TUTOGEN MEDICAL INC
Form 10-K
December 27, 2004

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

|X| Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2004.

| | Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File Number: 0-16128

TUTOGEN MEDICAL, INC.
(Name of Registrant as specified in Its Charter)

FLORIDA	59-3100165
(State of Incorporation)	(IRS Employer Identification No.)

1130 MCBRIDE AVENUE WEST PATERSON, NEW JERSEY 07424
(Address of principal executive offices)

(973) 785-0004
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act: None
Securities registered under Section 12(g) of the Exchange Act:
COMMON STOCK
(Title of Class)

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act 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
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Indicate by check mark if no disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. X

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates (approximately 5,397,000 shares), computed by reference to the bid and ask of such common equity on the American Stock Exchange, was $16,137,000 as of November 30, 2004.

As of November 30, 2004, there were 15,915,960 shares outstanding of the issuer's Common Stock, par value $.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

The discussion contained in this annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), for the issuer's fiscal year ended September 30, 2003 (this "Report"), contains forward-looking statements that involve risks and uncertainties. The issuer's actual results could differ significantly from those discussed herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Description of Business" and "Management's Discussion and Analysis or Plan of Operation" as well as those discussed elsewhere in this Report. Statements contained in this Report that are not historical facts are forward-looking statements that are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. A number of important factors could cause the issuer's actual results for 2004 and beyond to differ materially from those expressed in any forward-looking statement made by or on behalf of the issuer.

PART I

ITEM 1. BUSINESS.

Tutogen Medical, Inc., a Florida corporation, was formed in 1985, and with its consolidated subsidiaries (collectively, the "Company" or "Tutogen"), develops, manufactures and markets sterile biological implant products made from human (allograft) and animal (xenograft) tissue. Tutogen utilizes its Tutoplast(R) Process of tissue preservation and viral inactivation to manufacture and deliver sterile bio-implants used in spinal/trauma, urology, dental, ophthalmology, head and neck and general surgery procedures.

One of the Company's wholly owned subsidiaries, Tutogen Medical GmbH, designs, develops, processes, manufactures, markets, and distributes specialty surgical products and services to over 30 countries through a worldwide distribution network. Another subsidiary, Tutogen Medical (United States), Inc., was formed in 1994 to process, market and distribute allografts for the U.S. market.

The Company's corporate headquarters is in West Paterson, New Jersey, a manufacturing facility in Alachua, Florida, international executive offices and processing and manufacturing facilities in Neunkirchen, Germany, and a sales office in Boulogne, France.

The Company contracts with independent tissue banks and procurement organizations to provide donated human tissue for processing under the Company's proprietary TUTOPLAST process. The TUTOPLAST process utilizes solvent dehydration and chemical inactivation which is applied to two types of preserved allografts: soft tissue; consisting of fascia lata, fascia temporalis, pericardium, dermis, sclera, ligaments, tendons and cartilage, and bone tissue; consisting of various configurations of cancellous and cortical bone material. Processed pericardium, fascia lata and dermis are collagenous tissue used to repair, replace or line native connective tissue primarily in neurosurgery, ophthalmology, urology procedures, plastic and reconstructive surgeries, dermis is also used in pelvic floor reconstruction, sclera is used in ophthalmology

procedures such as, anterior and posterior segment patch grafting applications for glaucoma, retina and trauma surgery and oculoplastics as well as contour wrapping of an orbital implant, while ligaments, tendons and cartilage are used primarily in orthopedic and trauma repairs. Processed cortical and cancellous bone material is used in a wide variety of applications in spinal and dental surgeries. All processed tissues have a shelf life of five (5) years and require minimal time for rehydration. The Company processes bone and soft tissues in both manufacturing facilities.

The Tutoplast(R) processed allografts have been used successfully in over 1,000,000 procedures performed for over thirty (30) years.

In contrast to other processors using freeze-drying, deep freezing or cryopreservation for human tissues, the TUTOPLAST process utilizes a technique in which tissues are soaked and washed in a series of aqueous solutions and organic solvents, removing water and substances that could cause rejection or allergic reaction. This technique dehydrates the tissue keeping the tissue's structure intact, allowing it to act after implantation as a scaffold, which is replaced by newly formed body own tissue. During processing, the tissues are treated with agents shown to inactivate viruses such as hepatitis and HIV, the virus that causes

AIDS, to render the allografts safe for the recipient. Soft tissue is also treated with chemicals shown to be effective against the agent causing Creutzfeldt-Jakob Disease ("CJD"). Once packaged, tissues are terminally sterilized by low dosage radiation, which allows them to be labeled "sterile".

MANUFACTURING AND PROCESSING

All of the Company's Allografts and Xenografts are prepared, preserved and processed by application of Tutogen's proprietary manufacturing TUTOPLAST process. Allograft tissues are obtained from approved tissue procurement organizations and institutions and undergo an extensive donor-screening regimen prior to processing. Although several operations are automated, most of the process is manual and relies on trained, highly skilled personnel. The entire process takes place under controlled clean room processing conditions. All incoming, untreated tissue is stored in special quarantine cold-storage rooms or refrigerators until released by quality assurance for processing. To prevent possible cross-contamination and ensure constant tissue identification, all tissue is stored individually and strictly maintained in labeled containers during the entire process. Samples are taken from processed tissue for each donor for test purposes and reference samples are retained for ten (10) years beyond the date of expiration. Documentation allows reverse traceability of tissue implants to the donor and by the Tissue Utilization Records to the recipient. All processed implants have a batch number and a donor number printed on each single package. Processed tissue may be safely stored for up to five (5) years at room temperature storage.

QUALITY ASSURANCE - All tissues are accompanied by specific medical and donor documentation, including blood serum infectious disease testing results performed by independent laboratories appropriately certified for these tests under the Clinical Laboratory Improvement Amendment of 1988 (CLIA 1988). Tutogen's implants and processed tissues are subject to a series of biological, physical and chemical tests, from incoming unprocessed donated tissues to sterile, finished goods. Tissues that do not meet regulatory standards are rejected and destroyed. See "Government Regulations".

MARKETING AND DISTRIBUTION

Tutogen's products and processing services are provided through direct representatives in Germany and France, with the Company billing the hospital or end-user directly. Internationally, with a focus on Europe, the Company distributes and invoices directly to a network of contract distributors. Tutogen's personnel, with distributors and their representatives, conduct product training sessions, make joint customer calls, set objectives and evaluate their representatives' performance. Personnel also call on selected physicians and key hospital accounts in order to provide needed clinical and technical information services. In the U.S., Zimmer Spine Inc. ("Spine"), and Zimmer Dental Inc. ("Dental"), subsidiaries of Zimmer Holdings, Inc., provide marketing services for the Company's products for the spine and dental markets, with the Company, beginning in May 2003 billing Spine directly and in the case of Dental, billing the hospital or end-user directly.

Approximately 42% of the Company's revenues come from outside the United States. As a result of its foreign sales and facilities, the Company's operations are subject to the risks of doing business on an international level. A major effort is underway to increase penetration in the U.S. market, as it accounts for 70% of the world market for biomaterials. The Company's marketing efforts in the U.S. in recent years have focused on creating a market for the pericardium and fascia lata tissues from donor tissues sourced in the U.S. In addition, since the Company's foreign donor qualification standards are in full compliance with the donor suitability standards of the Food and Drug Administration ("FDA"), the Company has created a market for its bone tissue for spine and dental applications.

The Company's U.S. marketing efforts have concentrated on rebuilding the marketing and distribution organization [and re-entering the bone markets.] Presently, allografts are provided to hospitals in the U.S. either directly by the Company with the assistance of marketing services or through independent distribution companies. These distributors employ, in the aggregate, over 500 field representatives who call

on hospital and office-based medical practitioners, primarily surgeons. Tutogen supports their activities with various types of technical allograft literature, informational programs, reference materials, and training sessions and programs designed to increase distributor call volume. In 2004, the Company increased its independent distributor network for the distribution of allografts for fields of use (i.e., sports medicine/ligament repair, ENT, and general surgery) that are not otherwise covered under exclusivity. In addition, the Company has entered into exclusive marketing and distribution agreements with other medical device companies, under the TUTOPLAST label, for specialized indications. One such distribution agreement with IOP, Inc., ("IOP") which has been in effect since 1998, is for TUTOPLAST implants for ophthalmic use. A second project, for use of TUTOPLAST fascia lata in urological and gynecological indications, was concluded in January 1998 with Mentor Corporation ("Mentor"). In fiscal year 2004, Mentor has accounted for 9% and 11%, respectively, of the Company's total and U.S. revenues. In March 2000, a project was concluded with Spine for marketing in the U.S and distribution internationally of TUTOPLAST processed bone tissues for spinal applications. Marketing of these products began in September 2000. In September 2000, the Company entered into an agreement with Dental, whereby Dental will market in the U.S. and distribute TUTOPLAST processed bone tissue for dental applications in certain international markets. In October 2001, the Company entered into a project with Mentor for use of TUTOPLAST processed Dermis in urological and gynecological indication. In April 2003, the Company entered into an Exclusive License and Distribution Agreement ("Agreement") with Spine redefining the terms governing its relationship. Effective with this agreement, Spine will continue to market the Tutoplast products for the spine market, however, Spine has become a "stocking distributor", whereby Spine now purchases

the Company's products and invoices the customer directly. Finally, in August 2004, the Company expanded its dental market by signing an Exclusive Distribution Agreement with Zimmer Dental to market its products in Canada.

Internationally, the Company has implemented a marketing and sales restructuring plan, concentrating on an in-depth penetration of markets with major needs, i.e. in Europe, specifically with a "focus" on countries such as Germany, France, Italy, Spain and the U.K. The Company believes that the recent collaborations with Spine and Dental will increase its penetration of the international markets for processed bone tissue.

SOURCES OF TISSUE AND PRODUCTS

The Company receives donor tissue from multiple sites in Europe and the United States. This tissue is procured by independent procurement organizations and the Company reimburses these organizations for the costs of their procurement (recovery fees). The Company continuously strives to comply and remain current with existing laws and regulations related to procurement, donor screening, donor suitability, testing, processing, storage and distribution. It is anticipated that government laws and regulations involving human donor tissues will continue to change in the countries presently serviced by the Company (see Government Regulations). Accordingly, the Company continues to seek additional contacts with authorized health care agencies, accredited tissue banks, organ procurement organizations and governments. The Company expects that, in most markets, demand for its TUTOPLAST processed allografts will continue to exceed the current donor tissues available to the Company for processing.

Tissue recoveries, both in the United States and internationally are subject to a continuous quality program. The import program from Europe to the U.S. has been given high priority, and the levels of shipments are increasing steadily. The international tissue recovery base will be expanded to include Tissue Services Coordinators who will monitor the levels and types of recoveries. Domestic and European tissue recoveries are on track to meet the plan for fiscal 2005. The Company has recently hired a tissue procurement manager to expand the domestic tissue recovery base. While the Company continues to emphasize expanding its supply base, there can be no assurance that changing laws or donation trends, in the countries from which it presently obtains tissues, will not have a material adverse effect on the Company's operations.

The FDA has published a Draft-note for implementation Donor Eligibility Guidance to Industry document that discusses measures to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by human cells, tissue, and cellular and tissue-based products. This document represents the agencies current thinking on donor deferral criteria for donors that could have been potentially exposed to the Bovine Spongiform Encephalopathy (BSE) agent ("Mad Cow" disease). The draft is in the review stage, which precedes the adoption of a final version of the FDA's position on this matter. Since 1996 the vCJD and BSE epidemics have continued to evolve, and more BSE cases have been reported in Europe, including new reports of BSE in Spain, Italy, Germany, the Czech Republic, Greece, Slovenia, Slovakia, Austria, and Finland. Japan and Israel have also reported BSE, and many other countries, which also imported meat and bone meal from the UK from 1980 to 1996, may also have BSE. The impact of adoption of the draft document for Tutogen may be the ban of tissue from countries with known cases of BSE. This may result in a 10-15% reduction in importation of tissues to the US, however management does not believe that it will have material adverse affect on the Company's business, as new sources of tissues have been identified and are available.

BACK ORDER

While Tutogen worldwide has back orders on certain tissue types and tissue sizes, the allograft demand is most significant in the U.S. market. The U.S. is the largest market in the world for allografts and has historically represented the Company's largest market. The Company currently has back orders that are expected to be filled within the next three months; however, the Company cannot predict with absolute certainty its ability to fill specific orders in this time frame. As of September 30, 2004, the Company's back order for all tissues was approximately $110,000. Because orders may be canceled or rescheduled, the Company believes that backlog is not always an accurate indicator of results of operations for specific future periods.

COMPETITION

Tutogen is a leader in safe bioimplants for tissue repair. Tutogen's competitive advantage is based on its TUTOPLAST process of tissue preservation and viral inactivation. The TUTOPLAST process is based upon solvent dehydration, which preserves the tissue's integrity, and allows the implants to remodel in the course of normal healing. The TUTOPLAST process has an outstanding safety record. Since its introduction more than thirty (30) years ago, more than 1,000,000 procedures have been successfully performed using TUTOPLAST processed tissues, with no known complications from disease transmission or tissue rejection attributable to the implants. TUTOPLAST processed implants have been described in more than 400 published scientific papers.

The majority of the medical procedures suitable for allografts are currently being performed with autografts (tissues derived from the patient) requiring a second surgical procedure. The advantages of autografts include the decreased incident of tissue rejection and disease transmission. The disadvantages are the dual surgical procedures, increased pain and recovery time and the limitation on the amount and quality of tissue. Allograft advantages include the elimination of a second surgical site resulting in lower infection rates, the possible reduction in surgical procedure time, faster recovery times and lower costs, while disadvantages include availability and possible rejection. Availability and safety are the primary factors in the ability of TUTOPLAST processed allografts to compete with autografts for use by the surgical community.

The industry in which the Company operates is highly competitive. The 1996 departure of a major German competitor from the business of soft tissue allografts left Tutogen as the largest processor in the international market. Processors of allograft tissue for transplantation in the U.S. include commercial processors such as Osteotech, Inc., Regeneration Technologies, Inc. and CryoLife, Inc., companies well established in the fields of bones and heart valves respectively, and which have substantially greater financial resources than the Company. Not-for-profit tissue banks that procure and process tissue for distribution are

considered competitors for certain applications and in certain markets. Management believes that the TUTOPLAST process, with its impressive record for safety in the surgical community, gives the Company a competitive advantage over its competitors. However, due to government regulation, disrupted sources of availability and increasing competition, there can be no assurance that the Company will be able to continue to compete successfully. In addition, there can be no assurance that in the future the Company's allografts will be able to compete successfully with newly developed tissue substitutes being developed by other companies.

GROWTH STRATEGY

The Company estimates the worldwide market for its present products to be about $1 billion, including all procedures in its field of use. The Company's existing tissue supply network, established processing facilities and proven TUTOPLAST technology provides the foundation for continued growth into fiscal 2005 and beyond. The future growth may be aided by new sources of tissue, new applications and products and expansion into new markets.

TISSUE SUPPLY AND PROCESSING

The Company has an established network in the United States and Europe for tissue supply that meets or exceeds the high standards set by the FDA, the German Health Authority ("BfArM") and other regulatory agencies. This network incorporates a reliable logistic system that provides for a continuous supply of tissue with complete traceability. Individual tissue reference samples are stored for ten (10) years beyond the date of expiration. These high standards of recovery permit such tissue to be imported into the U.S. The Company is engaged in an aggressive program to expand its donor network in the U.S.

Tutogen operates two processing facilities, one in Alachua, Florida and the other in Neunkirchen, Germany. Both facilities are registered with the FDA Center for Biologics Evaluation and Research (CBER) in accordance with registration and listing requirements for human tissue based products; and have ISO 9001 and ISO 13485 certification. The Alachua, Florida facility is registered with the FDA Center for Devices and Radiological Health (CDRH) as a medical device manufacturer and is licensed in the States of New York and Florida. The German facility is registered as a pharmaceutical and medical device manufacturer. Tutogen is an accredited member of The American Association of Tissue Banks ("AATB"). The expansion of the Alachua facility into bone production complements a major expansion and modernization initiated at the Neunkirchen facility. These expansions will allow the Company to keep pace with growing product demands for the next several years.

XENOGRAFTS

The worldwide demand for allografts, tissue derived from human sources, is anticipated to represent a significant challenge. Faced with this constraint, the Company embarked on a program in 1993 to develop xenografts, tissue derived from animals, as an allograft substitute. The current revenue mix worldwide is approximately 85% allografts and 15% xenografts. As with allografts, xenografts processed using the Company's proprietary TUTOPLAST process have their biomechanical properties and remodeling capacity preserved with removal of antigenicity and infection risk. Studies have shown, that TUTOPLAST processed xenografts are at least equivalent to Allografts as demonstrated by actual clinical use and laboratory studies. To date, the Company has received CE-Marks, the European equivalent to an FDA medical device approval, for bovine pericardium (1998), bovine cancellous bone (1997) and bovine compact (cortical) bone (1999) which permits distribution throughout Europe of products derived from such tissues. In the US the Company has received FDA 510(k) clearances for bovine pericardium, allowing the Company to market the first xenograft tissues, Tutopatch(R) and Tutomesh(R), for indications of general and plastic surgery. Tutopatch(R) and Tutomesh(R) are intended to be produced from bovine pericardium obtained from U.S. cattle, a source

deemed free of Bovine Spongiform Encephalopathy ("BSE") and inspected/cleared by the United States Department of Agriculture (USDA).

The superior biomechanical properties of bovine tissues combined with the absence of those supply constraints associated with allografts, permits the use of xenograft tissues, in areas that cannot be optimally addressed with human tissue.

NEW APPLICATIONS AND PRODUCTS

A major component of Tutogen's growth strategy is focused on the introduction of new products and applications for TUTOPLAST processed tissues.

In November 2001, the Company developed a TUTOPLAST Processed Dermis(TM) product to be exclusively distributed by the Mentor Corporation. The TUTOPLAST Processed Dermis(TM) has application in Mentor's Suspend(TM) procedure that is used to treat female incontinence as well as for pelvic floor surgical procedures. Female incontinence is an extremely unpleasant medical condition suffered by a large and growing population. In the procedure the surgeon repositions and levels the bladder by creating a sling that cradles the bladder. The procedure was developed and pioneered by Mentor. The Company contributed their tissue engineering and preservation expertise knowledge to in the support of the development of the procedure. The procedure has won rapid and wide acceptance as a safe and effective treatment for this condition. The number of women electing to have this procedure each year continues to climb.

In September 2002, Tutogen entered the market for sports medicine with the introduction of its LigaTech(TM) product line for ligament replacement and repair. This product line includes TUTOPLAST processed specialty allograft products utilizing soft tissue and BTB combination products for ACL repair and reconstruction. There are over 200,000 ACL procedures performed in the U.S. annually with an aggregate market size of $500 million. TUTOPLAST soft membrane and bone allograft products have also been successfully used in shoulder, hip, and hand repair, as well as achilles tendon repair and reconstruction. These products are being distributed through a network of independent distributors in the U.S. and Europe.

In October 2002, the Company entered the European market with Tutomesh(R) a TUTOPLAST processed biological membrane for hernia and abdominal wall repair. In 2001, there were 880,000 hernia surgery procedures (in the U.S.), with an aggregate market size of $250 million. Tutomesh(R) has already been successfully used in abdominal wall surgery of neonates and children with hernia defects. These products are initially being sold through the Company's direct sales force in Germany. In Europe, a distributor network is being established, focusing on Italy, Spain and Great Britain.

In February 2003, the Company introduced the Cervical Spacer, an anterior cervical intervertebral fusion, marketed and distributed by Spine.

Several patents and trademarks have been submitted to the appropriate agencies in order to assist and accomplish the goals for expansion and growth.

EXPANSION INTO NEW MARKETS

TUTOPLAST processed tissues and products have application in numerous surgical indications. The Company enjoys high degrees of success in two such niches, ophthalmology and urological/gynecological with its strategic partners IOP and Mentor, and has established similar relationships to address additional markets. One such relationship was established in March 2000 with Spine for the worldwide distribution of TUTOPLAST processed bone tissues for spinal applications. Marketing of the traditional bone products began in September 2000. In November 2001, Spine commenced marketing of the Company's first biological specialty graft, the Tutogen Medical ALIF (Anterior Lumbar Interbody Fusion). Also, in September 2000,

the Company entered into collaboration with Dental whereby Dental will market in the U.S. and distribute internationally TUTOPLAST processed bone tissue for dental applications. In February 2002, Spine commenced marketing of an additional specialty graft, the Tutogen PLIF (Posterior Lumbar Interbody Fusion). In February 2003, Spine commenced marketing of the Cervical Spacer (anterior cervical intervertebral fusion) developed by the Company.

INTERNATIONAL OPERATIONS

Approximately 42%, 30% and 34% of the Company's net sales, respectively for fiscal years 2004, 2003 and 2002 were derived from outside the United States. The Company currently has sales in more than 30 countries located primarily in the United States and Europe. As a result of it foreign sales and facilities, the Company's operations are subject to the risks of doing business internationally.

(IN THOUSANDS)	United States	International	Consolidated
Revenues			
Year ended September 30,			
2004	$17,126	$12,204	$29,330
2003	$21,168	$ 9,092	$30,260
2002	$ 7,031	$13,716	$20,747

For a discussion of the Company's long-lived assets as of September 30, 2004, 2003 and 2002 see Note 9 of "Notes to Consolidated Financial Statements" and for the deferred tax assets for the years ended September 30, 2004, 2003 and 2002 see Note 10 of "Notes to Consolidated Financial Statements".

RESEARCH AND DEVELOPMENT

Tutogen continues to engage in research and development ("R&D"). The Company's scientific personnel and university level consultants contractively collaborate on research activities related to allograft and non-allograft tissue development. The Company follows an Internal Product Development plan and organizes all R&D activities, including the Zimmer Spine and Dental collaboration. R & D expenditures increased 70% from $826,000 in 2003 to $1,432,000 in 2004.

In allograft-related areas, R&D activities focus primarily on the development of surgical solutions, standardized and tailor-made products instead of offering grafting material to the surgeon. Also, continuing progress on the application of the Company's proprietary TUTOPLAST process to various other tissues has met with success. The Company continues to independently review its processing technology to improve tissue safety and efficacy. Non-allograft activities relate to explorations into the use of xenografts, tissue-engineered grafts and improving healing. Clinical studies, evaluation and follow-up are conducted on these activities. The Company's research efforts are subsidized by its collaboration with non-profit research institutions. These activities will

be expanded substantially pending the availability of the necessary financial resources. The Company is referred to in more than 400 publications.

CUSTOMERS

Spine and Mentor are principal customers to the Company, accounting for approximately 13% and 9%, respectively, of the Company's net sales for the year ended September 30, 2004. No other customer accounted for more than 10% of the Company's net sales for the fiscal year 2004. In April 2003, the Company entered into an Exclusive License and Distribution Agreement with Spine redefining the terms governing its relationship. Effective with this agreement, Spine will continue to market the TUTOPLAST products for the spine market, however, Spine has become a "stocking distributor", whereby Spine now purchases the spine products from the company and invoices the customers directly. The Company has Exclusive Distribution Agreements with Mentor granting a license to exclusively distribute the TUTOPLAST

Processed Fascia Lata, Pericardium and Dermis in their field of use, which is defined as all urological and gynecological applications and procedures in the United States and certain foreign markets.

PATENTS, LICENSES AND TRADEMARKS

Wherever possible, Tutogen seeks to protect its proprietary information, products, methods and technology by obtaining patent and trademark protection. Tutogen has 18 patents pending and has 15 registered trademarks covering several countries worldwide. In the United States, the Company has two FDA accepted 510(k) applications for its various products or processes. The Company believes that it has established itself through the TUTOPLAST trademark identity and a record of safety and quality assurance that will survive beyond the life of the patents.

GOVERNMENT REGULATION

Tutogen has contracts to receive, process and provide tissues worldwide. Every country has its own regulatory requirements that are constantly under review and subject to change. The Company believes it currently complies with all appropriate governmental requirements and standards in each country where it does business. There can be no assurance that changing governmental administration or laws will not negatively impact the Company.

In the United States, the FDA has determined that all xenograft tissues are subject to all provisions of the Food, Drug and Cosmetic Act and are regulated as a medical device. The FDA Title 21, code of Federal Regulations, Parts 1270 and 1271 Human Tissue Intended for Transplantation, currently regulates all human tissues processed currently by the Company. Similarly, tissue banks and procurement organizations, which provide the tissues to the Company for processing, also must comply with the FDA Parts 1270 and 1271 and its own country/state regulatory requirements.

In Germany, allografts are classified as drugs and the German government regulates Tutogen tissue processing and distribution within Germany under approvals as regulated by the German Drug Law. The European Commission has issued a human tissue directive on April 7, 2004 to regulate allografts within the European Community. At present, Tutogen's German facility is licensed and in compliance with German law.

Both the FDA and German regulatory agencies conduct inspections of processing facilities. The Company believes that worldwide regulation of

allografts is likely to intensify as governments increase their focus on the growing demand for this type of tissue and the need to ensure the health and welfare of its citizens. Management believes that the Company and its industry will always be subject to changing regulations that could have a material adverse effect on its financial condition and results of operations. Management further believes that they can reduce this exposure by continuing to work closely with government regulators in understanding the industry and drafting reasonable and proper legislation. While the Company believes that it is in compliance with all existing regulations, there can be no assurance that changing laws or interpretations of existing laws will not have a material adverse effect on the results of operations and cash flow.

ENVIRONMENTAL REGULATIONS

The Company's allografts and xenografts as well as the chemicals used in processing are handled and disposed of in accordance with country-specific, federal, state and local regulations. Since 1995, the Company has used outside third parties to perform all biohazard waste disposal.

The Company contracts with a third party to perform all gamma-terminal sterilization of its allografts. In view of the engagement of a third party to perform irradiation services, the requirements for compliance with radiation hazardous waste does not apply, and therefore the Company does not anticipate

that having any material adverse effect upon its capital expenditures, results of operations or financial condition. However, the Company is responsible for assuring that the service is being performed in accordance with applicable regulations. Although the Company believes it is in compliance with all applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on the Company's business.

TECHNOLOGICAL CHANGE AND COMPETITION

The biomedical field continues to experience rapid and significant technological change. Tutogen's success will depend upon its ability to establish and maintain a competitive position in the marketplace with its products and its ability to develop and apply its technology. There are many well-established companies and academic institutions with greater resources that are capable of developing products based on similar or new technology that could effectively compete with those products offered by the Company.

FOREIGN EXCHANGE RATES AND FOREIGN TRANSACTIONS

A significant portion of the Company's revenues is derived from its German operations, all of which are denominated in Euros. Fluctuations in the U.S. Dollar/Euro exchange rate may therefore have a significant effect on the Company's dollar results. Transactions with foreign suppliers and foreign customers could be materially adversely affected by possible import, export, tariff and other restrictions that may be imposed by the United States or other countries.

EMPLOYEES

As of September 30, 2004, the Company employed a total of 186 full-time and 18 part-time employees, of whom 35 full-time and 4 part-time were employed in the United States and the remainder in Germany. Management believes its relations with its employees are good.

ITEM 2. PROPERTIES.

UNITED STATES. The Company's domestic facilities are located in New Jersey and Florida. In West Paterson, New Jersey, the Company leases approximately 1,400 square feet of office space in which its administrative headquarters is located. The lease will expire in December 2006 and has a base rent of approximately $2,500 per month. The Company's processing plant in Alachua, Florida has expanded from approximately 13,449 square feet to 20,205 square feet of leased space. The Florida lease expires January 31, 2006 and rents for approximately $25,913 per month. The Company believes it is adequate in space and condition for its current needs.

GERMANY. The Company's facility in Neunkirchen consists of six buildings totaling some 28,000 square feet on approximately two acres of land. This property is owned by the Company and should be sufficient in size and condition to handle anticipated production levels for international markets into the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS.

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company. At September 30, 2004 and 2003, the Company accrued $476,000 and $836,000, respectively with respect to the remaining appeal and

legal costs. Management believes that such accrual is sufficient and the final settlement will not have a material impact on its results of operations or financial opinion.

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

There was no submission of matters to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

MARKET INFORMATION

Since August 17, 2000, the Company's Common Stock has been traded on the American Stock Exchange under the symbol "TTG". The following table sets forth the range of high and low closing price information for the Company's Common Stock for each quarter within the last two fiscal years.

Fiscal 2003	High	Low
First Quarter	$ 3.50	$ 2.30
Second Quarter	3.60	2.45
Third Quarter	3.49	2.40
Fourth Quarter	5.55	3.30
Fiscal 2004		
First Quarter	$ 5.50	$ 4.05

Second Quarter	5.06	3.85
Third Quarter	4.59	3.89
Fourth Quarter	4.16	2.79

Such market quotations reflect inter-dealer prices, without retail mark-ups, markdowns or commissions and may not necessarily represent actual transactions.

HOLDERS

As of November 30, 2004, the approximate number of holders of record of the Company's Common Stock was 372. The Company estimates that there are approximately 2,100 beneficial holders.

DIVIDENDS

The Company has not paid any cash dividends to date and does not anticipate or contemplate paying cash dividends in the foreseeable future until earnings would generate funds in excess of those required to provide for the growth needs of the Company.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth certain information regarding the Company's equity compensation plan as of September 30, 2004.

Plan Category	Number of securities to be Issued upon exercise of Outstanding options, warrants and rights	Weighted-average Exercise price of Outstanding options, Warrants and rights	N R F (e r
	(a)	(b)	(c
Equity compensation plan approved by Securities holders (1).....	2,138,768	$ 2.72	
Equity compensation plan not approved by Securities holders.....	-0-	-0-	
Total	2,138,768	$ 2.72	

(1) Reflects options to purchase shares of the Company's common stock and shares available for I Company's Stock Option Plan.

ITEM 6. SELECTED FINANCIAL DATA.

	YEARS ENDED SEPTEMBER 30,			
	2004	2003	2002	2001
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Revenues	$ 29,330	$ 30,260	$ 20,747	$ 13,162
Gross margin %	60%	62%	59%	34%
Operating income (loss)	3,528	3,820	1,666	(2,295)
Net income (loss)	1,503	2,262	901	(672)
Average shares outstanding for basic earnings (loss) per share	15,734,000	15,495,000	15,114,000	14,749,000
Basic earnings (loss) per share	0.10	0.15	0 .06	(0.05)
Average shares outstanding for diluted earnings (loss) per share	16,469,000	16,095,000	15,960,000	14,749,000
Diluted earnings (loss) per share	0.09	0.14	0.06	(0.05)
Balance Sheet Data:				
Working capital	$18,173	$15,783	$10,856	$8,805
Total assets	34,347	30,403	23,748	19,277
Long-term debt	827	728	693	707
Stockholders' equity	22,083	18,046	13,928	12,457

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

FOR THE YEARS ENDED SEPTEMBER 30, 2004 AND 2003

RESULTS OF OPERATIONS

REVENUE AND COST OF REVENUE

Revenue for the year ended September 30, 2004 decreased $1.0 million or 3% to $29.3 million from $30.3 million in 2003. The US operation revenues were $17.1 million or 19% lower than the 2003 revenues of $21.2 million. The decrease in revenue was due to the new arrangement with Zimmer Spine ("Spine"). In April 2003, the Company signed a renegotiated U.S. Distribution Agreement with Centerpulse Spine-Tech, now known as Zimmer Spine, whereby Spine has become a "stocking distributor". The effect of this new arrangement means that Spine has now been invoicing the end customer directly. The new agreement also has eliminated marketing fees paid to Spine included in Distribution and Marketing. The Company's U.S. revenues for the prior year would have been $17.2 million or $4.0 million lower under the new agreement with Spine as compared to the U.S. revenues of $17.1 million for 2004. The Spine business, after considering the new arrangement, decreased by $2.0 million, which is the direct result of over-buying by Spine at the end of the prior year. This decrease in the Spine business was fully offset by an increase in the demand for the Company's TUTOPLAST processed Puros(TM) Bone Grafting Material for dental applications sold by Zimmer Dental ("Dental"), the Company's marketing partner. This product

line contributed an increase in revenue of $3.2 million from the comparable year.

The International operation had revenues of $12.2 million or an increase of 24% or $2.2 million from the 2003 revenues of $9.1 million. The increase in revenues was positively impacted in the amount of $1.3 million by currency exchange rates. The balance of the increase in revenues was primarily due to increased penetration of the French market and improved distributor revenues worldwide.

Gross margins for the year ended September 30, 2004 decreased to 60% from 61% in 2003. The slightly lower margins were primarily due to an unfavorable mix of lower margin products from the dental product revenues versus the spine revenues. The Dental revenues as a percentage of total revenues increased to 24% of total revenues versus 12% a year ago. This unfavorable mix was partially offset by improved manufacturing efficiencies.

GENERAL AND ADMINISTRATIVE

General and Administrative expenses decreased 6% in 2004 to $4.2 million from $4.5 million in 2003. The overall decrease was due primarily to lower compensation from unfilled positions and lower bonus ($462,000) and reduced bad debt reserves ($237,000), partially offset by unfavorable foreign exchange variance ($227,000), merger and acquisition expenses ($190,000) and other expenses ($3,000). As a percentage of revenues, General and Administrative expenses remained at 15% in 2004 and 2003.

DISTRIBUTION AND MARKETING

Distribution and Marketing expenses were essentially flat decreasing $0.1 million in 2004 to $8.7 million from $8.8 million in 2003. The decrease was primarily due to lower marketing fees as a result of the new agreement with Spine, whereby the Spine marketing fees have been eliminated since May 1, 2003. The Spine marketing fees of $2.9 million in 2003 were completely eliminated in 2004, while the marketing fees paid to Dental increased from $1.7 million in 2003 to $3.2 million in 2004 as a result of increased Dental revenues. The reduction in overall marketing fees of $1.4 million was offset by unfavorable foreign exchange variance ($526,000), higher compensation due to the re-building of the direct sales force in Germany and new product managers in the U.S. ($398,000), product brochures and other marketing expenses

($175,000), higher travel expenses ($107,000), office expenses ($104,000), increased commissions ($80,000) and other expenses ($10,000). As a percentage of revenues, Distribution and Marketing expenses increased from 29% in 2003 to 30% in 2004.

RESEARCH AND DEVELOPMENT

Research and Development expenses increased 75% in 2004 to $1.4 million from $0.8 million in 2003. The increase was due to increased development efforts in the spine, dental and ligament product areas. It was noted in last years MD & A that the Company's R & D effort would increase in 2004. As a percentage of revenues, Research and Development expenses increased from 3% in 2003 to 5% in 2004.

LITIGATION CONTINGENCY

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor.

The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company by $406. At September 30, 2004 and 2003, the Company accrued $476 and $836, respectively with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and the final settlement will not have a material impact on its results of operations or financial opinion.

OTHER INCOME/EXPENSE

Other expense for 2004 increased $233,000 from $368,000 in 2003 to $601,000 in 2004. This was primarily the result of higher foreign exchange losses due to the weakness of the dollar versus the euro and higher inter-company balances at year-end.

INTEREST EXPENSE

Interest expenses in 2004 increased due to the leasing of capital expenditure equipment.

PROVISION FOR INCOME TAXES

The provision for income taxes is solely due to the foreign entity being taxed. The Company continues to record the existing valuation allowance on its U.S. operations.

NET INCOME

As a result of the above, net income for the year ended September 30, 2004 totaled $1.5 million, $0.10 basic and $0.09 diluted earnings per share as compared to a net income of $2.3 million, $0.15 basic and $0.14 diluted earnings per share for 2003. As a percentage of revenues, net income decreased from 7.5% in 2003 to 5.1% in 2004.

ACCOUNTS RECEIVABLE

The accounts receivable balance decreased in 2004 by 11% due to an increase in collection efforts resulting in a 32% improvement of the day's sales outstanding from 71 in 2003 to 50 in 2004.

INVENTORY

The inventory balance increased to $15.1 million at September 30, 2004 or 26% from $12.0 million at September 30, 2003. This increase was partially due to a 12% weakening of the dollar against the euro.

The higher inventory also reflects the meeting of contractual commitments in terms of safety stock with its two major marketing partners, Spine and Dental and the building of inventory associated with the introduction of two new product lines for dental applications.

FOR THE YEARS ENDED SEPTEMBER 30, 2003 AND 2002

RESULTS OF OPERATIONS

REVENUE AND COST OF REVENUE

Revenue for the year ended September 30, 2003 increased $9.5 million or 46% to $30.3 million from $20.7 million in 2002. The US operation revenues were

$21.2 million or 54% higher than 2002. The revenue increase was primarily due to an increase in the demand for the Company's TUTOPLAST processed bone products for spinal and dental applications sold by Spine and Dental, the Company's marketing partners. These products contributed $8.1 million of the increase in revenue. This increase was fueled by the introduction, by Spine in February of a new TUTOPLAST specialty graft, the C-Graft for cervical spine fusion, and increased sales levels for the Puros(TM) Symmetry(TM) PLIF Allograft System for spine applications and the Puros(TM) Bone Grafting Material for dental applications. The International operation had revenues of $9.1 million or an increase of 30% from 2002. The increase in revenues was primarily due to increased penetration of the German market and improved distributor revenues worldwide.

Gross margins for the year ended September 30, 2003 increased to 62% from 59% in 2002. The higher margins were primarily due to a favorable mix of higher margin products from the spinal revenues. The Spine revenues contributed $10.8 million versus $5.1 million in 2002. This combined with improved manufacturing efficiencies resulted in higher margins.

GENERAL AND ADMINISTRATIVE

General and Administrative expenses increased 34% in 2003 to $4.5 million from $3.3 million in 2002. The overall increase was due primarily to support the Company's 46% increase in revenue growth, resulting in additional staff ($359,000), foreign exchange variance ($296,000), increased provision for bad debts ($250,000), higher office expenses ($122,000), telephone expenses ($48,000), investor relations/banker ($23,000) and other expenses ($234,000). As a percentage of revenues, General and Administrative expenses decreased from 16% in 2002 to 15% in 2003.

DISTRIBUTION AND MARKETING

Distribution and Marketing expenses increased $2.5 million or 39% in 2003 to $8.8 million from $6.4 million in 2002. The increase was primarily due to the re-building of the direct sales force in Germany ($595,000), foreign exchange variance ($549,000), higher travel expenses ($124,000), product brochures and other marketing expenses ($295,000) and increased marketing fees paid under the agreements with Spine and Dental as a result of the increase in the spine and dental revenues ($897,000). Such fees increased from $3.7 million in 2002 to $4.6 million in 2003. As a percentage of revenues, Distribution and Marketing expenses decreased from 31% in 2002 to 29% in 2003.

RESEARCH AND DEVELOPMENT

Research and Development expenses decreased 10% in 2003 to $0.8 million from $0.9 million in 2002. The decrease was due to the timing of certain projects. It is anticipated that the Company's R & D effort will increase in 2004. As a percentage of revenues, Research and Development expenses decreased from 4% in 2002 to 3% in 2003.

LITIGATION CONTINGENCY

This represents a provision for a judgment received against the Company in Germany regarding a dispute between the Company and a former international distributor in the amount of $657,000 in 2003 and $46,000 in 2002. The judgment is expected to be appealed.

OTHER INCOME/EXPENSE

Other expense for 2003 increased substantially from income of $75,000 in 2002 to expense of $368,000 in 2003. This was primarily the result of unfavorable foreign exchange losses due to the weakness of the dollar versus the euro ($350,000) and other miscellaneous expense ($18,000).

INTEREST EXPENSE

Interest expenses in 2003 decreased 15% due to the Company's ability to maintain minimum revolving credit balances.

PROVISION FOR INCOME TAXES

The provision for income taxes is solely due to the foreign entity being taxed. The Company continues to record the existing valuation allowance on its U.S. operations.

NET INCOME

As a result of the above, net income for the year ended September 30, 2003 totaled $2.3 million $0.15 basic earnings and $0.14 diluted earnings per share as compared to a net income of $0.9 million or $0.06 basic and $0.06 diluted earnings per share for 2002. As a percentage of revenues, net income increased from 4.3% in 2002 to 7.5% in 2003.

ACCOUNTS RECEIVABLE

The accounts receivable balance increased in 2003 by 74% due to the 46% increase in revenues and a significant change in the mix of class of customer (doctors, hospitals, etc.) as a result of the increase in the spine and dental product revenues from year to year. The day's sales outstanding have increased from 60 in 2002 to 71 in 2003.

INVENTORY

The inventory balance increased in 2003 by 21% or $2.0 million while the total revenues increased by 46%. This increase was primarily due to the weakening of the dollar against the euro as the result of a 17% weakening of the dollar. The higher inventory also reflects the meeting of contractual commitments in terms of safety stock with its two major marketing partners, Spine and Dental.

CRITICAL ACCOUNTING POLICIES

The Company's significant accounting policies are more fully described in Note 2 to the consolidated financial statements in the annual report. However, certain of the accounting policies are particularly important to the portrayal of the financial position and results of operations and require the application of significant judgment by management; as a result, they are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on historical experience, terms of existing contracts, observance of trends in the industry, information provided by

customers and information available from other outside sources, as appropriate. The Company's significant accounting policies include:

INVENTORIES. Inventories are valued at the lower of cost (weighted average basis) or market. Work in process and finished goods includes costs

attributable to direct labor and overhead. Reserves for slow moving and obsolete inventories are provided based on historical experience, current product demand and the remaining shelf life. The adequacy of these reserves are evaluated quarterly.

REVENUE RECOGNITION AND ACCOUNTS RECEIVABLE. Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Oral or written purchase authorizations are generally obtained from customers for a specified amount of product at a specified price. Delivery is to have occurred at the time of shipment. Customers are provided with a limited right of return. Revenue is recognized at shipment. Reasonable and reliable estimates of product returns are made in accordance with SFAS No. 48 and allowances for doubtful accounts based on significant historical experience. Revenue from service sales is recognized when the service procedures have been completed or applicable milestones have been achieved. Revenue from distribution fees includes nonrefundable payments received as a result of exclusive distribution agreements between the Company and independent distributors. Distribution fees under these arrangements are recognized as revenue as products are delivered.

FOREIGN CURRENCY TRANSLATION. The functional currency of the Company's German subsidiary is the Euro for the years 2004, 2003 and 2002. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the year. The resulting translation adjustments, representing unrealized, non-cash losses are made directly to comprehensive income. Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in income as they occur. The Company recognized currency losses of $700,000, $350,000 and $51,000 in 2004, 2003 and 2002, respectively. The exchange rates at September 30, 2004, 2003 and 2002 were Euro 0.083/U.S. Dollar, Euro 0.86/U.S. Dollar and Euro 1.01/U.S. Dollar, respectively.

CONCENTRATION OF CREDIT RISK

The exposure to risk related to foreign currency exchange is limited primarily to inter-company transactions. The Company currently does not utilize forward exchange contracts or any other type of hedging instruments.

The Company's principal concentration of credit risk consists of trade receivables. Distribution of products and revenues is provided through a broad base of independent distributors. Two customers accounted for 22% of consolidated revenue in 2004 while the same two customers accounted for 30% of consolidated revenue in 2003 and one customer accounted for 22% in 2002. The Company does not believe that this concentration of sales and credit risks represents a material risk of loss with respect to the financial position as of September 30, 2004 and 2003.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2004 and 2003 the Company had working capital of $18.1 million and $15.8 million, respectively, an increase of 15%. In the past, the Company has relied upon its available working capital lines and institutional investors to fund operational cash flow, when needed.

Net cash remained flat from 2003 to 2004 primarily as the result of increased purchases of property and equipment, from purchases of $690 in 2003 to $1,759 in 2004.

Net cash provided from operating activities was $380,000 in 2004 compared to net cash provided from operating activities of $1,116,000 in 2003. The decrease resulted primarily from the decrease in net income of $759,000.

Net cash used in investing activities, representing purchases of capital expenditures, was $1,759,000 in 2004 and $690,000 in 2003. The increase was due to the construction of clean room facilities in Germany and expansion in the Florida facility and replacement manufacturing equipment.

Net cash from financing activities in 2004 and 2003 of $496,000 and $769,000 relates primarily to the exercise of stock options, partially offset by payments on long-term debt. In 2004, the Company financed the purchase of manufacturing equipment for the Florida facility through an equipment lease debt instrument.

The Company's future minimum commitments and obligations under current operating leases for its offices and manufacturing facilities in the U.S. and Germany, as well as several leases related to office equipment and automobiles through 2008 total $1,965,000. The Company considers these commitments and obligations to be reasonable in order to maintain the current and future business requirements.

The following table summarizes the Company's contractual obligations as of September 30, 2004:

(In thousands)	Total	2005	2006	2007	2008
Long-term debt	$1,000	$ 173	$182	$195	$60
Operating lease obligations	$1,965	$1,146	$521	$214	$64

The Company maintains current working capital credit lines totaling 1.5 million euros (approximately $1.9 million) with three German banks and a $1.0 million credit line with a U.S. bank. At September 30, 2004 the Company had no borrowings against these lines. There are no covenants on the credit lines and senior and equipment debt. The Company's ability to generate positive operational cash flow is dependent upon increasing processing revenue through increased recoveries by tissue banks in the U.S. and Europe, and the development of additional markets and surgical applications for its products worldwide. While the Company believes that it continues to make progress in both these areas, there can be no assurances that changing governmental regulations will not have a material adverse effect on results of operations or cash flow.

The Company may seek additional financing to meet the needs of its long-term strategic plan. The Company can provide no assurance that such additional financing will be available, or if available, that such funds will be available on favorable terms.

ITEM 7A. QUANTITATIVE STATEMENTS AND SUPPLEMENTARY DATA.

In the United States and in Germany the Company is exposed to interest rate risk. Changes in interest rates affect interest income earned on cash and cash equivalents and interest expense on revolving credit arrangements. The

Company does not enter into derivative transactions related to cash and cash equivalents or debt. Accordingly, we are subject to changes in interest rates. Based on September 30, 2004 cash and cash equivalents and long-term debt, a 1% change in interest rates would have a negligible impact on our results of operations.

The value of the U.S. dollar affects our financial results. Changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income. The Company does not maintain hedging programs to mitigate the potential exposures of exchange rate risk. Accordingly, the results of operations are adversely affected by the weakening of the U.S. dollar against the Euro, since

certain products are manufactured and imported form the Company's wholly owned subsidiary in Germany. Because of the foregoing factors, as well as other variables affecting the operating results, past financial performance should not be considered a reliable indictor of future performance.

ITEM 8. FINANCIAL STATEMENTS.

The information required by this Item is found immediately following the signature page of this Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

The Company's principal executive officer and principal financial officer evaluated the Company's disclosure controls and procedures (as defined in Rule 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended) as of a date within 90 days before the filing of this annual report (the "Evaluation Date"). Based on that evaluation, the principal executive officer and principal financial officer of the Company concluded that, as of the Evaluation Date, the disclosure controls and procedures, established by the Company were adequate to ensure that information required to be disclosed by the Company in reports that the Company files under the Exchange Act, is recorded, processed, summarized and reported on a timely basis in accordance with applicable rules and regulations. There have been no significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

ITEM 9B. OTHER INFORMATION.

None PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The following table sets forth the names and ages of the directors and executive officers of the Company (each, a "Director" and/or "Officer"), the positions and offices that each Director and Officer held with the Company, and the period during which each served in such positions and offices. Each Director serves for a term of one (1) year, until his successor is duly elected and qualified.

TABLE OF DIRECTORS AND EXECUTIVE OFFICERS

NAME	AGE	POSITIONS/OFFICES	
G. Russell Cleveland	66	Director	199
Roy D. Crowninshield, Ph.D.	56	Chairman of the Board and CEO Director	Jul 200
Robert C. Farone	62	Director	May
J. Harold Helderman, MD	59	Director	199
Manfred K. Kruger	58	President Chief Executive Officer Chief Operating Officer Director	Jul Dec 200 Jul Jun
George Lombardi	61	Chief Financial Officer, Treasurer and Secretary	199
Richard J. May	40	Director	Apr
Thomas W. Pauken	60	Director Chairman of the Board	Jan Apr
Carlton E. Turner, Ph.D.	64	Director	200

The following is a summary of the business experience of each of the Company's Officers and Directors listed in the above-referenced table, and of certain other significant employees of the Company, during the past five (5) years.

OFFICERS AND DIRECTORS

G. RUSSELL CLEVELAND is the President, Chief Executive Officer, sole Director, and majority shareholder of Renaissance Capital Group, Inc. ("Renaissance"). He is also President, Chief Executive Officer, and a director of Renaissance Capital Growth & Income Fund III, Inc. Mr. Cleveland is a Chartered Financial Analyst with more than thirty-five (35) years experience as a specialist in investments for smaller capitalization companies. A graduate of the Wharton School of Business, Mr. Cleveland has served as President of the Dallas Association of Investment Analysts. Mr. Cleveland currently serves on the Boards of Directors of Renaissance U.S. Growth & Income Trust PLC, Cover-All Technologies, Inc., Digital Recorders, Inc., Integrated Security Systems, Inc., and BFS U.S. Special Opportunities Trust PLC (London).

ROY D. CROWNINSHIELD, PH.D. is the current Chairman of the Board and CEO. Prior to joining Tutogen, Dr. Crowninshield served twenty-one (21) years in various capacities at Zimmer Holdings, Inc., including President of Zimmer's

U.S. operations and most recently as the Company's Chief Scientific Officer. Prior to joining Zimmer, Inc. in 1983, he was a faculty member at the University of Iowa where he led many research projects evaluating the function of total joint implants. He currently holds academic appointments as a professor in the Orthopedic Surgery Department at Rush Medical College in Chicago, Illinois and as an adjunct professor in the College of Engineering of the University of Notre Dame. He holds undergraduate and doctorate degrees from the University of Vermont. He has worked in the orthopedic industry for over twenty (20) years and has extensive experience in the research and development, manufacture, and clinical investigation of orthopedic implants. He has authored more than 100 journal articles, book chapters, and published abstracts in orthopedics and engineering.

ROBERT C. FARONE has been Vice President/General Manager of Samsonite Company Stores since June 2001. Samsonite Company Stores is a chain of 188 retail luggage stores. Mr. Farone had been President of Bag'n Baggage, Ltd. from June 1985 through February 2001. Bag'n Baggage is an 80-store retailer of luggage and leather goods operating in eight (8) states under the trade names Bag'n Baggage, Biagio, Houston Trunk Factory, Malm and Roberto's. Mr. Farone has also served as a director on the board of Caribbean Marine, Inc. from June 1985 to April 2001. From September 1985 to July 1986 he served as a director on the board of 50 Off Stores, and from August 1988 to September 1991 he served as Chairman of the Board. 50 Off Stores was a regional chain of deep discount stores specializing in ready to wear having 72 locations in five states.

J. HAROLD HELDERMAN, MD is Dean of Admissions and Professor of Medicine, Microbiology and Immunology at Vanderbilt University, Nashville, Tennessee, and is the Medical Director of the Vanderbilt Transplant Center. Dr. Helderman received his MD from the State University of New York, Downstate Medical Center in 1971, Summa Cum Laude. In addition to book and monograph writings, he has authored more than 125 publications in his field of transplant medicine. Dr. Helderman is past President of the American Society of Transplantation.

MANFRED K. KRUGER joined the Company in June 1997 as General Manager of the Company's German subsidiary. In that capacity, he was responsible for all scientific research and development, production, and distribution and sales. In February 1999, he became Chief Operating Officer and a member of the Company's Board of Directors. On July 1, 1999 he was appointed President of the Company. Prior to joining the Company, Mr. Kruger was Executive Vice President of Fresenius Critical Care International, a division of Fresenius Medical Care, AG. Prior to Fresenius, Mr. Kruger held management positions with Squibb Medical Systems and American Hospital Supply.

GEORGE LOMBARDI is the Company's Chief Financial Officer, Treasurer and Secretary. He joined the Company in March 1998. Mr. Lombardi was the Vice President, Chief Financial Officer of Sheffield Pharmaceuticals, Inc., a publicly held (AMEX) development stage pharmaceutical/biotech Company. Before that, he was the CFO and Director of Fidelity Medical, Inc. and a Senior Financial Executive for the New Jersey and New England Operations of National Health Laboratories, Inc. Prior to this, Mr. Lombardi held Senior Financial positions at the Boehringer Ingelheim Pharmaceutical Company and the Revlon Healthcare Group in New York. Mr. Lombardi is a CPA certified in the state of New Jersey and has a degree in accounting from Fairleigh Dickinson University.

MR. RICHARD J. MAY has been Vice President of Tax and Tax Counsel of Zimmer Holdings, Inc. since January 2004. Prior to this, he held both tax and finance senior executive positions with Centerpulse, which was recently acquired by Zimmer Holdings, Inc. His most recent position with Centerpulse was Group Vice President Finance and Tax Counsel, primarily responsible for the

worldwide/global tax function. Mr. May has over eighteen (18) years of experience in corporate tax, accounting and finance roles. Prior to joining Centerpulse (previously Sulzer Medica), he worked at Rockwell International and Arthur Andersen & Co. He holds a bachelor's degree in accounting (summa cum laude) from Texas A & M University and a Jurist Doctor degree (cum laude) from the University of Houston Law Center. He is a Certified Public Accountant and a member of the Texas Bar.

THOMAS W. PAUKEN currently serves as the Trustee for Capital Partners II, Ltd. Liquidating Trust. He also serves on the Board of TOR Minerals International, Inc. For six (6) years, Mr. Pauken served as Vice President and Corporate Counsel of Garvon, Inc., a Dallas-based venture capital company. From 1981 to 1985, Mr. Pauken served as Director of ACTION, an independent federal agency. He also served on the White House legal Counsel's staff during the Reagan Administration. Mr. Pauken's military service included a tour of duty in Vietnam as a Military Intelligence Officer. Mr. Pauken received a B.A. from Georgetown University and J.D. degree from Southern Methodist University Law School.

CARLTON E. TURNER, PH.D., D.SC. has been the President and Chief Executive Officer of Carrington Laboratories, Inc. ("Carrington") (NASDAQ: CARN) since April 1995. Carrington is a research-based pharmaceutical and medical device company in the field of wound care products. Dr. Turner has also served as the Chief Operating Officer from November 1994 to April 1995 and as the Executive Vice President of Scientific Affairs from January 1994 to November 1994 at Carrington. Before that, he was the President, Chief Operating Officer and Founder of Princeton Diagnostic Laboratories of America from 1987 to 1993. From 1981 to 1987 he was an Assistant to President Ronald Reagan with Cabinet Rank and Director of the White House Drug Policy Office. Previously, he was a Research Professor and Director of the Research Institute of Pharmacological Science, University of Mississippi.

COMPLIANCE WITH SECTION 16(A) OF THE SECURITIES EXCHANGE ACT OF 1934

The Company believes that the reporting requirements, under Section 16(a) of the Exchange Act, for all its executive officers, directors, and each person who is the beneficial owner of more than 10% of the common stock of a company were satisfied.

COMMITTEES OF THE BOARD OF DIRECTORS

Compensation Committee. The Compensation Committee is composed of Messrs. Farone, Pauken and Dr. Helderman and is chaired by Mr. Farone. This Committee approves, administers and interprets our compensation and benefit policies, including our executive bonus programs. It reviews and makes recommendations to our board of directors to ensure that our compensation and benefit policies are consistent with our compensation philosophy and corporate governance principles. This Committee is also responsible for establishing our CEO's compensation.

Audit Committee. The Audit Committee is composed of Messrs. Turner, Farone and Cleveland and is chaired by Dr. Turner. This Committee has general responsibility for the oversight and surveillance of our accounting, reporting and financial control practices. Among other functions, the Committee retains our independent public accountants. Each member of the Committee is a non-management director. Dr. Turner is a "financial expert" within the definition of that term under the regulations of the Securities Act.

Nominating Committee. The Nominating Committee is composed of Messrs

Cleveland, Farone, Helderman, Pauken and Turner. This committee nominates directors for election by the board or by stockholders and nominates directors for membership on the committees of the board.

ITEM 11. EXECUTIVE COMPENSATION.

COMPENSATION OF DIRECTORS

The Company's outside Directors each receive a $6,000 annual retainer, $1,500 per in-person attendance at Board and Committee meetings, $500 per telephonic meetings, plus reimbursement of out-of-pocket expenses.

COMPENSATION OF EXECUTIVE OFFICERS

The following table sets forth the compensation awarded to, or paid to all persons who have served as Chief Executive Officer and other officers or individuals whose compensation exceeded $100,000 for this period.

SUMMARY COMPENSATION TABLE

		Annual Compensation			Long Term Compe	
					Awards	
Name And Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Other Annual Compensation ($)	Restricted Stock Award(s) ($)	Securiti Underlyi Option (#)
Roy D. Crowninshield Chief Executive Officer	2004	21,000 (2)	0	0	0	100,000
Manfred K. Kruger	2004	428,550	0	0	0	0
President and Chief	2003	352,500	179,700	0	0	37,500
Operating Officer	2002	282,500	68,000	0	0	50,000
George Lombardi	2004	166,500	0	0	0	0
Chief Financial Officer	2003	160,125	67,500	0	0	20,000
Treasurer and Secretary	2002	152,300	29,000	0	0	0
Dr. Karl Koschatzky	2004	140,000	0	0	0	0
Vice President of	2003	107,600	32,400	0	0	45,000
R & D Worldwide	2002	91,200	18,750	0	0	15,000

(1) Includes pension and automobile leasing and other automobile related expenses.

(2) Dr. Crowninshield was appointed Chairman and interim Chief Executive Officer on July 1, 2004. As CEO of the Company, Dr. Crowninshield devotes at least one-third of his time on Company affairs for which he

is compensated at the rate of $7,000 per month and was granted options to purchase 100,000 shares of the Company's common stock.

EMPLOYMENT AGREEMENTS

On December 6, 2004, the Company entered into an employment agreement with Mr. Guy W. Mayer to serve as Chief Executive Officer (CEO) of the Company, commencing January 1, 2005. The term of employment is indefinite and terminates upon written notice by the Company, notice of termination by Mr. Mayer or termination of employment for cause. Minimum notice of termination by the Company, except for cause, is one (1) year from the end of any calendar quarter. Mr. Mayer's employment annual base salary will be $300,000. In addition, the employment agreement provides for a bonus for the balance of the Company's fiscal year 2005 in an amount up to 90% of his earned salary for fiscal 2005, subject to the Company realizing certain performance goals based on revenue and operating income. In addition, Mr. Mayer will be granted a ten (10) year option, upon commencement of employment, to purchase 250,000 shares of the Company's common stock, exercisable at the market price on the date of grant, 25% on the date of grant and

25% on each of the first three (3) anniversaries. At such time that Mr. Mayer assumes his duties as CEO, Mr. Crowninshield will resign as CEO but continue as a board member.

The Company has an employment agreement with Manfred Kruger, its President, Chief Operating Officer and Managing Director, International Operations. Pursuant to that agreement, the term of Mr. Kruger's employment with the Company commenced on June 16,1997. The agreement is for an indefinite period and shall terminate upon written notice by the Company, notice of his election to terminate, or the Company terminates his employment for cause. Minimum notice of termination by the Company, except for cause, is one year from the end of a calendar quarter. Mr. Kruger's annual base salary commencing April 1, 2005 will be $320,000. In addition, the employment agreement provides for an annual bonus in an amount up to 35% of his annual base salary, subject to the satisfaction of reasonable performance goals established by the board. In addition, Mr. Kruger has a "change of control" agreement whereby he is entitled to 12 months salary in the event he is terminated as the result of a change of control of the Company.

The Company has a severance agreement with George Lombardi, its Chief Financial Officer, Treasurer and Secretary. Pursuant to that agreement, upon written notice of his termination at least six weeks before a calendar quarter, the Company will provide six months salary including medical benefits. Mr. Lombardi's annual base salary is currently $166,500. The Company also provides an annual bonus in an amount up to 30% of his annual base salary, subject to the satisfaction of reasonable performance goals established by the board. In addition, Mr. Lombardi has a "change of control" agreement whereby he is entitled to 12 months salary including medical benefits in the event he is terminated as the result of a change of control of the Company.

STOCK OPTION PLANS

The Company has a 1996 Incentive and Non-Statutory Stock Option Plan (the "1996 Plan") to attract, maintain and develop management by encouraging ownership of the Company's Common Stock by Directors, Officers and other key employees. The following is a summary of the provisions of the 1996 Plan. This summary is qualified in its entirety by reference to the 1996 Plan, a copy of which may be obtained from the Company.

The 1996 Plan authorizes the granting of both incentive stock options, as defined under Section 422 of the Internal Revenue Code of 1986 ("ISO"), and non-statutory stock options ("NSSO") to purchase Common Stock. All employees of the Company and its affiliates are eligible to participate in the 1996 Plan. The 1996 Plan also authorizes the granting of NSSOs to non-employee Directors and consultants of the Company. Pursuant to the 1996 Plan, an option to purchase 10,000 shares of Common Stock shall be granted automatically to each outside Director who is newly elected to the Board. In addition, an option to purchase 10,000 shares of Common Stock shall be granted automatically, on the date of each annual meeting of shareholders of the Company, to each outside Director who has served in that capacity for the past six months and continues to serve following such meeting. Any outside Director may decline to accept any option granted to him under the 1996 Plan.

The Board of Directors or the Compensation and Stock Option Committee is responsible for the administration of the 1996 Plan and determines the employees to which options will be granted, the period during which each option will be exercisable, the exercise price, the number of shares of the Common Stock covered by each option, and whether an option will be a non-qualified or an incentive stock option. The exercise price, however, for the purchase of shares subject to such an option, cannot be less than 100% of the fair market value of the Common Stock on the date the option is granted. The Stock Option Committee has no authority to administer or interpret the provisions of the 1996 Plan relating to the grant of options to outside Directors. The current members of the Compensation and Stock Option committee are Robert C. Farone, J. Harold Helderman and Thomas W. Pauken.

No option granted pursuant to the 1996 Plan is transferable otherwise than by will or the laws of descent and distribution. The term of each option granted to an employee under the 1996 Plan is determined by the Board of Directors or the Compensation and Stock Option Committee, but in no event may such term exceed ten (10) years from the date of grant. Each option granted to an outside Director under the 1996 Plan shall be exercisable in whole or in part during the four (4) year period commencing on the date of the grant of such option. Any option granted to an outside Director should remain effective during the entire term, regardless of whether such Director continues to serve as a Director. The purchase price per share of Common Stock under each option granted to a Director will be the fair market value of such share on the date of grant.

The vesting period for options granted under the 1996 Plan are set forth in an option agreement entered into with the optionee. Options granted to an optionee terminate three (3) years after retirement. In the event of death or disability, all vested options expire one (1) year from the date of death or termination of employment due to disability. Upon the occurrence of a "change in control" of the Company, the maturity of all options then outstanding under the 1996 Plan will be accelerated automatically, so that all such options will become exercisable in full with respect to all shares that have not been previously exercised or become exercisable. A "change in control" includes certain mergers, consolidation, and reorganization, sales of assets, or dissolution of the Company.

The 1996 Plan presently reserves 3,500,000 shares of the Company's Common Stock for issuance thereunder. As of September 30, 2004, options have been issued for 3,092,097 shares and 407,903 shares remain available under the 1996 Plan. Unless sooner terminated, the 1996 Plan will expire on February 27, 2006.

OPTIONS GRANTED IN FISCAL YEAR 2004

The following table provides information as to options granted to the Company's Chief Executive Officer during the fiscal year ended September 30, 2004. All such options were granted under the Company's 1996 Stock Option Plan.

	Number of Securities Underlying Options Granted (#)	Percent of Total Options Granted To Employees	Exercise or Base Price ($/Sh)	Expiration Date	Pot V An Stock fo --
Roy D. Crowninshield	100,000	44.4%	$3.75	August 5, 2014	$61

(1) Potental realizable value is based on the assumption that the Common Stock appreciates at the annual rate shown (compounded annually) from the due date of grant until the expirationof the option term. These numbers are calculated based on the requirements of the SEC and do not reflect the Company's estimate of future price growth.

The following table sets forth the value of the unexercised options at September 30, 2004. No options were exercised during this fiscal year. The market price of the Company's common stock at September 30, 2004 was $2.99.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FY-END OPTION VALUES

Name	Number of Unexercised Options at September 30, 2004		Value of In-the-Mon Septembe
	Exercisable	Unexercisable	Exercisable
Roy D. Crowninshield	25,000	75,000	- 0 -
Manfred K. Kruger	568,750	31,250	$ 692,425
George Lombardi	208,000	10,000	$ 230,015
Dr. Karl Koschatzky	90,418	36,250	$ 119,619

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

The Compensation Committee consists of Messrs. Farone, Pauken and Dr. Helderman. There are no "interlocks" as defined by the SEC with respect ot any member of the committee.

COMPENSATION COMMITTEE REPORT

The following Report of the Compensation Committee and the information under the heading Performance Graph below shall not be deemed incorporated by reference by any general statement incorporating by reference into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934 together, the "Acts"), except to the extent that the Company specifically incorporates the information by reference, and shall not otherwise be deemed filed uner the Acts.

The Compensation Committee oversees the Company's compensation program. The goals of the Company's compensation program are to attract, retain, motivate and reward highly qualified management personnel and to provide them with long-term career opportunities. The Company's compensation philosophy is to provide its executives with a competitive total compensation package which motivates superior job performance, the achievement of the Company's business objectives, and the enhancement of shareholder value.

Compensation of the Company's executive officers is reviewed annually by the Board of Directors and the Compensation Committee. Changes proposed for these employees are evaluated and approved by the Compensation Committee on an individual basis. The Company's general approach to compensating executive officers is to pay cash salaries which generally are competitive within ranges of salaries paid to executives of other similar companies, although the Company does not attempt to meet salary levels of such companies. Instead, the Committee sets overall compensation at a level it believes to be fair, based upon a subjective analysis of the individual executive's experience and past and potential contributions to the Company. The Committee also establishes bonus goals for executive officers so as to compensate them on a performance basis. To assist in determining appropriate overall compensation, the Compensation Committee also reviews information regarding the Company's revenues and income.

Stock option grants to employees of the Company, including the Chief Executive Oficer, are made at the discretion of the Compensation Committee pursuant to the Company's 1996 Stock Option Plan. Factors and criteria to be used by the Committee in the award of stock options include individual

responsibilities, individual prerformenace and direct and indirect contributions to the profitability performance and direct and indirect contributions to the profitability of the Company.

Respectfully submitted,
The Compensation Committee

Robert C. Farone
Thomas W. Pauken
J. Harold Helderman, M.D.

PERFORMANCE GRAPH

The following graph shows a comparison of cumulative five (5) year total stockholder returns for the Company's Common Stock, with the cumulative return of the Nasdaq Stock Market - U.S. Index and an industry peer group. The industry peer group of companies selected by the Company is made up of the Company's publicly held competitors in the Medical Device industry. The graph assumes the investment of $100 on August 17, 2000, the date on which trading commenced on the American Stock Exchange. The comparisons reflect in the table and graph,

however, are not intended to forcast the future performance of the Common Stock and may not be indicative of such future performance.

COMPARE 5-YEAR CUMULATIVE TOTAL RETURN
AMONG TUTOGEN MEDICAL, INC.,
AMEX MARKET INDEX AND PEER GROUP INDEX

[PERFORMANCE GRAPH]

Note: Assumes $100 invested on August 17, 2000 and assumes dividends reinvested.

	8/17/00	12/31/00	12/31/01	12/31/02	12/31/03
TUTOGEN MEDICAL	100.00	64.71	47.84	51.76	70.75
PEER GROUP INDEX	100.00	87.66	106.68	86.27	126.91
NASDAQ MARKET INDEX	100.00	90.88	86.69	83.23	113.29

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information regarding the beneficial ownership of the Company's Common Stock as of November 30, 2004, by (i) each person known to the Company to own beneficially more than 5% of its Common Stock, (ii) each director and executive officer of the Company, and (iii) all directors and executive officers as a group. As of November 30, 2004, there were approximately 15,915,960 shares of Common Stock issued and outstanding.

NAME AND ADDRESS OF BENEFICIAL OWNER	AMOUNT AND N OF BENEFICIAL OW
Capital Partners II, Ltd. Liquidating Trust (5) (9) ..... 5646 Milton Street Suite 628 Dallas, TX 75206	2,924,9
SPV 1996 LP. ..... 101 Finsbury Pavement London, England EC2A 1EJ	1,896,7

Zimmer CEP (formerly Centerpulse) USA Holding Co. ..... Subsidiary of Zimmer Holdings, Inc. 345 East Main Street Warsaw, IN 46580	5,297,1
G. Russell Cleveland (4)	107,3
Roy D. Crowninshield (11).....	35,0
Robert C. Farone (5)	145,8
Dr. J. Harold Helderman (7)	118,5
Dr. Karl Koschatsky (8)	87,0
Manfred K. Kruger (8)	568,7
George Lombardi (8)	208,0
Richard J. May (6)	- 0
Thomas W. Pauken (9)	3,263,0
Carlton E. Turner (8).....	60,0
All directors and officers as a group (10 persons) (10)	9,890,5

* Less than 1%

1 In accordance with Rule 13d-3 promulgated pursuant to the Exchange Act, a person is deemed to be the beneficial owner of the security for purposes of the rule if he or she has or shares voting power or

dispositive power with respect to such security or has the right to acquire such ownership within sixty days. As used herein, "voting power" is the power to vote or direct the voting of shares and "dispositive power" is the power to dispose or direct the disposition of shares, irrespective of any economic interest therein.

2 Except as otherwise indicated by footnote, the persons named in the table have sole voting and investment power with respect to all of the common stock beneficially owned by them.

3 In calculating the percentage ownership for a given individual or group, the number of shares of common stock outstanding includes unissued shares subject to options, warrants, rights or conversion privileges exercisable within sixty days after November 30, 2004 held by such individual or group.

4 Includes 50,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days. Mr. Cleveland is the President and majority shareholder of Renaissance Capital Group, Inc. His business address is 8080 N. Central Expressway, Suite 210-LB 59, Dallas, TX 75206.

5 Includes 50,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days. Mr. Farone is a Supervisory Trustee of Capital Partners II, Ltd. Liquidating Trust.

6 Mr. May serves on the board as representative of Zimmer Holdings, Inc. Mr. May disclaims beneficial ownership of the shares owned by Zimmer CEP USA Holding Co., a subsidiary of Zimmer Holdings, Inc.

7 Includes 90,000 shares of common stock issuable upon exercise of options

and warrants exercisable within sixty (60) days.

8 All of the shares of common stock beneficially owned by Messrs. Koschatzky, Kruger, Lombardi, and Turner are derivative securities issuable upon exercise of options exercisable within sixty (60) days.

9 Includes all of the shares of common stock beneficially owned by Capital Partners II, Ltd Liquidating Trust. Mr. Pauken is the Trustee of Capital Partners II, Ltd. Liquidating Trust and has voting rights to all of the shares owned by the Trust. Mr. Pauken separately has beneficial ownership in 338,040 shares of common stock. It also includes 120,000 shares of common stock issuable upon exercise of options and warrants exercisable within sixty (60) days.

10 Includes shares owned by Zimmer CEP USA Holding Co., a subsidiary of Zimmer Holdings, Inc.

11 Includes 25,000 shares of common stock issuable upon exercise of options and warrants exercisable within sixty (60) days.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The Company has an exclusive license and distribution agreement with Spine, a wholly owned subsidiary of Zimmer Holdings, Inc., whereby Spine has been granted the right to act as the Company's exclusive distributor of bone tissue for spinal applications in the United States. For the year ended September 30, 2004, Spine revenues were $4.8 million.

The Company has also engaged Dental, a wholly owned subsidiary of Zimmer, to act as an exclusive distributor for the Company's bone tissue for dental applications in the United States and certain international markets. For the year ended September 30, 2004, Dental was paid commissions aggregating approximately $3.2 million on revenues of $6.9 million.

Centerpulse, a wholly owned subsidiary of Zimmer Holdings, Inc. is the owner of approximately 33.3% of the Company's outstanding shares of Common Stock and has representation on the Company's board of directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following table represents the aggregate fees billed for professional audit services rendered to the Company by Deloitte & Touche, LLP for the audit of the Company's annual financial statements for the

years ended September 30, 2004 and 2003, and all fees billed for other services by Deloitte & Touche LLP during those periods:

Year Ended September 30,	2004	2003
Audit fees (1)	$105,500	$126,873
Audit-related fees (2)	27,864	
Tax fees (3)	11,462	4,134
All other fees (4)		16,212
Total Accounting Fees and Services	$144,826	$143,085

(1) AUDIT FEES. These are fees for professional services for the audit of the Company's annual financial statements, and for the review of the financial statements included in the Company's filings on Form 10Q and for services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) AUDIT-RELATED FEES. These are fees for the assurance and related services reasonably related to the performance of the audit or the review of the Company's financial statements.

(3) TAX FEES. These are fees for professional services with respect to tax compliance, tax advice, and tax planning.

(4) ALL OTHER FEES. These are fees for permissible work that does not fall within any of the other fee categories, i.e., Audit Fees, Audit-Related Fees, or Tax Fees.

PRE-APPROVAL POLICY FOR AUDIT AND NON-AUDIT SERVICES

The Company's Audit Committee has responsibility for the approval of all audit and non-audit services before the Company engages an accountant. All of the services rendered to the Company by Deloitte & Touche for the fiscal years ended September 30, 2004 and 2003 were pre-approved by the Audit Committee before the engagement of the auditors for such services.

The Company and the Audit Committee are working with the Company's legal counsel to establish formal pre-approval policies and procedures for all future engagements of the Company's accountants. In accordance with the rules and regulations of the U.S. Securities and Exchange Commission relating to the independence of auditors, the Company's new pre-approval policies and procedures will be detailed as to particular services, will require that the Audit Committee be informed of each service, and will prohibit the delegation of any pre-approval responsibilities to the Company's management.

The Company's pre-approval policy will expressly provide for the annual pre-approval of all audit, audit-related and all non-audit services proposed to be rendered by the independent auditor for the fiscal year, as specifically described in the auditor's engagement letter, such annual pre-approval to be performed by the Audit Committee. The new policy will also provide that all additional engagements of the auditor that were not approved in the annual pre-approval process, and all engagements that are anticipated to exceed previously approved thresholds, shall be presented by the President or Chief Financial Officer of the Company to the Audit Committee for pre-approval, on a case-by-case basis, before management engages the auditors for any such purposes. The Audit Committee may be authorized to delegate, to one or more of its members, the authority to pre-approve certain permitted services, provided that the estimated fee for any such service does not exceed a specified dollar amount.

All pre-approvals shall be contingent on a finding, by the Audit Committee, or delegates thereof, as the case may be, that the provision of the proposed services by the Company's auditor is compatible with the maintenance of the auditor's independence in the conduct of its auditing functions. In no event shall any non-audit related service be approved that would result in the independent auditor no longer being considered independent under the applicable rules and regulations of the Securities and Exchange Commission.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(A) INDEX TO EXHIBITS

3.2 Articles of Incorporation of Registrant.**

3.3 Articles of Amendment to Articles of Incorporation Establishing Series A Preferred Stock.*

3.4 Articles of Amendment to Articles of Incorporation Establishing Series B Preferred Stock.*

3.5 Articles of Amendment to Articles of Incorporation Establishing Series C Preferred Stock.*

3.6 Articles of Amendment to Articles of Incorporation Increasing the Number of Authorized Shares.*

3.7 Articles of Amendment to Articles of Incorporation Amending the Terms of the Series C Preferred Stock.*

3.8 Articles of Amendment to Articles of Incorporation Effecting Reverse Stock Split*

10.7 Employment Agreement between the Registrant and Manfred Kruger dated June 9, 1997. *

10.8 Employment Agreement between Biodynamics International, Inc., and George Lombardi, dated March 30, 1998.*

10.9 Employment Agreement between the Registrant and Mr. Guy Mayer dated December 6, 2004.***

14 Code of Ethics***

21 Subsidiaries of Registrant.*

* Document incorporated by reference from previous Form 10-KSB filings.
** Document incorporated by reference from Exhibit 2 of Registration Statement, on Form 20-F, of American Biodynamics, Inc., effective October 2, 1987.
*** Filed herewith.

(b) FINANCIAL STATEMENT SCHEDULES

Schedules have been omitted because they are not required or are not applicable or because the information required to be set forth therein either is not material or is included in the financial statements or notes thereto.

(c) REPORTS ON 8-K

Reference is made to the Company's Form 8-K reports, dated November 3, 2003, December 16, 2003 and December 29, 2003, responding to Item 13.

SIGNATURES

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

Date December 23, 2004

TUTOGEN MEDICAL, INC.

/s/ Roy D. Crowninshield

Roy D. Crowninshield
Chief Executive Officer

/s/ Manfred K. Kruger

Manfred K. Kruger
President and Chief Operating Officer

/s/ George Lombardi

George Lombardi
Chief Financial Officer, Treasurer and Secretary

In accordance with the Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and the dates indicated.

Signature	Title	Date
/s/ G. Russell Cleveland G. Russell Cleveland	Director	December 23, 2004
/s/ Roy D. Crowninshield Roy D. Crowninshield	Director	December 23, 2004
/s/ Robert C. Farone Robert C. Farone	Director	December 23, 2004
/s/ J. Harold Helderman Dr. J. Harold Helderman	Director	December 23, 2004
/s/ Manfred K. Kruger Manfred K. Kruger	Director	December 23, 2004
/s/ Richard J. May Richard J. May	Director	December 23, 2004

/s/ Thomas W. Pauken Thomas W. Pauken	Director	December 23, 2004

/s/ Carlton E. Turner	Director	December 23, 2004

Carlton E. Turner

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

CONSOLIDATED FINANCIAL STATEMENTS

Years Ended September 30, 2004, 2003 and 2002

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Tutogen Medical, Inc. and Subsidiaries
West Paterson, New Jersey

We have audited the accompanying consolidated balance sheets of Tutogen Medical, Inc. and subsidiaries (the "Company") as of September 30, 2004 and 2003, and the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a

test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

November 19, 2004
New York, New York

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2004 AND 2003
(In Thousands)

	2004	2
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,063	$
Accounts receivable, net of allowance for doubtful accounts of $192 in 2004 and $429 in 2003	4,922	
Inventories - net	15,072	1
Deferred income taxes	425	
Other current assets	1,409	
Total current assets	26,891	2
PROPERTY, PLANT AND EQUIPMENT - Net	6,138	
DEFERRED INCOME TAXES	1,318	
TOTAL ASSETS	$ 34,347	$ 3
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and other accrued expenses	$ 6,521	$
Accrued commissions	1,521	
Current portion of deferred distribution fees	642	
Current portion of long-term debt	173	
Total current liabilities	8,857	

OTHER LIABILITIES:		
Deferred distribution fees	2,580	
Long-term debt	827	
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY	22,083	1
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 34,347	$ 3

See notes to consolidated financial statements.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME
YEARS ENDED SEPTEMBER 30, 2004, 2003 AND 2002
(In Thousands, Except for Share Data)

	2004	2003	
REVENUE	$ 29,330	$ 30,260	$
COST OF REVENUE	11,836	11,640	
Gross profit	17,494	18,620	
OPERATING EXPENSES:			
General and administrative	4,203	4,482	
Distribution and marketing	8,737	8,835	
Research and development	1,432	826	
Litigation contingency	(406)	657	
Total operating expenses	13,966	14,800	
OPERATING INCOME	3,528	3,820	
OTHER (EXPENSE) INCOME	(601)	(368)	
INTEREST EXPENSE	(118)	(53)	
INCOME BEFORE PROVISION FOR INCOME TAXES	2,809	3,399	
PROVISION FOR INCOME TAXES	1,306	1,137	
NET INCOME	1,503	2,262	

COMPREHENSIVE INCOME:			
Foreign currency translation adjustments	2,167	1,006	
COMPREHENSIVE INCOME	$ 3,670	$ 3,268	$
AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS PER SHARE	15,734,470	15,495,148	15
BASIC EARNINGS PER SHARE:	$ 0.10	$ 0.15	$
AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS PER SHARE	16,469,443	16,095,448	15
DILUTED EARNINGS PER SHARE:	$ 0.09	$ 0.14	$

See notes to consolidated financial statements.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2004, 2003 and 2002
(In Thousands)

	2004	2003
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 1,503	$ 2,26
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	760	61
Deferred distribution fees revenue	(640)	(57
Reserve for bad debts	(245)	25
Reserve for obsolescence	(953)	1,18
Deferred income taxes	869	1,15
Changes in assets and liabilities:		
Accounts receivable	969	(2,38
Inventories	(1,824)	(2,54
Other current assets	(241)	(63
Accounts payable and other accrued expenses	(894)	2,75
Accrued commissions	1,076	(94
Net cash provided by (used in) operating activities	380	1,11
CASH FLOWS USED IN INVESTING ACTIVITIES		
Purchase of property and equipment	(1,759)	(69

CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of common stock	367	85
Proceeds from revolving credit arrangements	-	34
Repayment of revolving credit arrangements	-	(34
Proceeds from long-term borrowings	224	
Repayment of long-term debt	(95)	(8
Net cash provided by (used in) financing activities	496	76
EFFECT OF EXCHANGE RATE CHANGES ON CASH	897	771
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14	1,96
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	5,049	3,08
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 5,063	$ 5,04
SUPPLEMENTAL CASH FLOW DISCLOSURE -		
Interest paid	$ 118	$ 5
Income taxes paid	$ 251	$

See notes to consolidated financial statements.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY YEARS ENDED SEPTEMBER 30, 2004, 2003 AND 2002 (In Thousands, Except for Share Data)

	COMMON SHARES ($.01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) (1)	ACCUMULAT DEFICIT
BALANCE, OCTOBER 1, 2001	$ 150	$ 34,820	$ (1,178)	$ (21,33
Stock issued on exercise of options	2	315	-	
Net income	-	-	-	90
Foreign currency translation adjustment	-	-	253	
BALANCE, SEPTEMBER 30, 2002	152	35,135	(925)	(20,43
Stock issued on exercise of options	5	845	-	
Net income	-	-	-	2,26
Foreign currency translation adjustment	-	-	1,006	

BALANCE, SEPTEMBER 30, 2003	157	35,980	81	(18,17
Stock issued on exercise of options	2	365	-	
Net income	-	-	-	1,50
Foreign currency translation adjustment	-	-	2,167	
BALANCE, SEPTEMBER 30, 2004	$ 159	$ 36,345	$ 2,248	$ (16,66

(1) Represents foreign currency translation adjustments.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED SEPTEMBER 30, 2004, 2003 AND 2002
(IN THOUSANDS, EXCEPT FOR SHARE DATA)

1. OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. with its consolidated subsidiaries (the "Company") processes, manufactures and distributes worldwide, specialty surgical products and performs tissue processing services for neuro, orthopedic, reconstructive and general surgical applications. The Company's core business is processing human donor tissue, utilizing its patented Tutoplast(R) process, for distribution to hospitals and surgeons. The Company processes at its two manufacturing facilities in Germany and the United States and distributes its products and services to over 30 countries worldwide.

2. SIGNIFICANT ACCOUNTING POLICIES

Significant accounting policies of the Company are presented below.

PRINCIPLES OF CONSOLIDATION - The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

FOREIGN CURRENCY TRANSLATION - The functional currency of the Company's German subsidiary is the Euro. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the year. The resulting translation adjustments, representing unrealized, noncash losses are made directly to comprehensive income. Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in income as they occur and are included in Other Expense (Income) in the Consolidated Statements of Income and Comprehensive Income. The Company recognized currency losses of $700, $350 and $51 in 2004, 2003 and in 2002, respectively. The exchange rates at September 30, 2004, 2003 and 2002 were Euro 0.83/U.S. Dollar and Euro 0.86/U.S. Dollar and Euro 1.01/U.S. Dollar, respectively.

FAIR VALUE OF FINANCIAL INSTRUMENTS - The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature. The estimated fair value of all other amounts has been determined by using available market information and appropriate valuation methodologies.

CASH AND CASH EQUIVALENTS - The Company considers all highly liquid investments purchased with a remaining maturity of three months or less to be cash equivalents. For cash and cash equivalents, the carrying amount approximates fair value due to the short maturity of those instruments.

INVENTORIES - Inventories are valued at the lower of cost (weighted average basis) or market. Work in process and finished goods includes costs attributable to direct labor and overhead. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand. The adequacy of these reserves are evaluated quarterly.

PROPERTY, PLANT AND EQUIPMENT - Property, plant and equipment are stated at cost. Depreciation is computed by using the straight-line method over the following estimated useful lives of the assets:

Building and improvements	40 years
Machinery, equipment, furniture and fixtures	3-10 years

LONG-TERM DEBT - The carrying value of long-term debt approximates fair value.

REVENUE AND COST OF REVENUE - Revenue includes amounts from surgical products and related services and distribution fees. Cost of revenue includes depreciation of $311, $404 and $280 for the years ended September 30, 2004, 2003 and 2002, respectively. Revenue from surgical products and related services is recognized upon the shipment of the processed tissues and when services are performed. The Company's terms of sale are FOB shipping point. Revenue from distribution fees includes nonrefundable payments received as a result of exclusive distribution agreements between the Company and independent distributors. Distribution fees under these arrangements are recognized as revenue on a straight line basis over the contract period.

RESEARCH AND DEVELOPMENT COSTS - Research and development costs are charged to operations as incurred.

EARNINGS PER SHARE - Basic earnings per share are computed by dividing net income by the weighted-average number of common shares outstanding. Diluted earnings per share are computed by dividing net income by the sum of the weighted-average number of common shares outstanding plus the dilutive effect of shares issuable through deferred stock units and the exercise of stock options and warrants.

USE OF ESTIMATES - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

TOTAL COMPREHENSIVE INCOME - The Company follows Statement of Financial Accounting Standard ("SFAS") No. 130, REPORTING COMPREHENSIVE INCOME (LOSS). Comprehensive income is defined as the total change in shareholders' equity during the period other than from transactions with shareholders, and for the Company, includes net income and cumulative translation adjustments.

INCOME TAXES - Deferred taxes are provided for the expected future income tax consequences of events that have been recognized in the Company's financial statements. Deferred tax assets and liabilities are determined based on the temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the temporary differences are expected to reverse.

STOCK-BASED COMPENSATION - SFAS No. 123, ACCOUNTING FOR STOCK-BASED COMPENSATION ("SFAS 123"), requires expanded disclosure of stock-based compensation arrangements with employees and encourages (but does not require) compensation cost to be measured based on the fair value of the equity instrument awarded. Corporations are permitted, however, to continue to apply Accounting Principles Board ("APB") Opinion No. 25, which recognizes compensation cost based on the intrinsic value of the equity instrument awarded. The Company has continued to apply APB Opinion No. 25 to its stock-based compensation awards to employees and has disclosed the required pro forma effect on net income.

The FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 148

provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. (Under the fair value based method, compensation cost for stock options is measured when options are issued). In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The Company adopted SFAS No. 148 beginning in the second fiscal quarter of fiscal 2003 and such disclosures are included as herein.

The following table reconciles net income and basic and diluted earnings pre share (EPS), as reported, to pro-forma net income and basic and diluted EPS, as if the Company had expensed the fair value of stock options as permitted by SFAS No. 123, as amended by SFAS No. 148, since it permits alternative methods of adoption.

	2004	2003	2002
Net Income, as reported:	$1,503	$2,262	$901
Pro-forma expense as if stock options were charged against net income	159	104	244
Pro-forma net income using the fair value method	$1,344	$2,158	$657

Basic EPS:			
As reported	$0.10	$0.15	$0.06
Pro forma using the fair value method	$0.09	$0.14	$0.04
Diluted EPS:			
As reported	$0.09	$0.14	$0.06
Pro forma using the fair value method	$0.08	$0.13	$0.04

NEW ACCOUNTING PRONOUNCEMENTS - In April 2003, the Financial Accounting Standards Board ("FASB") issued SFAS No. 149, AMENDMENT OF STATEMENT 133 ON DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES. SFAS No. 149 amends SFAS No. 133 for certain decisions made by the Board as part of the Derivatives Implementation Group process and is effective for contracts entered into or modified after June 30, 2003. The Company did not have derivative instruments or hedging activities at September 30, 2004.

In June 2003, the FASB issued SFAS No. 150, ACCOUNTING FOR CERTAIN FINANCIAL INSTRUMENTS WITH CHARACTERISTICS OF BOTH LIABILITIES AND EQUITY to improve the accuracy of securities issuers' accounting for such financial instruments. The adoption of SFAS No. 150 did not have an impact on the results of operations or financial position.

In January 2003, the FASB issued FIN No. 46, as restated by FIN No. 46R, "CONSOLIDATION OF VARIABLE INTEREST ENTITIES, AN INTERPRETATION OF ARB 51." FIN No. 46 defines when a business enterprise must consolidate a variable interest entity. This interpretation applies immediately to variable interest entities created after January 31, 2003. It applies in the first fiscal year or interim period beginning after December 15, 2003, to entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The Company does not have variable interest entities as of September 30, 2004.

EMPLOYEE SAVINGS PLAN - The Company maintains the Tutogen Medical, Inc. 401(k) Plan (the "Plan") for which all of the United States Employees are eligible. The Plan requires the attainment of the age of 21 and a minimum of six months of employment to become a participant. Participants may contribute up to the maximum dollar limit set by the Internal Revenue Service. The expenses incurred for the Plan were $73, $55 and $26 in 2004, 2003 and 2002, respectively.

RECLASSIFICATION - Certain reclassifications have been made to the prior financial statements to conform to the current presentation.

3. CONCENTRATION OF CREDIT RISK

The exposure to risk related to foreign currency exchange rate changes is limited primarily to intercompany transactions. The Company currently does not utilize forward exchange contracts or any other type of hedging instruments.

The Company's principal concentration of credit risk consists of trade receivables. Distribution of products and revenues is provided through a broad base of independent distributors. Two customers accounted for 13% and 9%, respectively, of consolidated revenue in 2004, two customers accounted for 17% and 13%, respectively of consolidated revenue in 2003 and one customer accounted for 22% of consolidated revenue for 2002. The 13% and 9% customers had accounts receivable balances at September 30, 2004 of $719 and $8, respectively. There are no other customers

accounting for greater than 10% of consolidated revenue in 2004, 2003 and 2002. The Company does not believe that this concentration of sales and credit risks represents a material risk of loss with respect to the results of operations or financial position.

4. INVENTORIES

Major classes of inventory at September 30, 2004 and 2003 were as follows:

	2004	2003
Raw materials	$ 2,171	$ 2,439
Work in process	6,560	3,316
Finished goods	8,791	9,335
	17,522	15,090
Less reserves for obsolescence	2,450	3,098
	$ 15,072	$ 11,992

5. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at September 30, 2004 and 2003 consisted of the following:

	2004	2003
Land	$ 512	$ 480
Buildings and improvements	4,348	3,306
Machinery and equipment	2,201	1,583
Office furniture and equipment	2,570	2,446
	9,631	7,815
Less accumulated depreciation and amortization	(3,493)	(2,973)
	$ 6,138	$ 4,842

The depreciation expense for the years ended September 30, 2004, 2003 and 2002 was approximately $760, $611 and $414, respectively.

6. REVOLVING CREDIT ARRANGEMENTS

Under the terms of revolving credit facilities with three German banks, all of which have no expiration, the Company may borrow up to Euros 1.5 million or approximately $1.9 million for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 9.15% to 10.5%. At September 30, 2004, and 2003 the Company had no borrowings under the revolving credit agreements.

The Company has a revolving credit facility in the U.S. for up to $1.0

million, expiring on January 1, 2005. At September 2004 and 2003, the Company had no borrowings under this credit facility. The U.S. accounts receivable and inventory assets secure the borrowing under the revolving credit facility.

7. LONG-TERM DEBT

Long-term debt at September 30, 2004 and 2003 consisted of the following:

Senior debt, 5.75% interest until March 30, 2008 when terms are renegotiable, due 2008	$ 776	$ 819
Equipment lease debt, 6.50% interest until September 1, 2007	224	-
	1,000	819
Less current portion	(173)	(91)
	$ 827	$ 728

Aggregate maturities of long-term debt are $173 in 2005; $182 in 2006; $195 in 2007; $60 in 2008; and the balance $390 due in 2009.

The Senior debt and one of the revolving credit facilities are with a German bank and are secured by a mortgage on the Company's German facility. The Senior debt is repayable in monthly installments through 2008. The debt has been incurred by the Company's German subsidiary but is guaranteed by the parent company. There are no financial covenants under this debt.

The Equipment lease debt is secured by a specific piece of equipment, a walk-in freezer, located at the Company's Florida manufacturing facility. The lease is payable in twelve quarterly installments of $21. There are no financial covenants under this lease.

8. SHAREHOLDERS' EQUITY

STOCK - The authorized stock of the Company consists of 30,000,000 shares of Common Stock and 1,000,000 shares of Preferred Stock.

PREFERRED SHARE PURCHASE RIGHT - On July 17, 2002, the Board of Directors of the Company declared a dividend distribution of one Preferred Share Purchase Right for each outstanding share of its common stock of record on July 31, 2002. The rights, which expire on July 30, 2012, are designed to assure that all of the Company's shareholders receive fair and equal treatment in the event of any proposed takeover of the Company. Each right will entitle its holder to purchase, at the right's then current exercise price, a number of the Company's common shares having a market value of twice such price.

STOCK OPTIONS - The Company maintains a 1996 Stock Option Plan (the "Plan") (3,500,000 shares authorized) under which incentive and nonqualified options have been granted to employees, directors and certain key affiliates. Under the Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

Changes in outstanding options for the Plan were as follows:

Outstanding October 1, 2001	2,247,068	$ 2.18
Granted	349,000	3.67
Canceled	(151,650)	2.82
Exercised	(226,750)	1.40
Outstanding September 30, 2002	2,217,668	2.44
Granted	452,500	2.91
Canceled	(204,800)	3.33
Exercised	(209,000)	1.81
Outstanding September 30, 2003	2,256,368	2.52
Granted	225,000	3.98
Canceled	(93,750)	4.45
Exercised	(248,850)	1.47
Outstanding September 30, 2004	2,138,768	$ 2.72

The following table provides information about stock options outstanding at September 30, 2004:

	OPTIONS OUTSTANDING			OPTIONS EXERC
RANGE OF EXERCISE PRICE	NUMBER OUTSTANDING AS OF 9/30/04	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AS OF 9/30/04
$0.94 to $1.25	306,600	4.9	$ 0.95	306,600
$1.56 to $2.22	572,568	3.5	1.71	572,568
$2.40 to $3.62	806,500	6.5	2.98	493,250
$3.75 to $11.00	453,100	4.5	4.67	374,350

$0.94 to $11.00	2,138,768	4.9	$ 2.72	1,746,768

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions: expected volatility of 47%, a risk-free interest rate range of 2.26% to 3.12% and an expected life of four years. A dividend yield of zero has been assumed. The weighted average fair value of options granted during the years ended September 30, 2004, 2003 and 2002 was $3.98, $2.91 and $3.67, respectively.

9. SEGMENT DATA

The Company operates principally in one industry providing specialty surgical products and tissue processing services. These operations include two geographically determined segments: the United States and Europe ("International"). The accounting policies of these segments are the same as those described in the summary of significant accounting policies. The Company evaluates performance based on the operating income. The Company accounts for intersegment sales and transfers at contractually agreed-upon prices.

The Company's reportable segments are strategic business units that offer products and services to different geographic markets. They are managed separately because of the differences in these markets as well as their physical location.

A summary of the operations and assets by segment as of and for the years ended September 30, 2004, 2003 and 2002 are as follows:

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 22,830	$ 17,126	$ 39,956
Less - intercompany	(10,626)	-	(10,626)
Total revenue - third party	$ 12,204	$ 17,126	$ 29,330
Depreciation and amortization	$ 506	$ 254	$ 760
Operating income	$ 4,549	$ (1,021)	$ 3,528
Interest expense	$ 79	$ 39	$ 118
Net income	$ 2,659	$ (1,156)	$ 1,503
Capital expenditures	$ 1,244	$ 515	$ 1,759

	========	========	========
Identifiable assets	$ 18,166	$ 16,181	$ 34,347
	========	========	========

2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 18,079	$ 21,168	$ 39,247
Less - intercompany	(8,987)	-	(8,987)
	--------	--------	--------
Total revenue - third party	$ 9,092	$ 21,168	$ 30,260
	========	========	========
Depreciation and amortization	$ 376	$ 235	$ 611
	========	========	========
Operating income	$ 4,005	$ (185)	$ 3,820
	========	========	========
Interest expense	$ 47	$ 6	$ 53
	========	========	========
Net income	$ 2,144	$ 118	$ 2,262
	========	========	========
Capital expenditures	$ 470	$ 220	$ 690
	========	========	========
Identifiable assets	$ 10,983	$ 19,420	$ 30,403
	========	========	========

2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 13,122	$ 13,716	$ 26,838
Less - intercompany	(6,091)	-	(6,091)
	--------	--------	--------
Total revenue - third party	$ 7,031	$ 13,716	$ 20,747
	========	========	========
Depreciation and amortization	$ 182	$ 232	$ 414
	========	========	========
Operating income	$ 1,837	$ (171)	$ 1,666
	========	========	========
Interest expense	$ 57	$ 5	$ 62
	========	========	========
Net income	$ 1,102	$ (201)	$ 901
	========	========	========

Capital expenditures	$ 148	$ 206	$ 354
Identifiable assets	$ 14,485	$ 9,263	$ 23,748

Total International long-lived assets of $5,282, $4,247 and $3,508 for the years ended September 30, 2004, 2003 and 2002, respectively are located in Germany.

10. INCOME TAXES

The provision for income taxes for the years ended September 30, 2004, 2003 and 2002 are summarized as follows:

	2004	2003	2002
Current:			
Federal	$ -	$ (15)	$ -
State	-	-	-
Foreign	1,153	-	643
	1,153	(15)	643
Deferred:			
Federal	607	171	(93)
State	133	36	(14)
Foreign	153	1,152	778
	893	1,359	671
Valuation allowance	(740)	(207)	(536)
Provision for income taxes	$ 1,306	$ 1,137	$ 778

The differences between the U.S. statutory rates and those in the consolidated financial statements of operations and comprehensive income are primarily due to the foreign entity being taxed at a lower rate and certain nondeductible items, as follows.

	2004	2003	2002
Income tax at federal statutory rate (35%)	$ 983	$ 1,190	$ 592
State tax	(133)	(29)	(14)
Valuation allowance	740	207	64
Foreign tax differential	(292)	(221)	120
Other	8	(10)	16

Total	$ 1,306	$ 1,137	$ 778

The tax effect of the temporary differences that give rise to the Company's net deferred taxes as of September 30, 2004, and 2003 are as follows:

	2004	2003
Assets		
Deferred tax assets:		
Current:		
Bad debt reserve	$ 35	$ 121
Inventory reserve	390	283
Subtotal	425	404
Noncurrent:		
Net operating loss & credits	5,745	5,025
Net deferred tax asset	6,170	5,429
Liability		
Deferred tax liability:		
Noncurrent:		
Fixed assets	(166)	(166)
Deferred revenue	(84)	(59)
Subtotal	(250)	(225)
Valuation allowance	(4,177)	(3,308)
Net deferred tax asset	$ 1,743	$ 1,896

The Company has recorded a valuation allowance to reflect the estimated amount of deferred tax assets that may not be realized due to the expiration of net operating losses and tax credit carryovers. The net increase in the valuation allowance is comprised primarily of increases in federal and state net operating losses and credit carryovers, which may not be realized, offset by the utilization of foreign net operating loss carryovers not previously benefited.

The Company has approximately $8,800 of federal net operating loss carryforwards expiring beginning in 2008, a $15 AMT credit carryforward, and a $21 credit on research and development that will expire in 2013 if unused. The Company also has state net operating loss carryforwards of approximately $11,500 that will begin to expire in 2005.

The Company has a corporate net operating loss carryforward for German income tax purposes of approximately $3,015 (2,425 Euros), and a trade net operation loss carryforward for German income tax

purposes of approximately $515 (414 Euros), which can be carried forward indefinitely. The Company continually reviews the adequacy and necessity of the valuation allowance in accordance with the provisions of FASB Statement No. 109, ACCOUNTING FOR INCOME TAXES. As of September 30, 2002, the Company eliminated the full valuation allowance on its International operations based upon future taxable income projections. As of September 30, 2004, the Company continues to record the existing valuation allowance on its U.S. operations.

The Company has not recorded deferred income taxes on the undistributed earnings of its foreign subsidiaries because it is management's intent to indefinitely reinvest such earnings. Upon distribution of these earnings, the Company may be subject to U.S. income taxes and/or foreign withholding taxes.

11. EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per share computations for the years ended September 30, 2004, 2003 and 2002:

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNT DATA)

	NET INCOME	SHARES	PER SHARE AMOUNT
2004			
Basic earnings per share	$ 1,503	15,734,470	$ 0.10
Effect of dilutive secured:			
Stock options	-	734,973	(0.01)
Diluted earnings per share	$ 1,503	16,469,443	$ 0.09
2003			
Basic earnings per share	$ 2,262	15,495,148	$ 0.15
Effect of dilutive secured:			
Stock options	-	600,300	(0.01)
Diluted earnings per share	$ 2,262	16,095,448	$ 0.14
2002			
Basic earnings per share	$ 901	15,114,412	$ 0.06
Effect of dilutive secured:			
Stock options	-	845,563	-
Diluted earnings per share	$ 901	15,959,975	$ 0.06

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12. COMMITMENTS AND CONTINGENCIES

The Company currently has operating leases for its corporate offices in the U.S. and Germany, as well as several leases related to office equipment and automobiles. Total rental expense was $1,103, $759 and $610 per year for the years ended September 30, 2004, 2003 and 2002, respectively. Future minimum rental payments required under these leases that have initial or remaining noncancelable lease terms in excess of one year as of September 30, 2004 are as follows:

2005	$ 1,146
2006	521
2007	214
2008	64
Balance	20
	$ 1,965

The Company is party to various claims, legal actions, complaints and administrative proceedings arising in the ordinary course of business. In management's opinion, the ultimate disposition of these matters will not have a material adverse effect on its financial condition, cash flows or results of operations.

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company by $406. At September 30, 2004 and 2003, the Company accrued $476 and $836, respectively with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and the final settlement will not have a material impact on its results of operations or financial opinion.

13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	2004 QUARTER ENDED			
	DECEMBER 31,	MARCH 31,	JUNE 30,	SEPTEMBER 30,
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Revenues	$ 7,485	$ 7,089	$ 6,823	$ 7,933
Gross profit	4,496	5,091	4,536	3,371
Operating expenses	3,638	3,899	3,466	2,963
Operating income	858	1,192	1,070	408
Net income (loss)	582	653	635	(367)

Earnings per share				
Basic	$ 0.04	$ 0.04	$ 0.04	$ (0.02)
Diluted	$ 0.04	$ 0.03	$ 0.04	$ (0.02)

	2003 QUARTER ENDED			
	DECEMBER 31,	MARCH 31,	JUNE 30,	SEPTEMBER 30,
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Revenues	$ 6,574	$ 6,743	$ 8,933	$ 8,010
Gross profit	3,728	4,223	5,312	5,357
Operating expenses	3,560	3,893	3,882	3,465
Operating income	168	330	1,430	1,892
Net income	131	135	818	1,178
Earnings per share				
Basic	$ 0.01	$ 0.01	$ 0.05	$ 0.08
Diluted	$ 0.01	$ 0.01	$ 0.05	$ 0.07

	2002 QUARTER ENDED			
	DECEMBER 31,	MARCH 31,	JUNE 30,	SEPTEMBER 30,
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Revenues	$ 5,012	$ 5,332	$ 5,400	$ 5,003
Gross profit	2,210	2,893	3,218	3,992
Operating expenses	2,059	2,597	2,881	3,064
Operating income	151	296	337	928
Net income	125	230	212	334
Earnings per share				
Basic	$ 0.01	$ 0.02	$ 0.01	$ 0.02
Diluted	$ 0.01	$ 0.01	$ 0.01	$ 0.02

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CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10K of Tutogen Medical, Inc. (the "Company") for the year ended September 30, 2004 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I George Lombardi, as the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: December 23, 2004

TUTOGEN MEDICAL, INC.

/s/ George Lombardi

George Lombardi
Chief Financial Officer

CERTIFICATION OF THE PRESIDENT AND CHIEF OPERATING OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10K of Tutogen Medical, Inc. (the "Company") for the year ended September 30, 2004 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I Manfred K. Kruger, as the President and Chief Operating Officer of the Company, hereby certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(2) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: December 23, 2004

TUTOGEN MEDICAL, INC.

/s/ Manfred Kruger

Manfred Kruger
President and
Chief Operating Officer

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10K of Tutogen Medical, Inc. (the "Company") for the year ended September 30, 2004 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I Roy D. Crowninshield, as the Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(3) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: December 23, 2004

TUTOGEN MEDICAL, INC.

/s/ Roy D. Crowninshield

Roy D. Crowninshield
Chief Executive Officer

CERTIFICATION

I, George Lombardi certify that:

1. I have reviewed this Annual Report on Form 10-K of Tutogen Medical, Inc.

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements and other financial information included in the Annual Report fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the "Evaluation Date"); and

   c) Presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves Management or other employees who have a significant role in the registrant's internal controls.

6. The registrant's other certifying officers and I have indicated in this Annual Report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: December 23, 2004

BY:
Name: /s/ George Lombardi

Title: Chief Financial Officer

CERTIFICATION

I, Manfred K. Kruger certify that:

1. I have reviewed this Annual Report on Form 10-K of Tutogen Medical, Inc.

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements and other financial information included in the Annual Report fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 (e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the "Evaluation Date"); and

c) Presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have

identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves Management or other employees who have a significant role in the registrant's internal controls.

6. The registrant's other certifying officers and I have indicated in this Annual Report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: December 23, 2004

BY:
Name: /s/ Manfred K. Kruger
Title: President and Chief Operating Officer

CERTIFICATION

I, Roy D. Crowninshield certify that:

1. I have reviewed this Annual Report on Form 10-K of Tutogen Medical, Inc.

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements and other financial information included in the Annual Report fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 (e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the "Evaluation Date"); and

c) Presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the

equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves Management or other employees who have a significant role in the registrant's internal controls.

6. The registrant's other certifying officers and I have indicated in this Annual Report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: December 23, 2004

BY:
Name: /s/ Roy D. Crowninshield
Title: Chief Executive Officer