COMPUTERIZED THERMAL IMAGING INC
Form 10KSB
October 13, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-KSB

(Mark One)

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

FOR THE FISCAL YEAR ENDED JUNE 30, 2004

|_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 1-16253

COMPUTERIZED THERMAL IMAGING, INC.

(Exact name of registrant as specified in its charter)

NEVADA	87-0458721
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1719 West 2800 South, Ogden, UT	84401
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number including area code: (801) 776-4700

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

Securities registered under Section 12(g) of the Act:
Common Stock
(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 |X| 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-KSB or any amendment to this Form 10-KSB. |_|

Revenues of the registrant for its most recent fiscal year were $356,710.

The aggregate market value of Common Stock held by non-affiliates of the registrant at September 1, 2004 was approximately $17 million. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded from this computation in that such persons may be deemed to be affiliates.

As of October 12, 2004, there were 114,561,698 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE None

COMPUTERIZED THERMAL IMAGING, INC.

FORM 10-KSB

ANNUAL REPORT

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PART I

PART I

THIS DOCUMENT, AND THE DOCUMENTS INCORPORATED BY REFERENCE, INCLUDING, BUT NOT LIMITED TO, CERTAIN STATEMENTS CONTAINED IN ITEM 1, "DESCRIPTION OF BUSINESS" AND ITEM 6, "MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS," CONTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS WHICH MAY CAUSE THE ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS OF THE COMPANY TO BE MATERIALLY DIFFERENT FROM ANY FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED. WHEN USED IN THIS DOCUMENT THE WORDS "EXPECTS," "ANTICIPATES," "INTENDS," "PLANS," "MAY," "BELIEVES," "SEEKS," "ESTIMATES" AND SIMILAR EXPRESSIONS GENERALLY IDENTIFY FORWARD-LOOKING STATEMENTS. ALL FORWARD-LOOKING STATEMENTS INCLUDED IN THIS DOCUMENT ARE BASED ON INFORMATION AVAILABLE TO THE COMPANY ON THE DATE HEREOF, AND WE ASSUME NO OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENT, EXCEPT AS OTHERWISE REQUIRED UNDER APPLICABLE LAWS AND REGULATIONS.

THIS DOCUMENT SHOULD BE READ IN CONJUNCTION WITH OUR AUDITED FINANCIAL STATEMENTS INCLUDED IN PART II BELOW AND "RISK FACTORS" NOTED BELOW.

ITEM 1. BUSINESS

INTRODUCTION

Computerized Thermal Imaging, Inc. ("we," "us," "CTI," or the "Company") designs, manufactures and markets thermal imaging and infrared devices and services used for clinical diagnosis, pain management and non-destructive testing of industrial products and materials. We are presently developing, manufacturing and/or marketing the following principal products:

- BREAST IMAGING: We are seeking pre-market approval from the U.S. Food and Drug Administration (the "FDA") of our breast imaging system, called the BCS 2100(TM), which, if approved and marketed, we believe will assist radiologists in their efforts to distinguish between benign and malignant breast masses. On January 23, 2003, the FDA declined to grant pre-market approval for the BCS 2100 and recommended additional data analysis, clinical trials and other steps that we might take to obtain FDA approval. As explained in greater detail in "Government Regulation--Pre-market Approval of the BCS 2100" beginning on page [15] below, we do not believe we currently have the resources necessary to conduct the additional clinical studies requested by the FDA, but we are

seeking to persuade the FDA to grant pre-market approval based on our existing data. Unless and until we receive final or conditional approval of the BCS 2100, we cannot sell, market or distribute the BCS 2100 in the United States, and lack of FDA approval significantly hinders marketing of this product in international markets. However, in April 2004 we received a Medical Device License from Health Canada to market the BCS 2100 in Canada. In late August 2004, we shipped the first BCS 2100 to Ville Marie in Montreal, Canada for a one-to-three month evaluation that may result in a lease of the device at the end of evaluation. We are also pursuing other potential customers in Canada.

- PAIN MANAGEMENT--PHOTONIC STIMULATOR: We are manufacturing and marketing our Photonic Stimulator, which emits infrared light that penetrates the skin in an effort to promote increased blood flow and circulation in order to provide temporary relief of minor aches and pains where heat is indicated.

- PAIN MANAGEMENT--THERMAL IMAGE PROCESSORS: We are manufacturing and marketing our Thermal Image Processor (or "TIP,") which uses the same infrared camera as the BCS 2100 to measure body heat naturally radiated by the patient as he/she stands (or sits) before the camera. The heat-measuring capabilities of the TIP are generally used to develop a physiological profile of a patient to assist in the diagnosis and treatment of a wide range of physiological and circulatory abnormalities, principally soft-tissue related injuries and pain. The TIP may also have application as a pre-screening device to identify persons with increased skin temperature at international parts of entry and other public facilities.

- TURBINE BLADE INSPECTION SYSTEM: Our Turbine Blade Inspection System (the "TBIS") is a quality assurance tool which, using techniques similar to our BCS 2100, meets industrial requirements for non-destructive testing and examination of turbine blades used in aircraft and power generation, and other industrial components, composite materials and metals.

We manufacture our products internally at our Ogden, Utah facility. Our Ogden facilities are certified to ISO 9000 quality standards.

Our common stock is quoted on the Over-the-Counter Bulletin Board or "OTCBB" under the symbol "CIOB." As of September 1, 2004, we had approximately 114 million shares of common stock outstanding held by approximately 20,000 shareholders. In addition to the outstanding shares of our common stock, there are outstanding exercisable warrants and options to acquire approximately 10 million shares of our common stock at exercise prices ranging from $0.22 to $5.00. Of the approximately 114 million fully-diluted shares of our common stock outstanding, 12.6 million shares are beneficially owned by insiders and affiliates. Other than our wholly-owned subsidiary, Bales Scientific, Inc., we have no interest in any other entity.

We were a development stage company and, to date, we have funded our business activities with funds raised through the private placement of common stock, debt and warrants, and the exercise of warrants and options. We are facing substantial financial challenges in that without sales we cannot support operations and without the cash from sales we cannot support a sales staff,

therefore we are seeking cash from either a private placement of equity or debt.

INDUSTRY OVERVIEW & TRENDS

The American Cancer Society estimated in 2003 that 211,300 new cases of invasive breast cancer would be diagnosed among women and an estimated 39,800 women in the United States would die from the disease during 2003. Except for skin cancer, breast cancer is the most commonly diagnosed cancer among American women, accounting for nearly one of every three new cancers diagnosed, and is the second leading cause of cancer death (after lung cancer). According to information compiled by Atairgin, a biotechnology company dedicated to improving the quality of care in women's health, each year more than 20 million women in the United States have a mammogram to screen for breast cancer. Approximately two million of those mammograms require additional follow-up due to a suspicious finding, and approximately 1.3 million abnormal mammograms require a breast biopsy to characterize the suspicious tissue as benign or malignant. The statistics compiled by Atairgin also indicate that approximately 20% of the suspicious tissues that are subjected to biopsies will turn out to be cancerous. In other words, more than 80% of these breast biopsies performed during 2002 were expected to yield benign results.

According to Atairgin's statistics, of the 1.3 million breast biopsies performed in the United States each year, approximately 800,000 are open surgical procedures where the patient is anesthetized or heavily sedated and a surgeon extracts the mass through an incision. The remaining approximately 500,000 biopsies are less invasive "core" biopsies, where a needle is guided to the region of interest and a sample is obtained without having to perform open surgery. We believe the trend is toward less invasive biopsy methods in an effort to reduce scaring, cost and emotional trauma.

If we receive pre-market approval from the FDA for our BCS 2100, we believe that, under prescribed circumstances, radiologists and surgeons will be able to use the physiological profile of the suspicious tissue produced by our BCS 2100 to determine whether breast masses are benign, without performing a biopsy. The target users of the BCS 2100 are the more than 10,000 certified mammography centers in the United States and more than 10,000 mammography centers throughout the rest of the world.

The primary target markets for our pain management products consist of over 50,000 chiropractors, pain management practitioners, occupational therapists, physical therapists and major sports teams in the United States looking for ways to diagnose and treat injuries and pain conditions effectively and quickly. Various reports estimate the number of Americans suffering from chronic pain at between 50 million and 80 million, and estimate that an additional 25 million Americans suffer acute injury-related pain, costing the United States economy between $50 billion and $100 billion annually in missed work days, emergency room visits, medications and other costs.

The primary target market for our industrial products is manufacturers of complex castings, particularly in the aerospace and power generation markets.

OUR PRODUCTS AND SERVICES

We have developed six significant proprietary technologies, four of which relate to the BCS 2100: 1) a climate-controlled examination unit to provide patient comfort and facilitate reproducible tests for the BCS 2100; 2) an imaging protocol designed to produce consistent results for the BCS 2100; 3) a statistical model that detects physiological irregularities for the BCS 2100; 4) infrared imaging and analysis hardware, including our proprietary heat-sensing camera, which is used in the BCS 2100 as well as our pain management and industrial systems (collectively, we refer to items 2-4 as our "Thermal Imaging Process"); 5) a system to treat pain and other symptoms of

diseases that restrict blood flow, which is used in the Photonic Stimulator; and 6) the TBIS.

Medical Products - BCS 2100

Our BCS 2100 provides a non-invasive, painless method to collect information that could supplement the information provided by mammograms for the evaluation of suspicious breast lesions. To receive a breast scan on the BCS 2100, a patient would lie face down on our device and expose one breast at a time to the flow of cold air. The breast is then observed by our infrared imager as it cools. Because malignant tissue is more vascular and less likely to constrict upon contact with cool air than benign tissue, malignancies are measurably warmer than benign tissue. The BCS 2100 captures 103 dynamic images of each breast and analyzes over 8.3 million temperature values per breast to measure minute changes in physiological and metabolic activity. From these measurements, the BCS 2100 is able to compute a mathematical probability and indicate the likelihood that a suspicious breast lesion is benign or malignant. We believe that this data, when combined with diagnostic information from mammograms, will provide radiologists with additional information that can be useful in determining more precisely when a surgical biopsy is needed.

Mammography and related imaging methods capture a snapshot of anatomical structure at a moment in time, but do not provide information about the behavior of the structures exposed. While mammography may detect the presence of an abnormality in the breast, a biopsy is required to determine whether the abnormality is benign or malignant. We believe our technology produces images that expose the physiology and function of breast tissue. If we receive FDA approval for the BCS 2100, we believe this physiological information can provide health professionals with a tool for more accurately discriminating between those cases that require invasive biopsy and those that do not; furthermore, we believe our BCS 2100 will be able to provide physiological data that can lead to fewer biopsies, 80% of which have benign findings.

We believe the BCS 2100 provides a tool that could detect cancer in almost all types of abnormal breast lesions: masses, micro-calcifications and architectural distortions. In our clinical trials, where BCS 2100 findings were confirmed by biopsy, we detected malignancy 96.4% of the time when cancer was present, and we believe we can improve this overall sensitivity with additional clinical research studies and statistical software development.

Our best sensitivity is with lesions classified as masses. According to our clinical trials, where BCS 2100 results were confirmed by biopsies, our BCS 2100 detected cancer in lesions described as masses 99.3% of the time when cancer was present. This means the BCS 2100 has a false negative rate of less than 1%. Our pre-market approval application addresses efficacy for all breast lesions, but later amendments and panel presentations focused on lesions described as "masses," which represent about half of all anomalies noted on mammograms referred for biopsy, and where the BCS 2100 had the best clinical sensitivity. If utilized as a decision tool, excluding all other factors, procedures and tests, we believe the BCS 2100 would have resulted in the deferral or avoidance of 19.2% of biopsies in women who had masses detected on their mammograms. The efficacy data presented shows a false positive rate (cases where results from the BCS 2100 indicated the possible presence of cancer when none existed) approximately 80% of the time when cancer was not present. We believe that ongoing clinical research and future developments in the software algorithms (statistical models), as part of the product maturation process and under FDA-approved procedures, will enable the BCS 2100 to safely achieve

significantly lower false positive rates, thereby leading to higher biopsy avoidance rates.

We view biopsy as the direct competition for the BCS 2100. According to the American College of Radiology, the average breast biopsy costs between $1,000 and $3,000 per patient. We believe that a breast scan on the BCS 2100 would cost a fraction of the cost of a biopsy and avoid the pain, risk of infection and other complications arising from an invasive surgical procedure.

We have not received FDA pre-market approval for the BCS2100 and, accordingly, are not presently permitted to market and sell the BCS 2100 in the United States. Medical device marketing and distribution efforts rely upon building relationships with other manufacturers (strategic alliances), equipment dealers, physicians and clinical investigators. Local distributors tend to have the essential relationships with hospitals that are difficult to duplicate with a captive sales force. In anticipation of possible FDA approval, we have initiated relationships with distributors who have established relationships in the radiology and medical imaging communities. Such persons have not, however, initiated efforts to market or sell the BCS 2100. We presently anticipate that unless and until we obtain FDA pre-market approval of the BCS2100, our marketing activities in the United States will be limited to our attendance at industry trade shows and professional conferences where we can present product information in an educational format to radiologists.

Curtailed operations and activities greatly hamper our ability to continue to sell at a level that will sustain operations.

Medical Products - Pain Management

We market two pain management devices used for diagnostic imaging and therapeutic treatment, the TIP and the Photonic Stimulator.

The TIP falls into a class of devices that the FDA permits to be marketed within the limitations of the following identification:

> A telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses in an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The TIP uses the same infrared camera as the BCS 2100 to measure body heat naturally radiated by the patient as he/she stands (or sits) before the camera. The heat-measuring capabilities of the TIP are generally used by our customers to develop a physiological profile of a patient to assist in the diagnosis and treatment of a wide range of physiological and circulatory abnormalities, principally soft-tissue related injuries and pain. We have not conducted clinical studies confirming the effectiveness of the TIP for any specific uses.

The TIP system competes indirectly with x-ray, computed tomography, ultrasound and magnetic resonance imaging ("MRI"). Medical practitioners typically view imaging technologies as elements of a toolkit, each uniquely

suited for the diagnosis of a specific problem or problems. The TIP also competes against infrared cameras available in the aftermarket and marketed by several small direct competitors.

The outbreak of Sudden Acute Respiratory Syndrome ("SARS") in recent years provided a new opportunity for employing the TIP as a pre-screening device at international ports of entry and other public facilities; e.g., train stations and airports. The TIP is not designed or calibrated to screen for SARS; however, the TIP is designed to provide an accurate reading of surface skin temperature. One of the outward symptoms of SARS (along with the common cold, flu and numerous other ailments) is elevated skin temperatures. The TIP can be used to identify persons with increased skin temperature, who would then be identified for further, more accurate and invasive testing procedures that could determine if the person is infected with SARS.

We have not marketed or sold any TIPs in the United States to entities that have expressed their intent to use the TIP as a pre-screening device for SARS. Because we have not sought or received pre-marketing approval of the TIP as a SARS screening device, we are not permitted to make claims that the TIP is effective as a SARS screening device. We may, however, make claims that the TIP is effective in reading surface skin temperatures. As described above, certain government authorities may find the ability of the TIP to detect elevated skin temperature useful in identifying symptoms that are consistent with (but not definitively indicative of) SARS or other diseases.

We have sold TIPs for pre-screening use into the People's Republic of China, and we are participating in a Canadian program to evaluate the use of infrared imaging for airport passenger screening. While these activities appear positive, we are uncertain whether SARS screening procedures using the TIP, or a competing thermal imaging device, will be adopted on a widespread basis. If adopted, we are uncertain that the TIP would be selected over alternative devices, which may be more suitable for such purpose.

The current suggested retail price for the TIP is $55,000. Our average selling price for new equipment during fiscal 2004 was $31,250 and during fiscal 2003 was $43,800. Our average selling price for reconditioned TIP is $28,000. Although we believe our TIP system competes favorably with aftermarket and other direct offerings in terms of capability and price, we expect TIP system prices to decline over time as a result of increased competition.

A complementary infrared light therapy device, our Photonic Stimulator, is a hand-held device that emits infrared energy which penetrates the skin to stimulate blood flow and promote circulation. The Photonic Stimulator falls into a class of devices that the FDA permits to be marketed within the limitations of the following identification:

> An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

In addition to its general classification, an approval statement of specifications attached to the authorization received from the FDA states: "The Photonic Stimulator emits infrared light that penetrates the skin to promote increased blood flow and circulation, thereby providing safe, temporary relief of minor aches and pains where heat is indicated."

The infrared light-focusing capabilities of the Photonic Stimulator are generally used by our customers to treat general aches and pains. Published reports written by practitioners who use the Photonic Stimulator indicate that infrared light therapy is also used in an attempt to promote circulation and speed healing. We have not conducted clinical studies confirming the effectiveness of the Photonic Stimulator for any specific uses.

The Photonic Stimulator competes with therapeutic ultrasound, electrical stimulation and newly-approved laser light therapy devices. The current suggested retail price of our Photonic Stimulator is $4,500. Our average selling price during 2004 was $2,600, and during 2003 was $2,130. We expect Photonic Stimulator resale prices to remain at current levels for the foreseeable future as we continue our efforts to expand unit volume and compete with other light therapy devices as light therapy becomes more accepted.

In order for us to expand our pain management segment, there must be increased market adoption of both the TIP and the Photonic Stimulator based on customer referrals, testimonials, and published third-party research in order to build credibility of products and earn expanded indications for use of the devices from the FDA. The adoption of new products may be adversely affected by general economic conditions, changes in insurance coverage offered by private insurers in response to the general economy and new competitive offerings. We cannot guarantee that customers will accept our products, or that we will be able to profitably manufacture and sell these products.

To date, pain management product marketing has relied upon trade advertising, word-of-mouth recommendations, public relations and media outreach, trade show attendance, direct and channel sales, and educational seminars, where products are demonstrated to groups of potential customers. We hold user group meetings and work with our current customer base to place articles and provide testimonials about how our pain management devices have impacted their practices and improved the condition of their patients.

We have a direct field sales team and a small inside sales team. To build credibility and to obtain additional market exposure, we have developed relationships with pain management dealers in California, Texas, Florida, New England and Asia who have established relationships and reputations in these markets.

Industrial - Non-Destructive Testing Products

Bales Scientific, Inc. ("Bales Scientific"), our wholly-owned subsidiary, provided industrial test services and has, for many years, designed and sold industrial test systems to customers who desire to perform their own testing. Our industrial non-destructive testing product focus has been the analysis of turbine blade defects. Turbine blades are very complex cast parts used in aircraft, power generation, pumps and compressors. Using techniques similar to those employed by our BCS 2100 and the infrared camera used in the BCS 2100 and TIP products, our TBIS creates thermal stress by rapidly heating a component, collecting a series of images as the component returns to ambient temperature, and then analyzing these images to determine the presence or absence of characteristics determined to correlate with certain manufacturing and usage-induced defects. The analysis identifies defects, abnormalities and flaws in the test material. This system can identify blockages in cooling holes as small as the diameter of a human hair. We believe that this technology is uniquely capable of testing blades automatically, quickly, inexpensively and without destroying or compromising the blade part. During the third quarter of fiscal 2003, to reduce cash outlays, we relocated this activity to our Ogden, Utah facility and closed the operations formerly conducted by Bales Scientific Walnut Creek, California.

The turbine blades tested using our TBIS include aircraft turbines employed in military aircraft, and electrical power turbines. TBIS sales have long lead times and require significant integration into the customer's production systems. TBIS sales have been infrequent, are dependent upon the health of the aerospace industry and general economic conditions, and there may be relatively few customers for this device.

TBIS base systems are generally priced in a range between $350,000 and $450,000 and compete with industrial x-ray, ultrasound and other technological approaches. This system provides a safe, effective and hygienic approach to locating product defects, and requires no disposable supplies; i.e., x-ray film. We also market smaller, less expensive systems utilizing our TIP and an alternative thermal stimulus device with a suggested retail price of approximately $130,000. We market these products directly to engine and power system manufacturers and other industrial customers. These products typically have long sales cycles, and demand is directly impacted by general economic conditions.

PATENTS

As of June 30, 2004, we had the following patents or patent applications pending before the United States Patent and Trademark Office:

- Patent No. 5,999,842, dated December 7, 1999, acquired by assignment from TRW on a Functional Thermal Imaging Apparatus (our BCS 2100 Patient Positioning Table).
- Patent No. 6,157,854, dated December 5, 2000, covering techniques designed to reduce or eliminate pain by the application of infrared therapy while monitoring the process as it is being conducted. The techniques involve the use of our Photonic Stimulator to apply infrared energy to a patient while using the TIP to monitor the patient's response to the therapy.
- Patent No. 6,366,802, dated April 2, 2002, covering techniques designed to reduce or eliminate pain by the application of infrared therapy while monitoring the process as it is being conducted. The techniques involve the use of our Photonic Stimulator to apply infrared energy to a patient while using the TIP to monitor the patient's response to the therapy.
- Patent No. 6,570,175, dated May 27, 2003, covering an infrared imaging arrangement for the turbine component inspection system covering the overall fixture and infrared imager arrangement
- Patent No. 6,711,506, dated March 23, 2004, covering software providing operator assistance during the use of an automated infrared inspection system of turbine components.
- Patent No. 6,750,454, dated June 15, 2004, covering software performing automated analysis of the thermal response of a turbine component to application of thermal stimuli by an infrared inspection system.
- Patent No. 6,757,412, dated June 29, 2004, covering an algorithm used to analyze imaging data collected through our BCS 2100 Patent application (Serial No. 10/062,862, dated January 31, 2002) for a heat exchanger for turbine component inspection system covering an improved convective heat exchanger design for use in the turbine component inspection system.
- Patent application (Serial No. 10/677,100, dated September 30, 2003) for design and evaluation of actively cooled turbine

components.

- Patent application (Serial No. 60/378,764, dated May 7, 2002) for the cold stimulus turbine component inspection system.

Subject to the availability of capital, we hope to pursue the registration of additional copyrights, patents and trademarks in the United States; however, we presently lack the resources to pursue any additional intellectual property protection. We believe that our patents and patent applications are valid and enforceable and provide some competitive protection for our products; however, any of our patents or other intellectual property rights may be challenged, invalidated or circumvented, or the rights granted thereunder may not provide any competitive advantage. We could also incur substantial costs in asserting our intellectual property or proprietary rights against others, including any such rights obtained from third parties, and/or defending any infringement suits brought against us. We do not currently possess the resources necessary to assert or defend our intellectual property rights. Although we generally enter into confidentiality and invention assignment agreements with our employees and consultants, there can be no assurance that we have done so with all relevant employees and consultants, that such agreements will be honored or that we will be able to effectively protect our rights to unpatented trade secrets and know-how. Moreover, there can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how. We may be required to obtain licenses to certain intellectual property or other proprietary rights from third parties. Such licenses or proprietary rights may not be made available under acceptable terms, if at all. If we do not obtain required licenses or proprietary rights, we could encounter delays in product development or find that the development or sale of products requiring such licenses is foreclosed.

SOURCE OF SUPPLY

Manufacture and assembly of our pain management and thermal imaging devices require standard electronic components, formed or machined metal and plastic parts, wiring harnesses, printed circuit boards and metal cases which are available from any number of suppliers with relatively short lead times. We single-source certain proprietary optical components and cooling equipment; these typically require 12 to 16-week lead times. To date, we have experienced no supply disruptions with these vendors. While there are alternative sources for these products, the loss of one of our current suppliers would require that we invest time developing and certifying a new supplier. Until the new vendor is located and certified, we could experience a disruption in ability to supply TIP systems, which are a component of the BCS 2100 and our industrial products.

BUSINESS STRATEGY AND PRODUCT DEVELOPMENT

We believe our products and technologies provide a unique collection of cost-effective diagnostic, pain management and product testing solutions for medical and industrial customers. Our target customers are hospital radiology departments, cancer research facilities and imaging centers, chiropractors and physical therapists, and manufacturers of products with complex cast components or processes.

Critical to our business strategy is to obtain the required approval from the FDA with respect to our BCS 2100 and our pain management products. As described in greater detail below under "Government Regulation," we have

obtained Section 510(k) approval for our Photonic Stimulator and TIP. Section 510(k) approval which permits us to market and sell such products for the uses described in the approval letter and the applicable section of the Code of Federal Regulations. As described in greater detail below, we have applied for, but have not received, pre-market approval with respect to our BCS 2100. We believe that securing pre-market approval for the BCS 2100 is essential to our efforts to develop and market the BCS 2100 because, without such approval, we will not be able to market the BCS 2100 as a breast cancer screening device in the United States, obtain insurance payment codes or develop physician acceptance of our system.

Our marketing efforts rely upon building relationships with manufacturers, local medical equipment dealers, physicians and clinical investigators. We established a medical advisory board to assist us in preparing for the FDA panel meeting and to help us devise programs and projects to facilitate acceptance in the market place. We have also attended trade shows and conferences and make direct sales calls to industrial customers and sponsor clinics, where we introduce and demonstrate our breast imaging, pain management and non-destructive testing products. We believe marketing our medical products directly and through a dealer channel, augmented with trade shows, conference presentations, direct mail and inside sales, provides a cost-effective approach to diagnostic imaging and pain management practitioners. As of August 31, 2004 our medical advisory board was dormant, we had discontinued trade show participation and had limited our marketing activities to user group meetings with current and potential customers and direct selling; however, if we are successful in securing additional capital, we plan to continue investing resources in these programs.

As with all medical devices, it is important that our BCS 2100 customers receive adequate reimbursements from third-party payers: insurance companies, Medicare and Medicaid reimbursement agencies. We applied for a reimbursement code from the American Medical Association during December 2001 for our BCS 2100. Our application will not be acted upon unless and until we receive FDA pre-market approval for the BCS 2100.

Our pain management products qualify for insurance reimbursement in most states at rates that vary on a state-by-state basis. Generally insurance providers offer coverage if the state's workers compensation scheme recommends coverage. Currently only New York, Montana and Minnesota do not recommend coverage for treatments that include infrared imaging or infrared therapy. Average reimbursement for an infrared imaging procedure with our TIP camera, in states offering reimbursement, is $198, with a high of $375 and a low of $96. Average reimbursement for an infrared treatment with the Photonic Stimulator is $12, with a high of $38 and a low of $4 per treatment.

In order to conserve cash as we seek FDA approval for the BCS 2100, we have scaled back operations and staffing levels by, among other things, reducing our research and development group from 16 full-time employees in the fall of 2002 to one part-time employee in August 2004 and reducing our manufacturing group from 20 full-time employees in the fall of 2002 to 2 full-time employees in August 2004. In addition, we were in the process of developing temperature screening software for the TIP to include a fever detection algorithm, color-map settings for fever threshold, reporting, and networking, but suspended development of the software in June 2003 due to lack of resources. Nevertheless, we continue to expend financial and technical resources improving and developing certain applications for our medical products. Specifically, we have upgraded

certain software developments for the camera used in the BCS 2100 and the TIP, have commenced but not completed a project to reduce the size and weight and improve operator efficiency and clinical effectiveness of the BCS 2100, have added circuitry to the camera detectors in order to reduce noise and improve imaging, and have upgraded the TIP application software (including new release targeted to healthcare professionals).

COMPETITION

MEDICAL IMAGING. The principal methods used to visualize internal human anatomy are x-ray, computed tomography, ultrasound and MRI. Physicians view these technologies as elements of a toolkit, each uniquely suited to the diagnosis of a specific problem or problems.

Our BCS 2100 provides physiological information that supplements the anatomical information obtained from mammography and does not compete directly with x-ray, computed tomography, ultrasound or MRI. Our system is painless, requires no radioactive materials and involves no invasive technology.

Our pain management products compete with ultra-sound, electrical stimulation, newly approved laser light therapy devices and infrared cameras purchased from competitors or in the aftermarket for infrared cameras.

Our industrial applications compete with industrial x-ray, and high pressure water and air techniques; which require skilled labor, are time consuming and may utilize dangerous radiation that requires special facilities. Our TBIS provides additional defect analysis more quickly by using less skilled labor and no special environment, and may replace high pressure water and air or x-ray for certain applications.

The companies that supply diagnostic and industrial imaging equipment range from large manufacturers to smaller specialized companies. Large diversified manufacturers, for which imaging systems define only a portion of their total business, include General Electric, Siemens, Toshiba, Hitachi and Philips.

NEW TECHNOLOGIES. Digital x-ray captures images electronically and may provide several important benefits relative to existing technologies: 1) reduced radiation dosage; 2) faster access to images, which is critical for emergency room use; 3) the ability to distribute and access an image through a computer, enabling remote consultation; and 4) reductions in labor and radiographic film costs. Our BCS 2100 does not compete with digital x-ray equipment. In fact, as mammography technology improves, we believe more women will be referred for biopsies. We believe this will create a greater demand for technologies, like our BCS 2100, that may be able to determine whether a patient's mass is benign without the use of an invasive surgical procedure.

Positron Emission Tomography ("PET"), a nuclear medicine-based diagnostic imaging technique for measuring the metabolic activity of human cells, may benefit patients suffering from certain types of cancer or certain conditions affecting the brain and heart. Many insurance carriers approve PET, but the technology is expensive and difficult to administer.

Optical imaging of the breast is based on laser transillumination. This technology is under investigation as a possible approach for medical imaging, and at least one potential competitor is attempting to secure FDA approval for its version of this technology. Laser transillumination has been investigated for over 20 years and recent implementations of this technology used computed tomography to improve the results. We believe our BCS 2100 competes favorably with this technology.

PROCEDURES. We view biopsies, either needle aspiration or open surgery, as direct competition for the BCS 2100. We believe that the BCS 2100, if approved by the FDA with the indications for use we have requested, will be adjunctive to mammography, and that every patient with an abnormal mammogram indicating a mass, who might be referred to biopsy under current protocols, will be a potential candidate for a BCS 2100 procedure. We believe that, through the product maturation process involving additional product development, we will be able to obtain expanded indications for use and effectively screen all patients referred for biopsy. To successfully market our product, which can occur in the United States only if we receive FDA approval, we will have to educate physicians about the BCS 2100 so that they will be able to recommend a BCS 2100 procedure to their patients, persuade hospitals and imaging centers to purchase the equipment and convince insurance carriers to provide reimbursement for the BCS 2100 procedure.

OUR SALES AND MARKETING STRATEGY

OVERVIEW. We plan to market our products with a multi-channel strategy incorporating independent distributors, direct marketing, telemarketing, the internet and corporate marketing. We plan to address the industrial market with a direct sales force augmented by distributors and dealer representatives as appropriate.

DISTRIBUTORS. We have retained and intend to continue to seek the services of distributors. Our distributors usually focus their efforts on a specific channel in a specific region; e.g. chiropractors and physical therapists in Northern California. We believe that distributors provide intimate local market knowledge and contacts critical to accessing hospital imaging facilities, radiologists, chiropractors and physical therapists, and local service capability. Our agreements with these distributors allow the distributor to purchase products at a discount from list price, usually 30%, and provide extended terms for an initial order of demonstration equipment, which we do not recognize as a sale until the distributor actually pays for the equipment. We retain the right to develop and service national accounts in the distributor's territory, but provide a period of limited exclusivity with regard to the distributor's own customers, which can be extended only if the distributor meets certain sales goals. To date, no distributor has met these goals. We also require the distributor to participate with us in certain marketing programs, such as user group meetings.

TELEMARKETING / TELESALES. We believe telemarketing/telesales provides important direct marketing, lead follow-up and customer service capability, particularly in the pain management segment. Telemarketing creates revenue through direct sales and generates leads for distributors. However, due to limited resources, our use of telemarketing and telesales has been limited.

INTERNET. We use the internet to provide information to current and potential customers. Our web address is www.cti-net.com.

USER GROUPS AND SEMINARS. We believe meeting with our customers and potential customers at informal user conferences and training sessions provides valuable market intelligence, product use information, and assists us in selling our products. We have conducted user group meetings at various sites across the United States and by conference call.

TRADE SHOWS AND ASSOCIATIONS. From time to time, we have attended medical and industrial trade shows and presented papers at professional conferences. We

believe attendance at trade shows and conferences allows us to build product awareness, demonstrate our products, educate customers and generate leads for future sales.

CORPORATE MARKETING. To the extent our working capital permits, we intend to develop product and corporate collateral materials, advertise in select trade journals, demonstrate our products and present papers, and research results at conferences and trade shows. We believe these activities will build product and corporate awareness and support our sales efforts in selected vertical markets.

INDUSTRIAL PRODUCTS. We have a small internal team pursuing industrial opportunities. This team manages relationships with existing and potential customers in the turbine power market and is exploring potential relationships with industrial customers requiring non-destructive testing capabilities.

SERVICE PROVIDERS AND CONTRACTOR RELATIONSHIPS

CONTRACTOR RELATIONSHIPS. Our business model relies upon contractors and suppliers to reduce our development risk and to provide necessary clinical resources. During the course of preparing our FDA pre-market approval application and conducting regular clinical studies, we engaged the services of certain contractors, including Battelle Memorial Institute, which assisted us in the preparation of regulatory submissions and provided technical consulting services, on a time and materials basis, in connection with algorithm development and statistical consultation for interaction with the FDA. We have terminated our relationship with Battelle because of a shortage of working capital. If we were to require such consulting services in the future in connection with a supplement to our pre-market approval application or otherwise, replacing Battelle would be costly and difficult (because any competing entity would be unfamiliar with our data). We hope Battelle would continue to work with us if needed in the future (if we provide a sufficient retainer), but we have no contractual commitments to that effect.

We have also used the services of Quintiles, Inc., an independent consulting firm authorized by the FDA, to verify clinical examination results, to provide clinical trial monitoring and FDA preparation support. We have terminated our relationship with Quintiles because we no longer need their services. If we were to require such consulting services in the future in connection with a supplement to our pre-market approval application or otherwise, we believe Quintiles would continue to work with us if we provided a sufficient retainer, but we have no contractual commitments to that effect. If we were unable to engage Quintiles again, we believe we could find alternative providers of similar services at similar rates.

CLINICAL TRIALS. Previously, we contracted with six hospitals to conduct the clinical trials necessary for FDA approval of the BCS 2100. The six hospitals are:

- USC/Norris Comprehensive Cancer Center, Los Angeles;
- Los Angeles County Hospital, Los Angeles;
- Mt. Sinai Hospital, Miami;
- St. Agnes Hospital, Baltimore;
- Lahey Clinic, Boston; and
- Providence Hospital, Washington, D.C.

We do not have any ongoing contractual relationships with any of these

institutions, and no clinical trials are ongoing. We continue to have periodic contacts with officials at the USC/Norris Comprehensive Cancer Center and the Lahey Clinic, and believe that such persons would be available for consulting and other services if requested, but we have no written commitments to such effect.

CLINICAL STUDIES. Clinical studies are clinical research conducted for purposes of developing expanded indications for use, testing product enhancements, identifying potential product issues and obtaining product trials by practitioners and patients. Clinical trials are experiments where patient results are withheld from us pursuant to experimental controls designed to ensure scientific accuracy and are conducted in connection with obtaining FDA pre-market approval.

If we obtain pre-market approval from the FDA for our BCS 2100, of which we can provide no assurance, we plan to expand our clinical studies utilizing the BCS 2100 with institutions and practitioners to obtain user feedback, test product enhancements and secure technical papers, and for training and educational marketing purposes. During 2002, we entered into a research relationship with McKay-Dee Hospital in Ogden, Utah for a study of up to 70 patients referred for biopsy of a single mass after undergoing conventional diagnostic procedures. We conducted this study to acquire information about the effectiveness of the BCS 2100 for women age 60 and over presenting with a lesion described as a mass. We ended this study during the third quarter of fiscal 2003, without conclusion, when it became apparent that the institution did not treat sufficient patients to complete the study in a timely fashion. A separate study at McKay-Dee Hospital involved 125 women to obtain baseline information regarding the characteristic thermal profile associated with normal breast tissue in women 21 and older. We concluded this study during March 2002 and are holding the data for further analysis if we receive FDA approval. We also initiated a study at Massachusetts General Hospital, Harvard Medical School's largest teaching hospital, for a clinical

study involving up to 250 patients referred for biopsy of a single mass after undergoing conventional diagnostic procedures. This study was intended to acquire information to study the effectiveness of the BCS 2100 in women age 60 and under who present with a lesion described as a mass. This study is on hold, pending the FDA's final decision regarding our application for pre-market approval of the BCS 2100. These studies could provide us with an opportunity to evaluate the form and function of the BCS 2100 and develop product enhancements for next generation products. We are currently conducting a study with the Photonic Stimulator, evaluating its effect on neck and shoulder pain. We are not currently conducting clinical studies or trials for our TIP or Photonic Stimulator.

In addition, we have utilized the services of Regulatory Insight, Inc., an independent clinical research organization, to conduct a study with our Photonic Stimulator to evaluate its effect on neck and shoulder pain after a limited course of treatment. Under our agreement with Regulatory Insight, they agreed to develop a protocol for the study, submit the protocol to the FDA for review, and conduct a study in accordance with the protocol in exchange for our payment of a fee, reimbursement of expenses and provision of training and materials. Regulatory Insight has completed their analysis of data collected, and the study is completed. We cannot guarantee customer acceptance, published results, expanded indications for use or the effectiveness of any product enhancement or protocol tested in connection with these efforts. We believe,

however, these efforts are important and intend to continue this activity if we obtain sufficient capital to continue our operations.

GOVERNMENT REGULATION

OVERVIEW. Our BCS 2100, Photonic Stimulator and TIP qualify as medical devices under U.S. federal law because they are intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease but do not interact chemically with the body. Medical devices are divided into three classes under FDA regulations. Low risk devices that are substantially similar to approved products already on the market are classified as Class I or Class II devices and may be marketed if approved by the FDA following submission of a fairly simple Section 510(k) filing. Sophisticated instruments that entail significant risk, or utilize unique or new technology, are classified as Class III devices and, as further described below, may not be marketed absent a comprehensive FDA review and pre-market authorization.

All Class I, II and III devices are subject to certain requirements after the marketing of the product is approved by the FDA, including rules requiring the following:

- that the manufacturer register with the FDA and list its devices with the FDA;
- that the manufacturer label the devices for their approved use and otherwise in accordance with governing rules;
- that the manufacturer maintain manufacturing processes in accordance with the FDA's regulations and prescribed procedures regarding manufacturing processes, including a quality assurance system, document control and manufacturing and design control requirements promulgated by the FDA;
- that the manufacturer report adverse events with respect to such devices and maintain a corrective and preventative action program; and
- that the manufacturer comply with certain export and import limitations.

In the event a manufacturer (including CTI) is found to be out-of-compliance with any of these regulations, the FDA may require the manufacturer to cease production and marketing until corrective measures have been implemented. The FDA also could require a product recall and could enforce civil and criminal penalties against the manufacturer, its officers and others.

Certain rules promulgated by the FDA, which relate to Class III products, do not generally relate to Class I or II products. Such rules include those mandating the following:

- that an investigational device exemption be obtained in connection with clinical studies,
- that the manufacturer adhere to specified clinical and investigational practices and procedures (called Good Clinical Practices) in connection with its studies,
- that the manufacturer obtain specified approvals from an institutional review board at each study site,

- that the manufacturer monitor, and permit the monitoring of, clinical sites and data to assure adherence to protocol,

- that the manufacturer report any adverse patient reactions that might occur in connection with its studies, and
- the manufacturer submit, as requested, to an FDA audit of clinical trials in connection with approving pre-market approval. During September 2002, the FDA conducted such an audit of our clinical trials at our Ogden, Utah, facility and concluded that our clinical trials were conducted in compliance with FDA regulations.

Most significantly, the FDA rules related to Class III medical devices prohibit making claims of efficacy in connection with the marketing and sale of the device unless and until pre-market approval has been obtained following a determination by the FDA that the pre-marketing application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use.

THE TIP AND PHOTONIC STIMULATOR. Our pain management products, the TIP and Photonic Stimulator, are Class II devices. The Photonic Stimulator received Section 510(k) approval under a generic category as "an infrared lamp ... intended for medical purposes that emits energy at infrared frequencies to provide topical heating" on April 15, 1998. Our TIP received Section 510(k) approval on April 26, 1990 under a generic category as a "telethermographic system for adjunctive diagnostic screening for detection of breast cancer or other uses in an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body." As required by governing rules, each of the TIP and the Photonic Stimulator is listed with the FDA and labeled, manufactured and designed according to governing rules. We have not experienced any adverse events with respect to the Photonic Stimulator or the TIP, have not had to recall either such product and have not had any penalty or legal remedies exercised against us by the FDA with respect to such products. In connection with our export of the Photonic Stimulator and TIP to foreign countries, we have obtained (in accordance with import regulations of the destination countries) certification of United States clearance and complied with specific labeling and quality management requirements. As explained above, because the TIP and Photonic Stimulator are not Class III devices, rules related to investigational device exemptions, clinical investigator monitoring, institutional review board approval and pre-market approval do not apply to such devices.

THE BCS 2100. The BCS 2100 is a Class III medical device. As a result, we obtained an investigational device exemption in connection with the commencement of clinical studies on the BCS 2100. In addition, our clinical studies with respect to the BCS 2100 were subject to monitoring and conducted in accordance with Good Clinical Practices. Our clinical studies were reviewed and monitored by institutional review boards at USC/Norris Comprehensive Cancer Center in Los Angeles, Mt. Sinai Hospital in Miami, St. Agnes Hospital in Baltimore, Lahey Clinic in Boston and Providence Hospital in Washington, D.C. As described in greater detail below, we have requested from the FDA pre-market approval for our BCS 2100 but have not obtained it. Until we obtain pre-market approval for the BCS2100, we are not permitted to market or sell the device in the United States or list it with the FDA. Because pre-market approval has not been obtained, FDA rules related to listing, labeling, and manufacturing (other than design controls) do not yet apply. In addition, because we are not yet marketing the BCS 2100, we have not had any adverse events, recalls or penalties from the FDA with respect thereto. We have sold a single BCS 2100 to a purchaser in the Peoples Republic of China, and we obtained the requisite export permit with respect to such single sale.

PRE-MARKET APPROVAL OF THE BCS 2100. As noted above, we are not permitted to market the BCS 2100 or make claims of efficacy with respect thereto unless and until our application for pre-market approval is approved by the FDA. An application for pre-market approval typically contains significant clinical

testing, manufacturing and other data, all of which are scrutinized by the FDA to demonstrate the product's safety, reliability and effectiveness, and that proposed indications and conditions for use are appropriate. Typically, less than 40 devices a year are granted pre-market approval. Only companies that are registered with the FDA can submit a 510(k) or pre-market approval application. As a registered company, we obtained the clearance necessary to conduct clinical tests and submit the request for pre-market approval of the BCS 2100 by the FDA.

For the past five years, we have pursued pre-market approval for our BCS 2100 as an adjunct diagnostic tool to mammography in patients with suspicious breast lesions that include mass being considered for biopsy. We believe pre-market approval is essential because pre-market approval 1) permits us to reference medical efficacy claims in our marketing; 2) leads to improved physician acceptance of our system; and 3) is a key step in the process of obtaining insurance reimbursement codes.

We submitted our application for pre-market approval in five modules. Module 1 provided:

- An introduction of the use of infrared imaging, its safety and effectiveness;
- Summary of indications for use of infrared imaging as an adjunct to mammography and clinical examination in the detection of breast cancer;
- Summary of incidence, diagnosis and prognosis of breast cancer;
- Description of current modalities for detecting breast cancer;
- Description of our BCS 2100, including major components and the population for which our device has clinical utility;
- Description of our clinical trial and the population of the trial; and
- Statement of marketing of our device for its intended use.

Module 2 provided:

- A detailed description of our BCS 2100 and its component parts;
- Detailed discussion of the clinical evaluation system required to analyze and interpret the clinical data obtained through the clinical trial; and
- Documentation of all software used in our BCS 2100, including software used in the development of our system and the acquisition of data in our clinical trial.

Module 3 provided:

- Manufacturing information concerning our BCS 2100, including a detailed discussion of the facilities, personnel, equipment and controls used to manufacture our system;
- Information concerning the distribution and installation of our system; and
- A description of the procedures and record keeping associated with the manufacture, testing and installation of our device.

Module 4 reiterated certain information and provided additional information regarding:

- The safety of our BCS 2100, including all non-clinical testing of

the structural and functional components of our device; and
- The safety of materials used in manufacturing our system.

Finally, Module 5 was an evaluation of our clinical trials, including the accumulation and analysis of all the clinical trials, efficacy data and an update to our indicated use as follows: "The CTI BCS 2100 is a dynamic, computerized infrared-based image acquisition device intended for use as an adjunct to mammography in patients with suspicious breast lesions that include masses being considered for biopsy. The CTI BCS 2100 provides additional information to guide a breast biopsy recommendation."

On December 10, 2002, the FDA's Radiological Devices Panel, which is composed of independent experts, was convened by the FDA and held a public hearing to evaluate our application in order to make a recommendation to the FDA whether to approve or disapprove the BCS 2100 for its intended uses. The panel, by a vote of 4-3, recommended that the FDA not approve the BCS 2100. On January 23, 2003, the FDA concurred with that recommendation. In a letter dated January 23, 2003, the FDA identified the following reasons for its denial of the application:

- The proposed indications for use (IFU) were revised (i.e., restricted to women with masses visible on mammography) on the basis of a retrospective analysis of the results of CTI's clinical study in the original approval dated June 15, 2001, which the FDA believed had the effect of limiting further use of the approval result for the purpose of supporting the proposed new IFU.

- The FDA concluded that the added clinical data from 69 of 275 subjects in the "post-approval" (the "PPMA") results were insufficient by themselves (i.e. too few subjects) to constitute an adequate study. The FDA concluded that combining the PPMA data with the original approval data, employing the Bonferroni correction, would be statistically inappropriate in the absence of multiple formal hypotheses.

- The FDA determined that the basis for enrollment was not consistent with the final proposed IFU. That is, the FDA believes enrollment was not limited to mammographically visible masses.

- The FDA concluded that the number of exclusions of enrolled subjects was excessive - over 50%.

In the same letter, the FDA explained that, in order to place our application for approval in approvable form, we should do the following:

- Perform a new, focused pre-market clinical study which clearly defines the target population for the device, and strictly adhere to this definition for the enrollment of subjects.

- Before beginning the new study, revise the IFU (in particular, the target population) based on exhaustive data mining of the approval/PPMA database.

- Perform a reproducibility study that takes into account the variations that may be encountered in clinical practice. This should include such things as patient positioning, room

temperature, different technologists, different radiologists (ROI selection variances), menstrual cycle, etc.

- Provide a validated quality assurance procedure that the user can perform on a daily basis to ensure that the device is performing properly. Include instructions for corrective action if it is not.

In light of our shortage of working capital, we do not currently have the resources necessary to conduct the additional clinical study requested by the FDA. We disagree with the FDA's conclusions, including the FDA's interpretation of data forming the basis for such conclusions In an attempt to secure approval without conducting the request clinical study and other tasks, we have corresponded and met face to face with the FDA's ombudsman, Deputy Commissioner, Chief Counsel and other staff on various occasions in an attempt to persuade them that the conclusions of the FDA's Radiological Devices Panel and the decision of the FDA were incorrect. We have also described our situation to government officials outside of the FDA, including the staffs of various congressmen, and asked such persons to encourage the FDA to reconsider its decision.

On March 19, 2004, we received from the FDA's Center for Devices and Radiological Health a memorandum addressing the potential bases for pre-market approval of the BCS 2100. The FDA's memorandum did not grant us pre-market approval of the BCS 2100; however, it did identify two additional approaches for obtaining pre-market approval, and indicated that, although a new clinical study would be required under either alternative approach, the number of subjects required to complete either study would be considerably less than the number of subjects that would be required to complete our pending studies.

Our management have reviewed the FDA's March 19, 2004 memorandum in an effort to determine the most efficient path to obtaining pre-market approval of the BCS 2100. We have also reviewed the FDA's alternative approaches to assess the anticipated impact of the two approaches on our ability to develop market and sell the BCS 2100, as well as the use of the BCS 2100 by our customers. We are pursuing the methods we believe to be fiscally responsible given our difficult financial situation to obtain FDA approval. Unless and until we receive approval or conditional approval), we cannot sell, market or distribute the BCS 2100 for commercial use in the United States. The BCS 2100 has been licensed for sale for commercial use in Canada and is in the approval process in China through our contracted affiliate NanDa.

On June 30, 2004 we filed a "Citizen Petition" with the FDA contending that consideration of our application for pre-market approval was severely and improperly prejudiced because of pervasive bias against CTI by the Food and Drug Administration staff reviewers who improperly undermined the Advisory Panel's review of our application and ultimately caused the FDA to reject that application. We seek internal documents within the FDA to help us understand what prejudiced the FDA staff. The full text of the full Citizen Petition and 23 exhibits thereto are available at http://www.fda.gov/ohrms/dockets/dailys/04/july04/070104/04p-0276-cp00001-toc.htm.

CURRENT EMPLOYEES

As of September 1, 2004, we had six full-time employees: three general and administrative, one sales and marketing, one research, software and

engineering, and one manufacturing and service. Though generally categorized as mentioned, the reduced number of employees requires each employee to "cross task" in each area of operation. Consultants are used in each area then needed. None of our employees are represented by a union and we consider our employee relations to be good.

RISK FACTORS

INVESTMENT IN SHARES OF OUR COMMON STOCK IS SUBJECT TO A NUMBER OF RISK FACTORS THAT, IF REALIZED OR COME TO FRUITION, MAY ADVERSELY AFFECT OUR PROFITABILITY AND THE VALUE OF THESE SHARES WHILE HELD BY OUR SHAREHOLDERS.

OUR AUDITORS HAVE QUESTIONED OUR ABILITY TO CONTINUE OUR OPERATIONS.

For the years ended June 30, 2004, 2003 and 2002, our auditors issued their audit report with a going concern qualification. This means that, based on our expected cash flow from operations and our existing current assets, our auditors did not believe that we would be able to continue our operations in their current form through the end of our 2005 fiscal year. At present, we are not generating sufficient operating revenues to offset our operating expenses. We have experienced a loss from operations in every fiscal year since our inception. As a result of these losses, we had working capital deficits throughout our 2004 fiscal year. Working capital is a measure of the amount of liquid assets an enterprise has available to build its business. Our working capital deficit is an indication that we currently lack the liquid funds required to operate our business. We can provide no assurance that we will ever generate sufficient revenues to restore our working capital or to continue our operations.

WE DO NOT CURRENTLY HAVE SUFFICIENT CAPITAL TO MEET OUR OBLIGATIONS.

As of June 30, 2004, we had $169 thousand in cash and a working capital deficit of $1.5 million. Accordingly, we did not have sufficient capital to conduct our operations or pay all of our debts when due. The only way we will be able to continue our business operations will be if we are able to obtain outside financing to fund our business operations and satisfy our liabilities. We hope to use a combination of equity and debt securities and instruments in order to secure additional funding; however, we do not presently have any funding or financing commitments from prospective investors or lenders, and can provide no assurance that we will be able to secure additional funding from any source or, if available, upon acceptable terms and conditions. We have actively sought to obtain funding from external sources and, except for limited circumstances, we have not been successful in obtaining capital necessary to continue operations throughout the next fiscal year. We may not be able to obtain the amount of additional capital we need or may be forced to pay an extremely high price for capital. Factors which may affect the availability and price of capital include the following:

- Market conditions affecting the availability and cost of capital generally;
- our financial results, particularly the absence of significant revenue;
- our success, or lack thereof, in obtaining FDA pre-market approval of BCS 2100;
- the amount of our capital needs;
- the market's perception of biotechnology stocks;

- the market's perception of our ability to generate revenues through the sale of our products and services; and

- the price, volatility and trading volume of our common stock.

If our losses continue and we are unable to obtain additional third-party financing or proceeds from the sale of certain of our assets, we will likely be unable to continue our business operations, may be forced to liquidate our assets and may elect to seek protection under federal bankruptcy laws, which could adversely affect us and our shareholders.

OUR FAILURE TO OBTAIN FDA APPROVAL OF OUR BCS 2100 HAS SIGNIFICANTLY LIMITED OUR BUSINESS OPERATIONS AND COULD RESULT IN THE COMPLETE TERMINATION OF OUR OPERATIONS.

On January 23, 2003, the FDA concurred with the recommendation of its Radiological Devices Advisory Panel to decline approval of our BCS 2100. The FDA's decision, if not modified, precludes us from marketing the BCS 2100 in the United States. Since the FDA's decision, we have advocated a reversal or modification of the decision through multiple channels, but have been unsuccessful in our efforts. We may formally appeal the FDA's non-approval decision; however, an appeal would be expensive and time-consuming, and we do not presently have the financial resources to sustain our operations or pursue an appeal. We do not know whether our negotiations or any appeal we might file will be successful. There is no assurance that we will receive FDA approval. Our efforts to obtain FDA pre-market approval of the BCS 2100 have substantially depleted our financial and other resources, which has led to significant reductions in our operations and threatens our ability to fund our operations. Failure to secure FDA approval would materially reduce or eliminate the market for our BCS 2100 and could result in the complete termination of our operations.

ONGOING INVESTIGATIONS BY THE SEC AND U.S. ATTORNEY ARE CAUSING US TO INCUR SIGNIFICANT LEGAL EXPENSES, WHICH HAVE NEGATIVELY AFFECTED OUR WORKING CAPITAL, OPERATIONS AND BUSINESS PROSPECTS.

Both the Securities and Exchange Commission (the "SEC") and the U.S. Attorney's Office for the Southern District of New York are conducting investigations involving possible violations of proscriptions on insider trading by our Chairman and Chief Executive Officer. Although we believe CTI is not currently a target of the investigations, we are incurring substantial legal expenses in responding to requests for information and documents from the SEC and the U.S. Attorney, preparing for and attending depositions by our officers, conducting investigations of our own affairs, and advancing legal fees on behalf of officers who are or may be entitled to indemnification in connection with these investigations. As of June 30, 2004, we had incurred expenses of approximately $825 thousand associated with these investigations. The expenses we have incurred to date have substantially and adversely affected our limited working capital and have negatively impacted our operations and limited our efforts to raise badly-needed capital. The investigations (although slowed in fiscal year 2004) are ongoing; and we anticipate that the expenses we will incur in the future will continue to adversely affect our working capital, distract management from day-to-day operations and limit our capital-raising activities, any of which may result in us having to materially reduce or terminate our operations.

WE HAVE LIMITED REVENUES FROM OPERATIONS AND MAY NEVER HAVE SUBSTANTIAL REVENUE FROM OPERATIONS.

With limited exceptions, our products have not been used in commercial applications and there is no assurance that the market will accept our products in sufficient volume to assure profitability. From inception on June 10, 1987 to June 30, 2004, we recorded $3.8 million in revenue. We have also recorded $96.5 million in operating expenses, resulting in aggregate accumulated operating losses as of June 30, 2004 of $96.7 million. We recorded revenues of approximately $356 thousand and $1.5 million for the fiscal years ended June 30, 2004 and 2003, respectively. We can provide no assurance that we will ever generate sufficient revenues to exceed our operating expenses. If our expenses continue to exceed our revenues, our business will fail.

FAILURE TO OBTAIN INSURANCE REIMBURSEMENT CODES FOR OUR BCS 2100 MAY MAKE THE BCS 2100 UNMARKETABLE, THEREBY ADVERSELY AFFECTING SHAREHOLDER VALUE.

Most healthcare providers, insurance companies and other third-party payers will not use or pay for the use of a medical device or a procedure unless it is has an accompanying insurance reimbursement code. In December 2001, we applied to the American Medical Association for an Emerging Technology Code, which is the first step in obtaining Medicare, Medicaid and private insurance reimbursement for procedures performed using our BCS 2100. Our application will not be acted upon unless and until we receive FDA approval for the BCS 2100. There can be no assurance that we will receive these codes, that Medicare, Medicaid or private insurers will provide reimbursement under these codes, or that our customers will find the reimbursements sufficient to warrant the use of our BCS 2100. If our customers cannot obtain adequate insurance reimbursement for their services, the market for our BCS 2100 would be reduced and this would have a material adverse effect on us and our shareholders.

WE EXPECT TO CONTINUE TO INCUR LOSSES, DEFICITS, AND DEFICIENCIES IN LIQUIDITY THAT WILL IMPAIR OUR OPERATIONS.

We must develop clinical applications, obtain regulatory approvals, market our BCS 2100 and develop further applications and markets for our other products in order to become profitable. There is no assurance that we will be able to accomplish these objectives. We have incurred substantial losses in the past and expect to continue to incur losses, deficits and deficiencies in liquidity due to the significant costs associated with the continuing development and commercialization of our products. From June 10, 1987 until June 30, 2004, we incurred accumulated losses of approximately $96.7 million. We recorded accumulated losses of $2.5 million and $11.7 million for the fiscal years ended June 30, 2004 and 2003, respectively. Such losses and deficiencies have had, and will likely continue to have, a material adverse impact on our operations and financial condition. Our losses have limited our operations, including our efforts to obtain critical regulatory approvals, and our product development efforts. If we continue to incur losses, our operations will be impaired and we may be unable to remain in business.

WE HAVE LIMITED MANAGEMENT AND OTHER KEY PERSONNEL, WHICH LIMITS OUR ABILITY TO EFFECTIVELY ADDRESS THE DEMANDS OF OUR BUSINESS.

During the 2004 fiscal year, our former President, former Controller, as well as other key management personnel resigned. In addition, during 2004 we were forced to reduce our total workforce from 24 full and part-time employees as of June 30, 2003 to 6 full and part-time employees as of June 30, 2004. We have not yet engaged a new President, nor have we replaced many of the other key

personnel who resigned or were subject to our reductions in force. As a result of these departures, the demands on our management team and key personnel are extreme; frequently, they lack the time and resources to effectively address the demands of our business. At present we lack the financial resources to expand our management team, and do not anticipate that we will be able to attract or engage additional management or qualified key personnel in the immediate future.

WE MAY SELL ASSETS OR REDUCE ACTIVITIES TO FUND OPERATIONS, WHICH COULD ADVERSELY AFFECT SHAREHOLDER VALUE.

If we are unable to secure adequate capital through the sales of securities, or as part of a funding arrangement, we may continue to seek raising capital by selling all or part of our intellectual property and know-how, enter into license agreements for all or part of our intellectual property rights (which might include manufacturing licenses) to third parties for certain territories or business segments, terminate operations in any of our business segments to reduce expenditures, or reduce our operations in any or all of our business segments to preserve our business until funding is available. There can be no guarantee that we will be successful in these efforts. If we are not successful, we may have to severely reduce or terminate all or some of our operations, either of which could severely reduce or completely eliminate any shareholder value.

WE HAVE TERMINATED INSURANCES LEAVING THE COMPANY AND COMPANY OFFICERS AND DIRECTORS VULNERABLE.

Due to our lack of resources, we have terminated many insurance policies including directors and officers insurance, clinical trials insurance, some employee life insurance. We continue to carry minimal general liability, product liability, employee health, workman's compensation and limited employee life insurance. The reduction in insurance policies leaves the Company, as well as our officers and directors vulnerable to clams against CTI and company directors and officers. The lack of directors and officers insurance will limit the company's ability to attract quality executives for future growth unless adequate funds are obtained to re-instate directors and officers insurance.

THE RECENT VOLATILITY IN THE MARKET PRICE OF OUR COMMON STOCK COULD CONTINUE TO ADVERSELY AFFECT SHAREHOLDER VALUE.

The market price of our common stock may continue to experience wide fluctuations, as it has in the recent past, which could be unrelated to our financial and operating results. Such volatility could result in a material loss in the value of an investment in our shares. Our stock price fluctuated between $4.97 and $1.44 during the year ended June 30, 2001, fluctuated between $4.05 and $.56 during the year ended June 30, 2002, fluctuated between $1.29 and $0.09 during the year ended June 30, 2003 and fluctuated between $.68 and $.06 during the year ended June 30, 2004. The price at which our common stock trades has been and will likely continue to be highly volatile and fluctuate substantially due to factors such as the following:

- General market conditions;
- Changes in or failure to meet investors' expectations; Speculation regarding the likelihood of success, or lack thereof, of our FDA application relating to the BCS 2100;
- Concerns related to our solvency, liquidity or cash balances;
- Actual or anticipated fluctuations in our operating results;

- Ability to meet announced or anticipated profitability goals;
- Developments with respect to intellectual property rights; and
- Announcements of technological innovations or the introduction of new products or services by us or our competitors;

THE LISTING OF OUR COMMON STOCK ON THE AMERICAN STOCK EXCHANGE WAS TERMINATED, WHICH CREATES SUBSTANTIAL UNCERTAINTY ABOUT THE ADEQUACY AND EFFICIENCY OF THE MARKET FOR OUR COMMON STOCK.

On March 29, 2004, our common stock ceased to be traded on the American Stock Exchange ("AMEX"), due to our failure to comply with the requirements for continued listing on AMEX. Within a few months following the delistment, our common stock became quoted on the Over-the-Counter Bulletin Board Market ("OTCBB"), with the changed symbol of COIB.

The termination of our AMEX listing has created substantial uncertainty about the adequacy and efficiency of the market for our common stock. An inadequate or inefficient trading market for our common stock will likely compound the market volatility risks described in the preceding paragraphs. However, we are hopeful that our stock's following as well as the increased ease of access to all stock exchanges will assist in the ability of our current shareholder to actively trade CTI shares of stock. We understand that the AMEX is more widely respected and controlled than the OTCBB; however, there are many very strong companies that trade on OTCBB and emerge to a more respected stock exchange. It is our intentions that when (or if) the company can gain sustained profitability then we would seek to be listed on a more reputable stock exchange.

WE COULD ISSUE PREFERRED STOCK AND THIS COULD HARM YOUR INTERESTS.

We have authorized 3 million shares of preferred stock, par value $5.00 per share, none of which are outstanding. The preferred stock, if issued, could have preferential voting, dividend and liquidation rights which could adversely affect the rights of our shareholders. Our authority to issue preferred stock without shareholder approval could discourage potential takeover attempts and could delay or prevent a change in control through merger, tender offer, proxy contest or otherwise by making such attempts more difficult and costly. The inability of a third party to enter into such a transaction may reduce the value of our shares. In connection with our efforts to raise capital, we could sell preferred stock to an investor. While we cannot quantify the impact at this time from any such issuance, this stock could offer conversion, dividend or other rights that could significantly dilute current shareholders of our common stock.

WE RELY ON THIRD PARTIES IN THE DEVELOPMENT AND MANUFACTURE OF KEY COMPONENTS FOR OUR PRODUCTS. IF OUR PRODUCTS FAIL TO PERFORM, FDA APPROVALS, PRODUCT DEVELOPMENT, AND/OR PRODUCTION COULD BE SUBSTANTIALLY DELAYED.

We depend upon third parties to assist us with clinical studies, product development and to supply product components. Our products are highly specialized and have component parts developed and manufactured according to unique specifications. Although there may be more than one developer or manufacturer for these components, failure to develop or manufacture in a timely manner could result in a loss of business and further result in substantial delays in FDA approvals and/or commercialization of our products. Such delays could adversely affect our operations and shareholder value.

IF WE ARE UNSUCCESSFUL IN PREVENTING OTHERS FROM USING OUR INTELLECTUAL PROPERTY, WE COULD LOSE A COMPETITIVE ADVANTAGE.

Our business activities depend, in part, on our ability to use and prevent others from using our patents, trademarks and other intellectual property. We currently hold eight patents and have submitted three patent applications. There can be no assurance that the steps we have taken to protect our property will protect our rights. Defense of our intellectual property rights could be expensive and time-consuming, and parties that misappropriate our intellectual property could have significantly more financial resources than us, making it financially impossible to protect our rights.

ITEM 2. PROPERTIES

We lease facilities under various operating leases requiring fixed monthly payments, adjusted periodically over their term as follows:

LAKE OSWEGO, OREGON LEASE AGREEMENT. Until March 1, 2003, we leased approximately 7,388 square feet of executive office space in Lake Owego, Oregon. By its terms, the lease continued through August 14, 2006 with respect to 2,088 square feet and August 15, 2005 with respect to the remaining 5,300 square feet. Pursuant to the lease, monthly lease payments were $15,700, plus operating expenses and property taxes. This space was used as our headquarters and housed our administrative, financial, executive, and marketing employees. On March 1, 2003, as part of our general reduction in our operating expenses, we vacated these premises and moved into approximately 1,800 square feet of executive office space. The lease for that space ran through June 2003 and thereafter continued on a month-to-month basis at $2,100 per month. In June of 2003, we vacated the executive office space and consolidated our operations in the Ogden, Utah facility identified below. The landlord for the space we vacated filed a lawsuit against us for the remaining rent owed under that lease. See Item 3. "Legal Proceedings." The litigation with our former landlord, St. Paul Properties, stems from our decision to consolidate our offices in Ogden, Utah. Our former landlord alleged that we breached our lease obligation and sought damages of approximately $667,000 plus interest and attorneys and other fees. In April 2004, we settled this litigation with our former landlord in Portland. The settlement involved an initial payment of $50,000 with monthly payment of $12,000 for the next five months totaling $110,000. We paid the final payment of $12,000 in August 2004, settling all legal obligations to the Portland landlord.

OGDEN, UTAH LEASE AGREEMENT. We lease approximately 7,660 square feet of manufacturing space in Ogden, Utah, on a month to month basis. Monthly payments under the lease are $5,783. All of our operations are consolidated in the Ogden facility. Although two employees work outside the Ogden office, both conduct business from their personal residence(s) in order to reduce our overhead.

We believe that our existing offices and other physical facilities are adequate for our present needs.

ITEM 3. LEGAL PROCEEDINGS

SETTLEMENT OF SHAREHOLDER SECURITIES LITIGATION

In July of 2004, the United States Court of Appeals for the Ninth Circuit has ruled in our favor in the appeal of the United States District Court decision to dismiss the plaintiffs' claims in the proceeding entitled IN RE: COMPUTERIZED THERMAL IMAGING, INC., SECURITIES LITIGATION. The Ninth Circuit decision upheld the determination of the District Court to dismiss the plaintiff's complaint because it failed to adequately plead a case. The suit, which was consolidated into a single suit during September 2002, alleged in substance that CTI violated Section 10(b) of the Securities Exchange Act of 1934, as amended, and accompanying regulations and relevant case law by

misleading shareholders regarding such things as the progress of FDA approval and other matters, which the plaintiffs alleged caused significant damage to the holders of our common stock at the time of these alleged misrepresentations and omissions. The plaintiffs had not specified their damages. On April 17, 2003, the consolidated litigation was dismissed without prejudice by the United States District Court. In a written opinion, the U.S. District Judge concluded that the alleged misstatements were either not material, not misleading, or not plead by plaintiffs with sufficient particularity to constitute a claim. Upon dismissal of their complaint, the plaintiffs did not replead, so the District Judge dismissed the case with prejudice on May 13, 2003.

SETTLEMENT OF SALAH AL-HASAWI ADVISORY SERVICES CLAIM

On March 29, 2000, Salah Al-Hasawi, a citizen and resident of Kuwait, filed an action in the United States District Court for the Southern District of New York, against us and our former Chief Executive Officer, alleging violations under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, for commissions allegedly due to the plaintiff in connection with the private placement of our securities. Shortly thereafter, the lawsuit was dismissed without prejudice, and on April 12, 2000 the plaintiff filed a similar complaint in the United States District Court for the District of Utah. The plaintiff's complaint sought specified damages of $15.5 million, attorneys' fees and unspecified damages pursuant to five separate causes of action, including breach of contract, fraud and unjust enrichment.

In December 2003, we reached a settlement with the plaintiff, pursuant to which we agreed to pay the aggregate amount of $100,000 in three installments ($50,000 paid on December 17, 2003, $25,000 paid in January 2004 and $25,000 paid in February 2004), and the plaintiff agreed to dismiss the litigation with prejudice. The settlement is set forth in a Settlement Agreement and Mutual Releases Agreement, which was filed with the Court in February 2004.

SEC AND DEPARTMENT OF JUSTICE INVESTIGATIONS

Both the Securities and Exchange Commission (the "SEC") and the U.S. Attorney's Office for the Southern District of New York are conducting investigations involving possible violations of proscriptions on insider trading by our Chairman and Chief Executive Officer. Although CTI is not currently a target of the investigations, we are incurring substantial legal expenses in responding to requests for information and documents from the SEC and the U.S. Attorney, preparing for and attending depositions by our officers, conducting investigations of our own affairs, and advancing legal fees on behalf of officers who are or may be entitled to indemnification in connection with these investigations. As of June 30, 2004, we had incurred expenses of approximately $825 thousand associated with these investigations. The expenses we have incurred to date have substantially and adversely affected our limited working capital and have negatively impacted our operations and limited our efforts to raise badly-needed capital. The investigations (although slowed in fiscal year 2004) are ongoing; and we anticipate that the expenses we will incur in the future will continue to adversely affect our working capital, distract management from day-to-day operations and limit our capital-raising activities, any of which may result in us having to materially reduce or terminate our operations.

In December 2002, we were requested to provide certain documents to the

SEC and the U.S. Attorney for the Southern District of New York in connection with their investigation of possible violations by our Chairman of the Board and Chief Executive Officer of the insider trading prohibitions found in the federal securities laws. During the year ended June 30, 2003 we incurred approximately $658 thousand in legal costs in complying with these requests. During the fiscal year ended June 30, 2004, we incurred approximately $168 thousand in additional legal costs associated with these investigations. We also may be required to indemnify our officers and directors for fees incurred for these investigations. For the year ended June 30, 2003, such indemnification obligations totaled approximately $36 thousand, and during the year ended June 30, 2003 we incurred approximately $12 thousand in additional indemnification obligations which are included in the previous figures.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of the security holders during the fiscal year ended June 30, 2004.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

On March 29, 2004, our common stock ceased to be traded on the American Stock Exchange ("AMEX"), due to our failure to comply with the requirements for continued listing on AMEX. Within a few months following the delisting of our common stock on AMEX, the Over-the-Counter Bulletin Board ("OTCBB") began quotation of transactions in our common stock with the changed symbol of COIB.

PRICE RANGE OF OUR COMMON STOCK

The following table summarizes the quarterly low and high bid prices per share for our common stock on AMEX and the OTCBB, as applicable, during the periods indicated. The bid prices reflect inter-dealer prices, without retail markup, markdown, or commission and may not represent actual transactions.

Year Ended June 30, 2003	Low Bid	High Bid
First Quarter	$ 0.54	$ 0.95
Second Quarter	$ 0.18	$ 1.29
Third Quarter	$ 0.09	$ 0.21
Fourth Quarter	$ 0.10	$ 0.76
Year Ended June 30, 2004		
First Quarter	$ 0.35	$ 0.68
Second Quarter	$ 0.21	$ 0.38
Third Quarter	$ 0.17	$ 0.52
Fourth Quarter	$ 0.06	$ 0.25

On June 30, 2004, the closing bid for our common stock as reported on the OTCBB was $0.12 per share. On June 30, 2004, we had approximately 20,000 beneficial shareholders of our common stock and approximately 114 million shares of our common stock outstanding.

We have not paid dividends with respect to our common stock, and do not presently possess the resources to pay dividends in the future.

RECENT SALES OF UNREGISTERED SECURITIES

PRIVATE OFFERING - THERFIELD HOLDINGS LTD

On July 10, 2003 we closed a private placement under Regulation S of the Securities Act, as amended, and sold 3,344,482 shares of our common stock to Therfield Holdings LTD ("Therfield"), for $1 million. We entered into

negotiations with Therfield in early June 2003 and offered a 15% discount off the then prevailing market price. The transaction process took over 30 days to conclude and involved document exchanges for the Common Stock Purchase and Registration Rights Agreements, including time to coordinate the funds transfer. The Company received the funds from the private placement on July 10, 2003. The securities issued to Therfield Holdings LTD were restricted securities which our management believes were acquired for investment. Certificates for the securities issued bore a restrictive legend and stop-transfer instructions were noted respecting such certificates on our transfer records. Each purchaser of such securities provided to us a purchase agreement containing representations and warranties upon which our management based its belief that an exemption from registration under the Securities Act was available, including representations and warranties that the investor is an "accredited investor," as defined in Rule 501 promulgated under the Securities Act, that the investor was acquiring the securities for investment purposes only, that the investor was the sole party in interest, and that the securities are "restricted," and may not be transferred unless registered or an exemption is available under applicable securities laws. Each of the foregoing transactions was affected in reliance on the exemption from registration provided in Section 4(2) of the Securities Act and Rule 506 of Regulation D adopted thereunder as transactions not involving any public offering.

PRIVATE OFFERING - CHARLES DAI

On January 30, 2004 we closed a private placement under Regulation S of the Securities Act, as amended, and sold 1,000,000 shares of our common stock to Charles Dai, for $220 thousand, $.22 per share. We entered into negotiations with Mr. Dai in early December 2003 and offered a 10% discount off the then prevailing market price at that time. Negotiations and the transaction process took over 60 days to conclude and involved document exchanges for the Common Stock Purchase and Registration Rights agreements, including time to coordinate the funds transfer. The Company received the funds from the private placement on February 4, 2003. The securities issued to Chares Dai were restricted securities which our management believes were acquired for investment. Certificates for the securities issued bore a restrictive legend and stop-transfer instructions were noted respecting such certificates on our transfer records. Each purchaser of such securities provided to us a purchase agreement containing representations and warranties upon which our management based its belief that an exemption from registration under the Securities Act was available, including representations and warranties that the investor is an "accredited investor," as defined in Rule 501 promulgated under the Securities Act, that the investor was acquiring the securities for investment purposes only, that the investor was the sole party in interest, and that the securities are "restricted," and may not be transferred unless registered or an exemption is available under applicable securities laws. Each of the foregoing transactions was affected in reliance on the exemption

from registration provided in Section 4(2) of the Securities Act and Rule 506 of Regulation D adopted thereunder as transactions not involving any public offering.

PRIVATE OFFERING - NABEEL AL MULLA

On May 14, 2004 we closed a private placement under Regulation S of the Securities Act, as amended, and sold 666,667 shares of our common stock to Nabeel Al Mulla, for $100 thousand, $.15 per share. We entered into negotiations with Mr. Al Mulla in early in 2004 and offered a discount off the then prevailing market price, however, at the time of the final agreement the our common stock had been removed from the American Stock Exchange and we were waiting to be listed on the Over-The-Counter Bulletin Board and were trading on "pink sheets" only. The Board of Directors and company management felt in view of the company's situation that $.15 per share would be a reasonable offering. The Company received the funds from the private placement on May 17, 2004. The securities issued to Nabeel Al Mulla were restricted securities which our management believes were acquired for investment. Certificates for the securities issued bore a restrictive legend and stop-transfer instructions were noted respecting such certificates on our transfer records. Each purchaser of such securities provided to us a purchase agreement containing representations and warranties upon which our management based its belief that an exemption from registration under the Securities Act was available, including representations and warranties that the investor is an "accredited investor," as defined in Rule 501 promulgated under the Securities Act, that the investor was acquiring the securities for investment purposes only, that the investor was the sole party in interest, and that the securities are "restricted," and may not be transferred unless registered or an exemption is available under applicable securities laws. Each of the foregoing transactions was affected in reliance on the exemption from registration provided in Section 4(2) of the Securities Act and Rule 506 of Regulation D adopted thereunder as transactions not involving any public offering.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

FORWARD-LOOKING STATEMENTS CONCERNING OUR BUSINESS

The following discussion should be read in conjunction with the Consolidated Financial Statements, the notes thereto and the other information included in this Report. Certain statements in this "Management's Discussion and Analysis or Plan of Operation" are forward-looking statements. When used in this document, the words "expects," "anticipates," "intends," "plans," "may," "believes," "seeks," "estimates," and similar expressions generally identify forward-looking statements. The forward-looking statements contained herein are based on current expectations and entail various risks and uncertainties that could cause actual results to differ materially from those expressed in such forward-looking statements. For a more detailed discussion of these and other business risks, see "Risk Factors."

OVERVIEW

Our mission is to improve the quality of life by raising the performance standards of infrared thermal imaging technology for both the medical device and industrial markets. We design, manufacture and market thermal imaging devices and services used for clinical diagnosis, pain management and industrial non-destructive testing. We provide inspection services and design and build non-destructive test systems for industrial customers.

Our current products are the BCS 2100, Photonic Stimulator, TIP, and our TBIS. We have historically marketed our products with an internal sales force and through independent distributors. At present, however, due to our troubled financial condition, we are not actively marketing our products. To date, our revenues have been generated principally from the sale of our Photonic Stimulator, TIP, TBIS and services provided in connection with our TBIS.

Given our inability to market our principal product unless we secure FDA pre-market approval, our need to raise capital to fund our operations, our history of losses ($96 million since inception), and the risk of pending or future litigation, our independent auditor's opinion dated September 24, 2004 contains a "going concern qualification," meaning that our independent auditors have indicated that there is substantial doubt as to our ability to continue as a going concern. Our efforts to raise additional funds to date have been only marginally successful. Since the FDA's rejection of our application for pre-market approval of the BCS 2100 in December 2002, we have raised $500 thousand in advances under an equity line of credit with Beach Boulevard, $1.32 million through a private issuance of restricted stock, $660 thousand from the NanDa License Agreement and $220 thousand from short-term notes. We have pursued additional financing transactions, but, as of the date of this report, we have been unsuccessful in our efforts to raise additional capital. Regardless of the FDA's ultimate decision regarding our application for pre-market approval of the BCS2100, we will require additional capital to execute our operating plan, which may include more clinical trials, research and development, marketing into Canada and marketing and manufacturing expenses.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements requires us to estimate the effect of various matters that are inherently uncertain as of the date of the financial statements. Each of these required estimates varies in regard to the level of judgment involved and its potential impact on our reported financial results. Estimates are deemed critical when a different estimate could have reasonably been used or where changes in the estimate are reasonably likely to occur from period to period, and would materially impact our financial condition, changes in financial condition or results of operations. Our significant accounting policies are discussed in Note 1 of the Notes to Consolidated Financial Statements; critical estimates inherent in these accounting policies are discussed in the following paragraphs. Our management has discussed the development and selection of these critical accounting policies with the Audit Committee of our Board of Directors.

REVENUE RECOGNITION--We believe revenue recognition is a significant business process that requires management to make estimates and assumptions. We recognize revenue from product sales after shipment when persuasive evidence of an agreement exists, delivery of the product has occurred, no significant obligations remain, the price or fee is fixed or determinable, and collectibility is probable. If these conditions are not met, revenue is deferred until such obligations and conditions are fulfilled.

Our standard domestic terms for our medical products to end-user customers are net 30 days and our standard international terms for our medical products are cash or a letter of credit before shipment. On occasion, we offer extended payment terms beyond our normal business practices, usually in connection with providing an initial order of demonstration equipment to a new domestic distributor. We consider fees on these extended terms agreements to not be fixed and collectibility to be less than probable. Accordingly, we defer the revenue until receipt of payment. We sell separate extended warranty contracts for our TIP and Photonic Stimulator and recognize revenue from those arrangements ratably over the contract life. We do not offer rights or return privileges in sales agreements.

Industrial sales are made pursuant to individually negotiated commercial contracts which specify payment terms that have ranged from 60 to 90 days from shipment or service completion. With industrial products, even if delivery and payment have occurred, we may retain a significant ongoing obligation under a sales arrangement for the delivery of components or customized software and customer testing, and we defer recognizing revenue until all the multiple elements of the sale are completed.

INVENTORY VALUATION--We value inventory at lower of cost or market. Inventory values are determined using standard purchase quantities and prices agreed with our vendors. If purchase costs decrease, any difference is recorded to cost of revenues and the carrying value of inventory is reduced. We have not experienced significant material cost increases for any production part.

INVENTORY RESERVES--We reserve for excess and obsolete inventory by comparing inventory on hand to estimated consumption during the next 12 months. Consumption is estimated by annualizing trailing three or six-month trailing sales volumes, adjusting those volumes for known activities and trends, and comparing forecast consumption to quantity on hand. Any difference between inventory on hand greater and estimated consumption is recorded to cost of revenues and an excess and obsolete reserve which is included as an element of net inventory reported on our balance sheet. Amounts charged into the inventory reserves are not reversed to income until the reserved inventory is sold or otherwise disposed.

IMPAIRMENT OF LONG-LIVED ASSETS--We follow the provisions of the Financial Accounting Standards Board ("FASB") SFAS No. 121, ACCOUNTING FOR THE IMPAIRMENT OF LONG-LIVED ASSETS AND FOR LONG-LIVED ASSETS TO BE DISPOSED OF, which requires that if the sum of the future undiscounted cash flows expected to result from the assets is less than the carrying value of the assets, then the asset is not recoverable and the company must recognize an impairment. The amount of impairment to be recognized is the excess of the carrying value of the assets over the fair value of those assets and is recorded as a component of impairment loss on our consolidated statement of operations. In estimating impairments, management makes assumptions about future cash flows, the likelihood of those cash flows occurring and fair values of the related assets based on estimates that may differ from actual results.

STOCK-BASED COMPENSATION--We measure compensation expense for our employee stock-based compensation plans using the intrinsic value method prescribed by Accounting Principles Board ("APB") Opinion 25, ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES and FASB Interpretation No. 44, ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION--AN INTERPRETATION OF ACCOUNTING PRINCIPLES BOARD (APB) OPINION NO. 25 ("FIN 44").

Pursuant to the prescribed guidelines, we have recorded adjustments associated with the exercise price of employee stock options, extension of the exercise period of employee stock options, issuing stock options at a strike price lower than the then prevailing price for our common stock and issuing stock to directors or stock to an employee.

During 2001, we modified the exercise price of certain stock options granted to certain executives and managers in connection with concluding severance agreements or to align the interests of executives, managers and shareholders. As a result, these options became subject to variable accounting.

Variable accounting requires us to adjust compensation expense for the increases or decreases in the intrinsic value of the modified awards in subsequent periods until the award is exercised, is forfeited, or expires unexercised.

We follow SFAS 123, ACCOUNTING FOR STOCK-BASED COMPENSATION, for non-employee stock options and warrants granted. Values have been estimated at the date of grant and beginning of the period respectively, using a Black-Scholes security pricing model. In determining values under the Black-Scholes pricing model, we make estimates and assumptions regarding our volatility, risk-free lending rate and the expected life of the security, which materially impact the security's value.

Our Board of Directors authorizes all stock option and warrant grants, and approves any changes to option or warrant terms.

RESULTS OF OPERATION

FISCAL YEARS ENDED JUNE 30, 2004 AND 2003

REVENUES

Total revenues for the fiscal year ended June 30, 2004 were $357 thousand, compared to $1.539 million for the fiscal year ended June 30, 2003, a decrease of $1.182 million, or 77%. The decrease in revenues for 2004 partly reflected the deferral of $342 thousand in revenues for our NanDa and Pratt & Whitney contracts. The Company recognizes revenue from its product sales to end customers upon shipment of products when persuasive evidence of an agreement exists, delivery of the product has occurred, no significant Company obligations remain, the fee is fixed or determinable, and collectibility is probable. If these conditions are not met, revenue is deferred until such obligations and conditions are fulfilled. If the Company retains an ongoing obligation under a sales arrangement, revenue is deferred until all of the Company's obligations are fulfilled. During 2003, we reduced the price of our Photonic Stimulators in efforts to reduce inventory, which resulted in increased sales of over $100 thousand for the Photonic Stimulator and we sold TIP cameras and Photonic Stimulators in a separate contract to NanDa for over $500 thousand. We attribute the remainder of the decrease to reductions in sales personnel and other staff, as well as shifting our limited resources to efforts to obtain FDA pre-market approval and open other markets such as Canada.

Our medical segment revenues were $269 thousand and $1.0 million for the fiscal years ended June 30, 2004 and 2003, respectively. The decrease of $731 thousand, or 73%, resulted primarily from decreased shipments of TIP units and Photonic Stimulators mentioned above.

The remaining $88 thousand and $539 thousand of revenues reported in 2004 and 2003, respectively, were attributable to our industrial segment. The primary factor in the decrease in industrial segment revenues was the recognition of a TBIS sale to Alstom Power, a major power turbine manufacturer, in 2003. Industrial contracts tend to be large contracts over several months. We did not have a contract to equal the Alstom Power contract in 2004. Our balance sheet dated June 30, 2004 does, however, reflect over $400 thousand in deferred revenue waiting to be recognized for another industrial contract with Pratt & Whitney once final adjustment and certifications are completed. We anticipate that these procedures will be completed during the fiscal year ending June 30, 2005. The $88 thousand in industrial revenue that we recognized during fiscal

2004 was primarily repair work on existing customer's cameras.

As of June 30, 2004, we did not have a backlog of industrial orders for our TBIS and industrial products, nor did we did we have backlog as of June 30, 2003. We generally have no backlog for pain management products, which are shipped promptly upon receipt of an order. Reported backlog represents the actual value of purchase orders issued to us for delivery of goods in the future. As of June 30, 2004, we had not recognized revenue for the sale of a TBIS to Pratt & Whitney because, even though the TBIS was delivered during the quarter ended March 31, 2003, we have not yet satisfied our post-delivery obligations related to customer acceptance tests, installation and training, and customization of software for the needs of Pratt & Whitney. We have not included the TBIS sold to Pratt & Whitney in backlog because an invoice with respect to such TBIS had been sent and was payable as of June 30, 2003. Revenue will be recognized as a gain on sale of fixed assets when all of our sales commitments and obligations have been fulfilled.

EXPENSES

GROSS MARGINS AND COST OF REVENUES. Total gross margins for the fiscal year ended June 30, 2004 were $190 thousand, compared to $215 thousand for the fiscal year ended June 30, 2002, a decrease of approximately 12%. This decrease is principally attributable to the 77% decrease in revenues. However, gross margins increased as a percentage of sales from 14% to 54%. This increase in gross margin as a percentage of revenue was due primarily to the decrease in costs allocated to cost of goods sold, such as salaries of the reduced employee staff. Total cost of goods sold for fiscal 2004 was $166 thousand, compared to $1.324 million in fiscal 2003, a 87% decrease in dollar value. As a percentage of revenue, cost of goods sold dropped from 86% in 2003 to 46% in 2004. The drop in percentage of revenue to cost of goods sold was primarily due to the reduced sales prices used to reduce inventory in 2003.

We have not tracked segment information beyond certain revenue levels due primarily to the similarity of inventoried products used in each segment. The absence of segmented information as also due to the fact that industrial revenues were principally repair-oriented for the fiscal year 2004.

Gross margins and cost of revenues as a percentage of sales for the fiscal years ended June 30, 2004 and 2003 were:

	TOTAL SALES 2004	PERCENTAGE OF SALES	TOTAL SALES 2003	PERCENTAGE OF SALES	INCREASE (DECREASE)	PE C
Revenues	$ 356,710	100%	$ 1,539,476	100%	$ 1,182,766	
Cost of revenues	(165,741)	46%	(1,324,267)	86%	(1,158,526)	
Gross margins	$ 190,969	54%	$ 215,209	14%	$ (215,209)	

OPERATING, GENERAL AND ADMINISTRATIVE. Operating, general and administrative expenses for the year ended June 30, 2004 were $1.235 million,

compared to $2.919 million for the year ended June 30, 2003. Operating, general and administrative expenses decreased by $1.684 million, or 58%, from fiscal 2003 to fiscal 2004. If we obtain FDA pre-market approval or funding to facilitate the steps suggested by the FDA, neither of which appears imminent at this point in time, or, if the market in Canada and China begin to purchase our BCS 2100, then our expense level would increase in connection with hiring the people needed to build the administrative infrastructure required to manufacture and market our BCS 2100.

Operating, general and administrative expenses decreased from fiscal 2003 to fiscal 2004 primarily due to: 1) a $542 thousand decrease in wages and related expenses; 2) a $668 thousand decrease in legal and other professional services expense; 3) a $196 thousand decrease in office expenses; 4) a $122 thousand decrease in shareholder services; 5) a $92 thousand decrease in insurance expense; and 6) a $66 thousand decrease in other expenses including travel, equipment, supplies, bad debt recoveries, and miscellaneous accrued expenses.

The decrease in wages was due primarily to a material decrease in the number of employees, as well as salary reductions. Legal and other professional services expenses we have incurred, primarily during fiscal 2003, were primarily attributable to a request by the SEC and the U.S. Attorney for the Southern District of New York to provide certain documents in connection with their investigation of possible violations by our Chairman of the Board and Chief Executive Officer of the insider trading prohibitions found in federal securities laws. During the year ended June 30, 2003, we incurred approximately $658 thousand in legal costs, principally in response to the requests submitted to us by the SEC and the U.S. Attorney. Comparatively, for the year ended June 30, 2004 we incurred approximately $168 thousand in additional legal costs for the same investigations. We may also be required to indemnify our officers and directors in connection for fees incurred in connection with these investigations. Also attributing to the decrease was the settlement of the three legal matters, as discussed in Item 3. Legal Proceedings, above.

Decreases in office expense was attributable to the office consolidation to one location in Utah and to continued efforts to reduce all expenses.

Operating, general and administrative expenses are allocated to segments using budgeted levels of various activities, e.g., headcount, square feet occupied and fixed assets. Comparative expenses allocated to these segments were affected by the factors discussed above. We have maintained this allocation method throughout the year for consistency; however, we intend to re-evaluate the methodology due to office consolidatio