TUTOGEN MEDICAL INC
Form 10-K
December 29, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended September 30, 2006.

[_] 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 Number)

13709 PROGRESS BOULEVARD, BOX 19, ALACHUA FLORIDA 32615
(Address of principal executive offices)

(386) 462-0402
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act

COMMON STOCK, $0.01 par value - American Stock Exchange

Securities registered under Section 12(g) of the Exchange Act: NONE

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No X

Indicate by check mark whether the registrant is a shell company. Yes No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No X

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

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. Yes X No
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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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As of November 30, 2006, there were 16,413,815 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, 2006 (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 2007 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"), designs, develops, processes, 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 dental, spinal, urology, ophthalmology, head and neck, and general surgery procedures. Our products are distributed throughout the United States and in over twenty (20) other countries.

The Company's corporate worldwide headquarters is located in Alachua, Florida. In addition, the Company has a manufacturing facility in Alachua, Florida, as well as international executive offices, 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 using 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, 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 dental, ophthalmology, urology, plastic and reconstructive surgeries. Dermis is also used in hernia repair and 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. Processed cortical and cancellous bone material is used in a wide variety of applications in spinal, orthopaedic and dental surgeries. All processed tissues have a shelf life of five (5) years, at room temperature, and require minimal time for rehydration. The Company processes bone and soft tissues in both manufacturing facilities.

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, while maintaining its structure and allowing it to act as a scaffold after implantation, which is subsequently 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 responsible for AIDS), rendering the allografts safe for the recipient. Soft tissue is also treated with chemicals shown to be effective against prions, the agent causing Creutzfeldt-Jakob Disease ("CJD"). Once packaged, tissues are terminally sterilized by low dosage gamma radiation.

MANUFACTURING AND PROCESSING

Tutogen considers itself a leader in the manufacturing 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. We believe our proprietary TUTOPLAST 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 and one-half million (1,500,000) 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 breaks down RNA and DNA into fragments not capable of replication and disease transmission while preserving the biological and mechanical properties. The TUTOPLAST process 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.

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 33,000 square foot facility in Neunkirchen, Germany. Major expansion projects were recently completed at both facilities, and will be in service by the first calendar quarter of 2007. These expansion projects are intended to ensure the availability of sufficient production capacity to address the increasing demand for the Company's allograft and xenograft products in the foreseeable future.

QUALITY ASSURANCE AND REGULATORY AFFAIRS - The Company maintains comprehensive quality assurance and regulatory compliance programs that provide oversight for all pertinent aspects of the Company's day-to-day operational activities. Among the responsibilities of the QA/RA organizations 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 Corrective and Preventive Action programs to reduce or eliminate any identified non-conformances

The Quality Assurance and Regulatory Affairs departments are independent from the manufacturing operation, functioning under the supervision of the Tissue Bank Director (a medical doctor) and senior management staff.

MARKETING AND DISTRIBUTION

Tutogen's products and processing services are provided globally through a combination of worldwide distributors, direct representatives and local distributors. Tutogen's personnel, along with distributors and their representatives, conduct product training sessions, make joint customer calls, set objectives and evaluate their representatives' performance. Personnel also call on select physicians and key hospital accounts in order to provide needed clinical and technical information services. The overall strategy is to work with each global distributor 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 international sales are derived primarily from Europe. Since Tutogen's foreign donor procurement practices are in full compliance with the donor suitability standards of the AATB and the U.S. Food and Drug Administration ("FDA"), the Company has worked closely with its distributors to expand into numerous market opportunities world wide. Tissue grafts are used in dental, spine, urology, ophthalmology, hernia, general surgery, head and neck applications, and plastic and reconstructive surgeries. Future objectives are to match this penetration into additional international 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 distributors. 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 applications, for select international markets.

Zimmer Dental Inc. ("Zimmer Dental") and Zimmer Spine Inc. ("Zimmer Spine"), subsidiaries of Zimmer Holdings, Inc., provide marketing services for the Company's products for the dental and spine markets. Starting in September 2000, Zimmer Dental entered into an agreement to represent TUTOPLAST processed bone, under the brand name Puros(R), for dental applications. Revenues from this relationship account for 46% of total consolidated and 69% of total U.S. revenues for the fiscal year ended September 30, 2006. Zimmer Dental markets the products to the end user and the Company ships and bills the customer directly. Distribution fees earned pursuant to the agreements are recognized ratably over the terms of these respective agreements. During 2006, the Company expanded its relationship with Zimmer Dental by adding pericardium and dermis soft tissue grafts for dental applications. The additions of these new products provide Zimmer Dental with a full line of products for the dental surgeons. During 2006, the Company extended Zimmer Dental's exclusivity into select international markets.

Also starting 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", therefore Zimmer Spine now purchases the Company's products and distributes 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 for 2006 represented 8% and 11%, of total consolidated and U.S. revenues, respectively.

The Company also manufactures products for surgical specialties which include urology, ophthalmology, ENT, hernia and aesthetics products. During 2006, sales from surgical specialties totaled 13% of consolidated revenue and 19% of US revenues.

For urological indications, the Company had partnered with Mentor Corporation ("Mentor") since 1998. During 2006, Mentor sold their urology business to Coloplast A/S of Denmark ("Coloplast"), and assigned the Tutogen agreement to Coloplast. As a stocking distributor, Coloplast currently markets TUTOPLAST fascia lata, pericardium, and dermis tissue implants. In April 2006, Tutogen and Mentor signed an agreement that extended the current contracts for one year to provide enough time for Mentor to consummate the sale of the urology business to

Coloplast. The transition to Coloplast is ongoing, and a new definitive agreement with Coloplast is in discussion.

IOP, Inc. ("IOP") has been a distributor since 1998, and is the exclusive distributor for TUTOPLAST processed tissue for ophthalmology applications. Sense Medical, a distributor since December 2004, has non-exclusive rights to distribute TUTOPLAST products for selected head and neck procedures.

In January 2006, the Company entered in to a four-year exclusive worldwide distribution agreement with Davol, Inc. ("Davol"), a subsidiary of C. R. Bard, Inc., to promote, market and distribute the Company's line of allograft biologic tissues for hernia repair and the reconstruction of the chest and abdominal walls. Under the agreement, Davol paid the Company $3.3 million in fees for the exclusive distribution rights. Davol is a stocking distributor, and entered the hernia market during the fourth quarter of fiscal year 2006.

In June 2006, the Company signed a new exclusive distribution agreement with Mentor Corporation ("Mentor") for the exclusive North American rights for the use of TUTOPLAST dermis in the dermatology and plastic surgery markets for breast reconstruction. The Company received an upfront payment in consideration for these distribution rights. Shipments to Mentor, and market release will occur during fiscal year 2007.

Internationally, the Company concentrates on an in-depth penetration of markets with major needs not covered by Tutogen's global distributors. 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, orthopedics and tissue processing. Approximately 40% of the total international sales are xenograft products. The Company believes that through a combination of international distribution strategies, Tutogen can increase its penetration of the international markets for processed tissue.

The following table summarizes the Company's markets, products, applications and distributors:

Distributor	Market	Estimated Market Size - U.S.	Products	Appli
Zimmer Dental	Dental	$169.0 million	Puros Cancellous Puros Cortical Puros Block Puros Pericardium Puros Dermis	Ridge Aug
Zimmer Spine	Spine	$656.0 million	Puros bone Specialty Machined Grafts (Puros C & Puros A)	Interbod Cervical
Davol	Hernia	$150.0 million	AlloMax (Human Dermis Product)	Hernia Reconstruc chest and wa
Coloplast	Urology	$200.0 million	Suspend fascia lata Axis dermis Pericardium	Urinary In Pelvic Reconst
Mentor	Breast	$25.0 - $50.0 million	NeoForm dermis	Breast Rec

	Reconstruction			
IOP	Ophthalmology	$9.0 million	IO Patch BioDome BioElevation BioSpacer	Glau Enucl Br Suspe
Sense Medical	ENT	$55.0 million	Fascia lata Fascia temporalis Pericardium	Tympno Rhino Septo

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 recipient.

These records accompany each donor tissue receipt, along with related serological test samples. The test samples are evaluated by independent Clinical Laboratory Improvement Amendment ("CLIA") 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 and C 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 and variant Creutzfeldt-Jakob Disease ("vCJD") by Human Cells, Tissues, and Cellular and Tissue-Based Products ("HCT/Ps")". This document reflects the FDA'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.

The Company embarked on a program in 1993 to develop xenografts (tissue derived from animals) as an allograft substitute. 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. Approximately 40% of the total products sold internationally are bovine. Tutogen Germany currently obtains bovine material from a "closed herd" in an internationally approved source country. In the US, the Company received FDA 510(k) clearance for bovine pericardium in 2000, allowing the

Company to market the first xenograft tissues (Tutopatch(R)) domestically, for indications of general and plastic surgery. Based on such approvals Tutogen Germany will be able to supply bovine products in the US. The Company is currently evaluating the introduction and timing of bovine products in the US. The unique biomechanical properties of bovine tissue, combined with the absence of the 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 providers are FDA registered, state licensed and accredited by the AATB, as appropriate. Tissues are not purchased from these companies, but rather the providers are reimbursed for the costs incurred in the tissue recovery process itself, at the time of delivery. Due to the growing demand for and the 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 and entered into multiple new arrangements during 2006.

In November 2006, the company entered into strategic tissue sourcing agreements with Regeneration Technologies, Inc. ("RTI"). Under the multi-year agreements, RTI has the first right of refusal to all soft tissue used in sports medicine surgeries recovered by Tutogen's tissue recovery providers. The Company, in turn, has the first right of refusal to all dermis, fascia and pericardium recovered by RTI donor services agencies.

Although the Company believes that it has the necessary contractual arrangements in place to ensure that there are sufficient tissues available to meet its needs for the foreseeable future, there can be no assurance that these supplies will continue or materialize as planned. Unavoidable interruptions in tissue supply (such as natural disasters, regulatory changes, financial set-backs) could have a material adverse effect on Tutogen's business operations.

COMPETITION

Tutogen considers itself 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 1,500,000 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 and peer-reviewed articles.

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

manufacturers such as Osteotech, Inc., RTI and LifeCell, Inc., companies well established in the fields of processing and distribution of bone and soft tissue implants, 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 in certain markets. Management believes that the TUTOPLAST process, with its impressive record for safety in the surgical community, gives the Company a marked advantage over its competitors. However, due to government regulation, disrupted sources of tissue supply 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 over $1.25 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 the foreseeable future. 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 the Company's internally developed new products and technology, a major component of the Company's growth strategy will be expanding its collaborations with each global distributor. Tutogen will continue to work with each organization to evaluate opportunities for new products and applications, and to determine the potential for international expansion. The ultimate goal is to provide each distributor with a full line of procedure specific implants, for their respective fields of use, and to leverage their sales strength in select international markets.

Currently, the Company'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 well accepted and is highlighted in various Zimmer Dental training courses. Globally, similar products processed from xenograft tissue, has helped generate growth as the Company focuses on expanding the international market for dental products. Additionally, the Company has developed membranes from TUTOPLAST processed dermis and pericardium for use as a barrier in dental applications. These products have been used in Europe, and the U.S. launch for pericardium was in February 2006 and for dermis in September 2006. The addition of these new products in the U.S. will provide Zimmer Dental with a full line of products for the dental surgeons.

The spine market for biologic materials was estimated at approximately $656 million in 2005. This allograft market is split between traditional allograft bone (19%), machined specialty grafts (49%), and demineralized bone matrix ("DBM") (32%). Tutogen continues its U.S. collaboration with Zimmer Spine in developing new, highly precise machined specialty grafts. During the fourth quarter of fiscal year 2006, the Company shipped to Zimmer Spine the first two machined specialty grafts (PurosC(R) - cervical graft and PurosA(R) - anterior lumbar interbody fusion graft) for spinal surgery. Zimmer Spine will release these products to the market during 2007. The Company will explore expanding its spinal products internationally during 2007.

During October 2002, the Company entered the European market with Tutomesh(R), a TUTOPLAST processed xenograft for hernia and abdominal wall repair. It has been well received in Europe, and has already been successfully used in abdominal wall surgery of neonates and children with hernia defects. The Company is evaluating this opportunity globally for both the Tutomesh, as well as for TUTOPLAST processed dermis. In December 2004, Tutogen received FDA 510(k) marketing clearance for a xenograft product and is currently investigating various options for its distribution in the U.S.

Internationally, the Company has internally developed a line of TUTOPLAST 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.

In January 2006, Tutogen entered into a four-year exclusive worldwide distribution agreement with Davol, a subsidiary of C. R. Bard, Inc., to promote, market and distribute Tutogen's line of allograft biologic tissues for hernia repair and the reconstruction of the chest and abdominal walls. Under the agreement, Davol paid Tutogen $3.3 million in fees for the exclusive distribution rights. Davol is a stocking distributor, and entered the hernia market during the fourth quarter of 2006. The US market for biologic grafts used for hernia repair is estimated at $150 million annually. The Company will work with Davol to grow its new hernia business during 2007 and beyond.

In June 2006, the Company signed a new exclusive distribution agreement with Mentor for the exclusive North American rights for the use of TUTOPLAST dermis in the dermatology and plastic surgery markets for breast reconstruction. Under the agreement, Mentor will pay the Company an upfront payment of $.5 million in consideration for these distribution rights. The initial estimated potential market in the U.S. is $25-50 million. Shipments to Mentor and market release will occur during fiscal year 2007.

INTERNATIONAL OPERATIONS

The Company currently has sales in more than 20 countries located primarily in Europe. Approximately 33%, 32% and 42% of the Company's consolidated sales, respectively for fiscal years 2006, 2005, and 2004 were derived from outside the United States, as follows:

Revenues (IN THOUSANDS) Year ended September 30,	United States	International	Consolidated
2006	$25,430	$12,517	$37,947
2005	$21,752	$10,108	$31,860
2004	$17,126	$12,204	$29,330

Approximately 40% of total international sales are bovine products and 60% are allograft products. Products are manufactured and supplied out of the Company's manufacturing facilities in Neunkirchen, Germany.

RESEARCH AND DEVELOPMENT

The Company continues to engage in research and development ("R&D") activities. The Company follows an internal product development plan and coordinates all R&D activities, including the Zimmer Dental and Zimmer Spine collaborations. R&D expenditures remain at 5% of total sales.

In allograft-related areas, R&D activities focus primarily on the development of surgical solutions and applications, 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 enhance tissue safety and efficacy. Non-allograft activities relate to explorations into the use of xenografts (specifically bovine), tissue-engineered grafts and improved healing. Clinical studies, evaluation and follow-up are conducted on these activities. The Company is referred to in more than 400 publications. The Company's research efforts are subsidized by its collaboration with non-profit research institutions and strategic business partners. These activities will be expanded pending the availability of the necessary financial resources.

CUSTOMERS

The Company has exclusive distribution agreements with Zimmer Dental, Zimmer Spine, Davol, Mentor, Coloplast and IOP. Zimmer Dental and Zimmer Spine accounted for approximately 46% and 8%, respectively, of the Company's revenue for the year ended September 30, 2006. No end user customer accounted for more than 10% of the Company's consolidated sales for the fiscal year 2006.

PATENTS, LICENSES AND TRADEMARKS

Wherever possible, the Company seeks to protect its proprietary information, products, methods and technology by obtaining patent and trademark protection. The Company has certain patents pending and has multiple registered trademarks covering several countries worldwide. In the United States, the Company is aggressively pursuing 510(k) submissions for its various products or processes and subsequent FDA clearances. 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

The Company procures, processes and markets its tissue products worldwide. Although some standards of harmonization exist, 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 FDA 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 standards of 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 European Union ("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. In June of 2006, the Company received approval to sell its first allograft product into Germany.

The FDA and international regulatory bodies conduct periodic compliance inspections of both the Company's 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 AATB and is licensed in the states of Florida, New York, California, Maryland, Delaware and Illinois. 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 independent, third parties 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.

EMPLOYEES

As of September 30, 2006, the Company employed a total of 222 full-time employees, of whom 80 full-time employees were employed in the United States and the remainder in Germany. Management believes its relations with its employees are good.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a number of very significant risks. You should carefully consider the following risks and uncertainties in addition to other information in this report in evaluating our Company and its business before purchasing shares of our Company's common stock. Our business, operating

results and financial condition could seriously be harmed due to any of the following risks. The risks described below are not the only ones facing our Company. Additional risks not presently known to us may also impair our business operations. You could lose all or part of your investment due to any of these risks.

WE DEPEND HEAVILY UPON A LIMITED NUMBER OF SOURCES OF HUMAN TISSUE, AND ANY FAILURE TO OBTAIN TISSUE FROM THESE SOURCES IN A TIMELY MANNER WILL INTERFERE WITH OUR ABILITY TO PROCESS AND DISTRIBUTE ALLOGRAFTS.

Our business is dependent on the availability of donated human cadavers tissue supplied by donor recovery groups. Donor recovery groups provide support to donor families, are regulated by the FDA, and are often affiliated with hospitals, universities or organ procurement groups. Our relationships with donor recovery groups, which are critical to our supply of tissue, can be affected by relationships they have with other organizations. Any negative impact of the regulatory and disease transmission issues facing the industry, as well as the negative publicity that these issues create, could have an impact on our ability to negotiate favorable contracts with recovery groups.

If our current sources can no longer supply human cadaveric tissue or our requirements for human cadaveric tissue exceed their current capacity, we may not be able to locate other sources on a timely basis, or at all. Any significant interruption in the availability of human cadaveric tissue would likely cause us to slow down the processing and distribution of our human tissue products, which could adversely affect our ability to supply the needs of our customers and materially and adversely affect our results of operations and our relationships with our customers.

AlloSource, our largest donor recovery group, supplied us with approximately 65% of our total human tissue for the year ended September 30, 2006. Our three largest recovery groups together supplied approximately 83% of our total tissue for the year ended September 30, 2006. If we were to lose any one of these sources of tissue, the unfavorable impact on our operating results would be material.

WE ARE HIGHLY DEPENDENT UPON INDEPENDENT DISTRIBUTORS TO GENERATE OUR REVENUES.

We currently derive the majority of our revenues through our relationships with two companies, Zimmer Dental and Zimmer Spine. For the year ended September 30, 2006, we derived approximately 46% and 8% of our consolidated revenues from distribution by Zimmer Dental and Zimmer Spine, respectively.

Zimmer provides nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for our line of dental and spinal allografts. If our relationship with Zimmer is terminated or reduced for any reason and we are unable to replace the relationship with other means of distribution, we would suffer a material decrease in revenues.

WE FACE INTENSE COMPETITION FROM COMPANIES, ACADEMIC INSTITUTIONS, TISSUE BANKS, ORGAN PROCUREMENT ORGANIZATIONS AND TISSUE PROCESSORS WITH GREATER FINANCIAL RESOURCES AND LOWER COSTS WHICH COULD ADVERSELY AFFECT OUR REVENUES AND RESULTS OF OPERATIONS.

The biotechnology field is highly competitive and is undergoing rapid and significant technological changes. Our success depends upon our ability to develop and commercialize effective products that meet medical needs as well as

our ability to accurately predict future technology and market trends. Many of our competitors have much greater financial, technical, research, marketing, distribution, service and other resources that are significantly greater than ours. Moreover, our competitors may offer a broader array of tissue repair treatment products and technologies or may have greater name recognition than we do in the marketplace.

Our competitors may develop or market technologies that are more effective or commercially attractive than ours, or that may render our technology uncompetitive, uneconomical or obsolete. For example, the successful development of a synthetic tissue product that permits remodeling of bones could result in a decline in the demand for allograft-based products and technologies and have a materially adverse effect on our financial condition and results of operation.

IF THIRD PARTY PAYERS FAIL TO PROVIDE APPROPRIATE LEVELS OF REIMBURSEMENT FOR THE USE OF OUR IMPLANTS, OUR REVENUES WOULD BE ADVERSELY AFFECTED.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. Any new Federal or state legislation could result in significant changes in the availability, delivery, pricing or payment for healthcare services and products. While we cannot predict what form any new legislation will take, it is possible that any significant healthcare legislation, if adopted, could lower the amounts paid to us for our services, which would decrease our revenues.

Our revenues depend largely on the reimbursement of patients' medical expenses by government healthcare programs and private health insurers. Governments and private insurers closely examine medical procedures incorporating new technologies to determine whether the procedures will be covered by payment, and if so, the level of payment which may apply. We cannot be sure that third party payers will continue to reimburse us or provide payment at levels which will be profitable to us.

OUR ALLOGRAFT AND XENOGRAFT IMPLANTS AND TECHNOLOGIES COULD BECOME SUBJECT TO SIGNIFICANTLY GREATER REGULATION BY THE FDA, WHICH COULD DISRUPT OUR BUSINESS.

The FDA and several states have statutory authority to regulate allograft processing and allograft-based materials. The FDA could identify deficiencies in future inspections of our facilities or promulgate future regulatory rulings that could disrupt our business, hurting our profitability.

FDA regulations of human cellular and tissue-based products, titled "Good Tissue Practices," went into full force as of May 2005. These regulations cover all stages of allograft processing, from procurement of tissue to distribution of final allografts. These regulations may increase regulatory scrutiny within our industry and lead to increased enforcement action which affects the conduct of our business. In addition, the effect of these regulations may have a significant effect upon recovery agencies which supply us with tissue and increase the cost of recovery activities. Any such increase would translate into increased costs to us, as we compensate the recovery agencies based on their cost of recovery.

Other regulatory entities include state agencies with statutes covering tissue banking. Of particular relevance to our business are regulations issued by Florida, New York, California and Maryland. Most states do not currently have tissue banking regulations. However, recent incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against us or against donor recovery groups or tissue banks, including those with which we have a relationship, about non-compliance with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action, or could cause

negative publicity for our business and our industry.

Some of our implants in development will contain tissue derived from animals, commonly referred to as xenografts. Xenograft implants are medical devices that are subject to pre-market approval or clearance by the FDA. We may not receive FDA approval or clearance to market new implants as we attempt to expand the quantity of xenograft implants available for distribution.

THE NATIONAL ORGAN TRANSPLANT ACT ("NOTA") COULD BE INTERPRETED IN A WAY THAT COULD REDUCE OUR REVENUES AND INCOME IN THE FUTURE.

Some aspects of our business are subject to additional local, state, federal or international regulation. Changes in the laws or new interpretations of existing laws could negatively affect our business, revenues or prospects, and increase the costs associated with conducting our business. The procurement and transplantation of allograft tissue is subject to federal regulation under the National Organ Transplant Act, or NOTA, a criminal statute that prohibits the purchase and sale of human organs, including bone and other tissue. NOTA permits the payment of reasonable expenses associated with the transportation, processing, preservation, quality control and storage of human tissue, which are the types of services we perform. If in the future, NOTA were amended or interpreted in a way that made us unable to include some of these costs in the amounts we charge our customers, it could reduce our revenues and therefore hurt our business. It is possible that more restrictive interpretations or expansions of NOTA could be adopted in the future which could require us to change one or more aspects of our business, at a substantial cost, in order to continue to comply with this statute.

OUR SUCCESS WILL DEPEND ON THE CONTINUED ACCEPTANCE OF OUR ALLOGRAFT AND XENOGRAFT IMPLANTS AND TECHNOLOGIES BY THE MEDICAL COMMUNITY.

Market acceptance of our allograph and xenograph implants can be affected by factors such as competitive tissue repair options, lack of third party reimbursement and the training of surgeons in the use of our tissue transplants, and rapid technological changes such as synthetic hormone tissue substitutes.

Market acceptance depends on our ability to demonstrate that our existing and new implants and technologies are an alternative to existing tissue repair treatment options. This will depend on surgeons' evaluations of the clinical safety, efficacy, ease of use, reliability and cost-effectiveness of these tissue repair options and technologies.

WE OR OUR COMPETITORS MAY BE EXPOSED TO PRODUCT LIABILITY CLAIMS WHICH COULD CAUSE US TO BE LIABLE FOR DAMAGES OR CAUSE INVESTORS TO THINK WE WILL BE LIABLE FOR SIMILAR CLAIMS IN THE FUTURE.

The development of allografts and technologies for human tissue repair and treatment entails an inherent risk of product liability claims, and substantial product liability claims may be asserted against us. We are a party to a number of legal proceedings related to product liability.

The implantation of donated cadaveric human tissue products creates the potential for transmissions of communicable disease. Although we comply with Federal and state regulations and guidelines intended to prevent communicable disease transmission, and our tissue suppliers are also required to comply with such regulations, there can be no assurances that: (i) our tissue suppliers will comply with such regulations intended to prevent communicable diseases

transmissions; (ii) even if such compliance is achieved, that our products have not been or will not be associated with transmission of disease; or (iii) a patient otherwise infected with disease would not erroneously assert a claim that the use of our products resulted in disease transmission.

We currently have $5 million of product liability insurance to cover claims. This amount of insurance may not be adequate for current claims if we are not successful in our defenses, and furthermore, we may not have adequate insurance coverage for any future claims that arise. Moreover, insurance covering our business may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which would harm our financial condition and liquidity. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. In addition, claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain surgeon endorsement of our allografts or to expand our business.

NEGATIVE PUBLICITY CONCERNING THE USE OF DONATED HUMAN TISSUE IN MEDICAL PROCEDURES COULD REDUCE THE DEMAND FOR OUR PRODUCTS AND NEGATIVELY IMPACT THE SUPPLY OF AVAILABLE DONOR TISSUE.

There has recently been negative publicity concerning the use and method of obtaining donated human tissue that is used in medical procedures. This type of negative publicity could reduce the demand for our products or negatively impact the willingness of families of potential donors to agree to donate tissue, or tissue banks to provide tissue to us. In such event, we might not be able to obtain adequate tissue to meet the needs of our customers. As a result, our relationships with our customers and our results of operations could be materially and adversely affected.

OUR SUCCESS DEPENDS ON THE SCOPE OF OUR INTELLECTUAL PROPERTY RIGHTS AND NOT INFRINGING THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS.

Our ability to compete effectively with other companies is materially dependent upon the success of our patents and how effective we are in enforcing them and protecting our trade secrets. If we are not successful and steadfast, it is highly likely that our competitors will exploit our proprietary technologies and innovations and will compete more effectively against us. It is also highly likely that our competitors, who also have greater resources than we do, will challenge our intellectual property rights, and attempt to invalidate, circumvent or render unenforceable any of our patents or propriety rights that we currently own or are licensed to us.

Because of the competitive nature of the biotechnology industry, there can be no assurances that we will not be required to litigate the enforcement of our patents and other intellectual rights.

Moreover, there can be no assurances that we will not have to defend our existing or proposed products or processes against third party claims of patent infringement and other intellectual property claims. However the litigation may arise, intellectual property litigation is always costly and ends up diverting our financial and management resources and damages our business.

WE MAY NEED TO SECURE ADDITIONAL FINANCING TO FUND OUR LONG-TERM STRATEGIC PLAN.

We expect to continue to make investments in our business to support our distribution efforts and future programs and initiatives, which may deplete our available cash balances. We believe that our available cash, cash equivalents, available lines of credit and anticipated future cash flow from operations will be sufficient to meet our cash needs for the foreseeable future. Our future liquidity and capital requirements will depend upon numerous factors, including but not limited to, the progress of our product development programs and the need for and associated costs relating to regulatory approval, if any, which may be needed to commercialize some of our products under development, or those commercialized products whose regulatory status may change.

We may need to raise additional funds through the issuance of equity and/or debt financing in private placements or public offerings to provide funds to meet the needs of our long-term strategic plan. Additional funds may not be available, or if available, may not be available on favorable terms. Further equity financings, if obtained, may substantially dilute the interest of our pre-existing shareholders. Any additional debt financing may contain restrictive terms that limit our operating flexibility. As a result, any future financings could have a material adverse effect on our business, financial condition or results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

As of September 30, 2006, there were no comment letters outstanding from the SEC.

ITEM 2. PROPERTIES.

UNITED STATES. The Company's domestic facilities are located in Alachua, Florida. The Company previously announced the relocation of the administrative offices to its facility in Alachua which occurred on December 31, 2005. In April 2005, the Company's offices and manufacturing facility in Alachua, Florida expanded from approximately 20,205 square feet to 26,000 square feet of leased space. The Florida lease expires January 31, 2009 with a renewal option through January 31, 2011, at a base rent of approximately $34,000 per month. There are various options for additional expansion space in the immediate area and the Company believes that it will have sufficient space to meet its current and future needs into the foreseeable future.

GERMANY. The Company's facility in Neunkirchen consists of six buildings totaling approximately 33,000 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 the facilities expansion project that is currently underway. The expansion project is expected to be completed by the first calendar quarter of 2007.

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 resulted in a reduction of the original proposed judgment received against the Company by $406,000. At September 30, 2006 and 2005, the Company maintained an accrual of $385,000 and $476,000, respectively (approximately 380,000 euros) with respect to the remaining appeal and legal costs. During October 2006, the Company completed a settlement of $360,000 (or approximately 280,000 euros) with the former international distributor.

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 notified all customers and distributors of record regarding this action. In connection with the recall, the Company wrote off $1,035,000 of inventory during 2005. Additionally, as of September 30, 2005, the Company had accrued $250,000 of related costs in connection with the recall. As of September 30, 2006, the accrual for these costs was $0, due in part to actual payments made for such costs and in part to an adjustment made by management during the three months ended March 31, 2006 to reduce the accrual by approximately $150,000 as a result of a change in management's estimate of the total recall related costs. The effect of this adjustment was to reduce cost of revenue by approximately $150,000.

In January 2006, the Company was named as one of several defendants in a class action suit related to the BioMedical recall. It is management's opinion that it is too early in the process to determine the effect of this class action on the financial condition of the Company.

However, the Company intends to vigorously defend this matter and does not believe that settlement of this class action will have an adverse material effect on the Company's operations, cash flow or financial position.

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

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 2005	High	Low
First Quarter	$3.13	$2.24

Second Quarter	2.60	2.30
Third Quarter	2.42	2.11
Fourth Quarter	4.56	2.35
Fiscal 2006		
First Quarter	$4.40	$2.62
Second Quarter	5.00	2.92
Third Quarter	5.20	4.55
Fourth Quarter	6.24	4.21

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, 2006, the approximate number of holders of record of the Company's Common Stock was 714.

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 plans as of September 30, 2006.

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	Nu Re For f Equit (ex refl
	(a)		
Equity compensation plan approved by Securities holders - 1996 Plan (1)	2,221,368	$2.63	
Equity compensation plan approved by Securities holders - 2006 Plan (1)	17,500	$4.92	
Equity compensation plan not approved by Securities holders	-0-	-0-	
Total	2,238,868	$2.65	

(1) Reflects options to purchase shares of the Company's common stock and shares available for Issuance under the Company's stock option plans.

ITEM 6. SELECTED FINANCIAL DATA.

	(IN THOUSANDS, EXCEPT PER SHARE DATA) YEARS ENDED SEPTEMBER 30,			
	2006	2005	2004	2003
Revenue	$ 37,947	$ 31,860	$ 29,330	$ 30,260
Gross margin %	57%	37%	60%	67%
Operating (loss) income	(287)	(7,227)	3,158	5,265
Net (loss) income	(589)	(7,017)	1,133	3,707
Average shares outstanding for basic earnings (loss) per share	16,027,469	15,919,286	15,734,470	15,495,148
Basic earnings (loss) per share	$ (0.04)	$ (0.44)	$ 0.07	$ 0.24
Average shares outstanding for diluted earnings (loss) per share	16,027,469	15,919,286	16,469,443	16,095,448
Diluted earnings (loss) per share	$ (0.04)	$ (0.44)	$ 0.07	$ 0.23
Balance Sheet Data:				
Working capital	$ 8,215	$ 8,433	$ 17,471	$ 15,342
Total assets	38,917	26,205	33,536	29,962
Long-term debt	4,770	814	827	728
Stockholders' equity	15,221	13,722	21,272	17,606

The company adopted SFAS 123R for the year ended September 30, 2006. The impact of this adoption is discussed in Item 7 below under general and administrative expenses.

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

Tutogen Medical, Inc., a Florida corporation, was formed in 1985 and with its consolidated subsidiaries (collectively, the "Company" or "Tutogen"), designs, develops, processes, manufactures and markets sterile biological implant products made from human (allograft) and animal (xenograft) tissue. Surgeons use our products to repair and promote the healing of a wide variety of bone and other tissue defects, including dental, spinal, urology, ophthalmology, head, neck and general surgery procedures. Our products are distributed in the United States and in over twenty (20) other countries.

We pursue a market approach to the distribution of our implants and establish strategic distribution arrangements in order to increase our penetration in selected markets. We have distribution agreements with Zimmer Dental and Zimmer Spine, subsidiaries of Zimmer Holdings, Inc. for the dental and spine markets, Mentor for breast reconstruction, IOP for ophthalmology, Davol for hernia, Coloplast for urology, and Sense Medical for ears, nose and throat. In all other markets that we serve, we use a network of independent distributors.

CRITICAL ACCOUNTING POLICIES

The Company's significant accounting policies are more fully described in Note 2 to the consolidated financial statements. 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:

SHARE-BASED COMPENSATION. We adopted Statement of Financial Accounting Standards No. 123R, SHARE-BASED PAYMENTS in the first quarter of fiscal year 2006. SFAS 123R requires the measurement and recognition of compensation expense for all share-based payment awards including employee stock options based on estimated fair values. Under SFAS 123R, we estimate the value of share-based payments on the date of grant using the Black-Scholes model, which was also used previously for the purpose of providing pro forma financial information as required under SFAS 123. The determination of the fair value of, and the timing of expense relating to, share-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as assumptions regarding a number of variables including the expected term of awards, expected stock price volatility and expected forfeitures.

Prior to the first quarter of fiscal year 2006, we used historical stock price volatility in preparing our pro forma information under SFAS 123. Under SFAS 123R, we use a combination of historical and implied volatility to establish the expected volatility assumption based upon our assessment that such information is more reflective of current market conditions and a better indicator of expected future volatility. SFAS 123R also requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate expected forfeitures, as well as the expected term of awards, based on historical experience. Future changes in these assumptions, our stock price or certain other factors could result in changes in our share-based compensation expense in future periods.

INVENTORIES. Inventories are valued at the lower of cost or market. Work in process and finished goods includes costs attributable to direct labor and overhead. Impairment charges for slow moving, excess and obsolete inventories are recorded based on historical experience, current product demand including meeting periodically with distributors, regulatory considerations, industry trends, changes and risks and the remaining shelf life. As a result of this analysis, the Company records an allowance to reduce the carrying value of any impaired inventory to its fair value, which becomes its new cost basis. If the actual product life cycles, demand or general market conditions are less favorable than those projected by management, additional inventory impairment charges may be required which would affect future operating results due to increases costs from the resulting adjustment. The adequacy of these impairment charges is 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. Title transfers 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 the Financial Accounting Standards Board - Statement of Financial Accounting Standard (SFAS) No. 48 and allowances for doubtful accounts are based on significant historical experience. 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 ratably to approximate services provided under the contract. Recognition of revenue commenced over the term of the distribution

agreement upon delivery of initial products.

VALUATION OF DEFERRED TAX ASSET. We record valuation allowances to reduce the deferred tax assets to the amounts estimated to be recognized. While we consider taxable income in assessing the need for a valuation allowance, in the event we determine it is more likely than not we would be able to realize our deferred tax assets in the future, an adjustment to the valuation allowance would be made and income increased in the period of such determination. Likewise, in the event we determine we would not be able to realize all or part of our deferred tax assets in the future, an adjustment would be made to the valuation allowance and charged to income in the period of such determination. We recorded a deferred tax asset valuation allowance of $6,166,000 and $6,309,000 at September 30, 2006 and 2005, respectively; representing 100% of existing U.S. net deferred tax assets.

FOR THE YEARS ENDED SEPTEMBER 30, 2006 AND 2005 - RESULTS OF OPERATIONS

REVENUE AND GROSS MARGIN

Revenue for the year ended September 30, 2006 increased to $37.9 million from $31.9 million in 2005. The U.S. revenues were $25.4 million or 17% higher than the 2005 revenues of $21.8 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, the company's distributor. In February 2006, the Company developed, in association with Zimmer Dental, a new pericardium product, and in September 2006, a new dermis product to augment ridge restoration. Sales of dental products increased 28% from a year ago. Spine revenues decreased 9% as the Company transitions from traditional spine grafts to specialty machined grafts. The Company introduced two new machined grafts, Puros C and Puros A during the fourth quarter of fiscal year 2006. Surgical specialties (primarily urology, ophthalmology and ENT) remained flat for 2006 compared to 2005.

The International operation had revenues of $12.5 million for the year ended September 30, 2006, an increase of 24% from the 2005 revenues of $10.1 million. The increase is primarily due to additional sales in Germany related to increased bovine product sales, dental sales and service processing and increased sales efforts by several key distributors in various countries.

An analysis of revenue follows:

($000's omitted)	FY 2006	FY 2005	FY 2004	4th Qtr. FY 2006	4th Qtr. FY 2005	4th Qtr. FY 2004
Dental	$17,616	$13,785	$ 6,893	$ 4,666	$4,115	$1,996
Spine	2,877	3,128	4,850	1,461	336	607
Surgical Specialties	4,937	4,839	5,383	1,417	1,129	1,445
Total-U.S.	$25,430	$21,752	$17,126	$ 7,544	$5,580	$4,048
Germany	$ 2,851	$ 1,980	$ 3,521	$ 497	$ 487	$1,390
Rest of World (ROW)	7,472	6,220	6,001	2,085	1,324	1,829
France	1,672	1,337	2,121	525	391	525
Other - Distribution Fees	522	571	561	135	170	141

Total-International	$12,517	$10,108	$12,204	$ 3,242	$2,372	$3,885
Total Consolidated	$37,947	$31,860	$29,330	$10,786	$7,952	$7,933

Gross margins for the year ended September 30, 2006 increased to 57% from 37% in 2005. The higher margins were due to (1) improved efficiencies in the U.S. manufacturing operations; and (2) the introduction of new products with higher margins. In addition, during fiscal year 2005, the gross margin was impacted by initial start-up manufacturing costs of $1.6 million associated with shifting production of the dental product lines from Germany to the U.S. and the recording of $1.25 million in expenses due to inventory write-down and certain accruals associated with the voluntary recall of products.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased in 2006 to $7.8 million from $5.8 million in 2005. The increase was due to several charges including $437,000 in severance costs associated with the replacement of the Managing Director of the Company's German subsidiary, $217,000 in legal, accounting and other professional costs associated with the restatement of prior period financial results and $262,000 related to strategic discussions with Zimmer Holdings. The Company incurred, for the first time, $451,000 in stock option expenses associated with the adoption of Statement of Financial Accounting Standards No. 123R. In addition, the Company incurred increased legal expenses of approximately $250,000 and accounting and audit fees of approximately $200,000 for various projects during the year. As a result, General and Administrative expenses, as a percentage of revenues, increased from 18% in 2005 to 20% in 2006.

DISTRIBUTION AND MARKETING

Distribution and Marketing expenses increased in 2006 to $12.3 million from $11.5 million in 2005. The increase was due mainly to higher marketing fees paid to Zimmer Dental of $7.2 million in 2006 versus $6.1 million a year ago as dental revenues increased to $17.6 million in 2006 up from $13.8 million in 2005. As a percentage of revenues, Distribution and Marketing expenses decreased from 36% in 2005 to 33% in 2006.

RESEARCH AND DEVELOPMENT

Research and Development expenses of $1.8 million were similar in 2006 to $1.7 million in 2005. As a percentage of revenues, Research and Development expenses remained at 5% in 2006 and 2005, respectively.

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 between the Company and a former international distributor. At September 30, 2005, the Company maintained an accrual of $476,000 with respect to the remaining appeal and legal costs. At September 30, 2006, the Company agreed to a settlement of $360,000 resulting from a dispute between the Company and a former international distributor and recorded a change in estimate of approximately $91,000 as a reduction of accrued expenses, which reduced the general and administrative expense for the year. The remaining accrual will be used to settle final nominal legal and court costs.

OTHER INCOME

Other income for 2006 increased to $108,000 compared to $77,000 in 2005. This was primarily the result of higher interest income on bank balances in 2006.

INTEREST EXPENSE

Interest expense in 2006 increased to $293,000 from $130,000 in 2005 due to increased borrowings for capital expenditures related to the facility expansion programs in Florida and Germany and interest expense associated with a $3.0 million convertible debenture issued in June 2006.

INCOME TAX (BENEFIT) EXPENSE

The income tax benefit is mainly due to the income tax benefit on the loss from the Company's foreign operations. The Company continues to record a full valuation allowance on its U.S. operations.

NET (LOSS) INCOME

The net loss for the year ended September 30, 2006 totaled $.6 million, $.04 basic and diluted loss per share as compared to a net loss of $7 million or $.44 basic and diluted loss per share for 2005. The reduction in net losses between the years is directly attributable to higher revenues and improved gross margins during 2006.

ACCOUNTS RECEIVABLE

The accounts receivable balance increased in 2006 to $6.2 million, up from $3.5 million in 2005 due to increased revenue growth, particularly during the fourth quarter of 2006. In addition, for certain international distributors, payment terms have been extended from 60 to 90 days contributing to higher receivable balances in 2006.

INVENTORY

The inventory balance increased to $12.7 million at September 30, 2006 from $9.6 million at September 30, 2005. The increase was primarily due to replacing $1.0 million of inventory written-off during 2005 due to the voluntary recall of certain products, and increased inventories associated with the recent introduction of new products.

FOREIGN CURRENCY TRANSLATION

The functional currency of the Company's German subsidiary is the Euro. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the period. The resulting translation adjustments, representing unrealized, non-cash gains and 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 and are included in Foreign exchange loss in the Consolidated Statements of (Loss) Income and Comprehensive (Loss) Income. The Company recognized transaction losses of $311,000, $173,000 and $700,000 in 2006, 2005 and 2004, respectively.

EFFECTS OF INFLATION

The Company believes the impact of inflation and changing prices on net sales revenues and on operations has been minimal during the past three years.

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 $2.6 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 36%, primarily due to significant purchases by Zimmer 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 for the year ended September 30, 2005, 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 of 2005, the resolution of certain regulatory issues in France and the temporary backlog of xenograft product lines.

Gross margins for the year ended September 30, 2005 decreased to 37% 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 (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. (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 during fiscal year 2005, 4), the estimated patient testing and other related expenses of $250,000 as a result of the product recall recorded in the fourth quarter of fiscal year 2005.

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 notified all customers and distributors of record regarding this action. In connection with this recall, the Company wrote off $1,035,000 of inventory, and accrued $250,000 of other related costs during the year ended September 30, 2005.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased 38% in 2005 to $5.8 million from $4.2 million in 2004. The increase was due to higher compensation costs related

to new personnel ($534,000), expenses related to the closing of the New Jersey Corporate Offices ($444,000), expenses related to Sarbanes-Oxley compliance ($118,000), unfavorable translation of Euro-based expenses ($84,000), and other expenses ($26,000). As a result, General and Administrative expenses, as a percentage of revenues, increased from 14% in 2004 to 18% in 2005.

DISTRIBUTION AND MARKETING

Distribution and Marketing expenses increased 32% or $2.8 million in 2005 to $11.5 million from $8.7 million in 2004. The increase was due mainly to higher marketing fees paid to Zimmer 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 $0.3 million in 2005 to $1.7 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 2004, a decision by the court of appeal in Germany resulted in a reduction of the original proposed judgment received against the Company by $406,000 between the Company and a former international distributor. At September 30, 2005 and 2004, the Company maintained an accrual of $476,000 with respect to the remaining appeal and legal costs.

OTHER INCOME/EXPENSE

Other income/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 borrowings for capital expenditure equipment related to the facility expansion programs in Florida and Germany.

INCOME TAX (BENEFIT) EXPENSE

Income Tax (Benefit) Expense is mainly due to the income tax benefit on the loss from the Company's foreign operations. The Company continues to record a full 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 $7.0 million, $0.44 basic and diluted loss per share as compared to a net income of $1.1 million, $0.07 basic and diluted earnings per share for 2004. As a percentage of revenues, net income decreased from 3.9% in 2004 to a net loss of twenty-two percent (22%) in 2005.

CONCENTRATION OF RISK

DISTRIBUTION--The majority of the Company's revenues are derived through the Company's relationships with two companies, Zimmer Dental and Zimmer Spine which contributed approximately 46% and 8%, respectively, of the Company's consolidated revenues during 2006. If the Company's relationship with Zimmer is terminated or further reduced for any reason and we are unable to replace the relationship with other means of distribution, the Company would suffer a material decrease in revenues.

TISSUE SUPPLY--The Company's business is dependent on the availability of donated human cadaver tissues supplied by donor recovery groups. Allosource, our largest donor recovery group, supplied the Company with approximately 65% of our total human tissue for the year ended September 30, 2006. Our three largest recovery groups together supplied approximately 83% of our total human tissue during 2006. Any significant interruption in the availability of human tissue would likely cause the Company to slow down the processing and distribution of the Company's human tissue products, which could adversely affect the Company's ability to supply the needs of the Company's customers and materially and adversely affect the results of operations and the relationships with customers.

TRADE RECEIVABLES--As of September 30, 2006, one customer, Zimmer Spine, represented 15% of the Company's outstanding trade receivables. No other customer represented more than 10% of the Company's outstanding trade receivables.

FOREIGN CURRENCY - The exposure to risk related to foreign currency exchange is limited primarily to inter-company transactions. At September 30, 2006 the Company substantially reduced its foreign currency exposure through the elimination of certain intercompany accounts.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2006 and 2005 the Company had working capital of $8.2 million and $8.4 million, respectively.

Cash and cash equivalents remained consistent from $3.6 million in 2005 to $3.5 million in 2006.

Net cash used in investing activities, representing purchases of capital expenditures, was $6.0 million in 2006 and $1.7 million in 2005. The continued spending on capital expenditures is due to the facility expansion in the Florida and German manufacturing locations and manufacturing equipment.

Net cash from financing activities in 2006 and 2005 totaled $7.9 million and $1.0 million, respectively from proceeds related to revolving credit facilities, a $3.0 million convertible debenture, additional long-term debt and capital leases.

Under the terms of revolving credit facilities with two German banks, the Company may borrow up to 1.5 million Euros (1 million Euros and .5 million Euros, respectively) or approximately $1.9 million for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 8.05% to 9.5%. At September 30, 2006 the Company had outstanding borrowings of 819,000 Euros or $1 million. At September 30, 2005, the Company had no borrowings under the revolving credit agreements. The .5 million Euro revolving credit facility is secured by accounts receivable of the German subsidiary. The 1 million Euro revolving credit facility is secured by a mortgage on the Company's German facility and a guarantee by the parent Company.

In November 2005, the Company entered into a revolving credit facility in the U.S. for up to $1.5 million, expiring on November 18, 2007. At September 30,

2006, the Company had outstanding $1.5 million on this credit facility to fund working capital needs. The U.S. accounts receivable and inventory assets secure the borrowing under the revolving credit facility. The Company is required to maintain a maximum senior debt to tangible net worth ratio of 2.0 to 1.0. As of September 30, 2006, the Company was in compliance with this covenant.

On June 30, 2006, the Company issued a $3 million convertible debenture with detachable warrants to purchase up to 175,000 shares of its common stock. The debenture bears interest at 5.0% per year, is due upon the earlier of August 1, 2007 or upon a change of control of the Company and is convertible into common stock at a price of $5.15 per share at any time at the election of the holder. The warrants are exercisable at $5.15 per share at any time at the election of the shareholder until the earlier of the third anniversary of the date of issuance or upon a change in control of the Company. The convertible debt is included in Short-term borrowings on the consolidated balance sheet at September 30, 2006. As of September 30, 2006, the Company was in compliance with the terms and conditions of the convertible debenture.

Senior debt consists of two loans with a German bank. The first loan ($576,000 as of September 30, 2006) has an interest rate of 5.75%, payable monthly, maturing March of 2011. The second loan ($1,744,000 as of September 30, 2006) has an interest rate of 5.15%, payable quarterly, maturing March of 2012.

The Senior debt, refinanced construction line of credit, and a revolving credit facility with a German bank are secured by a mortgage on the Company's German facility and is guaranteed up to 4.0 million euros by the parent company. There are no financial covenants under this debt.

The Company has an interim loan of 1 million Euros or approximately $1.3 million, at an annual interest rate of 5.75%, to finance its facility expansion project in Germany. The interim loan was converted to a long-term loan November 30, 2006. This loan has a 10 year term, payable semi-annually (55,000 Euros) at a fixed rate of 5.6%.

The Capital lease debt consists of two leases. The first lease (initially $1,3 million, $1.1 million as of September 30, 2006) is payable monthly at $55,000 per month and matures April of 2008. The lease is secured by leasehold improvements and equipment located at the Company's Florida tissue processing facility. The second lease (initially $224,000 and $85,000 as of September 30, 2006) is payable at $22,000 quarterly and matures September of 2007. The lease is secured by equipment located at the Company's Florida tissue processing facility. As of September 30, 2006, the Company is in compliance with the terms and conditions of the Capital lease 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 2010 total $2,111,000. 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, 2006:

(In Thousands)	TOTAL	2007	2008	2009	2010	2011	2012

Long Term debt (1)	$ 4,770	$1,097	$1,033	$533	$545	$482	$1,080
Operating Lease obligations	$ 2,111	$ 988	$ 748	$343	$ 32	$ 0	$ 0
Short-term borrowings (1)	$ 5,783	$5,783	$ 0	$ 0	$ 0	$ 0	$ 0
Total	$12,664	$7,868	$1,781	$876	$577	$482	$1,080

(1) Does not include interest

The Company maintains current working capital credit lines totaling 1.5 million Euros (approximately $1.9 million) with two German banks and a $1.5 million credit line with a U.S. bank. At September 30, 2006 the Company had outstanding balances of $1.0 million and $1.5 million for the working capital lines in Germany and the U.S., respectively. Management believes that the working capital as of September 30, 2006, together with the revolving lines of credit, will be adequate to fund ongoing operations. While the Company believes that it continues to make progress in 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. 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, controlling costs, and the development of additional markets and surgical applications for its products worldwide.

OFF-BALANCE SHEET ARRANGEMENTS

GUARANTEES - In October 2005, the Parent Company agreed to provide a guarantee up to 4 million Euros for the Company's German subsidiary's debt to a German bank. At September 30, 2006, total debt outstanding to the German bank was 3.2 million Euros.

The Company has no other off-balance sheet arrangements.

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. Except for an interest swap associated with $1.9 million of long term debt over six years starting March 31, 2006, 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, 2006 cash and cash equivalents and long-term debt, a 1% change in interest rates would have a de-minimus impact on our results of operations.

The value of the U.S. dollar compared to the euro affects our financial results. Changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income. The international operations currently transacts business primarily in the Euro. Intercompany transactions translate from the Euro to the U.S. dollar. Based on September 30, 2006 outstanding intercompany balances, a 1% change in currency rates would have a de-minimus impact on our results of operations.

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.

DISCLOSURE CONTROLS AND PROCEDURE

As of the end of the period covered by this Form 10-K, the Company's management, including the Chief Executive Officer and the Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-15 of the Securities Exchange Act of 1934. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired objectives. Based upon that evaluation and subject to the foregoing, the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, concluded that the design and operation of the Company's disclosure controls and procedures provided reasonable assurance that the disclosure controls and procedures are effective to accomplish their objectives.

The Company's management, including the Chief Executive Officer and Chief Financial Officer, concluded in its previous Form 10-K/A that disclosure controls and procedures were not effective as of September 30, 2005, due to a material weakness in the Company's internal control over financial reporting. Such material weakness related to a control activity relating to its inventory valuation and its policies and procedures over certain journal entries recorded in the financial close process. The Company's management remediated the material weakness during the quarter ended March 31, 2006, by designing and implementing a more effective and precise analytic model for calculating intercompany profit and a system for assuring the accuracy of this model. This system includes an enhanced reporting process for determining actual costs and transfer prices used in the calculation of intercompany profit to be eliminated during the consolidation process. Also, the Company has designed and documented new policies and procedures to strengthen its controls over certain journal entries recorded in its financial close process. During the year ended September 30, 2006, there were no other changes in internal control over financial reporting that have materially affected or are reasonably likely to affect the Company's internal control over financial reporting.

CHANGES IN CONTROL:

There has not been any change in our internal control over financial reporting during the quarter-ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, those controls.

ITEM 9B. OTHER INFORMATION.

The Company maintains an internet website at www.tutogen.com. We make available, free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8K. These reports may be found at the SEC website. Additionally, Tutogen's Board committee charters and code of ethics are available on the Company's website and in print to any shareholder who requests them. Tutogen does not intend for information contained in its website to be part of this Annual Report on Form 10-K.

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 and the Managing Director of the German subsidiary, the positions and offices held by each of them with the Company, and the period during which each served in such position. Each Director serves for a term of one (1) year, until his successor is duly elected and qualified if not re-elected.

NAME	AGE	POSITIONS/OFFICES	PERIOD SERVED IN OFFICE/POSITION
G. Russell Cleveland	68	Director	1997 - present
Roy D. Crowninshield, Ph.D.	58	Chairman of the Board Director Interim CEO	July 2004 - present 2003 - present July 2004 - December
Neal B. Freeman	66	Director	June 2005 - present
J. Harold Helderman, MD	61	Director	1997 - present
Udo Henseler, PH.D.	67	Director	June 2005 - present
L. Robert Johnston, Jr.	46	Chief Financial Officer & Secretary	February 2006 - Prese
Guy L. Mayer	55	President & Chief Executive Officer Director	January 2005 - presen January 2005 - presen
Claude O. Pering	60	Vice President US Operations	January 2005 - presen
Clifton J. Seliga	54	Vice President Sales & Marketing	January 2005 - presen
Adrian J. R. Smith	62	Director	June 2005 - present
Carlton E. Turner, Ph.D.	66	Director	2000 - present
Karl H. Koschatzky	59	Managing Director - German Subsidiary	June 2006 - 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., 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 Chief Executive Officer 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 the Dean of Admissions and Professor of Medicine, Microbiology and Immunology (since 1999) at Vanderbilt University, Nashville, Tennessee, and 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 currently President and principal/owner of MSI Management-Services-International (a private business since 1994). MSI provides services related to business development for companies at their various stages of their corporate evolution and contract CEO engagements, for biotechnology and life sciences firms, in domestic and international settings. From 2002 to 2005 Dr. Henseler was the CEO and Chairman and continued until February 2006 as a Director of eGene, Inc., a public biotechnology company. Dr. Henseler has extensive global public and private company leadership experience with over 40 years of combined service, in addition to the foregoing as: Director and EVP of ChemoKine Therapeutics Corporation, a biopharmaceutical company; VP and CFO of Qualicon Inc., a DuPont company; Director, SVP and CFO of the Pharmaceutical Andrx Inc.; VP and CFO of Genetic Systems Corp. - biopharmaceuticals; 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 and currently serves as Director of the public Spire Corporation.

L. ROBERT JOHNSTON, JR. is the Company's Chief Financial Officer and Secretary. Prior to Tutogen, Bob served as CFO of Power Medical Interventions (from 2004 to

2005), a privately held medical device company providing surgical stapling products and prior to Power Medical (from 2002 to 2004) as an independent consultant for Pittsburgh Life Sciences Greenhouse Executive Corps Program. For the 3 years prior to joining Pittsburgh Life Sciences, Mr. Johnston was Executive Vice President and Chief Financial Officer for Cellomics, Inc. a Pittsburgh, Pennsylvania company providing instrumentation, software and assays for automated cellular analysis for drug discovery in pharmaceutical, biotechnology and academia sectors. Prior experience also includes management positions with Oncormed, Inc. as CFO, American Mobile Satellite Corporation (now Motient Corp) as Assistant Treasurer, and Sovran Bank of Maryland as Assistant Vice President. Bob is a 1986 MBA Graduate of the Colgate Darden Graduate School of Business Administration, University of Virginia and received his BA in History and Spanish in 1982 from the University of Virginia.

GUY L. MAYER is the Company's Chief Executive Officer. In November 2006, Mr. Mayer was also appointed President of the Company. 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 Spire Corporation, a public company and private companies.

CLAUDE O. PERING is the Company's Vice President of U.S. Operations. Prior to Tutogen, Claude served as Principal of CoperTech, LLC (from 2002-2005) providing consulting services to client companies in the medical device, biotechnology and pharmaceutical industries. For the 3 years prior (1999-2002) Mr. Pering was President and Chief Operating Officer for Hayes Medical, Inc., a manufacturer and worldwide marketer of orthopaedic total joint implant products. For the 3 years prior to joining Hayes Medical, Inc., Mr. Pering was

Executive Vice President and Chief Operating Officer for Norian Corporation, a developer, manufacturer and global marketer of biotechnology products that was acquired by Synthes, Inc. Prior experience also includes 6 years as Vice President Operation/COO for Ace Medical Company (acquired by DePuy, Inc.) and 3 years as Corporate Director of Quality Assurance/Group Manager of Quality Engineering for Zimmer, Inc. Claude is an MBA Graduate, Indiana Wesleyan University, Marion, Indiana and received his BA in Chemistry, Microbiology, and Psychology from Drury University, Springfield, Missouri.

CLIFTON J. SELIGA is the Company's Vice President of Sales & Marketing. Prior to Tutogen, Clifton served as Principal of C. J. Seliga, LLC (from 2002-2005), providing consulting services to senior management in the areas of business planning, strategic development, marketing, new product planning, sales and distribution. For the 3 years prior (1998-2001) Mr. Seliga was Senior Vice President, General Manager for ETEX Corporation, a private biomedical company based in Cambridge, MA. For the 6 years prior to joining ETEX, Mr. Seliga held various senior positions at Zimmer, Inc., Division of Bristol Myers Squibb, including Vice President - Global Marketing and Director of Product Management. Prior experience also includes marketing and sales management positions with Richard-Allan Medical Industries and Richard Wolf Medical Instruments

Corporation. Clifton is an MBA Graduate, Marketing and Management, Northwestern University, Kellogg Graduate School of Management, Evanston, Illinois. He has a Master of Science (Research), Anatomy, St. Louis University and a BA in Biological Science, Chemistry (minor) from Southern Illinois University.

ADRIAN J.R. SMITH is Chief Executive Officer 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.

KARL H. KOSCHATZKY, PH.D. is the Managing Director of the Company's German subsidiary. Dr. Koschatzky has served in a variety of capacities within the Company, beginning in 1993 as the Technical Director of international operations. In 1994 Dr. Koschatzky's role expanded to include the planning and implementation of US operations. In 1999 he was promoted to Vice President Research and Development. In the third quarter 2006, Dr. Koschatzky was assigned the additional role of General Manager of German Operations. For the 11 years prior to Tutogen, Karl served as Manager of Operations, Wound Care Unit, Pfrimmer-Viggo GmbH (1984-1993) and Scientific Manager, Wound Care Business, Lyofil Pfrimmer GmbH (1982-1984). Karl received his Ph.D. from the University of Erlangen-Nurnberg in 1979 and Diplom-Chemist 1969-1976.

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 except for the following: Messrs. Helderman and Turner filed one late Form 4 Report, each relating to two transactions and Messrs. Crowninshield, Freeman, Henseler and Smith filed one late Form 4 Report, each relating to one transaction. All of the aforesaid transactions involved the granting or exercise of an option.

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 Dr. Henseler. 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. The Chairman of the Board receives $1,000 per month for his services as Chairman. Additionally, the Company's outside Directors each receive annually options to purchase 12,000 shares of the Company's common stock.

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, other executive officers and Dr. Karl Koschatzky, Managing Director of the Company's German subsidiary whose compensation exceeded $100,000 for this period.

		Annual Compensation			Long Term Compensatio	
					Awards	
Name And Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Other Annual Compensation ($)	Restricted Stock Award(s) ($)	Securities Underlying Options (#)
Guy L. Mayer (2)	2006	315,000	96,390	0	0	0
Chief Executive Officer	2005	225,000	24,300	0	0	300,000
L. Robert Johnston, Jr. Chief Financial Officer (3)	2006	149,100	21,803	0	0	60,000
Dr. Karl Koschatzky	2006	157,200	9,200	0	0	0
Managing Director	2005	148,700	13,100	0	0	0
German Subsidiary	2004	140,000	0	0	0	0
Claude O. Pering	2006	141,900	24,131	0	0	10,000

Vice President - US Operations	2005	83,100	20,925	0	0	50,000
Clifton J. Seliga	2006	141,900	24,131	0	0	0
Vice President - US Sales and Marketing	2005	83,100	20,925	0	0	50,000

(1) Includes 401(k) contributions, relocation, car allowances and expenses, and pension costs.

(2) Mr. Mayer was appointed Chief Executive Officer on January 1, 2005.

(3) Mr. Johnston was appointed Chief Financial Officer of the Company in February 2006.

EMPLOYMENT AGREEMENTS

On December 6, 2004, the Company entered into an employment agreement with Mr. Guy L. 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 $347,000. In addition, the employment agreement provides for a bonus for the balance of the Company's fiscal year 2006 in an amount up to 60% of his earned salary for fiscal 2006, 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. For his performance during 2005 Mr. Mayer was granted a ten (10) year option to purchase 50,000 shares of the Company's common stock, exercisable at the market price on the date of grant, 25% on the date of the grant and 25% of the first three (3) anniversaries.

Mr. Mayer has a "change of control" agreement whereby he is entitled to 24 months salary including medical benefits, in the event he is terminated as a result of a change of control of the Company.

The Company has a severance agreement with L. Robert, Johnston, Jr., Chief Financial Officer. Pursuant to that agreement, upon written notice of his termination, the Company will provide six months salary including medical benefits. Mr. Johnston's annual base salary is currently $200,000. 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. Johnston has a "change of control" agreement whereby he is entitled to 6 months salary including medical benefits in the event he is terminated as the result of a change of control of the Company.

In connection with their employment, the Company has agreed to a six (6) month severance package for Messrs. Pering and Seliga in the event of termination due to a change of control of the Company.

STOCK OPTION PLANS

The Company has a 1996 and 2006 Incentive and Non-Statutory Stock Option Plan (the "Option Plans") 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 Option Plans. This summary is qualified in its entirety by reference to the 1996 and 2006 Plan, a copy of which may be obtained from the Company.

The Option Plans authorize 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 Option Plans. The Option Plans also authorize the granting of NSSOs to non-employee Directors and consultants of the Company.

The 1996 Plan expired in February 2006 and no further options can be granted under the 1996 Plan. The 1996 Plan was superseded by the Tutogen Medical, Inc. Incentive and No-Statutory Stock Plan (the "2006 Plan") (1,000,000 shares authorized), adopted by the Board of Directors on December 5, 2005 and ratified by the shareholders on March 13, 2006. Under the 2006 Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

Pursuant to the 2006 Plan, an option to purchase 12,000 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 12,000 shares of Common Stock shall be granted automatically, on the date of each annual meeting of shareholders of the Company, to each outside Director who has served in that capacity for the past six months and continues to serve following such meeting. Any outside Director may decline to accept any option granted to him under the 2006 Plan.

The Board of Directors or the Compensation and Stock Option Committee is responsible for the administration of the 2006 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 2006 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 2006 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 2006 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 2006 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 2006 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 and unvested options are forfeited. Upon the occurrence of a "change in control" of the Company, the maturity of all options

then outstanding under the 2006 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.

As of September 30, 2006, there were outstanding options to purchase 2,221,268 shares of common stock under the 1996 Plan.

The 2006 Plan presently reserves 1,000,000 shares of the Company's Common Stock for issuance thereunder. As of September 30, 2006, options have been issued for 17,500 shares and 982,500 shares remain available under the 2006 Plan. Unless sooner terminated, the 2006 Plan will expire on December 5, 2015.

OPTIONS GRANTED IN FISCAL YEAR 2006

The following table provides information as to options granted to the Company's Chief Executive Officer and other Executive Officers during the fiscal year ended September 30, 2006. 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	Potenti Value Annua Stock P for O 5%
L. Robert Johnston, Jr. (1)	60,000	56%	$2.95	01/17/2016	$111,
Claude O. Pering	10,000	9	3.12	12/05/2015	19,

(1) Stock options related to Mr. Johnston's appointment as the new Chief Financial Officer of the Company in February 2006.

(2) Potential 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, 2006. No options were exercised during this fiscal year. The market price of the Company's common stock at September 30, 2006 was $4.50.

AGGREGATE OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

	Option Exercises	Number of Unexercised Options at September 30, 2006	Value o in-the-M Septe

Name	Shares Acquired on Exercise	Value Realized	Exercisable	Unexercisable	Exercisabl
Guy L. Mayer	0	$0	150,000	150,000	$245,750
L. Robert Johnston, Jr.	0	0	15,000	45,000	23,250
Dr. Karl Koschatzky	0	0	115,418	11,250	282,950
Claude O. Pering	0	0	12,500	47,500	14,750
Clifton J. Seliga	0	0	12,500	37,500	14,750

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 to any member of the committee.

COMPENSATION COMMITTEE REPORT

The following Report of the Compensation Committee and the information under the heading Performance Graph below shall not be deemed incorporated by reference by any general statement incorporating by reference into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934 together, the "Acts"), except to the extent that the Company specifically incorporates the information by reference, and shall not otherwise be deemed filed under 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 Officer, are made at the discretion of the Compensation Committee pursuant to the Company's Option Plans. Factors and criteria to be used by the Committee in the award of stock options include individual responsibilities, individual

performance 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 AMEX Market 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 September 30, 2001. The comparisons reflect in the table and graph, however, are not intended to forecast the future performance of the Common Stock and may not be indicative of such future performance.

[COMPARISON OF CUMULATIVE TOTAL RETURN OF ONE OR MORE COMPANIES, PEER GROUPS, INDUSTRY INDEXES AND/OR BROAD MARKETS GRAPHIC APPEARS HERE]

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

	FISCAL YEAR ENDING					
COMPANY/INDEX/MARKET	9/30/01	9/30/02	9/30/03	9/30/04	9/30/05	9/30/06
TUTOGEN MEDICAL INC	100.00	118.33	212.50	124.58	190.00	187.50
PEER GROUP INDEX	100.00	93.31	126.31	146.71	166.52	170.86
AMEX MARKET INDEX	100.00	108.63	134.25	154.97	187.60	195.30

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of the Company's common stock as of November 30, 2006, by (i) each person known to the Company to own beneficially more than five percent (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, 2006, there were 16,413,185 shares of common stock issued and outstanding.

NAME AND ADDRESS OF BENEFICIAL OWNER	AMOUNT AND NATURE OF BENEFICIAL OWNER (1)(2)	PERCENTAG OF CLASS (
SPV 1996 LP 101 Finsbury Pavement	1,896,794	11.56

London, England EC2A 1EJ		
Zimmer CEP (formerly Centerpulse) USA Holding Co. Subsidiary of Zimmer Holdings, Inc. 345 East Main Street Warsaw, IN 46580	5,297,124	32.27
G. Russell Cleveland (4)	124,300	*
Roy D. Crowninshield, Ph.D. (5)	62,000	*
Neal B. Freeman (6)	44,500	*
Dr. J. Harold Helderman (7)	117,000	*
Udo Henseler, Ph.D. (8)	24,500	*
L. Robert Johnston, Jr. (8)	15,000	*
Guy L. Mayer (8).	150,000	*
Claude Pering (8)	15,000	*
Clifton Seliga (9)	13,500	*
Adrian J. R. Smith (8)	24,500	*
Carlton E. Turner (10)	57,000	*
All directors and officers as a group (11 persons)	600,000	3.5

* Less than one percent (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 (60) 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 exercisable within sixty (60) days after November 30, 2006 held by such individual or group.

(4) Includes 47,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(5) Includes 42,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(6) Includes 24,500 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(7) Includes 87,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(8) All of the shares of common stock beneficially owned by Messrs. Henseler, Johnston, Mayer, Pering, Seliga and Smith are derivative securities issuable upon exercise of options exercisable within sixty (60) days.

(9) Includes 12,500 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(10) Includes 47,000 shares of common stock issuable upon exercise of options 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 years ended September 30, 2006, 2005 and 2004 product sales to Zimmer spine totaled $2,877, $3,128 and $4,850, respectively. Accounts receivable from Zimmer Spine were $952 and $44 at September 30, 2006 and September 30, 2005, respectively.

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. Under this distribution agreement, the Company sells directly to Zimmer Dental's customers. For the years ended September 30, 2006, 2005 and 2004, Zimmer Dental was paid commissions aggregating approximately $7,200, $6,055 and $3,213, respectively. Accounts payable to Zimmer Dental total $1,918 and $1,740 at September 30, 2006 and September 30, 2005, respectively.

As of September 30, 2006, Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc., is a 32% owner of the Company's outstanding shares of Common Stock.

On March 10, 2006, Zimmer Holdings Inc. ("Zimmer") filed an amended Schedule 13 (d) expressing its intention to initiate discussions with the Company which could possibly include further investment by Zimmer in securities of the Company or the acquisition by Zimmer of some or all of the outstanding common stock of the Company.

On August 9, 2006, representatives of Zimmer contacted the management of the Company telephonically to propose to the Company a non-binding indication of interest ("the Indication of Interest") with respect to a proposed acquisition of the Company at an indicative price range of $5.00 - $6.00 per share of Common Stock. Later on the same day, the Company contacted Zimmer and rejected the Indication of Interest. Subsequently, Zimmer filed an amended 13(d) expressing that they had determined not to pursue an acquisition of the Company at that time, but based on other factors deemed relevant by Zimmer, including, but not limited to, the price and availability of Common Stock, subsequent developments affecting Zimmer and the Company, the business prospects of Zimmer and the Company, general stock market and economic conditions and tax considerations, Zimmer may formulate other plans and/or make other proposals and take other actions with respect to its investment in the company that it deems to be appropriate.

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, 2006 and 2005, and all fees billed for other services by Deloitte & Touche LLP during those periods:

Year Ended September 30,	2006	2005
Audit fees (1)	$515,000	$143,000
Audit-related fees (2)	44,000	55,000
Tax fees (3)	33,000	4,000
All other fees (4)	39,000	--
Total Accounting Fees and Services	$631,000	$202,000

(1) AUDIT FEES. These are fees for professional services for the audit of the Company's annual financial statements, for the review of the financial statements included in the Company's filings on Form 10-Q and for services that are normally provided in connection with statutory and regulatory filings or engagements. For 2006, total audit fees include $173,000 for fees associated with the restatement of the prior year financial results in the 2005 Form 10-K/A and the results of the quarter ending December 31, 2005 in the Form 10-Q/A, $199,000 related to the 2005 audit and $56,000 for interim and planning procedures relating to the 2006 audit.

(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.

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 LLP for the fiscal years ended September 30, 2006 and 2005 were approved by the Audit Committee.

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 audits, 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.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(A) INDEX TO EXHIBITS

Exhibit Number	Description
3.1(a)	Certificate of Incorporation (b)
3.1(b)	Articles of Amendment increasing number of authorized shares of capital stock (c)
3.1(c)	Articles of Amendment effecting a reverse stock split (d)
3.2	Amended and Restated Bylaws (e)
4.1	See Exhibits 3.1 and 3.2 for the provisions of the Articles of Incorporation and Bylaws of the Company that define the rights of holders of the Company's common stock
10.4	1996 Incentive and Non-Statutory Option Plan (f)
10.5	2006 Incentive and Non-Statutory Option Plan (g)
10.8	Employment Agreement of Guy L. Mayer, dated December 6, 2004 (h)
10.9	Registration Rights Agreement dated June 30, 2006, by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd. (i)
10.10	Five percent (5%) Subordinated Convertible Debenture of Tutogen Medical, Inc. dated June 30, 2006 in an aggregate principal amount of $3,000,000 issued to Azimuth Opportunity, Ltd. (i)
10.11	Common stock Purchase Warrant dated June 30, 2006 issued to Azimuth Opportunity, Ltd. for the purchase of up to 175,000 shares of the

common stock of Tutogen Medical, Inc. (i)

10.12 Securities Purchase Agreement dated June 30, 006 by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd. (i)

10.13 Shareholders' Rights Agreement (j)

14.1 Code of Ethics (k)

21. Subsidiaries of the Registrant (Tutogen Medical GmbH incorporated in Germany and 100% owned).

23.1 Consent of the Independent Registered Public Accounting Firm

31.1 Certification of Chief Executive Officer, pursuant to Rule 13a-14. (a)

31.2 Certification of Chief Financial Officer, pursuant to Rule 13a-14. (a)

32. Certification of Chief Executive Officer and the Chief Financial Officer, pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (a)

(a) Filed herewith.

(b) Filed as Exhibit to Company's Registration Statement on Form 20-F effective October 2, 1987.

(c) Filed as an Exhibit to the Company's Form 10-K for the year ended September 30, 1998.

(d) Filed as an Exhibit to the Company's Form 10-K for the year ended September 30, 1998.

(e) Filed as Exhibit to Form 8-K Report August 16, 2006.

(f) Filed as Exhibit to Form S-8 filed October 31, 1996.

(g) Filed as Exhibit to Proxy Statement filed in connection with the Company's 2006 annual meeting of shareholders.

(h) Filed as Exhibit to Form 10-K/A Report for year ended September 30, 2005.

(i) Filed as Exhibit to Form 8-K Report July 6, 2006.

(j) Filed as Exhibit to Form 8-K Report July 17, 2002.

(k) Filed as Exhibit to Form 10-K Report for year ended September 30, 2004.

(B) FINANCIAL STATEMENT SCHEDULES

Schedule II - Valuation and Qualifying Accounts for the years ended September 30, 2006, 2005 and 2004.

Schedules other than that listed 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.

SIGNATURES

In accordance with the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Form 10-K to be signed on behalf by the undersigned, thereunto duly authorized.

Date: December 28, 2006

TUTOGEN MEDICAL, INC.

/s/ Guy L. Mayer

Guy L. Mayer
President & Chief Executive Officer

/s/ L. Robert Johnston Jr.

L. Robert Johnston Jr.
Chief Financial Officer

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

Signature	Title	Date
/S/ G. RUSSELL CLEVELAND G. Russell Cleveland	Director	December 28, 2006
/S/ ROY D. CROWNINSHIELD Roy D. Crowninshield	Director	December 28, 2006
/S/ NEAL B. FREEMAN Neal B. Freeman	Director	December 28, 2006
/S/ J. HAROLD HELDERMAN Dr. J. Harold Helderman	Director	December 28, 2006
/S/ UDO HENSELER Dr. Udo Henseler	Director	December 28, 2006

/S/ GUY L. MAYER Guy L. Mayer	Director	December 28, 2006
/S/ ADRIAN J. R. SMITH Adrian J. R. Smith	Director	December 28, 2006
/S/ CARLTON E. TURNER Carlton E. Turner	Director	December 28, 2006

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Tutogen Medical, Inc.
Alachua, Florida

We have audited the accompanying consolidated balance sheets of Tutogen Medical, Inc. and subsidiaries (the "Company") as of September 30, 2006 and 2005, and the related consolidated statements of (loss) income and comprehensive (loss) income, shareholders' equity and cash flows for each of the three years in the period ended September 30, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedules based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Tutogen Medical, Inc. and subsidiaries as of September 30, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2006, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ DELOITTE & TOUCHE LLP
Orlando, Florida

December 27, 2006

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2006 AND 2005
(In Thousands, Except for Share Data)

	2006	2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,463	$ 3,562
Accounts receivable - net of allowance for doubtful accounts of $483 in 2006 and $462 in 2005	6,202	3,473
Inventories - net	12,678	9,554
Deferred tax asset, net	471	1,149
Other current assets	1,436	623
	24,250	18,361
PROPERTY, PLANT, AND EQUIPMENT, NET	12,940	6,612
OTHER ASSETS	424	--
DEFERRED TAX ASSET, NET	1,303	1,232
TOTAL ASSETS	$ 38,917	$ 26,205
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,346	$ 1,365
Accrued expenses and other current liabilities	4,314	4,977
Accrued commissions	1,918	1,765
Short-term borrowings	5,783	1,048
Current portion of deferred distribution fees	1,577	589
Current portion of long-term debt	1,097	184
	16,035	9,928
NONCURRENT LIABILITIES		
Noncurrent deferred distribution fees and other noncurrent liabilities	3,988	1,925
Long-term debt	3,673	630
TOTAL LIABILITIES	23,696	12,483
Shareholders' Equity:		
Common stock, $0.01 par value, 30,000,000 shares authorized; 16,197,235 and 15,932,960 shares issued and outstanding	162	159
Additional paid-in capital	37,751	36,381
Accumulated other comprehensive income	2,393	1,678
Accumulated deficit	(25,085)	(24,496)
Total shareholders' equity	15,221	13,722

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 38,917	$ 26,205

See accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF (LOSS) INCOME AND COMPREHENSIVE (LOSS) INCOME
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004
(In Thousands, Except for Share and Per Share Data)

	2006	2005	2004
REVENUE	$ 37,947	$ 31,860	$ 29,330
COST OF REVENUE	16,336	20,129	11,852
Gross profit	21,611	11,731	17,478
OPERATING EXPENSES			
General and administrative	7,803	5,790	4,151
Distribution and marketing	12,261	11,509	8,737
Research and development	1,834	1,659	1,432
	21,898	18,958	14,320
OPERATING (LOSS) INCOME	(287)	(7,227)	3,158
FOREIGN EXCHANGE LOSS	(311)	(173)	(700)
OTHER INCOME	108	77	99
INTEREST EXPENSE	(293)	(130)	(118)
	(496)	(226)	(719)
(LOSS) INCOME BEFORE INCOME TAX (BENEFIT) EXPENSE	(783)	(7,453)	2,439
Income tax (benefit) expense	(194)	(436)	1,306
NET (LOSS) INCOME	$ (589)	$ (7,017)	$ 1,133
Other Comprehensive Income (Loss):			
Foreign currency translation adjustments	715	(570)	2,167
COMPREHENSIVE INCOME (LOSS)	$ 126	$ (7,587)	$ 3,300
AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS (LOSS) PER SHARE	16,027,469	15,919,286	15,734,470
BASIC (LOSS) EARNINGS PER SHARE	$ (0.04)	$ (0.44)	$ 0.07
AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS (LOSS) PER SHARE	16,027,469	15,919,286	16,469,443

DILUTED (LOSS) EARNINGS PER SHARE	$ (0.04)	$ (0.44)	$ 0.07

See accompanying Notes to Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004
(In Thousands)

	2006	2005	2004
Cash flows (used in) provided by operating activities			
Net (loss) income	$ (589)	$(7,017)	$ 1,133
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	778	984	760
Amortization of deferred distribution fees revenue	(835)	(640)	(640)
Amortization of debt discount	69	--	--
Reserve for bad debt	19	308	(83)
Provision for inventory write-downs	246	889	(597)
Share-based compensation	451	0	0
Deferred income taxes	797	(505)	869
Changes in assets and liabilities:			
Accounts receivable	(2,632)	1,106	807
Inventories	(3,394)	3,771	(1,810)
Other assets	(513)	798	(241)
Accounts payable and other accrued expenses	145	(497)	(894)
Accrued commissions	153	244	1,076
Deferred distribution fees	3,550	--	--
Net cash (used in) provided by operating activities	(1,755)	(559)	380
Cash flows used in investing activities			
Deposits on purchases of property and equipment	(300)	--	--
Purchase of property and equipment	(5,690)	(1,682)	(1,758)
Net cash used in investing activities	(5,990)	(1,682)	(1,758)
Cash flows provided by financing activities			
Issuance of common stock	647	36	366
Proceeds from long-term borrowings and capital lease arrangements	2,365	--	224
Proceeds from short-term borrowings	2,290	1,508	--
Issuance of convertible debt	3,000	--	--
Debt issuance costs	(263)	--	--
Repayment of short-term borrowings	(163)	(400)	--
Repayment of long-term debt	(543)	(164)	(95)
Net cash provided by financing activities	7,903	980	495
Effect of exchange rate changes on cash and cash equivalents	(257)	(240)	897
Net (decrease) increase in cash and cash equivalents	(99)	(1,501)	14

Cash and cash equivalents at beginning of period	3,562	5,063	5,049
Cash and equivalents at end of period	$ 3,463	$ 3,562	$ 5,063
Supplemental cash flow disclosures			
Interest paid	$ 578	$ 127	$ 118
Income taxes paid	$ --	$ 149	$ 251
Non-cash investing and financing activities relating to capital lease arrangement	$ 987	$ --	$ --

See accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004
(In Thousands, Except for Share Data)

	COMMON STOCK ($.01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (1)	ACCUM DEF
BALANCE, SEPTEMBER 30, 2003	$157	$35,980	$ 81	$(18
Stock issued on exercise of options	2	365	--	
Net income	--	--	--	1
Foreign currency translation adjustment	--	--	2,167	
BALANCE, SEPTEMBER 30, 2004	159	36,345	2,248	(17
Stock issued on exercise of options	--	36	--	
Net loss	--	--	--	(7
Foreign currency translation adjustment	--	--	(570)	
BALANCE, SEPTEMBER 30, 2005	159	36,381	1,678	(24
Stock issued on exercise of options	3	644	--	
Warrants issued	--	275	--	
Share-based compensation	--	451	--	
Net loss	--	--	--	
Foreign currency translation adjustment	--	--	715	
BALANCE, SEPTEMBER 30, 2006	$162	$37,751	$2,393	$(25

(1) Represents foreign currency translation adjustments.

See accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004
(IN THOUSANDS, EXCEPT FOR SHARE DATA)

1. OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. with its consolidated subsidiaries (the "Company") processes, manufactures and distributes worldwide, specialty surgical products and performs tissue processing services for neuro, orthopedic, reconstructive and general surgical applications. The Company's core business is processing human donor tissue, utilizing its patented TUTOPLAST(R) process, for distribution to hospitals and surgeons. The Company processes at its two manufacturing facilities in Germany and the United States and distributes its products and services to over 20 countries worldwide.

2. SIGNIFICANT ACCOUNTING POLICIES

Significant accounting policies of the Company are presented below.

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

FOREIGN CURRENCY TRANSLATION - The functional currency of the Company's German subsidiary is the Euro. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the period. The resulting translation adjustments, representing unrealized, noncash gains and losses are made directly to comprehensive income. Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in income as they occur and are included in Foreign Exchange Loss in the Consolidated Statements of (Loss) Income and Comprehensive (Loss) Income. The Company recognized transaction losses of $311, $173, and $700 in 2006, 2005 and in 2004, respectively.

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

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

INVENTORIES - Inventories are valued at the lower of cost or market. Work in process and finished goods includes costs attributable to direct labor and overhead. Impairment charges for slow moving, excess and obsolete inventories are recorded based on historical experience, current product demand including meeting periodically with distributors, regulatory considerations, industry trends, changes and risks and the remaining shelf life. As a result of this analysis, the Company reduces the carrying value

of any impaired inventory to its fair value, which becomes its new cost basis. If the actual product life cycles, demand or general market conditions are less favorable than those projected by management, additional inventory impairment charges may be required which would affect future operating results due to increases costs from the resulting adjustment. The adequacy of these impairment charges is evaluated quarterly.

DEBT ISSUANCE COSTS - Debt issuance costs include costs incurred to obtain financing. Upon funding of debt offerings, deferred financing costs are capitalized as debt issuance costs and are amortized to interest expense using the straight-line method, which approximates the effective interest method, over the life of the related debt. At September 30, 2006, debt issuance costs were $154 and are included in other assets in the accompanying balance sheets. The debt issuance costs amortize at $17 monthly through June 2007.

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

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

Amortization expense associated with assets financed by capital lease are included in the depreciation and amortization line of the consolidated cash flow statements.

IMPAIRMENT OF LONG-LIVED ASSETS - Periodically, the Company evaluates the recoverability of the net carrying amount of its property, plant and equipment by comparing the carrying amounts to the estimated future undiscounted cash flows generated by those assets. If the sum of the estimated future undiscounted cash flows were less than the carrying amount of the asset, a loss would be recognized for the difference between the fair value and the carrying amount.

In the event that facts and circumstances indicate that the cost of long-lived assets, primarily property, plant and equipment may be impaired, the Company performs a recoverability evaluation. If an evaluation is required, the undiscounted estimated future cash flows associated with the assets are compared to the assets' carrying amount to determine whether a write-down to fair value is required.

Impairment losses are measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. When fair values are not available, the Company estimates fair value using the expected future cash flows discounted at a rate commensurate with the risks associated with the recovery of the assets. Assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell.

DEFERRED REVENUE - The Company has entered into several distribution agreements which the distributor agreed to make certain upfront lump sum payments in exchange for certain distribution rights. These payments are recognized as revenue ratably to approximate services provided under the contract. Recognition of revenue commences over the term of the distribution agreement upon delivery of initial products. During 2006, Davol paid the Company $3,300 in fees for exclusive distribution rights and

for the commencement of the shipment of products. In addition, during 2006, Mentor agreed to pay the Company $500 associated with the exclusive distribution rights and the attainment of certain terms and conditions. At September 30, 2006, $250 has been paid to the Company.

REVENUE AND COST OF REVENUE - Revenue includes amounts from surgical product sales, tissue service processing, and distribution fees. Cost of revenue includes depreciation of $529, $686, and $311 for the years ended September 30, 2006, 2005 and 2004, respectively. 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. Revenue from surgical products is recognized upon the shipment of the processed tissues. The Company's terms of sale are FOB shipping point. Title transfers at time of shipment. Customers are provided with a limited right of return. Reasonable and reliable estimates of product returns are made in accordance with SFAS No. 48 and allowances for doubtful accounts are based on significant historical experience. 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 to approximate services provided under the contract. Recognition of revenue commenced over the term of the distribution agreement upon delivery of initial products.

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

EARNINGS PER SHARE - Basic earnings per share are computed by dividing net income (loss) by the weighted-average number of common shares outstanding. Diluted earnings per share are computed by dividing net income (loss) by the sum of the weighted-average number of common shares outstanding plus the potentially dilutive effect of shares issuable through the exercise of stock options and warrants or conversion of convertible debentures.

SHARE-BASED COMPENSATION - We estimate the value of share-based payments on the date of grant using the Black-Scholes model, which was also used previously for the purpose of providing pro forma financial information as required under SFAS 123. The determination of the fair value of, and the timing of expense relating to, share-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as assumptions regarding a number of variables including the expected term of awards, expected stock price volatility and expected forfeitures.

USE OF ESTIMATES - The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates related to the value of share-based compensation, inventory, accounts receivable, and deferred tax assets and liabilities are made by management at each reporting period. Actual results could differ from those estimates.

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

INCOME TAXES - Deferred taxes are provided for the expected future income tax consequences of events that have been recognized in the Company's financial statements. Deferred tax assets and liabilities are determined based on the temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the temporary differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to amounts, which are more likely than not to be realized.

The Company records valuation allowances to reduce the deferred tax assets to the amounts estimated to be recognized. While we consider taxable income in assessing the need for a valuation allowance, in the event we determine it is more-likely-than-not we would be able to realize our deferred tax assets in the future, an adjustment to the valuation allowance would be made and income increased in the period of such determination. Likewise, in the event we determine we would not be able to realize all or part of our deferred tax assets in the future, an adjustment to the valuation allowance would be made and charged to income in the period of such determination.

EMPLOYEE SAVINGS PLAN - The Company maintains the Tutogen Medical, Inc. 401(k) Plan (the "Plan") for which all of the United States employees are eligible. The Plan requires the attainment of the age of 21 and a minimum of six months of employment to become a participant. Participants may contribute up to the maximum dollar limit set by the Internal Revenue Service. The expenses incurred for the Plan were $95, $57 and $73 in 2006, 2005 and 2004, respectively.

RECLASSIFICATION - Certain reclassifications have been made to the prior financial statements to conform to the current presentation, including reclassing certain insurance premium costs previously expensed in cost of revenue to general and administrative expenses, and splitting out the previous balance sheet line item accounts payable and other accrued expenses into separate line items of accounts payable and accrued expenses and other current liabilities.

3. NEW ACCOUNTING PRONOUNCEMENTS

In November 2004, the FASB issued SFAS No. 151, INVENTORY COSTS, AN AMENDMENT OF ARB NO. 43. SFAS No. 151, which requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be excluded from the cost of inventory and expensed when incurred. It also requires that allocation of fixed overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement was effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151, effective at the beginning of year ended September 30, 2006, had no material impact on the Company's financial statements.

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, SHARE-BASED PAYMENT, that requires compensation costs related to share-based payment transactions to be recognized in the financial statements. The Company began complying with SFAS No. 123R at the beginning of the fiscal year ended September 30, 2006. In March 2005, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin ("SAB") No. 107, SHARE-BASED PAYMENT, which provides interpretive guidance related to the interaction between SFAS No. 123R and certain SEC

rules and regulations, as well as provides the SEC staff's views regarding the valuation of share-based payment arrangements. See Note 4, STOCK-BASED COMPENSATION, regarding the impact of these pronouncements on the Company's financial statements.

In May of 2005, the FASB issued SFAS 154, ACCOUNTING CHANGES AND ERROR CORRECTIONS. This statement replaces APB Opinion 20, ACCOUNTING CHANGES, and SFAS 3, REPORTING ACCOUNTING CHANGES IN INTERIM FINANCIAL STATEMENTS. This statement changes the requirements for the accounting for and reporting of a change in accounting principle, and applies to all voluntary changes in accounting principle. This statement also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. Previously, APB Opinion 20 required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In June of 2006, the FASB issued FASB Interpretation ("FIN") No. 48 ACCOUNTING FOR UNCERTAINTY IN INCOME TAXES. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under this interpretation, the evaluation of a tax position is a two-step process. First, the enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, based on the technical merits of the position. The second step is measuring the benefit to be recorded from tax positions that meet the more-likely-than-not recognition threshold, whereby the enterprise determines the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement, and recognizes that benefit in its financial statements.

FIN 48 also provides guidance on recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. Management has not yet determined the impact this pronouncement will have on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, FAIR VALUE MEASUREMENTS. This standard defines fair value, establishes a framework for measuring fair value in accounting principles generally accepted in the United States ("GAAP"), and expands disclosures about fair value measurements. This standard is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the requirements of SFAS 157 and has not yet determined the impact on the Company's financial statements.

In September 2006, the FASB issued SFAS 158, EMPLOYERS' ACCOUNTING FOR

DEFINED BENEFIT PENSION AND OTHER POSTRETIREMENT PLANS--An Amendment of SFAS Nos. 87, 88, 106 and 132(R). This standard requires an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur as a component of comprehensive income. The standard also requires an employer to measure the funded status of a plan as of the date of its year-end statement of financial position. The requirement to recognize the funded status of a defined benefit postretirement plan is effective as of the end of the fiscal year ending after December 15, 2006. The adoption of SFAS 158 is not expected to have a material impact on the Company's financial statements.

In September 2006, the SEC staff issued Staff Accounting Bulletin No. 108, CONSIDERING THE EFFECTS OF PRIOR YEAR MISTATEMENTS WHEN QUANTIFYING MISSTATEMENTS IN CURRENT YEAR FINANCIAL STATEMENTS. SAB 108 eliminates the diversity of practice surrounding how public companies quantify financial statement misstatements. It establishes an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the Company's financial statements and the related financial statement disclosures. SAB 108 must be applied to annual financial statements for their first fiscal year ending after November 15, 2006. Management does not believe the adoption of this standard will have a material impact on the Company's financial statements.

4. SHAREHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

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

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

STOCK OPTION PLANS - The Company maintains the 1996 Stock Option Plan (the "Plan") (4,000,000 shares authorized) under which incentive and nonqualified options have been granted to employees, directors and certain key affiliates. Under the Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant. This plan remains in effect for all options issued during its life.

The Plan was superseded by the Tutogen Medical Inc. Incentive and Non-Statutory Stock Option Plan (the "New Plan") (1,000,000 shares authorized), adopted by the Board of Directors on December 5, 2005 and ratified by the shareholders on March 13, 2006. Under the New Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

Effective October 1, 2005, the Company adopted the provisions of SFAS No. 123R which establishes the financial accounting and reporting standards for stock-based compensation plans. SFAS No. 123R requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors. Under the provisions of SFAS No. 123R, stock-based compensation cost is measured at the grant date, based on the calculated

fair value of the award, and is recognized as an expense over the requisite service period of the entire award (generally the vesting period of the award). As a result of adopting SFAS No. 123R, the Company's net loss before income taxes and net loss for the year ended September 30, 2006 was $451 more than if the Company had continued to account for stock-based compensation under Accounting Principles Board Opinion ("APB") No. 25, ACCOUNTING FOR STOCK ISSUED TO EMPLOYEES and its related interpretations.

Basic and diluted net loss per share for the year ended September 30, 2006 was $.03 more than if the Company had continued to account for stock-based compensation under APB 25. In addition, there was no statement of cash flow or tax effect related to the adoption of SFAS No. 123R due to the recording of a full valuation allowance against U.S. net deferred tax assets.

The Company elected to use the modified prospective transition method as permitted by SFAS No. 123R and, therefore, financial results for prior periods have not been restated. Under this transition method, stock-based compensation expense for the year ended September 30, 2006 includes expense for all equity awards granted prior to, but not yet vested as of October 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, ACCOUNTING FOR STOCK-BASED COMPENSATION as amended by SFAS No. 148, ACCOUNTING FOR STOCK-BASED COMPENSATION--TRANSITION AND DISCLOSURE. Since the adoption of SFAS No. 123R, there have been no changes to the Company's stock compensation plans or modifications to outstanding stock-based awards which would increase the value of any awards outstanding. Compensation expense for all stock-based compensation awards granted subsequent to October 1, 2005 was based on the grant-date fair value determined in accordance with the provisions of SFAS No. 123R. During the year ended September 30, 2006, the Company recognized compensation expense of $451 relating to stock options granted during the year ended September 30, 2006 in addition to the vesting of options outstanding as of October 1, 2005. All such expense was recognized within "General and administrative expense" in the Statement of Operations. There were no significant capitalized stock-based compensation costs at September 30, 2006.

Prior to October 1, 2005, the Company accounted for stock-based compensation in accordance with APB 25 and also followed the disclosure requirements of SFAS No. 123. Under APB 25, the Company accounted for stock-based awards to employees and directors using the intrinsic value method as allowed under SFAS No. 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in the Company's Statement of Operations because the exercise price of the Company's stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

The following table reconciles net income (loss) and basic and diluted earnings (loss) per share (EPS), as reported, to pro-forma net income (loss) and basic and diluted EPS, as if the Company had expensed the fair value of stock options.

	2005	2004

Net (loss) income	($7,017)	$1,133
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of related tax effects	102	159
Pro-forma net (loss) income	($7,119)	$ 974
Basic EPS:		
As reported	($0.44)	$ 0.07
Pro-forma	($0.45)	$ 0.06
Diluted EPS:		
As reported	($0.44)	$ 0.07
Pro-forma	($0.45)	$ 0.06

The fair value of each stock option grant is estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	September 30, 2006	September 30, 2005	September 30, 20
Expected volatility	50.2%	47%	
Risk-free interest rate (range)	4.5 - 4.7%	2.26 - 3.12%	2.26 - 3.
Expected term (in years)	5	5	

EXPECTED VOLATILITY. The Company's methodology for computing the expected volatility is based solely on the Company's historical volatility.

EXPECTED TERM. The expected term is based on employee exercise patterns during the Company's history and expectations of employee exercise behavior in the future giving consideration to the contractual terms of the stock-based awards.

RISK-FREE INTEREST RATE. The interest rate used in valuing awards is based on the yield at the time of grant of a U.S. Treasury security with an equivalent remaining term.

DIVIDEND YIELD. The Company has never paid cash dividends, and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield.

PRE-VESTING FORFEITURES. Estimates of pre-vesting option forfeitures of 10% are based on Company experience and industry trends. The Company will adjust its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a

cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

Presented below is a summary of the status of the Company's stock options as of September 30, 2006 and related transactions for the years then ended:

	Number of Common Shares	Weighted Average Exercise Price
Outstanding at September 30, 2003	2,256,368	$2.52
Granted	225,000	$3.98
Canceled	(93,750)	$4.45
Exercised	(248,850)	$1.47
Outstanding at September 30, 2004	2,138,768	$2.72
Granted	622,000	$2.99
Canceled	(262,400)	$4.03
Exercised	(17,000)	$2.17
Outstanding at September 30, 2005	2,481,368	$2.64
Granted	125,000	$3.34
Canceled	(103,225)	$3.84
Exercised	(264,275)	$2.45
Outstanding at September 30, 2006	2,238,868	$2.65
Vested or expected to vest	2,014,981	$2.65
Fully Vested at September 30, 2006	1,781,493	$2.55

As of September 30, 2006, 982,500 stock options were available for grant.

The following table provides information about stock options outstanding at September 30, 2006:

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICE	NUMBER OUTSTANDING AS OF 9/30/06	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AS OF 9/30/06	WEIGHTED-AVERAGE EXERCISE PRICE
$0.94 to $1.25	284,600	2.9	0.95	284,600	0.95
$1.56 to $2.22	536,568	1.7	1.76	529,068	1.76
$2.28 to $3.62	992,500	6.7	2.82	641,875	2.87
$3.95 to $11.00	425,200	5.4	4.41	325,950	4.60
$0.94 to $11.00	2,238,868	4.8	2.65	1,781,493	2.55

As of September 30, 2006, there was $371 of total unrecognized compensation cost related to nonvested stock options. That cost is expected to be recognized over a weighted-average period of 1.53 years. The intrinsic

value of options exercised during the years ended September 30, 2006, 2005 and 2004 were $561, $23, and $614, respectively. The total aggregate intrinsic value of options outstanding for the years ended September 30, 2006, 2005 and 2004 were $4,151, $4,765 and $608, respectively. The total aggregate intrinsic value of exercisable options outstanding for the years ended September 30, 2006, 2005 and 2004 were $3,479, $3,861 and $734, respectively. For the year ended September 30, 2006, the total fair market value of shares vested was $361. The weighted average fair value of options granted during the years ended September 30, 2006, 2005 and 2004 was $1.62, $1.38 and $1.82, respectively.

5. CONCENTRATION OF RISK

DISTRIBUTION--The majority of the Company's revenues are derived through the Company's relationships with two companies, Zimmer Dental and Zimmer Spine which distributed approximately 46% and 8%, respectively, of the Company's consolidated revenues during 2006. Zimmer Dental markets our products to the end user and the Company ships and bills the customer directly. If the Company's relationship with Zimmer is terminated or further reduced for any reason and we are unable to replace the relationship with other means of distribution, the Company would suffer a material decrease in revenues.

TISSUE SUPPLY--The Company's business is dependent on the availability of donated human cadaver tissues supplied by donor recovery groups. Allosource, our largest donor recovery group, supplied the Company with approximately 65% of our total human tissue for the year ended September 30, 2006. Our three largest recovery groups together supplied approximately 83% of our total human tissue during 2006. Any significant interruption in the availability of human tissue would likely cause the Company to slow down the processing and distribution of the Company's human tissue products, which could adversely affect the Company's ability to supply the needs of the Company's customers and materially and adversely affect the results of operations and the relationships with customers.

TRADE RECEIVABLES--As of September 30, 2006, one customer, Zimmer Spine, represented 15% of the Company's outstanding trade receivables. No other customer represented more than 10% of the Company's outstanding trade receivables.

6. INVENTORIES

Major classes of inventory at September 30, 2006 and 2005 were as follows:

	2006	2005
Raw materials	$ 2,017	$1,228
Work in process	5,811	4,943
Finished goods	4,850	3,383
	12,678	9,554

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at September 30, 2006 and 2005 consisted of the following:

	2006	2005
Land	$ 522	$ 495
Buildings and improvements	6,275	3,835
Machinery and equipment	5,174	2,329
Office furniture and other	1,284	2,787
Construction-in-progress	3,981	883
	17,236	10,329
Less accumulated depreciation	(4,296)	(3,717)
	$12,940	$ 6,612

The depreciation expense for the years ended September 30, 2006, 2005 and 2004 was $778, $984, and $760, respectively.

8. SEVERANCE COSTS

During the year ended September 30, 2006, the Company accrued compensation expense of $437 for severance costs upon the termination of the Managing Director of the Company's German subsidiary. These costs are a component of general and administrative expenses in the Consolidated Statement of (Loss) Income and Comprehensive (Loss) Income for the year ended September 30, 2006, and the accrual for these costs is included in Accrued expenses and other current liabilities in the Consolidated Balance Sheet as of September 30, 2006. These severance costs are being paid in twelve monthly equal payments during the period from July 1, 2006 through June 30, 2007. As of September 30, 2006, the remaining accrual is $334.

9. REVOLVING CREDIT ARRANGEMENTS AND SHORT TERM BORROWINGS

Under the terms of revolving credit facilities with two German banks, the Company may borrow up to 1,500 Euros (1,000 Euros and 500 Euros, respectively) or approximately $1,900 for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 8.05% to 9.5%. At September 30, 2006 the Company had outstanding borrowings of 819 Euros or $1,039. At September 30, 2005, the Company had no borrowings under the revolving credit agreements. The 500 Euro revolving credit facility is secured by accounts receivable of the German subsidiary. The 1,000 Euro revolving credit facility is secured by a mortgage on the Company's German facility and a guarantee up to 4.0 million euros by the parent Company.

In November 2005, the Company entered into a revolving credit facility in the U.S. for up to $1,500, expiring on November 18, 2007. At September 30, 2006, the interest rate on this credit facility was 8.3%. At September 30, 2006, the Company had outstanding $1,500 on this credit facility to fund working capital needs. The U.S. accounts receivable and inventory assets collateralize the borrowing under the revolving credit facility. The Company is required to maintain a maximum senior debt to tangible net worth ratio of 2.0 to 1.0. As of September 30, 2006, the Company was in compliance with this covenant. In addition, the Company maintains a lock box arrangement with the bank.

The Company prepays certain expenses including insurance premiums. From time to time, the Company enters into short term notes to finance insurance premiums. As of September 30, 2006, short term borrowings on the consolidated balance sheet included an outstanding balance of $449 related to such activity.

On June 30, 2006, the Company issued a $3,000 convertible debenture with detachable warrants to purchase up to 175,000 shares of its common stock. The debenture bears interest at 5.0% per year, is due upon the earlier of August 1, 2007 or upon a change of control of the Company and is convertible into common stock at a price of $5.15 per share at any time at the election of the holder. The warrants are exercisable at $5.15 per share at any time at the election of the shareholder until the earlier of the third anniversary of the date of issuance or upon a change in control of the Company. The convertible debt is included in short-term borrowings on the Consolidated Balance Sheet at September 30, 2006. As of September 30, 2006, the Company was in compliance with the terms and conditions of the convertible debenture.

The relative fair value of the detachable warrants at inception of the convertible debenture agreement was $275 and was computed using the Black-Scholes pricing model under the following assumptions: (1) expected life of 3 years; (2) volatility of 53.5%, (3) risk free interest of 5.13% and dividend yield of 0%. The proceeds of the convertible debenture were allocated to debt and warrants based on their relative fair values. The relative fair value of the warrants was recorded to additional paid-in capital and resulted in a discount on the convertible debenture, which will be amortized to interest expense over the one-year

term of the debenture. The remaining unamortized balance of the warrants as of September 30, 2006 is $205. The convertible debenture balance of $2,725, net of debt discount, is included in short-term borrowings. In addition, $205 of direct costs incurred relating to the issuance of the convertible debenture was recorded as debt issuance costs in other current assets, which will also be amortized to interest expense over the one-year term of the debenture.

10. LONG-TERM DEBT

Long-term debt at September 30, 2006 and 2005 consisted of the following:

	2006	2005
Senior debt	$ 3,635	$ 651
Capital lease	1,135	163
	4,770	814
Less current portion	(1,097)	(184)
	$ 3,673	$ 630

Aggregate maturities of senior debt are $480 in 2007; $515 in 2008; $533 in 2009; $545 in 2010; $482 in 2011; $1,080 beyond 2011.

The Senior debt consists of two loans with a German bank. The first loan ($576 as of September 30, 2006) has an interest rate of 5.75%, payable monthly, maturing March of 2011. The second loan ($1,744 as of September 30, 2006) has an interest rate of 5.15%, payable quarterly, maturing March of 2012.

The Senior debt, refinanced construction line of credit, and a revolving credit facility with a German bank are secured by a mortgage on the

Company's German facility and is guaranteed up to 4.0 million euros by the parent company. There are no financial covenants under this debt.

The Company has an interim construction loan of 1,037 Euros or approximately $1,316, at an annual interest rate of 5.75%, to finance its facility expansion project in Germany. The interim loan was converted to a long-term loan November 30, 2006. This loan has a 10 year term, payable semi-annually (55 Euros) at a fixed rate of 5.6%.

The Capital lease debt consists of two leases. The first lease (initial cost of $1,300, with $250 of accumulated amortization as of September 30, 2006) is payable monthly at $55 per month and matures April of 2008. The lease is secured by leasehold improvements and equipment located at the Company's Florida tissue processing facility. The second lease (initial cost of $224, with $139 of accumulated amortization as of September 30, 2006) is payable at $22 quarterly and matures September of 2007. The lease is secured by equipment located at the Company's Florida tissue processing facility. As of September 30, 2006, the Company is in compliance with the terms and conditions of the Capital lease debt. Capital lease assets and related liabilities are included within the captions "Property, plant, and equipment, net" and "Long-term debt" on the accompanying consolidated balance sheet. The table below represents the future minimum capital lease payments.

	TOTAL	2007	2008
Principal	$1,135	$617	$518
Interest	170	135	35
Total	$1,305	$752	$553

For the year ended September 30, 2006, $987 related to a non-cash capital lease agreement has been excluded from the purchase of property and equipment, and proceeds from long-term borrowings on the accompanying consolidated statement of cash flows.

For the year ended September 30, 2006, the Company incurred interest costs of $578. Of this amount, $285 was capitalized to property, plant and equipment for assets constructed during the year and $293 was charged to interest expense.

11. DERIVATIVE INSTRUMENTS

The Company accounts for its hedging activities in accordance with SFAS No. 133, "ACCOUNTING FOR DERIVATIVES AND HEDGING ACTIVITIES", as amended. SFAS No. 133 requires that all hedging activities be recognized in the balance sheet as assets or liabilities and be measured at fair value. Gains or losses from the change in fair value of hedging instruments that qualify for hedge accounting are recorded in other comprehensive income. The Company's policy is to specifically identify the assets, liabilities or future commitments being hedged and monitor the hedge to determine if it continues to be effective. The Company does not enter into or hold derivative instruments for trading or speculative purposes. The fair value of the Company's interest rate swap agreement for its 1,500 Euro ($1,900) long-term loan is based on dealer quotes and was not significant as of September 30, 2006. The construction loan payable is due on March 30, 2012 in monthly installments of approximately $78 (63 Euros) including principal and interest based on an adjustable rate as determined by one month EURIBOR, fixed by a swap agreement for the life of the loan with the lender

at 3.7% as a cash flow hedge. The proceeds were used to construct new facilities.

As indicated in Note 9, on June 30, 2006, the Company issued a $3,000 convertible debenture which contained features that qualify as embedded derivatives that require bifurcation, however, the value ascribed to these features was determined to be de-minimus to the overall financial statement presentation and accordingly, value was not allocated to these features and the carrying value of the convertible debenture was not reduced.

As of September 30, 2006, the estimated change in the fair values of these features remained a de-minimus amount.

12. SEGMENT DATA

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

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

A summary of the operations and assets by segment as of and for the years ended September 30, 2006, 2005 and 2004 are as follows:

2006	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$16,039	$25,430	$41,469
Less - intercompany	(3,522)	--	(3,522)
Total revenue - third party	$12,517	$25,430	$37,947
Depreciation and amortization	$ 471	$ 307	$ 778
Operating income (loss)	$ 168	$ (455)	$ (287)
Interest expense	$ 81	$ 212	$ 293
Income tax benefit	$ (194)	$ 0	$ (194)
Net income (loss)	$ 332	$ (921)	$ (589)
Capital expenditures	$ 3,248	$ 2,742	$ 5,990
Identifiable assets	$18,477	$20,440	$38,917

2005	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$17,344	$21,752	$39,096
Less - intercompany	(7,236)	--	(7,236)
Total revenue - third party	$10,108	$21,752	$31,860
Depreciation and amortization	$ 615	$ 369	$ 984
Operating Loss	$ (974)	$(6,253)	$(7,227)
Interest expense	$ 61	$ 69	$ 130
Income tax benefit	$ (436)	$ 0	$ (436)
Net Loss	$(1,037)	$(5,980)	$(7,017)
Capital expenditures	$ 1,468	$ 213	$ 1,682
Identifiable assets	$16,200	$10,005	$26,205

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 22,830	$ 17,126	$ 39,956
Less - intercompany	(10,626)	--	(10,626)
Total revenue - third party	$ 12,204	$ 17,126	$ 29,330
Depreciation and amortization	$ 506	$ 254	$ 760
Operating income (loss)	$ 4,179	$ (1,021)	$ 3,158

Interest expense	$ 79	$ 39	$ 118
Income tax expense	$ 1,306	$ 0	$ 1,306
Net income (loss)	$ 2,289	$ (1,156)	$ 1,133
Capital expenditures	$ 1,244	$ 515	$ 1,758
Identifiable assets	$ 18,166	$ 15,370	$ 33,536

Total International long-lived assets of $8,995, $5,912, and $5,282 for the years ended September 30, 2006, 2005 and 2004, respectively are located in Germany.

A summary of revenues by segment for the years ended September 30, 2006, 2005 and 2004 are as follows:

	FY 2006	FY 2005	FY 2004
Dental	$17,616	$13,785	$ 6,893
Spine	2,877	3,128	4,850
Surgical Specialties	4,937	4,839	5,383
Total-U.S.	$25,430	$21,752	$17,126
Germany	$ 2,851	$ 1,980	$ 3,521
Rest of World (ROW)	7,472	6,220	6,001
France	1,672	1,337	2,121
Other - Distribution Fees	522	571	561
Total-International	$12,517	$10,108	$12,204
Total Consolidated	$37,947	$31,860	$29,330

13. INCOME TAXES

The (benefit) provision for income taxes for the years ended September 30, 2006, 2005 and 2004 are summarized as follows:

	2006	2005	2004
Current:			
Federal	$ 8	$ --	$ --
State	--	--	--
Foreign	(953)	--	1,153
	(945)	--	1,153
Deferred:			
Federal	116	(2,260)	(737)
State	19	(194)	(162)
Foreign	759	(571)	153
	894	(3,025)	(746)
Valuation allowance	(143)	2,589	899
(Benefit) provision for income taxes	$(194)	$ (436)	$1,306

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

	2006	2005	2004
Income (benefit) tax at federal statutory rate (34%)	$(250)	$(2,536)	$ 854
State tax	10	(194)	(162)
Valuation allowance	(143)	2,589	899
Foreign tax differential	(3)	(303)	(293)
Foreign exchange loss	(364)	--	--
Stock options	124	--	--
Foreign dividend income	423	--	--
Other	9	8	8
Total	$(194)	$ (436)	$1,306

The tax effect of the temporary differences that give rise to the Company's net deferred taxes as of September 30, 2006, and 2005 are as follows:

	2006	2005
Deferred tax assets:		
Current:		
Other liabilities	$ 2	$ 70
Management fees	576	402
Bad debt reserve	53	44
Inventory reserve	545	594
Vacation pay	53	--
Stock options	34	--
Distribution fees	19	--
Insurance reserve	117	39
Subtotal	1,399	1,149
Noncurrent:		
Net operating loss carryforward and tax credits	6,737	7,006
Distribution fees	38	786
Other liabilities	17	70
Deferred tax asset	8,191	9,011
Deferred tax liability:		
Noncurrent:		
Fixed assets	(252)	(225)
Deferred revenue	--	(96)
Subtotal	(252)	(321)
Valuation allowance	(6,166)	(6,309)
Net deferred tax asset	$ 1,773	$ 2,381

During 2006, the Company had approximately $192 ($65 tax effected) related to current year excess tax deductions from the exercise of nonqualified stock options. Because the Company has net operating loss carryforwards,

the Company has not yet realized the tax benefit from the nonqualified stock option deduction. Pursuant to SFAS No. 123R, this excess tax benefit is not included as a component of the Company's deferred tax assets, as realization of the benefit has not yet occurred. Therefore, the $65 of excess tax benefit is not reflected in the net operating loss and credit amount in the above deferred tax asset schedule.

The Company has recorded a valuation allowance to reflect the estimated amount of deferred tax assets that may not be realized due to the expiration of net operating losses and tax credit carryovers. The net decrease in the valuation allowance is comprised primarily of the utilization of federal and state net operating loss carryforwards to offset current year taxable income.

As of September 30, 2006, the Company has approximately $13,281 of federal net operating loss carry forwards expiring beginning in 2009, a $29 AMT credit carry forward, and a $21 credit on research and development that will expire in 2013 if unused. The Company also has state net operating loss carry forwards of approximately $12,784 that will begin to expire in 2007.

As of September 30, 2006, the Company has a corporate net operating loss carry forward for German income tax purposes of approximately $4,114 (3,242 Euros), and a trade net operation loss carry forward for German income tax purposes of approximately $2,139 (1,686 Euros), which can be carried forward indefinitely. The Company continually reviews the adequacy and necessity of the valuation allowance in accordance with the provisions of SFAS No. 109, ACCOUNTING FOR INCOME TAXES. As of September 30, 2006, the Company has recorded a valuation allowance on deferred tax assets related to its U.S. operations. The Company does not maintain a valuation allowance on its international deferred tax assets, because management believes it is more likely than not that these tax benefits will be realized through the generation of future international taxable income.

Historically, the Company has not recorded deferred income taxes on the undistributed earnings of its foreign subsidiaries because it is management's intent to indefinitely reinvest such earnings. During 2006, the Company eliminated certain intercompany accounts, requiring the utilization of some undistributed earnings of its German subsidiary. The resulting tax was absorbed by the utilization of net operating loss carryforwards.

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

14. EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted (loss) earnings per share computations for the years ended September 30, 2006, 2005 and 2004. The Company has excluded 1,457,000, 419,000 and 367,000 shares of stock as such stock are anti-dilutive to the calculation:

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

2006	NET (LOSS) INCOME	SHARES	PER SHARE AMOUNT
Basic earnings per share	$ (589)	16,027,469	$ (0.04)
Effect of dilutive securities:			
Stock options, warrants and convertible debentures	--	--	--
Diluted earnings per share	$ (589)	16,027,469	$ (0.04)
2005			
Basic loss per share	$(7,017)	15,919,286	$ (0.44)
Effect of dilutive securities:			
Stock options	--	--	--
Diluted loss per share	$(7,017)	15,919,286	$ (0.44)
2004			
Basic earnings per share	$ 1,133	15,734,470	$ 0.07
Effect of dilutive securities:			
Stock options	--	734,973	--
Diluted earnings per share	$ 1,133	16,469,443	$ 0.07

15. COMMITMENTS AND CONTINGENCIES

The Company currently has operating leases for its corporate offices in the U.S. and Germany, as well as several leases related to office equipment and automobiles. Total rental expense was $959, $1,212, and $1,103 for the years ended September 30, 2006, 2005 and 2004, respectively. Future minimum rental payments required under these leases that have initial or remaining noncancelable lease terms in excess of one year as of September 30, 2006 are as follows:

2007	$ 988
2008	748
2009	343
2010	32
Thereafter	--
	$2,111

The Company is party to various claims, legal actions, complaints and administrative proceedings arising in the ordinary course of business. In management's opinion, the ultimate disposition of these matters will not have a material adverse effect on its financial condition, cash flows or results of operations. In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs

was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company by $406. At September 30, 2005 the Company maintained an accrual of $476 with respect to the remaining appeal and legal costs. At September 30, 2006, the Company agreed to a settlement of $360. As a result of the settlement the Company recorded a change in estimate of approximately $91 as a reduction of accrued expenses, which reduced the operating loss for the year ended September 30, 2006. The remaining accrual will be used to settle final nominal legal and court costs.

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 and notified all customers and distributors of record regarding this action. In connection with the recall, the Company wrote off $174 of inventory during 2005, and reserved $861 for quarantined inventory, which was written off at September 30, 2006. Additionally, as of September 30, 2005, the Company had accrued $250 of related costs in connection with the recall. As of September 30, 2006, the accrual for these costs was $0, due in part to actual payments made for such costs and in part to an adjustment made by management during the three months ended March 31, 2006 to reduce the accrual by approximately $150 as a result of a change in management's estimate of other related costs. The effect of this adjustment was to reduce cost of revenue by approximately $150.

In January 2006, the Company was named as one of several defendants in a class action suit related to the BioMedical recall. It is management's opinion that it is too early in the process to determine the effect of this class action on the financial condition of the Company. The Company intends to vigorously defend this matter.

16. RELATED PARTY

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 years ended September 30, 2006, 2005 and 2004 product sales to Zimmer spine totaled $2,877, $3,128 and $4,850, respectively. Accounts receivable from Zimmer Spine were $952 and $44 at September 30, 2006 and 2005, respectively.

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. Under this distribution agreement, the Company sells directly to Zimmer Dental's customers. For the years ended September 30, 2006, 2005 and 2004, Zimmer Dental was paid commissions aggregating approximately $7,200, $6,055 and $3,213, respectively. Accounts payable to Zimmer Dental total $1,918 and $1,740 at September 30, 2006 and 2005, respectively.

Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc., is a 32% owner of the Company's outstanding shares of common stock.

On March 10, 2006, Zimmer Holdings Inc. ("Zimmer") filed an amended Schedule 13 (d) expressing its intention to initiate discussions with the

Company which could possibly include further investment by Zimmer in securities of the Company or the acquisition by Zimmer of some or all of the outstanding common stock of the Company. During the due diligence period in 2006, the Company incurred approximately $262,000 in legal, accounting and other transaction related expenses. The transaction expenses are included as a component of general and administrative expenses.

On August 9, 2006, representatives of Zimmer Holdings, Inc. contacted management of the Company telephonically to propose to the Company a non-binding indication of interest ("the Indication of Interest") with respect to a proposed acquisition of the Company at an indicative price range of $5.00 - $6.00 per share of Common Stock. Later on the same day, the Company contacted Zimmer and rejected the Indication of Interest. Zimmer has determined not to pursue an acquisition of the Company at this time, but based on other factors deemed relevant by Zimmer, including, but not limited to, the price and availability of Common Stock, subsequent developments affecting Zimmer and the Company, the business prospects of Zimmer and the Company, general stock market and economic conditions and tax considerations, Zimmer may formulate other plans and/or make other proposals and take other actions with respect to its investment in the Company that it deems to be appropriate.

17. SUBSEQUENT EVENT

In November 2006, the Company entered into strategic tissue sourcing agreements with Regeneration Technologies, Inc., ("RTI"). Under the multi-year agreements, RTI has the first right of refusal to all of the tissue used in sports medicine surgeries recovered by Tutogen's recovery partners. The Company, in turn, has the first right of refusal to all dermis, fascia and pericardium recovered by RTI donor services agencies.

18. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following is a summary of unaudited quarterly financial results for the year ended September 30, 2006:
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	2006 QUARTER ENDED			
	DECEMBER 31,	MARCH 31,	JUNE 30,	SEPTEMBER 30,
Revenues	$8,034	$9,115	$10,000	$10,798
Gross Profit	4,705	5,098	4,780	7,028
Operating expenses	4,948	5,236	6,026	5,688
Operating (loss) income	(243)	(138)	(1,246)	1,340
Income tax (benefit) expense	(106)	(213)	(413)	538
Net (loss) income	(81)	22	(1,129)	599
Comprehensive (loss) income	(284)	421	(752)	489
(Loss) earnings per share				
Basic	$(0.01)	$ 0.00	$ (0.07)	$ 0.04
Diluted	$(0.01)	$ 0.00	$ (0.07)	$ 0.04

	2005 QUARTER ENDED			
	DECEMBER 31,	MARCH 31,	JUNE 30,	SEPTEMBER 30,
Revenues	$ 7,073	$ 7,554	$ 9,281	$ 7,952
Gross Profit	2,875	2,957	3,275	2,624
Operating expenses	4,337	4,621	4,779	5,221
Operating loss	(1,462)	(1,664)	(1,504)	(2,597)
Income tax (benefit) expense	(148)	(344)	88	(32)
Net loss	(1,914)	(1,129)	(1,278)	(2,696)
Comprehensive loss	(1,628)	(1,473)	(822)	(3,664)
Loss per share				
Basic	$ (0.12)	$ (0.07)	$ (0.08)	$ (0.17)
Diluted	$ (0.12)	$ (0.07)	$ (0.08)	$ (0.17)

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TUTOGEN MEDICAL, INC.
SCHEDULE II -- VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004

	Balance at Beginning of Period	Additions (Reversals) Charged to (Credited) to Costs and Expenses	Deductions (1)	Balance End of Period
Allowance for doubtful accounts:				
YEAR ENDED SEPTEMBER 30, 2006	$ 462	$ 19	$ (2)	$ 483
Year ended September 30, 2005	192	308	38	462
Year ended September 30, 2004	429	(83)	154	192
Allowance for product returns				
YEAR ENDED SEPTEMBER 30, 2006	$ 244	$ 0	$ 244	$ 0
Year ended September 30, 2005	241	183	180	244
Year ended September 30, 2004	117	124	0	241
Valuation allowance for net deferred tax assets:				
YEAR ENDED SEPTEMBER 30, 2006	$6,309	$ (143)	$ 0	$6,166
Year ended September 30, 2005	4,523	1,786	0	6,309
Year ended September 30, 2004	3,496	1,027	0	4,523

(1) NET WRITE-OFFS AND RECOVERIES.

S-II