TUTOGEN MEDICAL INC
Form 10-K
December 22, 2005

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)
[ ] Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2005.

[ ] 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
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The aggregate market value of the voting and non-voting common equity held by non-affiliates (approximately 8,649,000 shares), computed by reference to the bid and ask of such common equity on the American Stock Exchange, was $28,282,000 as of November 30, 2005.

As of November 30, 2005, there were 15,950,460 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 currently located in West Paterson, New Jersey. However, the Company announced that effective December 31, 2005, the worldwide headquarters will be in Alachua, Florida. In addition, the Company has 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 autologous 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

Tutogen Medical is a leader in the manufacture and marketing of human allograft and animal xenograft tissue implant products, which significantly improve surgical outcomes for the medical professional and quality of life for patient recipients. Our proprietary TUTOPLAST(R) tissue preservation and sterilization process has the greatest longevity of any similar methodology in the industry today. In use for more than thirty (30) years, there have been well over one million (1,000,000) Tutogen products implanted without a single documented case of disease transmission.

Donated bone and soft tissues are received and quarantined by Tutogen Quality Control (QC) until release by the Quality Assurance (QA) department and Tutogen's Medical Director, a licensed physician. In the interim, tissues are stored in a controlled environment, limited-access area according to requirements set forth by the American Association of Tissue Banks (AATB). Each tissue is given a unique identification number in order to maintain full traceability. Once released for processing, tissues are transferred to manufacturing and kept in a refrigerated or frozen state until issued to a specific production work order.

Following assignment to a manufacturing work order, tissue materials go through appropriate preprocessing operations and into the multi-stage Tutoplast process. This process removes blood, lipids and extraneous materials, inactivates viruses and prions and yields a dehydrated semi-processed product that may be stored at room temperature for extended periods of time. This tissue is subsequently processed to size and/or shape and packaged for terminal sterilization. All Tutogen packaged products are subjected to low dose gamma irradiation, which further enhances tissue safety and eliminates ancillary contamination that may be present from pre-sterilization handling. This terminal

sterilization is performed by a third-party contractor, utilizing a validated cycle, which yields a Sterility Assurance Level (SAL) of 10-6, or one chance in one million of a viable microorganism remaining on the product.

While some of the TUTOPLAST processing steps are automated, the majority are manual, and rely on highly-skilled personnel for their proper execution. Such skilled labor is readily available in the surrounding geographic areas and management feels that there should be no adverse affect on the business related to the labor market.

Tutogen operates two tissue processing facilities; a 26,000 square foot facility in Alachua, Florida and a 32,000 square foot facility in Neunkirchen, Germany. Major expansion projects are currently underway at both facilities, with completion dates of the first and third calendar quarters of 2006, respectively. These expansion projects are intended to insure the availability of sufficient production capacity in order to address the increasing demand for the Company's allograft and xenograft products.

QUALITY ASSURANCE - Tutogen Medical maintains a comprehensive quality assurance program that provides oversight to all pertinent aspects of the Company's day-to-day operational activities. Among the responsibilities of the QA organization are:

- Maintenance of an extensive documentation and change-control system (specifications, standard operating procedures and engineering drawings)
- Internal and external auditing for compliance with international and domestic regulatory body or accrediting organization regulations or requirements

- Review and approval of donor medical record information and screening/test documentation
- Product and process document review and release for distribution
- Evaluation and follow-up of all Tutogen-related product complaints
- Management of a Corrective and Preventive Action program to reduce or eliminate any identified non-conformances

The Quality Assurance department is independent from the manufacturing operation, operating under the supervision of the Tissue Bank Director (a medical doctor).

MARKETING AND DISTRIBUTION

Tutogen's products and processing services are provided globally through a combination of worldwide marketing and distribution partners ("partners"), direct representatives and local 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. The overall strategy is to work with each global partner to expand penetration into currently covered regions, develop additional global opportunities, and to broaden the product portfolio with procedure-specific products. In markets not covered by its global distributors, Tutogen's focus is on adding local

distributors or direct operations capable of market penetration.

Approximately 70% of the Company's revenues are derived within the United States, while the remaining Global sales are derived mostly from Europe. Since Tutogen's foreign donor qualification standards are in full compliance with the donor suitability standards of the Food and Drug Administration ("FDA"), the Company has worked with its partners to expand into numerous market opportunities in the United States. Tissue grafts are used in Urology, Gynecology, Ophthalmology, Orthopaedics, Spine, Dental, General Surgery, and Head and Neck applications. Future objectives are to match this penetration into additional global and specialty markets, using either TUTOPLAST Processed Human Allograft or Xenograft tissue implants.

The Company's U.S. marketing efforts have concentrated on building a Marketing and Distribution organization, capable of supporting its various partners. The Company has entered into several exclusive marketing and distribution agreements with global medical device companies. These agreements have established exclusive distribution for TUTOPLAST processed implants in specialized indications and surgical specialties, for select global markets.

Zimmer Spine Inc. ("Zimmer Spine"), and Zimmer Dental Inc. ("Zimmer Dental"), subsidiaries of Zimmer Holdings, Inc., provide marketing services for the Company's products for the spine and dental markets. Starting in September 2000, Zimmer Spine began representing Tutogen bone products for applications in the Spine Market. Initially Tutogen shipped and billed the customers directly, but in April 2003 the Company entered into an Exclusive License and Distribution Agreement with Zimmer Spine. Effective with this agreement Zimmer Spine became a "stocking distributor", whereby Zimmer Spine now purchases the Company's products and invoices the customer directly. Zimmer Spine distributes both traditional bone and specialized bone products processed with the Company's TUTOPLAST process. Revenues from Zimmer Spine represent 10% and 14%, respectively, of total consolidated and U.S. revenues.

Also in September 2000, Zimmer Dental entered into an agreement to represent Tutoplast Bone, under the brand name Puros(R), for Dental applications. Revenues from this relationship account for 43% of

Global and 62% of U.S. revenues. Zimmer Dental represents the products to the end user and Tutogen ships and bills the customer directly.

For urological and gynecological indications, the Company has partnered, since 1998, with Mentor Corporation ("Mentor"). In fiscal year 2005, Mentor accounted for 8% and 12%, respectively, of the Company's total and U.S. revenues. As a stocking distributor, they currently market TUTOPLAST Fascia Lata, Pericardium, and Dermis tissue implants. In April 2005, Tutogen and Mentor signed an agreement that extended current contracts for one year. The intent of this extension is to provide enough time to develop and sign a new definitive agreement, incorporating points from the original 1998 agreement and the succeeding four (4) amendments.

Other agreements signed in the past fiscal year include a new Distribution Agreement with IOP, Inc. (IOP). IOP has been a distributor since 1998, and the new agreement extends for another two (2) years their exclusivity to distribute TUTOPLAST processed tissue for Ophthalmology applications. During 2005, IOP represented approximately 5% of total Company revenue. A new partner, Sense Medical signed an exclusive distribution agreement in December 2004, expanding TUTOPLAST products into selected Head and Neck procedures. First year sales for Sense Medical represented 1% of total Company revenue.

Internationally, the Company has implemented a marketing and sales restructuring plan, concentrating on an in-depth penetration of markets with major needs, not covered by Tutogen's Global partners. In Europe, the specific focus is on countries such as Germany, France, Italy, Spain and the U.K., and in major specialty areas, such as Dental and Orthopaedics. The Company believes that through a combination of international distribution strategies, Tutogen can increase its penetration of the international markets for processed tissue.

TISSUE PROCUREMENT

The Company sources donor tissues from multiple independent recovery organizations in Europe and the United States. Recovery agencies obtain donor consent, verify proper donor identity, conduct extensive medical and social history evaluations and recover appropriate donated tissues. Each donor tissue is assigned a unique identification number in order to assure full traceability, from recovery to end user. These records accompany each donor tissue receipt, along with related serological test samples. The test samples are evaluated by independent CLIA (Clinical Laboratory Improvement Amendment) certified laboratories for such transmissible diseases as Hepatitis B surface Antigen (HBsAg), Hepatitis B total core (HBc, IgG/IgM), Hepatitis C virus antibody (HCV Ab), Hepatitis B Nucleic Acid Test (HBV/HCV NAT), Human Immunodeficiency Virus 1&2 antibodies (HIV 1&2 Ab), HIV Nucleic Acid Test (HIV NAT), Human T-Lymphotropic Virus 1&2 (HTLV 1&2) and Syphilis (RPR/STS).

In June of 2002, the FDA published its draft Guidance for Industry document, "Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)". This document reflects the Agency's current thinking on donor deferral criteria for individuals that may have been exposed to a Bovine Spongiform Encephalopathy (BSE) agent, or "Mad Cow" disease. The document draft is in the review and comment stage, which precedes the adoption of a final version of the FDA's position on this matter. As a part of this document, the FDA provided a listing of countries applicable to donor deferral. None of the tissue products that Tutogen distributes in the United States or Canada incorporate tissues from countries identified by the FDA.

With regard to xenograft tissue, Tutogen Germany currently obtains bovine material from a "closed herd" in an internationally approved source country. The U.S. operation is currently in discussions with a potential U.S. bovine tissue provider. This provider would supply specific bovine tissue from a domestic,

FDA registered and USDA inspected "closed herd". Failure to secure an animal tissue source could have a material adverse effect on the Company's U.S. operations.

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.

Tutogen allograft tissue recovery partners are FDA or government registered, state licensed and AATB accredited, as appropriate. Tissues are NOT purchased from these companies, but rather they are reimbursed for the costs incurred in the tissue recovery process, itself. Due to the growing demand for and limited supply of allograft tissue, the Company is continually seeking to form additional alliances with reputable hospital, tissue bank and organ procurement organization tissue recovery firms. Although the Company believes that it has the necessary contractual arrangements in place to insure that there are sufficient tissues available to meet its needs for the foreseeable future, there can be no assurance that these supplies will materialize as planned. Unavoidable interruptions in tissue supply (natural disasters, regulatory changes, financial set-backs, etc.) could have a material adverse effect on Tutogen's business operations.

BACK ORDERS

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, 2005, the Company's back order for all tissues was under $100,000. 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 consists of multiple steps that assure a safe, viable product and, at the same time, preserves the tissue structure, biomechanics and remodeling characteristics. The TUTOPLAST process is very robust, and has been proven effective in removing antigenicity and inactivating conventional and unconventional viruses and prions. The implants are terminally sterilized, have a five (5) year shelf life, and can be stored at room temperature. The TUTOPLAST process has an outstanding safety record. Since its introduction over 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. Processors of allograft tissue for transplantation in the U.S. include commercial processors such as Osteotech, Inc., Regeneration Technologies, Inc. and LifeCell, Inc., companies well established in the fields of processing and distribution of bone and soft tissue implants, 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 new tissue substitutes being developed by other companies.

GROWTH STRATEGY

The Company estimates the worldwide market for its present products to be approximately $1 billion, including all procedures in the various fields of use. The Company's existing tissue supply network, established processing facilities and proven TUTOPLAST technology provides the foundation for continued growth into fiscal 2006 and beyond. Future growth will be aided by new sources of tissue, new procedures and products, and expansion into new markets. The Company will focus on applications for both Human allograft and Xenograft tissue implants.

Besides Tutogen's internally developed new products and technology, a major component of Tutogen's growth strategy will be its collaboration with each Global partner. Tutogen will continue to work with each organization to evaluate opportunities for new products and applications. The ultimate goal is to provide each partner with a full line of procedure specific implants, for their respective fields of use.

Currently, Tutogen's focus is on the introduction of new products and applications for TUTOPLAST processed tissues. In January 2005, the Company developed, in association with Zimmer Dental, a new bone block to augment ridge restoration. In the U.S. the Puros block graft has been very well accepted and is highlighted in various Zimmer Dental training courses. Globally, similar products processed from Xenograft tissue, has helped generate growth as Tutogen focuses on expanding the international market for dental products. Additionally, Tutogen has developed membranes from TUTOPLAST processed dermis and pericardium for use as a barrier in dental applications. These products are being used in Europe and a U.S. launch is planned for early in 2006.

In October 2002, the Company entered the European market with Tutomesh(R), a TUTOPLAST processed biological membrane for hernia and abdominal wall repair. It has been very well received in Europe, and has already been successfully used in abdominal wall surgery of neonates and children with hernia

defects. In December 2004, Tutogen received FDA 510(k) marketing clearance for a product and is currently

investigating various options for distribution in the U.S. It is estimated that, in the U.S. approximately 1,000,000 hernia procedures are performed each year, creating an estimated $150,000,000 market. Focus for the Company is on globally developing this opportunity for both the Tutomesh, as well as for TUTOPLAST processed Dermis.

The Orthopaedic market for Biologic Materials is currently estimated at just over $1 billion for 2005. Allograft makes up about 33% of this revenue, split between traditional allograft bone and machined specialty grafts, another 23% of this market is Demineralized Bone Matrix (DBM). Tutogen has development programs in each of these areas. In the Spinal Market, Tutogen continues its collaboration with Zimmer Spine in developing new, highly precise and specialized implants for spinal fusion. In the Orthopaedic arena, Tutogen has internally developed a line of TUTOPLAST processed, machined bone implants for the repair of orthopaedic fractures and soft tissue ruptures. The Tutofix(R) line of implants was released in Europe in 2004. The current strategy is to broaden its release internationally, and to develop a distribution strategy for the U.S. market.

The Company's tissues and products have application in numerous surgical indications. The Company, in association with its partners and distributors, enjoys high degrees of success in various markets, including ophthalmology, urological/gynecological, spine, and dental. The Company will continue its efforts in developing new products for these specialties, and in investigating potential new markets for its TUTOPLAST processed tissue.

INTERNATIONAL OPERATIONS

Approximately 32%, 42% and 30% of the Company's net sales, respectively for fiscal years 2005, 2004 and 2003 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,			
2005	$21,752	$10,108	$31,860
2004	$17,126	$12,204	$29,330
2003	$21,168	$ 9,092	$30,260

For a discussion of the Company's long-lived assets as of September 30, 2005, 2004 and 2003 see Note 9 of "Notes to Consolidated Financial Statements" and for the deferred tax assets for the years ended September 30, 2005, 2004 and

2003 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 Zimmer Dental collaboration. R & D expenditures increased 16% from $1,432,000 in 2004 to $1,659,000 in 2005.

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

Zimmer Spine and Mentor are principal customers to the Company, accounting for approximately 10% and 8%, respectively, of the Company's net sales for the year ended September 30, 2005. No other customer accounted for more than 10% of the Company's net sales for the fiscal year 2005. In June 2005, the Company entered into an Amendment of its Exclusive License and Distribution Agreement with Spine redefining the terms governing its relationship. 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 procures, processes and markets its tissue products worldwide. Although some standards harmonization exists, each country in which the Company does business has its own specific regulatory requirements. These requirements are dynamic in nature and, as such, are continually changing. New regulations may be promulgated at any time and with limited notice. While the Company

believes that it is in compliance with all existing pertinent international and domestic laws and regulations, there can be no assurance that changes in governmental administrations and regulations will not negatively impact the Company's operations.

In the United States, the Company's allograft products are regulated by the Food and Drug Administration under Title 21 of the Code of Federal Regulations, Parts 1270 and 1271, "Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products". Xenograft tissues are regulated as medical devices and subject to 21 CFR, Part 820 (Current Good Manufacturing Practices for Medical Devices) and related statutes. The Company has obtained a 510(k) marketing clearance from the FDA for bovine pericardium, for use in general and plastic surgery applications and will be seeking further approvals for other xenograft tissues and indications. In addition, the U.S. operation is subject to certain state and local regulations, as well as compliance to the Tissue Bank industry's accrediting organization, the AATB.

In Germany, allografts are classified as drugs and the German government regulates such products in accordance with German Drug Law. On April 7, 2004, the European Commission issued a human tissue directive to regulate allografts within the EU. Tutogen's Neunkirchen facility is presently licensed by the German Health Authorities and in compliance with applicable international laws and regulations, allowing the Company to market its human and animal implant products globally.

The FDA and international regulatory bodies conduct periodic compliance inspections of both the Tutogen U.S. and German processing facilities. Both operations are registered with the U.S. FDA Center for Biologics Evaluation and Research (CBER) and are certified to ISO 9001:2000 and ISO 13485:2003. The Alachua facility is also accredited by the American Association of Tissue Banks and is licensed in the states of Florida, New York and California. The Neunckirchen facility is registered with the German Health Authority (BfArM) as a pharmaceutical and medical device manufacturer and is subject to German drug law. The Company believes that worldwide regulation of allografts and xenografts is likely to intensify as the international regulatory community focuses on the growing demand for these implant products and the attendant safety and efficacy issues of citizen recipients. Changes in governing laws and regulations could have a material adverse effect on the Company's financial condition and results of operations. Company management further believes that it can mitigate this exposure by continuing to work closely with government and industry regulators in understanding the basic tenets of the business and participating in the drafting of reasonable and appropriate legislation.

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, 2005, the Company employed a total of 193 full-time and 20 part-time employees, of whom 49 full-time and 7 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 announced the relocation of the administrative offices to its facility in Alachua, Florida at December 31, 2005. The Company's offices and manufacturing facility in Alachua, Florida have expanded from approximately 20,205 square feet to 25,525 square feet of leased space. The Florida lease expires January 31, 2009 with an option through January 31, 2011 at a current base rent of approximately $36,500 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 approximately 32,000 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. In addition, the Company is renting office space of approximately 23,000 square feet at $ 12,500 per month expiring at various periods in the later part of 2006. The intent is to eliminate and consolidate the current rental offices as part of expansion efforts underway. The expansion project is expected to be completed by the fourth fiscal quarter 2006.

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, 2005 and 2004, the Company maintains an accrual of $476,000 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 2004	High	Low
First Quarter	$ 5.50	$ 4.05
Second Quarter	5.06	3.85
Third Quarter	4.59	3.89
Fourth Quarter	4.16	2.79

Fiscal 2005		
First Quarter	$ 3.13	$ 2.24
Second Quarter	2.60	2.30
Third Quarter	2.42	2.11
Fourth Quarter	4.56	2.35

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, 2005, the approximate number of holders of record of the Company's Common Stock was 828. The Company estimates that there are approximately 2,700 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, 2005.

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
	(a)	(b)
Equity compensation plan approved by Securities holders (1).....	2,481,368	$ 2.64
Equity compensation plan not approved by Securities holders.....	-0-	-0-
Total	2,481,368	$ 2.64

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

ITEM 6. SELECTED FINANCIAL DATA.

	YEARS ENDED SEPTEMBER 30,			
	2005	2004	2003	20021
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
Revenues	$ 31,860	$ 29,330	$ 30,260	$ 20,747
Gross margin %	36%	60%	62%	59%
Operating income (loss)	(6,966)	3,528	3,820	1,666
Net income (loss)	(6,621)	1,503	2,262	901
Average shares outstanding for basic earnings (loss) per share	15,919,286	15,734,000	15,495,000	15,114,000
Basic earnings (loss) per share	(0.42)	0.10	0.15	0 .06
Average shares outstanding for diluted earnings (loss) per share	15,919,286	16,469,000	16,095,000	15,960,000
Diluted earnings (loss) per share	(0.42)	0.09	0.14	0.06

Balance Sheet Data:				
Working capital	$ 9,052	$ 18,173	$ 15,783	$ 10,856
Total assets	27,142	34,347	30,403	23,748
Long-term debt	630	827	728	693
Stockholders' equity	14,728	22,083	18,046	13,928

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

FOR THE YEARS ENDED SEPTEMBER 30, 2005 AND 2004

RESULTS OF OPERATIONS

REVENUE AND GROSS MARGIN

Revenue for the year ended September 30, 2005 increased $2.5 million or 9% to $31.9 million from $29.3 million in 2004. The U.S. revenues were $21.8 million or 27% higher than the 2004 revenues of $17.1 million. The increase in U.S. revenues was fueled by the continuing increase in the demand for the company's TUTOPLAST(R) bone products for dental applications sold by Zimmer Dental ("Dental"), the company's marketing partner. In January 2005, The Company developed, in association with Zimmer Dental, a new bone block to augment ridge restoration. The Dental business increased 100% from a year ago. The spine revenues decreased 37%, primarily due to significant purchases by Zimmer Spine ("Spine") in 2004. The urology business was essentially flat with a decrease of 6% from a year ago as this business is decreasing due to the increased reliance on synthetics for incontinence. However, Mentor continues to do well in the pelvic floor reconstruction market, with a slight increase in revenues for this product line. The Ophthalmic business was essentially flat as this is a mature and niche business.

The International operation had revenues of $10.1 million, a decrease of $2.1 million or 17% from the 2004 revenues of $12.2 million. The decrease in revenues was primarily due to the temporary delay in the renewal of the CE marks ("European Conformity") on certain products, which was resolved at the end of the first quarter, the resolution of certain regulatory issues in France and the temporary backlog of xenograft product lines.

An analysis of revenues are as follows:

($000's omitted)	FY 2005	FY 2004	4th Qtr. FY 2005	4th Qtr. FY 2004
Dental	13,785	6,893	4,115	1,996
Spine	3,318	4,850	336	607
Urology	2,633	2,809	540	770
Ophthalmic	1,505	1,553	452	414

Other	701	1,021	136	361
Total - U.S.	21,752	17,126	5,579	4,049
Germany	1,980	3,521	487	1,390
ROW	6,220	6,001	1,324	1,829
France	1,337	2,121	391	525
Other	571	561	170	141
Total-International	10,108	12,204	2,372	3,885
Total Consolidated	31,860	29,330	7,951	7,934

Gross margins for the year ended September 30, 2005 decreased to 36% from 60% in 2004. The lower margins were due to several factors, 1), 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 43% of total revenues versus 24% a year ago, 2), initial start-up manufacturing costs of $1.6 million, expensed in the third quarter, associated with shifting production of the dental product lines from Germany to the U.S. The production transfer has been fully completed, 3), the recording in the fourth quarter of $1.0 million for the inventory reserve impact of the voluntary recall of products and 4), the estimated patient testing and other related expenses of $250,000 as a result of the product recall recorded in the fourth quarter.

VOLUNTARY RECALL. On October 12, 2005, the Company issued a voluntary recall of all product units, which utilized donor tissue received from BioMedical Tissue Services/BioTissue Recovery Services ("BioMedical"). This action was taken because the Company was unable to satisfactorily confirm that BioMedical had properly obtained donor consent. The Company quarantined all BioMedical products in its inventory, having a value of $1,035,000 and has notified all customers and distributors of record regarding this action. In connection with this recall, the Company has destroyed $174,000 and accrued $861,000 of inventory reserve and $250,000 of other related costs at September 30, 2005.

GENERAL AND ADMINISTRATIVE

General and Administrative expenses increased 28% in 2005 to $5.4 million from $4.2 million in 2004. The increase was due to higher compensation from new and unfilled positions ($534,000), expenses related to the closing of the New Jersey Corporate Offices ($444,000), expenses related to the Sarbanes -Oxley compliance ($118,000), unfavorable translation of Euro-based expenses ($84,000), and other expenses

($20,000). As a result, General and Administrative expenses, as a percentage of revenues, increased from 14% in 2004 to 17% in 2005.

DISTRIBUTION AND MARKETING

Distribution and Marketing expenses were increased 32% or $2.8 million in 2005 to $11.5 million from $8.7 million in 2004. The increase was soley due to higher marketing fees paid to Dental of $6.1 million in 2005 versus $3.2 million a year ago or an increase of $2.9 million. This is a result of a 100% increase in dental revenues in 2005, from $6.9 million of revenues in 2004 to $13.8 million in 2005. As a result, Distribution and Marketing expenses, as a percentage of revenues, increased from 30% in 2004 to 36% in 2005.

RESEARCH AND DEVELOPMENT

Research and Development expenses increased 16% or $0.2 million in 2005 to $1.6 million. The increase was due to increased development efforts in the dental and spine product areas. As a percentage of revenues, Research and Development expenses remained at 5% in 2005 and 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 $406,000. At September 30, 2005 and 2004, the Company continues to maintain an accrual of $476,000 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 position.

OTHER INCOME/EXPENSE

Other expense for 2005 decreased $505,000 from $601,000 in 2004 to $96,000 in 2005. This was primarily the result of lower foreign exchange losses due to the strengthening of the dollar versus the euro and lower inter-company balances at year-end.

INTEREST EXPENSE

Interest expense in 2005 increased due to the leasing of capital expenditure equipment related to the facility expansion programs in Florida and Germany.

(BENEFIT OF) PROVISION FOR INCOME TAXES

The (benefit of) provision for income taxes is solely due to the income tax benefit on the loss from the foreign entity. The Company continues to record the existing valuation allowance on its U.S. operations.

NET (LOSS) INCOME

As a result of the above, net loss for the year ended September 30, 2005 totaled $6.6 million, $0.42 basic and diluted loss per share as compared to a net income of $1.5 million, $0.10 basic and $0.09 diluted earnings per share for 2004. As a percentage of revenues, net income decreased from 5.1% in 2004 to a net loss of 20.8% in 2005.

ACCOUNTS RECEIVABLE

The accounts receivable balance decreased in 2005 by 29% due to an

increase in collection efforts resulting in a 16% improvement of the day's sales outstanding from 50 in 2004 to 42 in 2005.

INVENTORY

The inventory balance decreased to $10.6 million at September 30, 2005 or 30% from $15.1 million at September 30, 2004. The decrease was primarily due to the successful effort to improve production planning and control and reduce overall inventory levels. Approximately $1.0 million of the decrease represents inventory written-off due to the voluntary recall of certain products.

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 $406,000. 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 position.

OTHER 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 expense 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.

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 2005, 2004 and 2003. 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 between 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 $173,000, $700,000 and $350,000 in 2005, 2004 and 2003, 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 18% of consolidated revenue in 2005 while the same two customers accounted for 22% of consolidated revenue in 2004 and 30% in 2003. 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, 2005 and 2004.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2005 and 2004 the Company had working capital of $9.1 million and $18.0 million, respectively, a decrease of 49%. In the past, the Company has relied upon its available working capital lines and institutional investors to fund operational cash flow, when needed. This decrease is primarily due to a concerted effort to reduce inventory levels by $4.5 million and an improvement in the accounts receivable DSO (days sales outstanding) from 50 to 42 or $1.5 million, partially offset by an increase in short-term borrowing of $1.0 million.

Net cash decreased from $5.0 million in 2004 to $3.6 million 2005 primarily as the result of the effect of the net loss in 2005 of $6.4 million versus a net income of $1.5 million in 2004. The decrease in cash due to the net loss in 2005 was partially offset by significant reductions in inventory levels and accounts receivable balances as aforementioned above.

Net cash used in operating activities was $561,000 in 2005 compared to net cash provided from operating activities of $380,000 in 2004. The decrease resulted primarily from the decrease in net income partially offset by the reductions on inventory and accounts receivable.

Net cash used in investing activities, representing purchases of capital expenditures, was $1,681,000 in 2005 and $1,759,000 in 2004. The continued spending on capital expenditure is due to the facility expansion in the Florida and German manufacturing locations and replacement manufacturing equipment.

Net cash from financing activities in 2005 and 2004 of $981,000 and $496,000 relates primarily to the proceeds from revolving credit arrangements to finance the expansion program in Germany, partially offset by the repayments of long-term debt.

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 2009 total $3,340,000. 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, 2005:

(In thousands)	Total	2006	2007	2008	2009
Long-term debt	$ 814	$ 184	$ 197	$ 433	$ 0
Operating lease obligations	$ 3,340	$ 1,064	$ 787	$ 632	$ 557

The Company maintains current working capital credit lines totaling 1.5 million euros (approximately $1.8 million) with three German banks and a $1.0 million credit line with a U.S. bank. At September 30, 2005 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 AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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, 2005 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	PERIOD SERVED OFFICE/POSITIO
G. Russell Cleveland	67	Director	1997 - present
Roy D. Crowninshield, Ph.D.	57	Chairman of the Board	July 2004 - present

		Director	2003 - present
		Interim CEO	July 2004 - December
Neal B. Freeman	65	Director	June 2005 - present
J. Harold Helderman, MD	60	Director	1997 - present
Udo Henseler, PH.D.	65	Director	June 2005 - present
Manfred K. Kruger	59	President, International	January 2005 - prese
		President	July 1999 - December
		Chief Executive Officer	December 1999 - June 2004
		Chief Operating Officer	July 1999 - December
		Director	June 1997 - March 20
George Lombardi	62	Chief Financial Officer, Treasurer and Secretary	1998 - present
Guy L. Mayer	54	Chief Executive Officer	January 2005 - prese
		Director	January 2005 - prese
Adrian J. R. Smith	61	Director	June 2005 - present
Carlton E. Turner, Ph.D.	65	Director	2000 - present

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 Camino-Soft, Inc. and Precis, Inc.

ROY D. CROWNINSHIELD, PH.D. is the current Chairman of the Board. From July 2004 to December 2004, Dr. Crowninshield was the Interim Chief Executive Officer of the Company. 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.

NEAL B. FREEMAN is the Chairman and CEO of The Blackwell Corporation (since 1981), an advisory firm, with clients in the communications, defense and wealth management industries. He is also Chairman of the Foundation Management Institute; Chairman of the Board of Advisors of the investment advisory firm, Train Babcock Advisors and Director of North American Management Corp.

J. HAROLD HELDERMAN, MD is Dean of Admissions and Professor of Medicine, Microbiology and Immunology, since 1999, at Vanderbilt University, Nashville, Tennessee, and is the Medical Director of the Vanderbilt Transplant Center since 1989. 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.

UDO HENSELER, PH.D., is presently acting as the principal/owner of MSI Management Services International (first activated 1994) and serves currently on the Board of Directors of the public companies of eGene, Inc., Spire Corporation and Tutogen Medical, Inc. From 2002 to July 2005 Dr. Henseler was CEO, Director and Chairman of eGene, Inc., a public biotechnology company. From 1999 to June 2002, Dr. Henseler was a Director and from June 2001 to March 2002, he was the Executive Vice President, Director and CFO of ChemoKine Therapeutics Corporation. From 2000 to June 2001, he was the Senior Vice President and CFO of Isotag Technology, Inc., a biotechnology Company. Dr. Henseler has extensive global public company leadership experience with approximately 40 years of combined service as: VP and CFO of the biotechnology Qualicon Inc., a DuPont company; Director, Senior VP and CFO of the Pharmaceutical Andrx Inc.; VP and CFO of Genetic Systems Corp.; Chair Executive Committee, VP and CFO of Coulter Corporation (life Sciences); group Finance Chief at Beckman, Inc. (life-sciences). Dr. Henseler earned his B.A. in Germany, and Master's and Ph.D. degrees from the Claremont Graduate University in Claremont, California. Dr. Henseler is also a Certified Public Accountant.

MANFRED K. KRUGER is the Company's President, International Operations. He 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.

GUY MAYER is the Company's CEO. Prior to Tutogen, Guy served as Chairman and CEO of Visen Medical (from 2003 to 2004), a private Biotech company focused on Molecular Imaging technologies and prior to Visen (from 2000 to 2003), as President and CEO of ETEX Corporation, a private biomedical company based in Cambridge, MA. For 13 years prior to joining ETEX, Mr. Mayer held various senior positions at Zimmer Inc., then a division of Bristol Myers Squibb, with sales in excess of $1.2 billion. Mr. Mayer's positions at Zimmer included President Global Products Group, President Orthopedics Implant division, President Zimmer Japan and Sr. Vice President Zimmer International. Prior experience includes general management positions with Picker International in diagnostic imaging, and American Hospital Supply Corporation. Guy is a 1974 Graduate of the University of Ottawa and currently serves on the Board of Directors of several public and private companies.

MR. ADRIAN J.R. SMITH is CEO of The Woolton Group, since 1997, and a Non-Executive Director of Carter & Carter Group plc, since 2002), a UK company providing learning solutions and outsource services to large corporate organizations. His business career includes 13 years in the professional services industry and 26 years with two Fortune 500 companies. He has been a Global Managing Partner, Marketing & Communication at Deloitte & Touche, the CEO of Grant Thornton LLP, and a Managing Partner at Arthur Andersen in the early to mid-1990's. He held senior international management roles with Ecolab Inc. and also with Procter & Gamble. He serves on the board of Harbor Branch Oceanographic Institution, and the Education Foundation of Indian River County in Florida.

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 Dr.

Helderman, Dr. Turner and Mr. Freeman, and is chaired by Dr. Turner. 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. Cleveland, Smith and Dr. Henseler and is chaired by Mr. Cleveland. 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. All members of the Audit Committee are considered to be "financial experts" within the definition of that term under the regulations of the Securities Act.

Nominating Committee. The Nominating Committee is composed of Messrs Smith, Freeman, Dr. Helderman, and Dr. Henseler and is chaired by Dr. Helderman. 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 (#)
Guy L. Mayer (2) Chief Executive Officer	2005	225,000	24,300	0	0	300,00

Roy D. Crowninshield (2)	2005	21,000	0	0	0	0
Chief Executive Officer	2004	21,000	0	0	0	100,00
Manfred K. Kruger	2005	391,000	34,700	0	0	0
President, International	2004	428,550	0	0	0	0
Operations	2003	352,500	179,700	0	0	37,50
George Lombardi	2005	166,500	20,500	0	0	0
Chief Financial Officer	2004	166,500	0	0	0	0
Treasurer and Secretary	2003	160,125	67,500	0	0	20,00
Dr. Karl Koschatzky	2005	148,700	13,100	0	0	0
Vice President of	2004	140,000	0	0	0	0
R & D Worldwide	2003	107,600	32,400	0	0	45,00

(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 devoted at least one-third of his time on Company affairs for which he was compensated at the rate of $7,000 per month and was granted options to purchase 100,000 shares of the Company's common stock. Dr. Crowninshield resigned as the interim Chief Executive Officer on December 31, 2005, but retained his current position as Chairman of the Company. Dr. Crowninshield was replaced by Mr. Mayer on January 1, 2005.

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 current annual base salary is $315,000. 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 was 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.

The Company has an employment agreement with Manfred Kruger, its President, 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 is currently $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 and 401(K) 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 2,500 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 Dr. Turner, Dr. Helderman and Mr. Freeman.

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 4,000,000 shares of the Company's Common Stock for issuance thereunder. As of September 30, 2005, options have been issued for 3,451,697 shares and 548,303 shares remain available under the 1996 Plan. Unless sooner terminated, the 1996 Plan will expire on February 27, 2006.

OPTIONS GRANTED IN FISCAL YEAR 2005

The following table provides information as to options granted to the Company's Chief Executive Officer during the fiscal year ended September 30, 2005. 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	St
Guy L. Mayer	250,000	40.2%	$2.60	January 3, 2015	$5
	50,000	8.0%	$4.17	September 26, 2015	$

(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 expiration of 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, 2005. No options were exercised during this fiscal year. The market price of the Company's common stock at September 30, 2005 was $4.56.

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

	Number of Unexercised	Value of Unexer

Name	Options at September 30, 2005		In-the-Money Opt September 30,	
	Exercisable	Unexercisable	Exercisable	Un
Guy L. Mayer	75,000	225,000	$ 127,375	
Manfred K. Kruger	590,625	9,375	$ 1,363,600	
George Lombardi	213,000	5,000	$ 542,475	
Dr. Karl Koschatzky	104,168	22,500	$ 258,087	

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

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

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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

Dr. Carlton E. Turner, Chairman
Dr. J. Harold Helderman
Neal B. Freeman

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]

ASSUMES $100 INVESTED ON SEPT. 30, 2000
ASSUMES DIVIDEND REINVESTED
FISCAL YEAR ENDING SEPT. 30, 2005

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

COMPARISON OF CUMULATIVE TOTAL RETURN OF ONE OR MORE
COMPANIES, PEER GROUPS, INDUSTRY INDEXES AND/OR BROAD MARKETS

	FISCAL YEAR ENDING					
COMPANY/INDEX/MARKET	9/30/00	9/30/01	9/30/02	9/30/03	9/30/04	9/30/05
TUTOGEN MEDICAL INC	100.00	40.85	48.34	86.81	50.89	77.62
NASDAQ MEDICAL DEVICE	100.00	97.71	91.18	123.43	143.36	162.71
AMEX MARKET INDEX	100.00	74.98	81.46	100.67	116.21	140.67

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, 2005, 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, 2005, there were approximately 15,950,460 shares of Common Stock issued and outstanding.

NAME AND ADDRESS OF BENEFICIAL OWNER	AMOUNT AND NATURE OF BENEFICIAL OWNER (1)(2)	PERC OF C
SPV 1996 LP..... 101 Finsbury Pavement London, England EC2A 1EJ	1,896,794	
Zimmer CEP (formerly Centerpulse) USA Holding Co..... Subsidiary of Zimmer Holdings, Inc. 345 East Main Street Warsaw, IN 46580	5,297,124	

G. Russell Cleveland (4).....	99,800	
Roy D. Crowninshield (5).....	47,500	
Neal B. Freeman (7).....	20,000	
Dr. J. Harold Helderman (8).....	102,500	
Udo Henseler, Ph.D (6).....	10,000	
Dr. Karl Koschatsky (6).....	107,918	
Manfred K. Kruger (6).....	590,625	
George Lombardi (6).....	215,000	
Guy L. Mayer (6).....	75,000	
Adrian J. R. Smith (6).....	10,000	
Carlton E. Turner (6).....	42,500	
All directors and officers as a group (11 persons).....	1,321,343	

* 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, 2005 held by such individual or group.

4 Includes 42,500 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 27,500 shares of common stock issuable upon exercise of options and warrants exercisable within sixty (60) days.

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

7 Includes 10,000 of common stock issuable upon exercise of options and warrants exercisable within sixty (60) days.

8 Includes 82,500 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 Zimmer Spine, a wholly owned subsidiary of Zimmer Holdings, Inc., whereby Zimmer 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, 2005, Spine revenues were $3.3 million.

The Company has also engaged Zimmer Dental, a wholly owned subsidiary of Zimmer Holdings, Inc., 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, 2005, Zimmer Dental was paid commissions aggregating approximately $6.1 million on revenues of $13.8 million.

Zimmer CEP (formerly Centerpulse) USA Holding Co. is the owner of approximately 33.3% of the Company's outstanding shares of Common Stock.

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, 2005 and 2004, and all fees billed for other services by Deloitte & Touche LLP during those periods:

Year Ended September 30,	2005	2004
Audit fees (1)	$143,000	$105,500

Audit-related fees (2)	55,000	27,900
Tax fees (3)	4,000	3,100
All other fees (4)	-	-
Total Accounting Fees and Services	$202,000	$136,500

(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, 2005 and 2004 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 AND FINANCIAL STATEMENT SCHEDULES.

(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. *

10.9 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.
**** Filed with the Company Form 10-K for the year ended September 30, 2004.

(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.

REPORTS ON 8-K

Reference is