note M to the Financial Statements, Theragenics Corporation® adopted Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations, effective January 1, 2003.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2005, expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ GRANT THORNTON LLP  
GRANT THORNTON LLP

Atlanta, Georgia  
March 1, 2005

Report of Independent Registered Public Accountants

Board of Directors  
Theragenics Corporation®

We have audited management's assessment included in Management's Report on Internal Controls Over Financial Reporting included in Theragenics Corporation® Form 10-K for 2004, that Theragenics Corporation® (a Delaware Corporation) maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Theragenics Corporation's® management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Theragenics Corporation® maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. Also in our opinion, Theragenics Corporation® maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Theragenics Corporation® as of December 31, 2004 and 2003, and the related statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 1, 2005 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP  
GRANT THORNTON LLP

Atlanta, Georgia  
March 1, 2005

Theragenics Corporation®

BALANCE SHEETS

December 31,

(Amounts in thousands, except per share data)

ASSETS

	<u>2004</u>	<u>2003</u>
<b>CURRENT ASSETS</b>		
Cash and short-term investments	\$ 28,450	\$ 45,104
Marketable securities	33,811	21,327
Trade accounts receivable, less allowance of \$177 in 2004 and \$118 in 2003	5,787	3,831
Inventories	2,996	1,851
Deferred income tax asset	410	189
Prepaid expenses and other current assets	<u>4,221</u>	<u>4,760</u>
Total current assets	75,675	77,062
<b>PROPERTY, PLANT AND EQUIPMENT - AT COST</b>		
Buildings and improvements	43,618	42,344
Machinery and equipment	61,560	56,456
Office furniture and equipment	810	773
	<u>105,988</u>	<u>99,573</u>
Less accumulated depreciation	41,226	34,418
	64,762	65,155
Land and improvements	822	822
Construction in progress	<u>4,631</u>	<u>7,395</u>
	70,215	73,372
<b>OTHER ASSETS</b>		
	<u>2,788</u>	<u>2,355</u>
Total Assets	<u>\$ 148,678</u>	<u>\$ 152,789</u>

Theragenics Corporation®

BALANCE SHEETS - Continued

December 31,

(Amounts in thousands, except per share data)

**LIABILITIES AND SHAREHOLDERS' EQUITY**

	<u>2004</u>	<u>2003</u>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,871	\$ 2,138
Accrued salaries, wages and payroll taxes	608	577
Other current liabilities	<u>607</u>	<u>338</u>
Total current liabilities	3,086	3,053
<b>LONG TERM LIABILITIES</b>		
Deferred income taxes	6,920	6,830
Decommissioning retirement	549	515
Other liabilities	<u>63</u>	<u>65</u>
Total long term liabilities	7,532	7,410
<b>SHAREHOLDERS' EQUITY</b>		
Common stock - authorized 100,000 shares of \$.01 par value; issued and outstanding, 29,989 in 2004 and 29,944 in 2003	300	299
Additional paid-in capital	61,987	61,778
Deferred compensation	(23)	-
Retained earnings	75,930	80,240
Accumulated other comprehensive income	<u>(134)</u>	<u>9</u>
Total shareholders' equity	<u>138,060</u>	<u>142,326</u>
	<u>\$ 148,678</u>	<u>\$ 152,789</u>

The accompanying notes are an integral part of these statements.



Theragenics Corporation®

STATEMENTS OF OPERATIONS

Year ended December 31,

(Amounts in thousands, except per share data)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Revenue			
Product sales	\$ 33,030	\$ 35,393	\$ 41,512
Licensing fees	308	187	352
	<u>33,338</u>	<u>35,580</u>	<u>41,864</u>
Cost of sales	<u>14,122</u>	<u>15,628</u>	<u>14,677</u>
Gross profit	19,216	19,952	27,187
Operating expenses			
Selling, general and administrative	17,619	13,788	12,845
Research and development	<u>9,583</u>	<u>7,467</u>	<u>6,538</u>
	<u>27,202</u>	<u>21,255</u>	<u>19,383</u>
Earnings/(loss) from operations	(7,986)	(1,303)	7,804
Other income (expense)			
Interest income	1,209	1,040	1,067
Interest and financing costs	(171)	(167)	(99)
Other	<u>96</u>	<u>21</u>	<u>(71)</u>
	<u>1,134</u>	<u>894</u>	<u>897</u>
Earnings/(loss) before income tax and cumulative effect of change in accounting principle	(6,852)	(409)	8,701
Income tax expense/(benefit)	(2,542)	(319)	3,145
Earnings/(loss) before cumulative effect of change in accounting principle	<u>(4,310)</u>	<u>(90)</u>	<u>5,556</u>
Cumulative effect of change in accounting principle, net of tax of \$131	-	(222)	-
NET EARNINGS/(LOSS)	<u>\$ (4,310)</u>	<u>\$ (312)</u>	<u>\$ 5,556</u>

Theragenics Corporation®

STATEMENTS OF OPERATIONS - Continued

Year ended December 31,

(Amounts in thousands, except per share data)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
<b>NET EARNINGS/(LOSS) PER COMMON SHARE</b>			
<i>Basic:</i>			
Earnings/(loss) before cumulative effect of change in accounting principle	\$ (0.14)	\$ (0.00)	\$ 0.19
Cumulative effect of change in accounting principle, net of tax	<u>-</u>	<u>(0.01)</u>	<u>-</u>
Net earnings/(loss) per common share	<u>\$ (0.14)</u>	<u>\$ (0.01)</u>	<u>\$ 0.19</u>
<i>Diluted:</i>			
Earnings/(loss) before cumulative effect of change in accounting principle	\$ (0.14)	\$ (0.00)	\$ 0.19
Cumulative effect of change in accounting principle, net of tax	<u>-</u>	<u>(0.01)</u>	<u>-</u>
Net earnings/(loss) per common share	<u>\$ (0.14)</u>	<u>\$ (0.01)</u>	<u>\$ 0.19</u>
<b>WEIGHTED AVERAGE SHARES:</b>			
Basic	29,971	29,902	29,746
Diluted	29,971	29,902	29,994
Net earnings/(loss)	\$ (4,310)	\$ (312)	\$ 5,556
Comprehensive income/(loss)			
Unrealized gain/(loss) on securities available for sale:	<u>(143)</u>	<u>(34)</u>	<u>43</u>
Total comprehensive income/(loss)	<u>\$ (4,453)</u>	<u>\$ (346)</u>	<u>\$ 5,599</u>

The accompanying notes are an integral part of these statements.

## STATEMENTS OF SHAREHOLDERS' EQUITY

For the three years ended December 31, 2004

(Amounts in thousands, except per share data)

	<u>Common Stock</u>			<u>Deferred Compensation</u>	<u>Retained earnings</u>	<u>Accumulated other comprehensive income</u>	<u>Total</u>
	<u>Number of shares</u>	<u>Par value \$0.01</u>	<u>Additional Paid-in capital</u>				
Balance, December 31, 2001	29,690	\$ 297	\$ 60,714	\$ -	\$ 74,996	\$ -	\$ 136,007
Exercise of stock options	60	1	244				245
Employee stock purchase plan	10		63				63
Stock-based compensation			67				67
Unrealized gain on securities available-for-sale						43	43
Income tax effect from stock options and stock purchase plan			109				109
Net earnings for the year					5,556		5,556
Balance, December 31, 2002	29,760	\$ 298	\$ 61,197	\$ -	\$ 80,552	\$ 43	\$ 142,090
Exercise of stock options	162	1	434				435
Employee stock purchase plan	22		70				70
Stock-based compensation			72				72

Theragenics Corporation®

STATEMENTS OF SHAREHOLDERS' EQUITY - Continued

For the three years ended December 31, 2004

(Amounts in thousands, except per share data)

Unrealized loss on securities available-for-sale						(34)	(34)
Income tax effect from stock options and stock purchase plan			5				5
Net loss for the year						(312)	(312)
Balance, December 31, 2003	<u>29,944</u>	<u>\$ 299</u>	<u>\$ 61,778</u>	<u>\$ -</u>	<u>\$ 80,240</u>	<u>\$ 9</u>	<u>\$ 142,326</u>
Exercise of stock options	18	1	29				30
Employee stock purchase plan	20		78				78
Stock-based compensation	7		102	(23)			79
Unrealized loss on securities available-for-sale						(143)	(143)
Net loss for the year						(4,310)	(4,310)
Balance, December 31, 2004	<u>29,989</u>	<u>\$ 300</u>	<u>\$ 61,987</u>	<u>\$ (23)</u>	<u>\$ 75,930</u>	<u>\$ (134)</u>	<u>\$ 138,060</u>

The accompanying notes are an integral part of these statements.

Theragenics Corporation®

STATEMENTS OF CASH FLOWS

Year ended December 31,

(Amounts in thousands)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:			
Net earnings/(loss)	\$ (4,310)	\$ (312)	\$ 5,556
Adjustments to reconcile net earnings/(loss) to net cash provided by operating activities:			
Cumulative effect of change in accounting principle, net of tax	-	222	-
Depreciation & amortization	6,946	6,553	6,347
Deferred income taxes	(131)	547	468
Income tax effect from stock options	-	5	109
Stock-based compensation	79	72	67
Deferred rent	(2)	(3)	(4)
Provision for allowances	78	(1)	(153)
Loss on disposal of equipment	15	3	16
Changes in assets and liabilities:			
Accounts receivable	(2,015)	987	2,583
Inventories	(1,164)	(790)	(85)
Prepaid expenses and other current assets	539	(2,479)	(404)
Other assets	58	(25)	(15)
Trade accounts payable	(267)	584	758
Accrued salaries, wages and payroll taxes	31	88	(212)
Other current liabilities	<u>269</u>	<u>(3)</u>	<u>248</u>
Net cash provided by operating activities	126	5,448	15,279
Cash flows from investing activities:			
Purchases and construction of property and equipment	(3,263)	(2,542)	(3,565)
Proceeds from disposal of plant and property	2	7	60
Cash paid for acquisition	(1,000)	(5,243)	-
Purchases of marketable securities	(27,624)	(28,249)	(13,445)
Maturities of marketable securities	<u>14,997</u>	<u>18,834</u>	<u>12,335</u>
Net cash used in investing activities	<u>(16,888)</u>	<u>(17,193)</u>	<u>(4,615)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options and stock purchase plan	<u>108</u>	<u>505</u>	<u>307</u>
Net cash provided by financing activities	<u>108</u>	<u>505</u>	<u>307</u>

Theragenics Corporation®

STATEMENTS OF CASH FLOWS - Continued

Year ended December 31,

(Amounts in thousands)

	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net increase/(decrease) in cash and short-term investments	\$ (16,654)	\$ (11,240)	\$ 10,971
Cash and short-term investments at beginning of year	<u>\$ 45,104</u>	<u>\$ 56,344</u>	<u>\$ 45,373</u>
Cash and short-term investments at end of year	<u><u>\$ 28,450</u></u>	<u><u>\$ 45,104</u></u>	<u><u>\$ 56,344</u></u>

Supplementary Cash Flow Disclosure

Interest paid, net of amounts capitalized	\$ 101	\$ 167	\$ 99
Income taxes paid	\$ 21	\$ 1,113	\$ 2,661

The accompanying notes are an integral part of these statements.

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

NOTE A - ORGANIZATION AND DESCRIPTION OF BUSINESS

Theragenics Corporation® is the manufacturer of TheraSeed®, a rice-sized, FDA-cleared device used to treat solid localized tumors, primarily prostate cancer, with a one-time, minimally invasive procedure. Theragenics™ is the world's largest producer of palladium-103, the radioactive isotope that supplies the therapeutic radiation for its TheraSeed® device. Physicians, hospitals and other healthcare providers, primarily located in the United States, utilize the TheraSeed® device. The TheraSeed® device has also been approved for marketing throughout the member countries of the European Union by obtaining its CE Mark. Sales of the TheraSeed® device in Europe have not been significant. The majority of sales are channeled through two third-party distributors. The Company also sells its TheraSeed® devices directly to physicians.

Early in 2003 the Company diversified its product line with the purchase of the U.S. iodine-125 prostate brachytherapy business of BEBIG Isotopen-und Medizintechnik GmbH (BEBIG), formerly distributed by Isotope Products Laboratories (both subsidiaries of a publicly traded German company, Eckert & Ziegler AG). The purchase gives Theragenics™ exclusive U.S. manufacturing and distribution rights to an FDA-cleared iodine-125-based medical device for the treatment of prostate cancer. Theragenics™ began distribution of the iodine-125-based medical device early in 2003, and subsequently began to produce I-Seed (the Theragenics™ iodine-125-based medical device) early in 2004, utilizing the automated production equipment procured in the business acquisition. The Company sells the I-Seed device directly to physicians, hospitals and other healthcare providers. The non-exclusive distributors of the TheraSeed® device have no distribution rights for the I-Seed device. Non-exclusive rights to distribute the TheraSeed® device in Europe were granted to BEBIG as part of the transaction.

The U.S. Department of Energy (DOE) has granted Theragenics™ access to unique DOE technology, known as plasma separation process or PSP, for use in production of isotopes, including palladium-102 (the "PSP Operation"). The Company has constructed a facility in Oak Ridge, Tennessee to house the equipment, infrastructure and work force necessary to support the production of isotopes, including palladium-102, using this DOE technology. The building and the PSP became operational during the latter half of 2002. The Company also has access to and has made investments in other unique DOE resources. Additional equipment in the amount of \$1.7 million, which is physically located within DOE facilities in Oak Ridge, has not yet been placed in service and is recorded as construction-in-progress on the accompanying balance sheets.

In connection with the Company's ongoing program targeted at diversifying its future revenue stream, the Company continues to explore new applications for the PSP technology. Among other things, the PSP technology enables the Company to conduct feasibility runs designed to validate isotope usage in various diverse industries and potential markets. The Company is active in the Federal budget process, and is working to ensure that the PSP's capabilities are known to Federal agencies such as the Departments of Defense and Energy.

In the first quarter of 2004 the Company's Oak Ridge operations began to enrich palladium-102, which can be activated in a nuclear reactor to produce palladium-103. The enriched palladium-102, along with access to specialized reactor and related capabilities, could potentially supply the palladium-103 radioisotope to support TheraSeed® production, if necessary. In addition, the production of palladium-102 allows the Company to study the PSP and its interaction with palladium-102 in order to calibrate the PSP and determine predictable yields generated by the PSP.

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

The Company's diversification program also includes the clinical trial that utilizes a palladium-103 device, called the TheraSource® Intravascular Brachytherapy System, designed to prevent restenosis or renarrowing of arteries following treatment of peripheral vascular disease by percutaneous transluminal angioplasty, and the TheraSight® Ocular Brachytherapy System, a device intended to treat exudative (wet) age-related macular degeneration (AMD), a disease that leads to loss of eyesight and in some cases complete blindness.

The Company has also identified potential opportunities, utilizing its cyclotrons, for production of radiochemical products, which are typically used in medical nuclear imaging procedures. During 2004, the Company began regular shipments to customers of two radiochemicals, produced on the Company's cyclotrons. The revenue recognized during the twelve months ended December 31, 2004 was not material. The Company has received a Drug Master File for these products from the FDA, which will potentially allow access to a wider range of customers. The Company also continues to assess the markets for other radiochemicals it is able to produce using the existing cyclotrons.

The Company is also searching for, reviewing and evaluating external opportunities for diversification in the form of joint ventures, partnerships, and/or acquisitions of technologies, products and companies.

#### NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies consistently applied in the preparation of the accompanying financial statements follows:

##### 1. Use of Estimates

In preparing financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP), Management is required to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities, at the date of the balance sheet, and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

##### 2. Revenue Recognition

Product sales represent orders for the TheraSeed® and I-Seed devices and radiochemical products. The implantable radiation devices produced according to patient and procedure requirements are sold to third-party distributors, as well as to direct customers. Radiochemical products, typically used in medical nuclear imaging procedures, are sold to direct customers. All revenues from product sales are recognized upon shipment and are generally not returnable. Licensing fees are recognized in the periods to which they relate.

##### 3. Cash and Short-Term Investments

For purposes of reporting cash flows, cash and short-term investments include cash on hand, cash in banks, variable rate demand notes, treasury investments and U.S. obligations and commercial paper with maturities equal to or less than 90 days from purchase.



Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

4. Marketable Securities

Marketable securities consist primarily of high-credit quality corporate and municipal obligations in accordance with the Company's investment policies. Marketable securities are classified as available-for-sale and are reported at fair value, based upon quoted market prices at the balance sheet date. The estimated fair value of marketable securities by contractual maturity at December 31, 2004, is as follows (amounts in thousands):

Due in one year or less	\$ 23,070
Due after one year through five years	\$ 10,741

5. Inventories

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method. Inventories as of December 31, 2004 and 2003 were comprised of the following (amounts in thousands):

Inventories	<u>December 31,</u> <u>2004</u>	<u>December 31,</u> <u>2003</u>
Raw materials	\$ 894	\$ 1,439
Work in progress	1,813	206
Finished goods	8	9
Shipping supplies	<u>281</u>	<u>197</u>
 Total	 <u>\$ 2,996</u>	 <u>\$ 1,851</u>

6. Property, Equipment, and Amortization

Property and equipment are recorded at historical cost. Depreciation and amortization is provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives on a straight-line basis. Depreciation and amortization expense related to property and equipment charged to operations was approximately \$6,872,000, \$6,545,000 and \$6,265,000 for 2004, 2003 and 2002, respectively. Estimated service lives are 30 years for buildings and improvements, and 3 to 15 years for machinery, equipment and furniture.

A significant portion of the Company's depreciable assets is utilized in the production of its product. Management periodically evaluates the realizability of its depreciable assets in light of its current industry environment. Management believes that no impairment of depreciable assets exists as of December 31, 2004. It is possible, however, that Management's estimates concerning the realizability of the Company's depreciable assets could change in the future.

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

7. Goodwill and Intangible Assets

The Company accounts for goodwill and other intangible assets in accordance with the provisions of Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142"). Under SFAS 142, goodwill and intangible assets with indefinite lives are not amortized to expense and must be reviewed for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. The first step of the impairment test, used to identify potential impairment, compares the fair value of a reporting unit with its carrying amount, including goodwill and intangible assets with indefinite lives. The Company operates as one reporting unit and therefore compares its book value to market value (market capitalization plus a control premium). If fair value exceeds book value, goodwill is considered not impaired, and the second step of the impairment test is unnecessary. If book value exceeds market value, the second step of the impairment test is performed to measure the amount of impairment loss, if any. For this step the implied fair value of the goodwill is compared with the book value of the goodwill. If the carrying amount of the goodwill exceeds the implied fair value of the goodwill, an impairment loss would be recognized in an amount equal to that excess. Any loss recognized cannot exceed the carrying amount of goodwill. After an impairment loss is recognized, the adjusted carrying amount of goodwill is its new accounting basis. Subsequent reversal of a previously recognized impairment loss is prohibited once the measurement of that loss is completed. The Company completed its annual goodwill impairment assessment as of November 28, 2004 and determined that goodwill was not impaired and no impairment charge was recorded.

Goodwill and other intangible assets are included in other assets in the accompanying balance sheets. The Company has recorded goodwill of \$2.6 million and \$1.6 million at December 31, 2004 and 2003, respectively, which represents the excess of the aggregate purchase price over the fair value of the tangible assets acquired as part of the acquisition of the U.S. iodine-125 prostate brachytherapy business of BEBIG (See Note A, above). Other intangibles, which include patent costs and other intellectual property, were \$59,000 and \$82,000, net of accumulated amortization of \$174,000 and \$151,000, at December 31, 2004 and 2003 respectively. Other intangibles are being amortized over periods of five to nineteen years. The Company recognized \$24,000, \$24,000 and \$28,000 of amortization expense in the years ended December 31, 2004, 2003 and 2002, respectively.

8. Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets when it is more likely than not that the asset will not be realized.

9. Research and Development Costs

Research and development (R&D) costs are expensed when incurred.

10. Advertising

The Company expenses the cost of advertising as incurred. Advertising expense was approximately \$2,833,000, \$2,291,000 and \$2,956,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

11. Earnings Per Share and Common Stock

Basic net earnings/(loss) per common share is based upon the weighted average number of common shares outstanding during the period. Diluted net earnings/(loss) per common share is based upon the weighted average number of common shares outstanding plus dilutive potential common shares, including options, rights and warrants outstanding during the period. Stock options, rights and warrants to purchase 95,000 and 77,000 common shares for the years ended December 31, 2004 and 2003, respectively, were not included in the computation of diluted earnings/(loss) per share for those years because their effect would have been anti-dilutive.

12. Stock Based Compensation

Stock options, restricted stock and other equity incentives issued to employees are accounted for under Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," using the intrinsic value method in which compensation expense is recognized for the amount, if any, that the fair value of the underlying common stock exceeds the exercise price at the date of grant. Stock options and other equity instruments issued in exchange for goods or services with non-employees are accounted for based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more readily measurable. See Note H for a more detailed discussion of stock based compensation plans.

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." SFAS 148 amends SFAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure requirement of SFAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of SFAS 148 are effective for fiscal years ending after December 15, 2002. The Company elected the disclosure-only alternative under SFAS No. 123, "Accounting for Stock-Based Compensation." No stock-based compensation cost related to options issued to employees is included in net earnings, as all such options granted have an exercise price equal to the market value of the stock on the date of grant. Stock-based compensation costs of \$26,000 and \$5,000 are included in the results for the years ended December 31, 2004 and 2003, respectively, related to restricted stock issued to directors. Stock-based compensation costs of \$75,000 are included in the results for the year ended December 31, 2004 related to restricted stock rights granted to executive management. In accordance with SFAS No. 148, "Accounting for Stock Based Compensation-Transition and Disclosure," the following table presents the effect on net earnings and net earnings per share had compensation cost for the Company's stock plans been determined consistent with SFAS No. 123 (in thousands, except per share data):

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

		2004	2003	2002
Net earnings/(loss)	As reported	\$ (4,310)	\$ (312)	\$ 5,556
	Pro forma	(4,799)	(1,190)	4,455
Basic net earnings/(loss) per common share	As reported	\$ (0.14)	\$ (0.01)	\$ 0.19
	Pro forma	(0.16)	(0.04)	0.15
Diluted net earnings/(loss) per common share	As reported	\$ (0.14)	\$ (0.01)	\$ 0.19
	Pro forma	(0.16)	(0.04)	0.15

The weighted average fair value of the options granted during 2004, 2003, and 2002 was \$2.77, \$2.79 and \$3.55, respectively. The fair values were estimated using the Black-Scholes options-pricing model with the following weighted average assumptions:

	2004	2003	2002
Expected dividend yield	0.0%	0.0%	0.0%
Expected stock price volatility	64.1%	72.7%	71.0%
Risk-free interest rate	3.2%	3.4%	3.0%
Expected life of option (years)	5.4	5.5	5.0

### 13. Fair Value of Financial Instruments

The Company's financial instruments include cash, cash equivalents and marketable securities. The carrying value of cash and cash equivalents approximates fair value due to the relatively short period to maturity of the instruments. Marketable securities are classified as available-for-sale and are reported at fair value, with unrealized gains or losses excluded from earnings and included in other comprehensive income, net of applicable taxes.

Available-for-sale securities consist of:

(in thousands)	2004		
	Amortized Cost	Gross Unrealized Loss	Estimated Fair Value
State and municipal securities	\$ 4,726	\$ (8)	\$ 4,718
U.S. government and agency securities	6,994	(46)	6,948
Corporate and other securities	22,225	(80)	22,145
<u>Total</u>	<u>\$ 33,945</u>	<u>\$ (134)</u>	<u>\$ 33,811</u>

### 14. Segment Information

Operating segments are defined by Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of an Enterprise and Related Information*, as components of an enterprise about which separate financial information is available that is evaluated regularly by the Company's chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company reports as a single segment. All of the Company's assets are located within the United States and revenue outside the United States is not material for any year in the three years ended December 31, 2004. Information related to major customers is discussed in Note D, Marketing and Sales Agreements and Major Customers.

### 15. Reclassifications

Certain amounts included in the 2003 and 2002 financial statements have been reclassified to conform to the 2004 presentation.

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NOTE C - CONSTRUCTION IN PROGRESS AND PURCHASE COMMITMENTS

The U.S. Department of Energy (DOE) has granted Theragenics™ access to unique DOE technology (plasma separation process or "PSP") for use in production of isotopes, including palladium-103. The Company has constructed a facility in Oak Ridge, Tennessee to house the equipment, infrastructure and work force necessary to support the production of isotopes, including palladium-103, using this DOE technology. The building and the PSP became operational during the latter half of 2002. Additional equipment in the amount of \$1.7 million has not yet been placed in service and is recorded as construction-in-progress on the accompanying balance sheets.

In June 2004 the Company entered into an asset purchase agreement with a contractor for the design and manufacture of certain equipment. The capital asset purchase agreement in the amount of \$570,000 should be completed in early 2005. At year-end 2004, progress payments in the amount of approximately \$114,000 had been paid in relation to the purchase agreement.

NOTE D - MARKETING AND SALES AGREEMENTS AND MAJOR CUSTOMERS

The Company sells its TheraSeed® device directly to health care providers and to third party distributors. Theragenics™ also manufactures and distributes I-Seed, an iodine-125 based medical device, directly to health care providers. At the beginning of 2003, the Company had non-exclusive distribution agreements in place with four companies. During the first quarter of 2003, the distribution agreement with one distributor was discontinued upon notification of the acquisition of the distributor by another TheraSeed® distributor. In addition, during the second quarter of 2003, Theragenics™ was notified that this same distributor acquired another TheraSeed® distributor. Currently, the Company has non-exclusive distribution agreements in place with two companies for the distribution of the TheraSeed® device, C. R. Bard and Medi-Physics, Inc. (formerly d/b/a Nycomed Amersham and now part of Oncura, a company formed by a merger of the brachytherapy business of Amersham plc and Galil Medical Ltd. and referred to herein as "Oncura"). The non-exclusive distribution agreements for the distribution of the TheraSeed® device give each distributor the right to distribute the TheraSeed® device in the U.S., Canada and Puerto Rico for the treatment of prostate cancer and other solid localized cancerous tumors. These non-exclusive agreements give the distributors the option to distribute the TheraSeed® device internationally. The domestic and international distribution agreements with Oncura allow each party the right to give notice of non-renewal of the agreements at the end of December 2004, which would be effective December 31, 2005. During December 2004, the Company was notified by Oncura that it would not be renewing the distribution agreements, effective December 31, 2005. C. R. Bard has exercised its option to extend its distribution agreement with the Company through December 2006.

Total sales to the two existing and the two previous non-exclusive distributors represented approximately 81%, 81% and 83% of product revenue for the years ended December 31, 2004, 2003 and 2002, respectively, with sales to two of the four non-exclusive distributors each exceeding 10% of total revenue for each year.

Accounts receivable from the two non-exclusive distributors represented approximately 74% and 74% of accounts receivable at December 31, 2004 and 2003, respectively, with each of the two non-exclusive distributors noted above each exceeding 10% of total accounts receivable.

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NOTE E - INCOME TAXES

The income tax provision consisted of the following (in thousands):

	2004	2003	2002
Current			
Federal	\$ (2,248)	\$ (804)	\$ 2,442
State	<u>(163)</u>	<u>(62)</u>	<u>235</u>
	<u>(2,411)</u>	<u>(866)</u>	<u>2,677</u>
Deferred			
Federal	(148)	500	126
State	<u>17</u>	<u>47</u>	<u>342</u>
	<u>(131)</u>	<u>547</u>	<u>468</u>
	<u>\$ (2,542)</u>	<u>\$ (319)</u>	<u>\$ 3,145</u>

The Company's temporary differences result in a deferred income tax liability at December 31, 2004 and 2003, summarized as follows (in thousands):

	December 31,	
	2004	2003
Deferred tax assets:		
Non-deductible accruals and allowances	\$ 127	\$ 74
Inventories	172	115
Stock compensation	338	314
Asset retirement obligation	202	191
Credits	343	-
Other	<u>83</u>	<u>29</u>
Gross deferred tax assets	1,265	723
Deferred tax liabilities:		
Property and equipment	(7,671)	(7,324)
Other	<u>(104)</u>	<u>(40)</u>
Gross deferred tax liabilities	<u>(7,775)</u>	<u>(7,364)</u>
Net deferred tax liability	<u>\$ (6,510)</u>	<u>\$ (6,641)</u>

The net deferred tax liability is classified in the accompanying balance sheets as follows (in thousands):

	December 31,	
	2004	2003
Current deferred tax asset	\$ 410	\$ 189
Long-term deferred tax liability	<u>(6,920)</u>	<u>(6,830)</u>
Net deferred tax liability	<u>\$ (6,510)</u>	<u>\$ (6,641)</u>

A reconciliation of the statutory federal income tax rate and the effective tax rate follows:

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	2004	2003	2002
Tax at applicable federal rates	(35.0)%	(35.0)%	35.0%
State tax, net of federal income tax	(2.0)	(2.0)	2.0
Tax exempt interest	(1.7)	(52.0)	(1.5)
Other	1.6	11.0	0.6
	(37.1)%	(78.0)%	36.1%

The Company has research and development tax credit carryforwards of approximately \$203,000 which expire by 2024 and alternative minimum tax credit carryforwards of approximately \$140,000.

NOTE F - CREDIT AGREEMENT

The Company executed a Credit Agreement with a financial institution on October 29, 2003. The Credit Agreement, which expires October 29, 2006 (subject to earlier termination by the lender upon the occurrence of certain events of default), provides for revolving borrowings of up to \$40.0 million at any time outstanding, including a \$5.0 million sub-limit for letters of credit. Interest on outstanding borrowings is payable at the rate of interest periodically designated by the financial institution as its base rate, or, at the option of the Company, interest may accrue at a LIBOR based rate, plus an applicable margin which is subject to quarterly adjustment. Interest on base rate loans is payable monthly, while interest on LIBOR loans is payable on the last day of the applicable one, two or three month interest period.

The Credit Agreement is unsecured, but provides for a "springing lien" to be established on certain assets of the Company (subject to certain exceptions) in the event certain events of default occur under the Credit Agreement. The Credit Agreement contains representations and warranties, as well as affirmative, reporting and negative covenants, customary for financings of this type. Among other things, certain provisions of the Credit Agreement limit the incurrence of additional debt and require the maintenance of certain financial ratios. The Company was in compliance with these debt covenants at December 31, 2004.

The Company has letters of credit outstanding under the Credit Agreement as of December 31, 2004 for approximately \$933,000. These letters of credit are related to asset retirement liabilities of long-lived assets, as well as a utility deposit to the City of Oak Ridge, Tennessee. The letters of credit are subject to terms identical to those of borrowings under the Credit Agreement.

NOTE G - COMMITMENTS AND CONTINGENCIES

Licensing Agreement

The Company holds a worldwide exclusive license from the University of Missouri for the use of technology, patented by the University, used in the Company's TheraSphere® product. The licensing agreement provides for the payment of royalties based on the level of sales and on lump sum payments received pursuant to a licensing agreement with Nordion International, Inc. (see below).

The Company has granted certain of its geographical rights under the licensing agreement with the University of Missouri to Nordion International, Inc., a Canadian company that is a producer, marketer and supplier of radioisotope products and related equipment. Under the Nordion agreement, the Company is entitled to licensing fees for each geographic area in which Nordion receives new drug approval. The Company will also be entitled to a percentage of revenues earned by Nordion as royalties under the agreement. Royalties from this agreement are recorded as "Licensing fees" in the accompanying statements of operations.

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Lease Commitments

The Company leases land, space and equipment under non-cancelable leases that expire at various dates through April 2029. Approximate minimum lease payments under the leases are as follows: 2005, \$341,000; 2006, \$332,000; 2007, \$319,000; 2008, \$317,000; 2009, \$257,000 and \$2,639,000 thereafter.

Rent expense was approximately \$366,000, \$289,000 and \$345,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Contingencies

In January 1999, the Company and certain of its officers and directors were named as defendants in certain securities actions alleging violations of the federal securities laws, including Sections 10(b), 20(a) and Rule 10b-5 of the Securities and Exchange Act of 1934, as amended. These actions were consolidated into a single action in the U.S. District Court for the Northern District of Georgia. The complaint, as amended, purported to represent a class of investors who purchased or sold securities during the time period from January 29, 1998 to January 11, 1999. The amended complaint generally alleged that the defendants made certain misrepresentations and omissions in connection with the performance of the Company during the class period and sought unspecified damages. On May 14, 1999 a stockholder of the Company filed a derivative complaint in the Delaware Court of Chancery purportedly on behalf of the Company, alleging that certain directors breached their fiduciary duties by engaging in the conduct that was alleged in the consolidated federal class action complaint. The derivative action was stayed by the agreement of the parties. On July 19, 2000, the Court granted the Company's motion to dismiss the consolidated federal class action complaint for failure to state a claim against the Company, and granted the plaintiffs leave to amend their complaint. On August 21, 2000, the plaintiffs filed a second amended complaint and on March 30, 2001, the Court denied the defendant's motion to dismiss the plaintiffs' second amended complaint. The Court also denied the Company's motion for reconsideration. Subsequently, the Court certified the class and the parties commenced discovery. Discovery was completed, and the Company filed a motion for summary judgment on September 30, 2003.

On July 1, 2004, while the summary judgment motion was pending, the Company, the Company's directors and officers' liability insurance carrier, and the plaintiffs' counsel reached an agreement to settle the consolidated federal class action for an amount within the remaining limits of the Company's directors and officers' liability insurance. The plaintiffs dismissed their lawsuit against the defendants and, on behalf of the settling class, released defendants from any and all liability arising from the incidents alleged in the second amended complaint. The Company was not required to make any financial contribution toward the settlement. On September 29, 2004, the Court gave final approval to the settlement, with no objectors and no requests for exclusion. The final approval allowed the right to appeal the final order until November 1, 2004. No appeals were made to the final order and the case was officially over as of that date. The derivative lawsuit is still pending. Its status is currently being reevaluated in light of the settlement of the securities class action lawsuit.



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The Company and one of its distributors, Oncura, are currently arbitrating claims arising in connection with the Company's non-exclusive distribution agreement with Oncura. Oncura claims that the Company has not addressed Oncura's concerns about pricing by renegotiating pricing in good faith. Oncura is seeking a change in the pricing terms of the distribution agreement through the arbitration proceeding, and has indicated that it will seek to recover a portion of payments previously made. The Company filed a counterclaim against Oncura alleging that Oncura breached its obligations under the distribution agreement concerning marketing brachytherapy products and the use of the Company's trademarks. The arbitrators have been appointed and the parties are conducting discovery. Management believes that Oncura's claims are without merit and is opposing them vigorously. Management believes the Company has meritorious counter-claims against Oncura.

From time to time the Company may be a party to claims that arise in the ordinary course of business, none of which, in the view of Management, is expected to have a material adverse effect on the consolidated financial position or results of operations of the Company.

#### NOTE H - STOCK BASED COMPENSATION

The Company provides stock-based compensation under equity incentive plans approved by stockholders. The plans collectively provide for the granting of stock options, restricted stock and other equity incentives. As of December 31, 2004 there were 2,500,133 options and 94,500 restricted stock rights (representing from 61,950 to 141,000 shares depending on performance as described below) outstanding and 277,429 shares of Common Stock remaining available for issuance under the Company's equity incentive plans (based on assumed vesting of outstanding rights at target performance level).

##### Stock Options

Stock option grants to date have required the exercise price of the options granted to be at least equal to 100% of market value on the date granted. Stock options granted to date provide for the expiration of options ten years from the date of grant and become exercisable over a three to five-year vesting period. At the May 11, 2004 meeting of the Board of Directors, the Board approved the vesting of all underwater options (defined as those options with exercise prices greater than the closing price for the Company's stock on May 11, 2004) as of May 11, 2004. The acceleration was approved in anticipation of the issuance of Statement of Financial Accounting Standards No. 123R, discussed in Note N, Recently Issued Accounting Standards. This approval resulted in 352,000 of previously unvested options immediately becoming vested on May 11, 2004. Each of these options had exercise prices greater than \$4.73, the closing price of the Company's stock on May 11, 2004. This acceleration of vesting did not result in any charge to the Company's results of operations.

Stock option transactions for each of the three years in the period ended December 31, 2004, are summarized below (shares in thousands):

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	2004		2003		2002	
	Shares	Weighted average exercise price	Shares	Weighted average exercise price	Shares	Weighted average exercise price
Outstanding, beginning of year	2,535	\$ 9.54	2,778	\$ 9.53	2,324	\$ 10.21
Granted	33	4.81	30	4.34	514	5.83
Exercised	(18)	1.63	(155)	2.80	(60)	4.10
Forfeited	(50)	2.69	(118)	16.73	-	-
Outstanding, end of year	<u>2,500</u>	\$ 9.67	<u>2,535</u>	\$ 9.54	<u>2,778</u>	\$ 9.53

The following table summarizes information about stock options outstanding at December 31, 2004 (shares in thousands):

Range of exercise prices	Options Outstanding			Options Exercisable		
	Number outstanding	Weighted-average remaining contractual life	Weighted-average exercise price	Number exercisable	Weighted-average exercise price	
\$ 1.63 - \$ 5.61	576	6.3	\$ 4.29	450	\$ 4.26	
\$ 6.88 - \$11.75	1,407	3.9	8.45	1,407	8.45	
\$16.56 - \$26.63	517	3.3	18.98	517	18.98	
	<u>2,500</u>	<u>4.3</u>	\$ <u>9.67</u>	<u>2,374</u>	\$ <u>9.95</u>	

The Company follows the practice of recording amounts received upon the exercise of certain options by crediting common stock and additional paid-in capital. No charges are reflected in the statements of operations as a result of the grant or exercise of options to or by employees. The Company realizes an income tax benefit from the exercise of certain stock options and the exercise and early disposition of the shares acquired via certain other stock options. This benefit results in a reduction to income taxes payable and an increase to additional paid-in capital.

#### Restricted Stock

Beginning in 2003, each non-officer director began receiving 1,000 shares of restricted stock per year, with one year vesting, as one component of director compensation. The Company issued 7,000 shares of restricted stock to the non-officer directors in November, 2003 which vested in November, 2004. The total compensation cost associated with these restricted shares, \$30,740, was recognized over the vesting period and is included in selling, general and administrative expense in the accompanying statements of operations for the years ended December 31, 2004 and 2003. The Company issued an additional 7,000 restricted shares to non-officer directors in November, 2004 which will vest in November, 2005. The total compensation cost related to these restricted shares, \$27,370 will be recognized over the vesting period and is included in selling, general and administrative expense in the accompanying statements of operations for the year ended December 31, 2004.

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Restricted Stock Rights

In August 2004, the Board of Directors granted restricted stock rights to the Company's Executive Officers. Specifically, the Company granted an aggregate of 48,000 restricted stock rights on August 10, 2004, to the Executive Officers. Each right represents one share of common stock to be issued upon vesting, provided that the Executive Officer remains in the Company's employ until the vesting date of December 31, 2005. The Company recognized \$55,000 of stock-based compensation related to these restricted stock rights in the year ended December 31, 2004. In June 2004, the Company also granted performance restricted stock rights to the Executive Officers as part of a long-term incentive program. Under the long-term incentive program, the number of shares issuable upon vesting of each performance restricted stock right will depend on the company's stock price appreciation plus dividends paid (total shareholder return, or "TSR") relative to an industry peer group based on a fixed schedule. Each performance restricted stock right represents the right to a minimum of 0.30 of a share of common stock provided that the Executive Officer remains in the Company's employ as of the vesting date, and a maximum of two shares of common stock depending on the Company's TSR. TSR will be measured for the period from January 1, 2004 through December 31, 2006, and rights will vest under the program as of December 31, 2006. The performance restricted rights will vest at the target achievement level upon a change of control. The number of shares that could be earned in respect of the performance restricted stock rights ranges from 13,950 shares to 93,000 shares based on TSR performance. The Company recognized \$20,000 of stock-based compensation related to the 13,950 share minimum in the year ended December 31, 2004. Management will monitor the TSR of the Company, compared to the industry peer group, during the vesting period for the June 2004 grants and recognize additional, or adjust previously recorded compensation expense, as appropriate. As of December 31, 2004, no additional stock-based compensation expense was recorded based on TSR during the year ended December 31, 2004.

Stock Options Issued to Non-Employees

During 1998, the Company issued 100,000 stock options to an individual for medical and cancer consulting services. The Company recorded consulting expenses based on the estimated fair value of the options at the grant date over the consulting term of five years. Consulting expenses related to this agreement were approximately \$42,000 and \$67,000 during 2003 and 2002, respectively. The Company did not recognize any consulting expense related to these options during 2004.

NOTE I - EARNINGS/(LOSS) PER SHARE

Earnings/(loss) per common share was computed as follows (in thousands, except per share data):

	Year ended December 31,		
	2004	2003	2002
	<u>          </u>	<u>          </u>	<u>          </u>
Numerator for basic and diluted earnings/(loss)			
Per share - income available to common Shareholders	\$ (4,310)	\$ (312)	\$ 5,556
Denominator for basic earnings/(loss) per share	29,971	29,902	29,746
Adjusted weighted average shares			
Effect of dilutive stock options and warrants	<u>          -</u>	<u>          -</u>	<u>          248</u>
Denominator for diluted earnings/(loss) per share			
Adjusted weighted average shares	<u>          29,971</u>	<u>          29,902</u>	<u>          29,994</u>
Basic earnings/(loss) per share	<u>          \$ (0.14)</u>	<u>          \$ (0.01)</u>	<u>          \$ 0.19</u>
Diluted earnings/(loss) per share	<u>          \$ (0.14)</u>	<u>          \$ (0.01)</u>	<u>          \$ 0.19</u>

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The diluted loss per share for the years ended December 31, 2004 and 2003 does not include the effect of stock options, rights and warrants as their impact would be anti-dilutive. Stock options, rights and warrants to purchase 95,000 and 77,000 common shares for the years ended December 31, 2004 and 2003, respectively, were not included in the computation of diluted earnings/(loss) per share for those years.

NOTE J - EMPLOYEE BENEFIT PLAN

401(k) Savings Plan

The Company has a 401(k) savings plan providing retirement benefits to all employees at least 21 years of age. The Company makes matching contributions of 20%-60% of each participant's contribution, up to 6% of salary. The percentage of matching contributions is discretionary, based on Company results and is made in the form of Company common stock. Matching contributions are charged to operating expenses and totaled approximately \$168,000, \$49,000 and \$90,000 in 2004, 2003 and 2002, respectively.

Employee Stock Purchase Plan

The Theragenics Corporation® Employee Stock Purchase Plan (the ESPP ) allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each quarterly offering period. As of December 31, 2004 and 2003, there were 111,000 and 131,000 shares of common stock reserved and un-issued for the ESPP, respectively, and 89,000 and 69,000 shares had been issued under the plan, respectively.

NOTE K - RELATED PARTY TRANSACTIONS

An officer and director of the Company was a director of a vendor that provides radiation measurement services to Theragenics™ until May 2004. Theragenics™ paid this vendor approximately \$32,000, \$37,000 and \$29,000 during 2004, 2003 and 2002, respectively, for these services. The same officer and director of the Company was a director of the American Cardiovascular Research Institute (ACRI) for a portion of 2003. ACRI performed animal studies related to the Company's research initiatives. Theragenics™ paid ACRI approximately \$51,000, \$60,000 and \$117,000 during 2004, 2003, and 2002, respectively, for these animal studies.

The same officer is related to the principal of an outside consultant, Medical Equities, which provides real estate advisory services. Theragenics™ paid this consultant approximately \$5,000 in 2003 for these services.

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NOTE L - QUARTERLY FINANCIAL DATA (UNAUDITED)

The following summarizes certain quarterly results of operations (*in thousands, except per share data*):

Year ended December 31, 2004	Quarter ended			
	April 4	July 4	October 3	December 31
Net revenue	\$ 7,953	\$ 8,646	\$ 8,283	\$ 8,456
Gross profit	4,555	5,179	5,001	4,481
Net loss	(966)	(934)	(1,122)	(1,289)
Net loss per common share				
<i>Basic:</i>				
Loss per common share (basic)	\$ (0.03)	\$ (0.03)	\$ (0.04)	\$ (0.04)
<i>Diluted:</i>				
Loss per common share (diluted)	\$ (0.03)	\$ (0.03)	\$ (0.04)	\$ (0.04)
Year ended December 31, 2003:	April 6	July 6	October 5	December 31
Net revenue	\$ 11,102	\$ 8,949	\$ 8,519	\$ 7,010
Gross profit	6,565	4,990	4,905	3,492
Earnings/(loss) before cumulative effect of change in accounting principle	1,219	266	(388)	(1,187)
Cumulative effect of change in accounting principle	(222)	-	-	-
Net earnings/(loss)	997	266	(388)	(1,187)
Net earnings/(loss) per common share				
<i>Basic:</i>				
Earnings/(loss) before cumulative effect of change in accounting principle	\$ 0.04	\$ 0.01	\$ (0.01)	\$ (0.04)
Cumulative effect of change in accounting principle	(0.01)	-	-	-
Net earnings/(loss) per common share (basic)	\$ 0.03	\$ 0.01	\$ (0.01)	\$ (0.04)
<i>Diluted:</i>				
Earnings/(loss) before cumulative effect of change in accounting principle	\$ 0.04	\$ 0.01	\$ (0.01)	\$ (0.04)
Cumulative effect of change in accounting principle	(0.01)	-	-	-
Net earnings/(loss) per common share (diluted)	\$ 0.03	\$ 0.01	\$ (0.01)	\$ (0.04)

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NOTE M - ASSET RETIREMENT OBLIGATIONS

In September 2001, the FASB issued Statement of Financial Accounting Standards No. 143, *Accounting for Asset Retirement Obligations*, which was effective for the Company's 2003 fiscal year. Under Statement 143, a future retirement obligation relating to future decommissioning costs of the Company's equipment and buildings is recorded at present value by discounting the Company's estimated future asset retirement obligation using the Company's estimated credit-adjusted borrowing rate. The offset to the liability is capitalized as part of the carrying amount of the related long-lived asset. The asset retirement obligation (ARO) has been recorded in the accompanying balance sheets and will be adjusted to fair value over the estimated useful lives of the assets as an accretion expense.

At January 1, 2003 the Company adopted Statement 143 and recognized an initial ARO of approximately \$478,000 and net capitalized costs of \$126,000. The impact of adopting the Statement was recognized as a cumulative effect of change in accounting principle in the amount of \$353,000 (\$222,000 after income taxes). The Company has recognized an increase in the ARO of approximately \$34,000 and \$36,000 for the years ended December 31, 2004 and 2003, respectively, representing the accretion expense. Approximately \$13,000 and \$30,000 in amortization expense was recognized related to the capitalized cost for the years ended December 31, 2004 and 2003, respectively.

NOTE N - RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142"). Under SFAS 142, companies are no longer required to amortize goodwill and other intangible assets with indefinite lives but will be required to test these assets periodically for impairment. SFAS 142 is effective for fiscal years beginning after December 15, 2001. The Company adopted SFAS 142 effective January 1, 2002.

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 143, *Accounting for Asset Retirement Obligations*, which was effective for the Company's 2003 fiscal year (see "Note M" above).

The FASB issued Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ("SFAS 144"), in August 2001. SFAS 144 establishes a single accounting model for the impairment or disposal of long-lived assets and new standards for reporting discontinued operations. SFAS 144 superseded Statement of Financial Accounting Standards No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and APB Opinion No. 30, *Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. The provisions of SFAS 144 are effective in fiscal years beginning after December 15, 2001 and, in general, are to be applied prospectively. The Company adopted SFAS 144 effective January 1, 2002 and such adoption had no material impact on the financial statements.

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December 31, 2004 and 2003

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ("SFAS 146"), which addresses financial accounting and reporting for costs associated with exit or disposal activities and supersedes Emerging Issues Task Force ("EITF") Issue 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. SFAS 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF Issue 94-3, a liability for an exit cost as defined in EITF Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. SFAS 146 also establishes that the liability should initially be measured and recorded at fair value. SFAS 146 is effective for exit and disposal activities initiated after December 31, 2002. The adoption of this pronouncement did not have a material impact on the Company's financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees and Indebtedness of Others* ("FIN 45"). FIN 45 elaborates on the disclosures to be made by the guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and measurement provisions of this interpretation are applicable on a prospective basis to guarantees issued or modified after December 31, 2002; while the provisions of the disclosure requirements are effective for financial statements of interim or annual reports ending after December 15, 2002. The Company adopted the disclosure provisions of FIN 45 during the fourth quarter of fiscal 2002 and such adoption had no material impact on its financial statements.

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* ("SFAS 148"). SFAS 148 amends Statement No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), to provide alternative methods for voluntary transition to SFAS 123's fair value method of accounting for stock-based employee compensation. SFAS 148 also requires disclosure of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net earnings (loss) and earnings (loss) per share in annual and interim financial statements. The provisions of SFAS 148 are effective in fiscal years beginning after December 15, 2002. The Company has adopted the disclosure option of this pronouncement and will continue to account for stock options under the intrinsic method.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities* ("FIN 46"). In general, a variable interest entity is a corporation, partnership, trust, or any other legal structure used for business purposes that either (a) does not have equity investors with voting rights or (b) has equity investors that do not provide sufficient financial resources for the entity to support its activities. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company expects that the provisions of FIN 46 will not have a material impact on its financial statements upon adoption since the Company currently has no variable interest entities.

Theragenics Corporation®  
NOTES TO FINANCIAL STATEMENTS  
December 31, 2004 and 2003

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, *Revenue Recognition* ("SAB 104"), which supersedes Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* ("SAB 101"). The primary purpose of SAB 104 is to rescind accounting guidance contained in SAB 101 related to multiple element revenue arrangements, which was superseded as a result of the issuance of Emerging Issues Task Force 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ("EITF 00-21"). SAB 104 also incorporated certain sections of the SEC's "Revenue Recognition in Financial Statements—Frequently Asked Questions and Answers" document. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104. Management believes that the Company's revenue recognition policy is in compliance with SAB 104.

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4* ("SFAS 151"). SFAS 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials and requires that such items be recognized as current-period charges regardless of whether they meet the "so abnormal" criterion outlined in ARB No. 43. In addition, SFAS 151 requires that allocation of fixed production overhead to the cost of conversion be based on normal capacity of the production facilities. SFAS 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. While the Company is still evaluating the impact of this statement, it does not currently believe it will have a material impact on its financial statements.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-based Payments* ("SFAS 123R"), which replaces the prior SFAS No. 123, "Accounting for Stock-based Compensation," and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires compensation costs related to share-based payment transactions to be recognized in the financial statements based on the grant date fair value of the award. Compensation cost will be recognized over the period during which an employee is required to provide services in exchange for the award, usually the vesting period. SFAS 123R will also require companies to measure the cost of employee services received in exchange for Employee Stock Purchase Plan ("ESPP") awards. SFAS 123R is effective for interim or annual periods beginning after June 15, 2005, which would be the Company's third fiscal quarter of 2005. The Company is in the process of determining the impact SFAS 123R will have on its financial statements.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29* ("SFAS 153"). SFAS 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The Company is currently evaluating SFAS 153, but does not believe it will have a material impact on its financial statements.



**Report of Independent Registered Public Accountants on Schedule**

Board of Directors  
Theragenics Corporation®

In connection with our audit of the financial statements of Theragenics Corporation referred to in our report dated March 1, 2005, which is included in the annual report to security holders and incorporated by reference in Part II of this form, we have also audited Schedule II for each of the three years in the period ended December 31, 2004. In our opinion, the schedule presents fairly, in all material respects, the information required to be set forth therein.

/s/ GRANT THORNTON LLP  
GRANT THORNTON LLP

Atlanta, Georgia  
March 1, 2005

Theragenics Corporation®

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

For each of the three years in the period ended December 31, 2004  
(Amounts in thousands)

Column A - Description	Column B	Column C - Additions		Column D	Column E
		(1)	(2)		
	Balance at beginning of period	Charged to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
Year ended December 31, 2004					
Allowance for doubtful accounts receivable	\$ 118	\$ 59	\$ 0	\$ 0	\$ 177
Allowance for doubtful inventory	\$ 94	\$ 19	\$ 0	\$ 0	\$ 113
Year ended December 31, 2003					
Allowance for doubtful accounts receivable	\$ 147	\$ 106	\$ 0	\$ 135 (a)	\$ 118
Allowance for doubtful inventory	\$ 65	\$ 29	\$ 0	\$ 0	\$ 94
Year ended December 31, 2002					
Allowance for doubtful accounts receivable	\$ 300	\$ (153)	\$ 0	\$ 0	\$ 147
Allowance for doubtful inventory	\$ 548	\$ 0	\$ 0	\$ 483 (b)	\$ 65

(a) - write-off of uncollectible amounts

(b) - disposal of inventory

## THERAGENICS CORPORATION

### INDEX TO EXHIBITS

- 10.19 Additional Compensation Information
- 10.20 Short-Term Incentives
- 10.21 Long-Term Incentives
- 10.22 Forms of Option Award
- 10.23 Form of Restricted Stock Award
- 24.1 Consent of Independent Registered Public Accounting Firm for Incorporation by Reference of Audit Report into Registration Statements
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Chief Executive Officer pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Chief Financial Officer pursuant to Section 1350, Chapter 63 of Title 18, United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**CERTIFICATION**

I, M. Christine Jacobs, President and Chief Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of Theragenics Corporation®;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 15, 2005

/s/ M. Christine Jacobs

M. Christine Jacobs  
Chief Executive Officer

CERTIFICATION

I, James A. MacLennan, Chief Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of Theragenics Corporation®;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 15, 2005

/s/ James A. MacLennan  
James A. MacLennan  
Chief Financial Officer

CERTIFICATION PURSUANT TO  
SECTION 1350, CHAPTER 63 OF TITLE 18, UNITED STATES CODE,  
as adopted pursuant to  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Theragenics Corporation®, (the “Company”) on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, M. Christine Jacobs, President and Chief Executive Officer, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods referred to in the Report.

By: /s/ M. Christine Jacobs  
M. Christine Jacobs  
Chief Executive Officer  
March 15, 2005

A signed original of this written statement required by Section 906 has been provided to Theragenics Corporation® and will be retained by Theragenics Corporation® and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO  
SECTION 1350, CHAPTER 63 OF TITLE 18, UNITED STATES CODE,  
as adopted pursuant to  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Theragenics Corporation®, (the “Company”) on Form 10-K for the fiscal year ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, James A. MacLennan, Treasurer and Chief Financial Officer, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods referred to in the Report.

By: /s/ James A. MacLennan  
James A. MacLennan  
Treasurer and Chief Financial Officer  
March 15, 2005

A signed original of this written statement required by Section 906 has been provided to Theragenics Corporation® and will be retained by Theragenics Corporation® and furnished to the Securities and Exchange Commission or its staff upon request.

## Shareholder Information

### Investor Community Relations

Shareholders, registered representatives, professional investment managers and financial analysts who would like additional information about Theragenics Corporation® are invited to contact:

James A. MacLennan  
CFO and Treasurer  
Theragenics Corporation®  
5203 Bristol Industrial Way  
Buford, Georgia 30518  
800.998.8479 or 770.271.0233

### Access to SEC Filings

The Company's website address is [www.theragenics.com](http://www.theragenics.com). The Company's Annual Report on Form 10-K, quarterly reports on Forms 10-Q, current reports on Forms 8-K and all amendments to those reports are available free of charge through its website by clicking on the "Investor Relations" page and selecting "SEC Filings." These reports will be available as soon as reasonably practicable after such material has been electronically filed with, or furnished to, the SEC. These reports are also available through the SEC's website at [www.sec.gov](http://www.sec.gov). The information on these websites and the information contained therein or connected thereto are not intended to be incorporated by reference into this Annual Report on Form 10-K.

In addition, the Company will provide paper copies of these filings (without exhibits) free of charge to its shareholders upon request.

### Independent Certified Public Accountants

Grant Thornton LLP, Atlanta, Georgia

### General Counsel and Corporate Secretary

Tracy C. Caswell  
Theragenics Corporation®

### Annual Meeting

The Annual Meeting of the Shareholders will be held Tuesday, May 10, 2005, at 9:00 a.m., EDT, at:  
The Ritz-Carlton New York, Battery Park  
Two West Street and Battery Place  
New York, New York 10004

### Common Stock Price Ranges

Theragenics Corporation's® common stock is traded on the New York Stock Exchange (NYSE) under the symbol "TGX." The following table sets forth the quarterly high and low closing sale prices for the periods indicated as reported by the NYSE. The prices shown represent sale prices without retail markups, markdowns or commissions.

### Share Price of Common Stock

	2004		2003	
	High	Low	High	Low
First Quarter	\$ 6.20	\$ 5.00	\$ 4.71	\$ 3.12
Second Quarter	\$ 5.42	\$ 4.20	\$ 4.81	\$ 3.55
Third Quarter	\$ 4.60	\$ 3.53	\$ 6.02	\$ 4.05
Fourth Quarter	\$ 4.35	\$ 3.50	\$ 6.20	\$ 4.31

### Transfer Agent and Registrar

Shareholders wishing to change the name on their certificates, change their address or report a lost certificate should contact the transfer agent:

SunTrust Banks, Inc.  
Stock Transfer Department  
P.O. Box 4625  
Mail Code 008  
Atlanta, Georgia 30302  
404.588.7817

### Common Shareholders of Record

As of March 11, 2005, Theragenics™ had 529 holders of record of common stock.

### Dividend Policy

Theragenics™ has never paid cash dividends on its common stock and has no current plans to begin paying cash dividends.

**theragenics Corporation®**

**5203 Bristol Industrial Way, Buford, Georgia 30518**

**800.998.8479 or 770.271.0233 [www.theragenics.com](http://www.theragenics.com)**