TUTOGEN MEDICAL INC
Form 10-K
December 14, 2007

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, 2007

[ ] 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. o Yes x No

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

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

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. xYes oNo

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. xYes oNo

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

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As of November 30, 2007, there were 19,376,939 shares outstanding of the issuer's Common Stock, par value $.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K under Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), for the registrant's fiscal year ended September 30, 2007 (this "Report"), are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve a number of substantial risks and uncertainties. When used in this Annual Report on Form 10-K, the words "anticipate," "may," "could," "plan," "believe," "estimate," "expect" and "intend" and similar expressions are intended to identify such forward-looking statements.

Such statements are based upon management's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially from those set forth in or implied by the forward-looking statements. Actual results may differ materially from those projected or suggested in such forward-looking statements as a result of various factors, including, but not limited to, the risks discussed in Item 1 of Part 1, "Business", Item 1A of Part 1, "Risk Factors" and Item 7 of Part II, . "Management's Discussion and Analysis of Financial Condition and Results of Operations".

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 registrant'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 registrant. Neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this Report to conform these statements to actual results or to changes in our expectations, except as may be required by law.

PART I

ITEM 1. BUSINESS.

Tutogen Medical, Inc., a Florida corporation, was formed in 1985 and with its consolidated subsidiaries (collectively, the "Company," "Tutogen," "we," "us" or "our"), designs, develops, processes, manufactures and markets sterile biological implant products made from human (allograft) and animal (xenograft) tissue. Tutogen utilizes its TUTOPLAST® 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 Marseilles, 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, all tissues are terminally sterilized by low dosage gamma radiation.

Proposed Merger

On November 12, 2007, the Company, Regeneration Technologies, Inc. and Rockets FL Corp., a newly formed, wholly owned subsidiary of Regeneration Technologies, entered into an Agreement and Plan of Merger to combine Regeneration Technologies and the Company in a tax-free, stock-for-stock exchange. The merger is discussed more fully below under the caption "Proposed Merger with Regeneration Technologies."

The Company maintains an internet website at –www.tutogen.com. The Company makes available, free of charge on or through the Investor Relations section of our website our annual report on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, and all amendments to these reports, as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission ("SEC"). These reports also may be found at the SEC's website at www.sec.gov. 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.

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 34,384 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. 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; and
- 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 primarily in the United States and Europe 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 distributor to expand penetration into currently covered markets, develop additional global opportunities, and to broaden the product portfolio with procedure-specific products. In markets not covered by its 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 partners 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 domestic and 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®, for dental applications. Revenues from this relationship account for 48% of total consolidated and 69% of total U.S. revenues for the fiscal year ended September 30, 2007. 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. In August 2007, the Company entered into an agreement to extend Zimmer Dental's exclusivity internationally into Europe, the Middle East and Asia. The new international agreement includes both human and bovine bone and soft tissue grafts and allows Zimmer to provide the dentist with a complete product offering for the regenerative procedure.

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 2007 represented 10% and 11% of total consolidated and U.S. revenues, respectively.

The Company also manufactures products for surgical specialties which include urology, gynecology, ophthalmology, ENT, hernia and reconstruction products. During 2007, sales from surgical specialties totaled 15% of consolidated revenue and 21% of U.S. 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. In May 2007, Tutogen signed a new agreement with Coloplast extending the current distribution agreement and expanding its scope both internationally, and to include Tutogen's Tutoplast processed Bovine Pericardium. As a stocking distributor, Coloplast currently markets TUTOPLAST fascia lata, pericardium, and dermis tissue grafts.

IOP, Inc. ("IOP") has been a distributor since 1998, and is the exclusive distributor for TUTOPLAST processed tissue for ophthalmology applications.

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 initially entered the hernia market during the fourth quarter of fiscal year 2006 and has continued to expand release during 2007.

In June 2006, the Company signed a new 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. Mentor initiated distribution during the fourth quarter of 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 30% 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	Applications
Zimmer Dental	Dental	$169.0 million	Puros Cancellous Puros Cortical Puros Block Puros Pericardium Puros Dermis	Ridge Augmentation
Zimmer Spine	Spine	$656.0 million	Puros bone Specialty Machined Grafts (Puros C, Puros A & Puros P)	Interbody Fusion, Cervical and Lumbar
Davol	Hernia	$150.0 million	AlloMax (Human Dermis Product)	Hernia Repair Reconstruction of the chest and abdominal walls
Coloplast	Urology	$200.0 million	Suspend fascia lata Axis dermis Pericardium	Urinary Incontinence Pelvic Floor Reconstruction
Mentor	Breast Reconstruction	$25.0 - $50.0 million	NeoForm dermis	Breast Reconstruction
IOP	Ophthalmology	$9.0 million	IO Patch BioDome BioElevation BioSpacer	Glaucoma Enucleation Brow Suspension
TBD	ENT	$55.0 million	Fascia lata Fascia temporalis Pericardium	Tympnoplasty Rhinoplasty Septoplasty

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 30% 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 U.S., the Company received FDA 510(k) clearance for bovine pericardium in 2000, allowing the Company to market the first xenograft tissues (Tutopatch®) domestically, for indications of general and plastic surgery. Based on such approvals Tutogen Germany will be able to supply bovine products in the U.S. The Company plans to introduce bovine products in the U.S. for dental, hernia and other surgical specialty applications during 2008. 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 2007.

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.

Many 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. Also, Tutogen competes with well established companies in the area of xenograft tissue processing, such as Synovis, LifeCell, and Cook Surgical. 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, both allograft and xenograft. 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. provides 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® - cervical graft and PurosA® - anterior lumbar interbody fusion graft) for spinal surgery. Zimmer Spine released these products to the market during 2007. The Company added a Puros P® specialty graft and plans to introduce two new specialty grafts during 2008. The Company will also explore expanding its spine products internationally during 2008.

During October 2002, the Company entered the European market with Tutomesh®, 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® 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 initially entered the hernia market during the fourth quarter of 2006 and further expanded distribution during the second quarter of fiscal year 2007. The U.S. market for biologic grafts used for hernia repair is estimated at $150 million annually.

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 paid the Company $.5 million in consideration for these distribution rights. The initial estimated potential market in the U.S. is $25-50 million. Mentor initiated distribution during the fourth quarter of fiscal year 2007.

INTERNATIONAL OPERATIONS

The Company currently has sales in more than 20 countries located primarily in Europe. Approximately 29%, 33%, and 32% of the Company's consolidated sales, respectively, for fiscal years 2007, 2006, and 2005 were derived from outside the United States, as follows:

	United States	International	Consolidated
Revenues *(in thousands)*			
Year ended September 30,			
2007	$ 37,984	$ 15,835	$ 53,819
2006	$ 25,430	$ 12,517	$ 37,947
2005	$ 21,752	$ 10,108	$ 31,860

Approximately 30% of total international sales are bovine products and 70% 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 approximately 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.

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 48% and 10%, respectively, of the Company’s revenue for the year ended September 30, 2007. No end user customer accounted for more than 10% of the Company’s consolidated sales for the fiscal year 2007.

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, 2007, the Company employed a total of 239 full-time employees, of whom 107 full-time employees were employed in the United States and the remainder in Germany. Management believes its relations with its employees are good.

PROPOSED MERGER WITH REGENERATION TECHNOLOGIES

On November 12, 2007, the Company entered into an Agreement and Plan of Merger with Regeneration Technologies, Inc. and Rockets FL Corp., a newly formed, wholly owned subsidiary of Regeneration Technologies. Under the terms of the Agreement, Rockets FL Corp. shall be merged with and into the Company, with the Company being the surviving corporation. As a result, the Company will become a wholly owned subsidiary of Regeneration Technologies. The proposed merger is structured as a tax free stock-for-stock exchange pursuant to which the Company's shareholders will receive 1.22 shares of Regeneration Technologies' common stock for each share of the Company's common stock. Upon completion of the merger, Regeneration Technologies stockholders will own approximately 55 percent of the combined company and the Company's stockholders will own approximately 45 percent of the combined company, on a fully diluted basis.

The proposed merger is subject to approval by the respective shareholders of the Company and Regeneration Technologies, as well as customary closing conditions and regulatory approvals. If the Company terminates the proposed Agreement and Plan of Merger, under certain limited conditions, the Company could owe a termination fee of $6.5 million. The proposed merger is estimated to be completed during March, 2008.

The combined company will be headquartered in Alachua, FL. Brian K. Hutchison, currently Chairman, President and Chief Executive Officer of Regeneration Technologies, will be the Chairman and Chief Executive Officer of the combined company. Thomas F. Rose, currently Vice President, Chief Financial Officer and Secretary of Regeneration Technologies, will serve in the same capacity of the combined entity. Guy L. Mayer, currently President and Chief Executive Officer of Tutogen, will become President of the combined company, with a focus on international activities and sales and marketing. Mr. Mayer will also join the board of directors of the combined company. L. Robert Johnston, currently Vice President and Chief Financial Officer of Tutogen, will serve as Vice President of Finance for the combined company.

The board of directors of the combined company will be comprised of all seven directors from Regeneration Technologies' current board and five directors from Tutogen's board, bringing the total number of directors to 12, including Messrs. Hutchison and Mayer.

The Company's board of directors and the board of directors of Regeneration Technologies have both approved the merger.

The foregoing description of the merger does not purport to be complete and is qualified in its entirety by reference to the Company's Current Report on Form 8-K, filed November 19, 2007, and the merger agreement filed as an exhibit to that Form 8-K and incorporated into this report by reference.

Satisfaction of the closing conditions could take several months or longer. There can be no assurance that the conditions necessary to complete the merger will be met, or that the proposed merger will be completed at all.

Statements made in this Form 10-K relating to the Company's business strategies, operating plans, planned expenditures, expected capital requirements and other forward-looking statements regarding the Company's business do not take into account potential future impacts of the Company's proposed merger with Regeneration Technologies

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 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.

The pending merger with Regeneration Technologies may create uncertainty for our suppliers, employees and business partners.

On November 13, 2007, we announced that we had entered into a merger agreement with Regeneration Technologies, Inc. The merger is currently expected to close in March, 2008. While the merger is pending, donor recovery groups may delay or defer decisions to become Tutogen suppliers and existing suppliers may experience uncertainty about our service, including the results of any integration of our business with that of Regeneration Technologies. This may adversely affect our ability to gain new suppliers and retain existing suppliers, which could adversely affect our revenues as well as the market price of our common stock. Current employees may experience uncertainty about their post-merger roles with Tutogen and key employees may depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with Tutogen following the merger. Other parties with whom we have or are pursuing relationships, such as distributors, hospitals and surgeons, may defer agreeing to further arrangements with us, or may opt not to become a business partner of ours at all.

The merger with Regeneration Technologies is subject to various approvals and may not occur.

We and Regeneration Technologies must obtain shareholder approval and governmental approvals, including approvals related to antitrust matters. If we do not receive these approvals, or do not receive them in a timely manner or on satisfactory terms, then we may not be able to complete the merger. Governmental agencies may impose limitations on the business of the combined company or require divestiture of assets as a condition to approval of the merger, which may result in one of the parties to the merger being entitled to and electing not to proceed with the merger or reduce the anticipated benefits of the merger. We cannot assure you that the merger will be completed in the anticipated time frame or at all. A failure to complete the merger may result in a decline in the market price of our common stock.

We will incur significant transaction and merger-related costs in connection with the merger.

We have already incurred and will continue to incur transaction fees and other costs related to the merger, and expect to incur significant costs associated with completing the merger and combining the operations of the two companies, which cannot be estimated accurately at this time. Further, diversion of attention from ongoing operations on the part of management and employees could adversely affect our business. Although, after the merger closes, we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, may offset incremental transaction and transaction-related costs over time, this net benefit may not be achieved in the near term, or at all. In addition, speculation regarding the likelihood of closing the merger could increase the volatility of our stock price, and pendency of the merger could make it difficult to effect other significant transactions, to the extent opportunities arise to engage in such transactions. We will incur these costs, as well as face the disruptions to our business and the potential harm to our relationships with suppliers, employees and business partners discussed above, even if the merger is not completed.

The merger may not provide all of the anticipated benefits.

If we are able to complete the merger, we expect to achieve various benefits from combining our and Regeneration Technologies' resources, as well as significant cost savings from a combined operation. Achieving the anticipated benefits of the merger will depend in part upon whether our two companies integrate our businesses in an efficient and effective manner. To date, we have operated independently from Regeneration Technologies and legal restrictions have in the past and will in the future limit planning for integration of the two companies. Accordingly, we may not be able to accomplish this integration process smoothly or successfully or in a timely manner. Any inability of management to integrate successfully the operations of our two companies, or to do so in a timely manner, could have an adverse effect on the combined company or the expected benefits from the merger.

We depend heavily upon a limited number of sources ofhuman tissue, and any failure to obtain tissue from these sources ina 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.

In October, 2007, we entered into a new five year Tissue Procurement, Processing and Supply Agreement with Allosource, Inc. pursuant to which Allosource will provide us with various human tissues used in our dental and spinal product lines. We also entered into multiple other tissue sourcing agreements during 2007.

In November 2006, we 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. We, in turn, have the first right of refusal to all dermis, fascia and pericardium recovered by RTI donor services agencies.

Our four largest recovery groups together supplied approximately 91% of our total human tissue during 2007. 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, 2007, we derived approximately 48% and 10% 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 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, 2007, there were no comment letters outstanding from the SEC.

ITEM 2. PROPERTIES.

UNITED STATES. The Company's headquarters and U.S. manufacturing facilities are located in Alachua, Florida and total approximately 34,384 square feet of leased space as of September 30, 2007. The Florida lease expires January 31, 2009 with a renewal option through January 31, 2011. 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.

ITEM 3. LEGAL PROCEEDINGS.

At September 30, 2005, the Company had an accrual recorded of $476,000 (approximately 395,000 Euros) related to a dispute with a former international distributor. During 2006, the dispute was settled for $360,000 (approximately 280,000 Euros) and the Company recorded a change in estimate and reduced the accrual by approximately $91,000 (approximately 71,400 Euros), which also reduced general and administrative expense. The settlement amount and outstanding legal costs were paid in 2007.

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 $174,000 of inventory during 2005 and $861,000 for quarantined inventory at September 30, 2006. 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 during fiscal year 2006.

In January 2006, the Company was named as one of several defendants in a class action suit related to the BioMedical recall. The Company intends to vigorously defend this matter and does not believe that the outcome of this class action will have an adverse material effect on the Company’s operations, cash flows, financial position, or financial statement disclosures.

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 2006	**High**	**Low**
First Quarter	$ 4.40	$ 2.62
Second Quarter	5.00	2.92
Third Quarter	5.20	4.55
Fourth Quarter	6.24	4.21
Fiscal 2007		
First Quarter	$ 7.27	$ 4.32
Second Quarter	8.80	6.32
Third Quarter	11.15	8.29
Fourth Quarter	11.80	8.20

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, 2007, the approximate number of holders of record of the Company's common stock was 632.

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.

UNREGISTERED SALES OF SECURITIES

Not applicable.

ISSUER PURCHASES OF EQUITY SECURITIES

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA.

The following table sets forth consolidated financial data with respect to the Company for each of the five years in the period ended September 30, 2007. The selected financial data for each of the five years in the period ended September 30, 2007 have been derived from the consolidated financial statements of the Company, which financial statements have been audited by Deloitte & Touche, LLP, an independent registered public accounting firm. The Company's consolidated financial statements and the report thereon are included elsewhere in this Report. The information below should be read in conjunction with the consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in Item 7.

	(In thousands, except per share data) **Years Ended September 30,**				
	2007	**2006**	**2005**	**2004**	**2003**
Revenue	$ 53,819	$ 37,947	$ 31,860	$ 29,330	$ 30,260
Gross margin %	57%	57%	37%	60%	67%
Operating income (loss)	3,535	(287)	(7,227)	3,158	5,265
Net income (loss)	6,758	(589)	(7,017)	1,133	3,707
Average shares outstanding for basic earnings (loss) per share	17,682,750	16,027,469	15,919,286	15,734,470	15,495,148
Basic earnings (loss) per share	$ 0.38	$ (0.04)	$ (0.44)	$ 0.07	$ 0.24
Average shares outstanding for diluted earnings (loss) per share	19,080,164	16,027,469	15,919,286	16,469,443	16,095,448
Diluted earnings (loss) per share	$ 0.36	$ (0.04)	$ (0.44)	$ 0.07	$ 0.23
Balance Sheet Data:					
Working capital	$ 29,086	$ 8,215	$ 8,433	$ 17,471	$ 15,342
Total assets	59,250	38,917	26,205	33,536	29,962
Long-term debt	4,559	4,770	814	827	728
Stockholders' equity	40,359	15,221	13,722	21,272	17,606

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R "*Share Based Payment*" ("SFAS 123(R)") 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.

PROPOSED MERGER

On November 12, 2007, the Company entered into an Agreement and Plan of Merger with Regeneration Technologies, Inc. and Rockets FL Corp., a newly formed, wholly owned subsidiary of Regeneration Technologies. Under the terms of the Agreement, Rockets FL Corp. shall be merged with and into the Company, with the Company being the surviving corporation

Statements in the following discussion and analysis relating to the Company's business strategies, operating plans, planned expenditures, expected capital requirements and other forward-looking statements regarding the Company's business do not take into account potential future impacts of the Company's proposed merger with Regeneration

Technologies.

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 repair and Coloplast for urology. 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 SFAS No. 123(R) in the first quarter of fiscal year 2006. SFAS 123(R) 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 123(R), 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, vesting periods 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 123(R), 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 123(R) 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, with cost determined using the first-in-first-out method. 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 determined in part through periodic meetings 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. The adequacy of these inventory impairment charges is evaluated quarterly.

Revenue Recognition and Accounts Receivable. Revenue on product sales and tissue processing 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 SFAS No. 48 "*Revenue Recognition When Right of Return Exists"* ("SFAS 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 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 Assets. We record valuation allowances to reduce the net deferred tax assets to the amounts estimated to be realizable. 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. During 2007, the Company recorded a tax benefit of $6.2 million due to the reversal of a previously recorded valuation allowance related to our U.S. operations since we have determined that it is more likely than not that our existing deferred tax assets will be utilized.

Valuation of Long-Lived Assets. Long-lived assets on our balance sheet are stated at the lower of cost, net of depreciation and amortization, or fair value. The factors in this valuation which require significant estimates and judgments are: (1) determination of the estimated useful life of each asset, which determines expense per period, number of periods of expense, and the carrying value of each asset at any time; and (2) determination of the fair value of assets, which may result in other than temporary impairment charges when fair value is lower than the carrying value of assets, which we would recognize as a charge to earnings during the period in which we made the determination. If we overestimate the useful life of an asset, or overestimate the fair value of an asset, and at some time in the future we dispose of that asset for a lower amount than its carrying value, our historically reported total assets and net income would have been higher than they would have been during periods prior to our recognition of the loss on disposal of assets, and lower during the period when we recognize the loss.

FOR THE YEARS ENDED SEPTEMBER 30, 2007 AND 2006 - RESULTS OF OPERATIONS

REVENUE AND GROSS MARGIN

Consolidated revenue for the year ended September 30, 2007 increased to $53.8 million from $37.9 million in 2006, or a 42% increase. The U.S. revenues were $38.0 million or 49% higher than the 2006 revenues of $25.4 million. The increase in U.S. revenues was fueled by the continuing increase in the demand for the Company's TUTOPLAST® 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 from $17.6 million a year ago to $24.3 million in 2007, or a 38% increase. Spine revenues increased 92%, from $2.9 million to $5.5 million, as the Company introduced two new machined grafts, Puros C and Puros A during the fourth quarter of fiscal year 2006 and an additional machined graft, Puros P, during 2007. Surgical specialties (primarily hernia repair, breast reconstruction, urology, ophthalmology and ENT) increased to $8.1 million in 2007 compared to $4.9 million in 2006, or a 65% increase, due to increased product sales in the new markets of hernia repair and breast reconstruction.

The International operation had revenues of $15.8 million for the year ended September 30, 2007, an increase of 27% from the 2006 revenues of $12.5 million. The increase is primarily due to increased sales in certain key countries as well as $1.0 million in product sales to Zimmer Dental International related to the sale of an initial stocking order in August 2007.

An analysis of revenue follows (In Thousands):

	2007	2006	2005	4th Qtr FY 2007	4th Qtr FY 2006	4th Qtr FY 2005
Dental	$ 24,329	$ 17,616	$ 13,785	$ 6,232	$ 4,666	$ 4,115
Spine	5,516	2,877	3,128	1,794	1,461	336
Surgical Specialties	8,139	4,937	4,839	2,394	1,417	1,129
Total U.S.	37,984	25,430	21,752	10,420	7,544	5,580
Gemany	4,667	2,851	1,980	1,937	497	487
Rest of World	9,179	7,472	6,220	2,334	2,085	1,324
France	1,425	1,672	1,337	340	525	391
Other - Distribution Fees	564	522	571	146	135	170
Total International	15,835	12,517	10,108	4,757	3,242	2,372
Total Consolidated	$ 53,819	$ 37,947	$ 31,860	$ 15,177	$ 10,786	$ 7,952

Gross margins for the year ended September 30, 2007 remained the same at 57% compared to 2006.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased in 2007 to $9.3 million from $7.8 million in 2006. The increase was due to unusual charges during the fourth quarter of 2007 of $717,000 (associated with initial year audit and consulting costs related to complying with the Sarbanes-Oxley Act of 2002 of $427,000 and the relocation of Company executives of $290,000), as well as increased stock option expense related to increased option activity in 2007 of

$310,000. We also had increased personnel salary, benefit and other compensation expense of $696,000 which was directly related to the growth of the Company during 2007. General and Administrative expenses, as a percentage of revenues, decreased from 20% in 2006 to 17% in 2007.

DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased in 2007 to $15.8 million from $12.3 million in 2006. The increase was due mainly to higher marketing fees paid to Zimmer Dental of $9.8 million in 2007 versus $7.2 million a year ago as U.S. dental revenues increased to $24.3 million in 2007 up from $17.6 million in 2006. In addition sales and marketing expenses increased internationally due to increased expenses related to personnel, travel and other expenses due to the continued growth internationally. As a percentage of revenues, Distribution and Marketing expenses decreased from 32% in 2006 to 29% in 2007.

RESEARCH AND DEVELOPMENT

Research and development expenses totaled $2.2 million in 2007 compared to $1.8 million in 2006. As a percentage of revenues, Research and development expenses were 4% and 5% in 2007 and 2006, respectively.

INTEREST AND OTHER INCOME

Other income for 2007 increased to $367,000 compared to $108,000 in 2006. This was primarily the result of higher interest income from the $11.5 million in net proceeds received by the Company upon the completion of a private placement financing in April 2007.

INTEREST AND OTHER EXPENSE

Interest expense in 2007 increased to $1,198,000 from $293,000 in 2006 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

In 2007, an income tax benefit of $4.2 million was recorded that consisted primarily of a valuation allowance reversal in the U.S. of $6.2 million, offset by income tax expense of $334,000 resulting from a reduction of the Company's German tax rate, with the remaining $1.7 million primarily relating to the utilization of net operating losses associated with taxable income. The valuation allowance in the U.S. was reversed since we have determined that it is more likely than not that our existing deferred tax assets will be realized.

NET (LOSS) INCOME

The net income for the year ended September 30, 2007 totaled $6.8 million, $0.38 basic and $0.36 diluted income per share as compared to a net loss of $0.6 million or $0.04 basic and diluted loss per share for 2006. The increase in net income between the years is directly attributable to higher revenues, maintaining gross margins and the overall tax benefit of $4.2 million.

ACCOUNTS RECEIVABLE

The accounts receivable balance nominally increased in 2007 to $6.5 million, up from $6.2 million in 2006.

INVENTORY

The inventory balance increased to $17.4 million at September 30, 2007 from $12.7 million at September 30, 2006. The increase was primarily due to the continued growth of the Company and increased inventories associated with the introduction of new spine, hernia and breast reconstruction 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 recorded and presented as a component of 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 $118,000, $311,000 and $173,000 in 2007, 2006 and 2005, 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, 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® 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.

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. 123(R). In addition, the Company incurred increased legal expenses of approximately $250,000 and accounting and audit fees of approximately $200,000 for various projects in 2006. 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 in 2005 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. There was no effect related to the U.S. operations since the Company had recorded a full valuation allowance.

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.

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 48% and 10%, respectively, of the Company's consolidated revenues during 2007. Internationally, Zimmer Dental is a stocking distributor for the Company. 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 and it would materially and adversely affect the results of operations.

Tissue Supply — The Company's business is dependent on the availability of donated human cadaver tissues supplied by donor recovery groups. Our four largest recovery groups together supplied approximately 91% of our total human tissue during 2007. 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, 2007, there were no customers that represented more than 10% of the Company's outstanding trade receivables.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2007 and 2006, the Company had working capital of $29.1 million and $8.2 million, respectively. The increase was primarily due from net proceeds of $11.5 million from a private placement financing completed in April 2007, increased revenues and profits for 2007 and the reduction of short term borrowings and long-term debt in 2007 of $5.6 million.

Cash, cash equivalents and short-term marketable securities increased to $12.8 million in 2007 from $3.5 million in 2006 as a direct result of the private placement financing in April and increased revenues and profits during 2007.

Net cash used in investing activities, representing purchases of capital expenditures, was $2.3 million in 2007 and $6.0 million in 2006. The continued spending on capital expenditures is due to the facility expansion in the Florida and German manufacturing locations and manufacturing equipment to support the continued growth of the Company.

Net cash from financing activities in 2007 totaled $9.8 million as a result of net proceeds of $11.5 million, and $1.8 million from the exercise of stock options offset by the repayment of short-term and long-term debt. Net cash from financing activities for 2006 totaled $7.9 million as a result of 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 $2.1 million for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 7.25% to 10.25%. At September 30, 2007, the Company had no borrowings under the revolving credit agreements. At September 30, 2006, the Company had outstanding borrowings of 819,000 Euros or $1 million. 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, 2008. At September 30, 2007, the Company had no outstanding borrowings on this credit facility. 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, 2007, the Company was in compliance with this covenant.

On June 30, 2006, the Company issued a $3.0 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 12 months 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. In April and May of 2007, the $3.0 million debenture holders fully converted into common stock. In November, 2007, the 175,000 warrants had been fully exercised into common stock.

Senior debt consists of four loans with a German bank. The first loan ($516,000 as of September 30, 2007) has an interest rate of 5.75%, payable monthly, maturing March of 2011. The second loan ($1,606,000 as of September 30, 2007) has an interest rate of 5.15%, payable quarterly, maturing March of 2012. The third loan ($1,491,000 as of September 30, 2007) payable semi-annually (55,000 Euros) is at a fixed rate of 5.6% maturing December 2016. The fourth loan ($321,000 as of September 30, 2007) is payable quarterly at a fixed rate of 5.75% maturing September 2012.

The senior debt and a revolving credit facility with a German bank are secured by a mortgage on the Company's German facility and is guaranteed by the parent company. There are no financial covenants under this debt.

The capital lease debt consists of two leases. The first lease (initially $1.3 million, with $470,000 of accumulated amortization as of September 30, 2007) 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 $240,000, with $157,000 of accumulated amortization as of September 30, 2007) is payable at $21,000 quarterly and matures March 31, 2008. The lease is secured by equipment located at the Company’s Florida tissue processing facility. As of September 30, 2007, 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 2013 total $2,295,000. 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, 2007:

(In Thousands)	**Total**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**
Long-term debt obligations (1)	$ 4,047	$ 769	$ 772	$ 756	$ 684	$ 360	$ 706
Operating lease obligations	2,295	1,336	691	162	83	21	2
Capital lease obligations (1)	512	512	-	-	-	-	-
Short-term borrowings (1)	356	356	-	-	-	-	-
Total	$ 7,210	$ 2,973	$ 1,463	$ 918	$ 767	$ 381	$ 708

The Company maintains current working capital credit lines totaling 1.5 million Euros (approximately $2.1 million at September 30, 2007) with two German banks and a $1.5 million credit line with a U.S. bank. At September 30, 2007, the Company had no outstanding balances on the working capital lines in Germany and the U.S. Management believes that the working capital as of September 30, 2007 is adequate to fund ongoing operations for at least the next 12-months. 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. While the Company believes that it continues to make progress in these areas, there can be no assurances.

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, 2007, total debt outstanding to the German bank was 2.8 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 $1.6 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, 2007 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, 2007 outstanding intercompany balances, a 1% change in currency rates would have a de-minimus impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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.

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management carried out an evaluation required by paragraph (b) of Rule 13a-15 and 15d-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), under the supervision and with the participation of our Chairman, President and Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure

controls and procedures as defined in Rule 13a-15(e) and 15d-15(f) under the Exchange Act ("Disclosure Controls"). Based on the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2007, our Disclosure Controls are effective in timely alerting them to material information required to be included in our reports filed with the SEC.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934. Under the supervision and with the participation of the Company's management, including its principal executive officer and principal financial officer, the Company conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of September 30, 2007 as required by the Securities Exchange Act of 1934 Rule 13a-15(c). In making this assessment, the Company used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. Based on its evaluation, management concluded that its internal control over financial reporting was effective as of September 30, 2007.

The Company's internal control over financial reporting as of September 30, 2007 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein..

Changes in Internal Controls

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

Please see page F-1 of our financial statements included herein.

ITEM 9B. OTHER INFORMATION.

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE .

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 (who is determined to be a key employee), 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.

Name	Age	Positions/Offices	Period Served in Office/Position
G. Russell Cleveland	69	Director	1997 – present
Roy D. Crowninshield, Ph.D.	59	Chairman of the Board Director Interim Chief Executive Officer	July 2004 – present 2003 – present July 2004 - December 2004
Neal B. Freeman	67	Director	June 2005 – present
J. Harold Helderman, MD	62	Director	1997 – present
Udo Henseler, PH.D.	68	Director	June 2005 – present
L. Robert Johnston, Jr.	47	Chief Financial Officer & Secretary	February 2006 – Present
Guy L. Mayer	56	President & Chief Executive Officer Director	January 2005 – present January 2005 – present
Claude O. Pering	61	Vice President and Chief Operating Officer	January 2005 – present
Clifton J. Seliga	55	Vice President of Global Sales & Marketing	January 2005 – present

Adrian J. R. Smith	63	Director	June 2005 – present
Carlton E. Turner, Ph.D.	67	Director	2000 - present
Karl H. Koschatzky	60	President of International Operations	June 2006 – Present

The following is a summary of the business experience of each of the persons listed in the above-referenced table.

G. RUSSELL CLEVELAND has been the President, Chief Executive Officer, sole Director, and majority shareholder of Renaissance Capital Group, Inc. 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 has been the Chairman of the Board 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 and 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 has been a Professor of Medicine, Microbiology and Immunology since 1999 and the Medical Director of the Vanderbilt Transplant Center since 1989. From, 1999 to 2007, he served as the Dean of Admissions at Vanderbilt University, Nashville, Tennessee. . Dr. Helderman received his medical degree 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., has been the President and proprietor of Management Services International , a private business, since 1994. MSI provides business development services for biotechnology and life sciences firms at various stages of their corporate evolution. From 2002 to 2005, Dr. Henseler was the Chief Executive Officer and Chairman of eGene, Inc., a public biotechnology company, and further served as a Director in 2006. Dr. Henseler has over forty (40) years combined global public and private company leadership experience in the biopharmaceutical and life science sectors, including positions as Director, Board Chair, Audit Committee Chair, Chief Executive Officer, Chief Financial Officer, and Executive Vice President. He also taught at the now Peter F. Drucker and Masatoshi Ito Graduate School of Management, CGU. Dr. Henseler earned his B.A. in Germany, an MBA from Fairleigh Dickinson University in New Jersey, and Master's and Ph.D. degrees from the Claremont Graduate University in Claremont, California. Dr. Henseler is also a Certified Public and Certified Management Accountant and currently serves as Director and Chair of the Audit Committee of Spire Corporation, a public company.

L. ROBERT JOHNSTON, JR. has been the Company’s Chief Financial Officer and Secretary since 2006. Prior to joining Tutogen, Mr. Johnston served as Chief Financial Officer of Power Medical Interventions , a privately held medical device company providing surgical stapling products, from 2004 to 2005. Prior to joining Power Medical, from 2002 to 2004, Mr. Johnston served as an independent consultant for Pittsburgh Life Sciences Greenhouse

Executive Corps Program. For the four 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 Chief Financial Officer, American Mobile Satellite Corporation (now Motient Corp) as Assistant Treasurer, and Sovran Bank of Maryland as Assistant Vice President. Mr. Johnston 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 has been the Company's President and Chief Executive Officer since 2005. Prior to joining Tutogen, Mr. Mayer served as Chairman and Chief Executive Officer of Visen Medical, a private Biotech company focused on Molecular Imaging technologies, from 2003 to 2004. Prior to joining Visen, Mr. Mayer served as President and Chief Executive Officer of ETEX Corporation, a private biomedical company based in Cambridge, Massachusetts from 2000 to 2003. 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. Mr. Mayer is a 1974 Graduate of the University of Ottawa and currently serves on the Board of Directors of Spire Corporation , a public company, and on the Board of Directors of several private companies.

CLAUDE O. PERING has been the Company's Vice President and Chief Operating Officer of U.S. Operations since 2005. Prior to joining Tutogen, Mr. Pering served as Principal of CoperTech, LLC from 2002 to 2005 providing consulting services to client companies in the medical device, biotechnology and pharmaceutical industries. For the three years prior from 1999 to 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 three 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 six years as Vice President Operation/Chief Operating Officer for Ace Medical Company (acquired by DePuy, Inc.) and three years as Corporate Director of Quality Assurance/Group Manager of Quality Engineering for Zimmer, Inc. Mr. Pering 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 has been the Company's Vice President of Global Sales and Marketing since 2005. Prior to joining Tutogen, Mr. Seliga served as Principal of C. J. Seliga, LLC from 2002 to 2005, providing consulting services to senior management in the areas of business planning, strategic development, marketing, new product planning, sales and distribution. For the three years prior from 1998 to 2001, Mr. Seliga was Senior Vice President, General Manager for ETEX Corporation, a private biomedical company based in Cambridge, Massachusetts. For the six 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. Mr. Seliga 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 has been the Chief Executive Officer of The Woolton Group since 1997. He is also the Non-Executive Chairman of Gaming VC S.A., and a Non-Executive Director of Byotrol plc. His business career includes 13 years in the professional services industry and 24 years with two Fortune 500 companies. He has been a Global Managing Partner, Marketing & Communication at Deloitte Touche Tohmatsu, the Chief Executive Officer 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 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 President of International Operations for 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 U.S. 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, Dr. Koschatzky served as Manager of Operations, Wound Care Unit, Pfrimmer-Viggo GmbH from1984 to1993 and Scientific Manager, Wound Care Business, Lyofil Pfrimmer GmbH from 1982 to 1984. Dr. Koschatzky received his Ph.D. from the University of Erlangen-Nurnberg in 1979 and Diplom-Chemist from 1969 to 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. Cleveland, Crowninshield, Freeman, Helderman, Henseler, Mayer, Pering, Seliga and Smith filed a late Form 4 Report, each relating to one transaction involving the granting or exercise of an option. Dr. Turner filed two late Form 4 Reports, one relating to the grant of an option and the other relating to the exercise of options and sale of the shares received upon exercise.

CODE OF ETHICS

We have adopted a code of business conduct and ethics that applies to all of our employees, including our principal executive officer, principal financial officer and directors. The text of the code of business conduct and ethics is posted on our website at www.tutogen.com. Disclosure regarding any amendments to, or waivers from, provisions of the code of business conduct and ethics that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting of such amendments or waivers is then permitted by the rules of the American Stock Exchange, Inc.

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. Each member of the Committee is a non-management director. 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 and 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. All of the members of the Audit Committee are independent, as such term is defined by Section 121.A of the American Stock Exchange listing standards.

Nominating Committee. The Nominating Committee is composed of Messrs. Smith and Freeman, Dr. Helderman and Dr. Henseler and is chaired by Dr. Helderman. Each member of the Committee is a non-management director. 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 DISCUSSION AND ANALYSIS

Compensation Philosophy

The Company’s overall compensation philosophy for our executive officers is to provide compensation programs that are simple and flexible so that our arrangements are understandable by our employees and shareholders and so as to permit us to make responsive adjustments to changing market conditions.

Goals

The goals of the Company’s compensation program are to:

- Successfully attract and retain the key employees necessary to achieve the long-term success of the Company;
- Provide incentive compensation that varies in concert with both Company performance against established goals based upon the Company’s operating plan and the value of the individual contribution to that performance;
- Motivate and reward executives whose knowledge, skills and performance are critical to our success; and
- Set compensation and incentive levels that reflect competitive market practices.

Elements of Compensation

Our Compensation Committee has established a compensation program with four (4) basic elements to support and balance the goals:

- *Base Salary*– The base salary is intended to provide a foundation to motivate continued services to the Company and should appropriately reflect the duties and responsibilities related to the position. Establishing the base salary level is critical in allowing the Company to successfully attract and retain the employees necessary for its long-term success.

- *Cash Incentive Bonuses*– Our executives are eligible to receive annual cash incentive bonuses primarily based upon their performance during the year as measured against predetermined Company and personal performance goals established by us, including financial measures and the achievement of strategic objectives. The primary objective of our annual cash incentive bonuses is to motivate and reward our employees, including our named executive officers, for meeting our short-term objectives using a pay-for-performance program with objectively determinable performance goals.

- *Equity Incentive Awards*– The long-term component of the Company's incentive compensation program consists of the grant of traditional stock options. Grants are made pursuant to the terms of the Company's stock option plans. These equity incentives are designed to create a mutuality of interest with shareholders by motivating the executive officers to make effective decisions and manage the Company's business so that the shareholders' investment will grow in value over time. The equity incentives also reward longevity and increase retention, as the Company does not maintain a defined benefit pension plan or provide other post-retirement medical or life insurance benefits. The equity incentives awarded are intended to provide incentives for executive officers to enhance long-term Company performance, as reflected in stock price appreciation over the long term, thereby increasing shareholder value.

- *Severance and Change-in-Control Benefits*– Each of the Company's executive officers have certain severance benefits in the event of involuntary termination, resulting from a change-in-control as defined. These severance provisions are described in the "Employment Agreements" section included in this Report.

Determination Process

Compensation Committee meetings typically have included preliminary discussions with our Chief Executive Officer prior to our Compensation Committee deliberating without any members of management present. Our Compensation Committee has also involved outside counsel in its deliberations as needed. For compensation decisions, including decisions regarding the grant of stock options relating to executive officers (other than our Chief Executive Officer), the Compensation Committee considers the recommendations of our Chief Executive Officer and includes him in its discussions.

Compensation Program for Fiscal Year 2007

Base Salaries

Base salaries are determined by evaluating an executive officer's level of responsibility and experience and the Company's performance. Increases to base salaries, if any, are driven primarily by individual performance and comparative data from our peer group. Individual performance is evaluated by reviewing the executive officer's success in achieving business results, promoting our core values and demonstrating leadership abilities.

In setting the base salary of the executive officers for fiscal year 2007, the Compensation Committee reviewed the compensation of comparable executive officers from our peer group. The Compensation Committee also considered the Company's achievement of its short- and long-term goals.

The salaries paid to the executive officers during fiscal year 2007 are shown in the Summary Compensation Table on page 28.

Cash Bonus Awards

Under the Bonus Plan, an executive's potential bonus is established at a specific targeted dollar amount and consists of non-discretionary awards that are tied to the financial performance of the Company. Each year, in formulating the bonus targets, the Compensation Committee members consider the anticipated financial achievement of the Company. The Committee evaluates the executive officer's responsibilities and role in the Company and such other factors as they deem relevant to motivate such executives to achieve certain performance levels. In addition to the financial performance measures that the Compensation Committee uses to determine bonuses under the Bonus Plan, there is also a subjective management criteria based on individual objectives.

Annual Bonus Plan for 2007 for Executive Officers

and Dr. Karl Koschatzky

	Mr. Mayer	Mr. Johnston	Mr. Pering	Mr. Seliga	Mr. Koschatzky
Target Incentive Compensation (% of Base Salary)	60%	30%	30%	30%	30%

In 2006, bonuses were approved as follows: Mr. Mayer ($226,113), Mr. Johnston ($65,162), Mr. Pering ($63,533), Mr. Seliga ($60,275) and Dr. Koschatzky ($52,927). These bonuses were paid in November 2007 by the Compensation Committee based on the standards set out above.

Stock Options

An important objective of the long-term incentive program is to strengthen the relationship between the long-term value of our stock price and the potential financial gain for employees. Stock options provide executive officers with the opportunity to purchase our common stock at a price fixed on the grant date regardless of future market price. Stock options generally vest and become exercisable over a four-year period.

A stock option becomes valuable only if our common stock price increases above the option exercise price and the holder of the option remains employed during the period required for the option to "vest" thus, providing an incentive for an option holder to remain employed by the Company. In addition, stock options link a portion of an employee's compensation to stockholders' interests by providing an incentive to make decisions designed to increase the market price of our stock.

The exercise prices of the stock options granted to the executive officers during fiscal year 2007 are shown in the Grants of Plan-Based Awards Table on page 29. Additional information on these grants, including the number of shares subject to each grant, also is shown in the Grants of Plan-Based Awards Table.

Executives who join us are awarded initial stock options. The amount of the initial stock option award is determined based on the executive's position with us and an analysis of the competitive practices of the companies similar in size to us represented in the compensation data that we review with the goal of creating a total compensation package for new employees that is competitive with other similar companies and that will enable us to attract high quality people.

Our practice is to make annual stock option awards a part of our overall compensation program. Options generally are granted annually to executive officers in November, at the same time as grants to the general eligible employees, after final determination of our previous year operating results. Option grants are made at a Compensation Committee meeting scheduled in advance to meet appropriate deadlines for compensation related decisions. Our practice is that the exercise price for each stock option is the market value on the date of grant.

There is a limited term in which the executive officers can exercise stock options. The option term is generally ten years from the date of grant. At the end of the option term, the right to purchase any unexercised options expires. Option holders generally forfeit any unvested options if their employment with us terminates.

Other Compensation

We maintain broad-based benefits that are provided to all employees, including health, life and disability insurance and a 401(k) plan.

Severance/Change of Control

Our named executive officers each have a severance arrangement in the event an involuntary termination due to a change-in-control. If such were to occur, Mr. Mayer will be entitled to 24 months salary and Messrs. Johnston, Pering and Seliga will be entitled to 12 months salary.

COMPENSATION OF EXECUTIVE OFFICERS

The following table shows the total compensation paid or accrued during the year ended September 30, 2007 to (1) our Chief Executive Officer, (2) our Chief Financial Officer, (3) our next two most highly compensated executive officers, and (4) Dr. Koschatzky, President of International Operations, whose compensation exceeded $100,000 during this period.

SUMMARY COMPENSATION TABLE

Name And Principal Position	Fiscal Year	Salary ($) (1)	Option Awards ($) (2)	Non-Equity Incentive Plan Compensation ($) (3)	All Other Compensation ($) (4)	Total ($)
Guy L. Mayer Chief Executive Officer	2007	338,802	124,490	226,113	280,839	970,244
L. Robert Johnston, Jr. Chief Financial Officer	2007	211,098	32,513	65,162	27,556	336,330
Dr. Karl Koschatzky President of International Operations	2007	205,525	48,412	52,927	57,141	364,005
Claude O. Pering Vice President and Chief Operating Officer	2007	181,635	56,814	63,533	9,608	311,590
Clifton J. Seliga Vice President of Global Sales and Marketing	2007	176,635	51,379	60,275	9,223	297,513

(1) Includes amounts earned but deferred at the election of the Named Executive Officers pursuant to our 401(k) employee savings and retirement plan.

(2) Represent the amount of compensation cost recognized by us related to stock option awards granted in fiscal year 2007 and prior years, as described in Statement of Financial Accounting Standards No. 123R. For discussion of

valuation assumptions, see Note 4 to our Consolidated Financial Statements. See also our discussion of share-based compensation under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies".

(3) Includes amounts paid in November 2007 based on our Compensation Committee's review of corporate performance and indiviudal achievements for fiscal year 2007.

(4) Includes amounts for relocation assistance, matching contributions under our 401(k) plan and contributions under our pension plan for Dr. Koschatzky.

GRANTS OF PLAN-BASED AWARDS

The following table provides information as to options granted during the fiscal year ended September 30, 2007 to each of the executive officers named in the Summary Compensation Table. All such options were granted under the Company's 2006 Stock Option Plan.

		Estimated Future Payouts Under Non-Equity Incentive Plan Awards			All Other Option Awards: Number of Secruities Underlying	Exercise or Base Price of Option Awards	Grant Date Fair Value of Stock and Option
Name	Grant Date	Threshold ($)	Target ($) (1)	Maximum ($)	Options (#) (2)	($/Sh)	Awards ($) (3)
Guy L. Mayer	11/06/06	-	240,000	-	75,000	6.01	183,000
L. Robert Johnston, Jr.	11/06/06	-	66,000	-	30,000	6.01	73,200
Dr. Karl Koschatzky	11/06/06	-	74,918	-	20,000	6.01	48,800
	03/19/07				10,000	8.55	34,560
Claude O. Pering	11/06/06	-	64,500	-	30,000	6.01	73,200
	03/19/07				20,000	8.55	69,120
Clifton J. Seliga	11/06/06	-	61,500	-	40,000	6.01	97,600
	03/19/07				10,000	8.55	34,560

(1) Actual amounts paid in November 2007 based on our Compensation Committee's review of corporate performance and individual achievements for fiscal year 2007 are included in the "Non-Equity Incentive Plan Compensation" column of the "Summary Compensation Table" above.

(2) Represents options granted in fiscal year 2007.

(3) Represents the grant date fair value, pursuants to SFAS 123R. For a discussion of valuation assumptions, see Note 4 to our Consolidated Financial Statements. See also our discussion of share-based compensation under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies".

NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE AND GRANTS OF PLAN-BASED AWARDS TABLE

Employment Agreement with Mr. Guy L. Mayer

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 $400,000. In addition, the employment agreement provides for a bonus for the Company's fiscal year 2007 in an amount up to 60% of his earned salary for fiscal 2007, 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 and 2006, Mr. Mayer was granted a ten (10) year option to purchase 50,000 and 75,000 shares of the Company's common stock, respectively, 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 is entitled to certain benefits in connection with a change of control of the Company discussed below under "—Potential Payments Upon Termination or Change in Control".

Letter Agreements with Other Executive Officers

We do not have formal employment agreements with any of our executive officers other than Mr. Mayer and each of these executive officers is employed with us on an at-will basis. However, certain elements of the executive officers' compensation and other employment arrangements are set forth in letter agreements that we executed with each of them at the time their employment with us commenced. The letter agreements provide, among other things, the executive officer's initial annual base salary and initial stock grant. Since the date of the letter agreements entered into with our executive officers, the compensation paid to each has been increased and additional stock options have been granted.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

The following table shows grants of stock options outstanding on the last day of the fiscal year ended September 30, 2007 to each of our executive officers named in the Summary Compensation Table.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Options Exercise Price ($)	Vesting Period (In Years)	Option Expiration Date
Guy L. Mayer	187,500	62,500	2.60	3	01/03/15
	37,500	12,500	4.17	3	09/26/15
	18,750	56,250	6.01	3	11/06/16
L. Robert Johnston, Jr.	30,000	30,000	2.95	3	01/17/16
	7,500	22,500	6.01	3	11/06/16
Dr. Karl Koschatzky	2,000	-	1.56	0	12/09/08
	24,000	-	0.94	4	10/01/09
	10,000	-	4.25	4	12/12/10
	15,000	-	2.63	4	12/09/12
	15,000	-	2.71	4	04/08/13
	15,000	-	3.27	4	06/17/13
	-	20,000	6.01	4	11/06/16
	2,500	7,500	8.55	3	03/19/17
Claude O. Pering	12,500	12,500	2.47	4	01/10/15
	12,500	12,500	4.17	4	09/26/16
	2,500	7,500	3.12	4	12/05/15
	-	30,000	6.01	4	11/06/16
	5,000	15,000	8.55	3	03/19/17
Clifton J. Seliga	12,500	12,500	2.47	4	01/10/15
	12,500	12,500	4.17	4	09/26/16
	-	40,000	6.01	4	11/06/16
	2,500	7,500	8.55	3	03/19/17

OPTION EXERCISES

The following table shows the number of shares acquired upon exercise of stock options by each executive officer named in the Summary Compensation Table during fiscal year 2007:

Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($) (1)
Dr. Karl Koschatzky	45,668	455,855

(1) Amounts shown in this column do not necessarily represent actual value realized from the sale of the shares acquired upon exercise of options because in many cases the shares are not sold on exercise but continue to be held by the executive officer exercising the option. The amounts shown represent the difference between the option exercise price and the market price on the date of exercise, which is the amount that would have been realized if the shares had been sold immediately upon exercise.

Note: Dr. Koschatzky represents the only executive officer who exercised stock options during 2007.

PENSION BENEFITS

We do not have any qualified or non-qualified defined benefit plans.

NONQUALIFIED DEFERRED COMPENSATION

We do not have any non-qualified defined contribution plans or other deferred compensation plans.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE-IN-CONTROL 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. In addition, all outstanding options held by Mr. Mayer will vest in full. If Mr. Mayer had been terminated for change of control as of September 28, 2007, he would have been entitled to $690,000, plus benefits.

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 $220,000. In addition, Mr. Johnston has a "change of control" agreement whereby he is entitled to 12 months salary including medical benefits in the event he is terminated as the result of a change of control of the Company.

In connection with their employment, the Company has agreed to a 12-month severance package for Messrs. Pering and Seliga in the event of termination due to a change of control of the Company.

In the event of termination due to a change of control of the Company, all outstanding stock options held by our executive officers will vest in full.

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 Non-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. On December 11, 2006 an additional 500,000 shares authorized was adopted by the Board of Directors and ratified by the shareholders on March 19, 2007. The total shares authorized under the 2006 Plan is 1,500,000. 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.

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 remains 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 is 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) months 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 Option Plans 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, 2007, there were outstanding options to purchase 1,997,700 shares of common stock under the 1996 and 2006 Plans.

The 2006 Plan presently reserves 1,500,000 shares of the Company's Common Stock for issuance thereunder. As of September 30, 2007, options have been issued for 590,000 shares and 910,000 shares remain available under the 2006 Plan. Unless sooner terminated, the 2006 Plan will expire on December 5, 2015.

DIRECTOR COMPENSATION

The table below summarizes the compensation paid or accrued during the fiscal year ended September 30, 2007 to each of our non-employee directors.

Name	Fees Earned or Paid in Cash ($) (1)	Option Awards ($) (2)	Total ($)	Options Outstanding (#)
G. Russell Cleveland	20,500	44,202	64,702	37,000
Roy D. Crowninshield, Ph.D.	21,000	42,374	63,374	42,000
Neal B. Freeman	19,000	41,054	60,054	24,500
J. Harold Helderman, MD	20,000	44,202	64,202	37,000
Udo Henseler, Ph.D	23,750	41,054	64,804	24,500
Adrian J. R. Smith	21,000	41,054	62,054	24,500
Carlton E. Turner, Ph.D	21,500	44,202	65,702	14,500

(1) Includes annual cash retainer and fees for serving on our Board and committeses of our Board.

(2) Represent the amount of compensation cost expensed by us related to stock option awards granted in fiscal year 2007, as described in Statement of Financial Accounting Standards No. 123R. For discussion of valuation assumptions, see Note 4 to our Consolidated Financial Statements. See also our discussion of share-based compensation under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies".

Director Compensation Policy

The Company's outside Directors, except Chairman of the Board, each receive a $10,000 annual retainer, $1,500 per person for each Board or Committee meeting attended, and $500 per telephonic meeting, paid quarterly at the end of the period, plus reimbursement of out-of-pocket expenses. The Chairman of the Board receives a $20,000 annual retainer, $1,500 per in-person attendance at Board and Committee meetings, and $500 per telephonic meeting, paid quarterly at the end of the period, plus reimbursement of out-of-pocket expenses for his services as Chairman. In addition to the above referenced outside Director compensation, the Chairman of the Audit Committee receives a $5,000 annual retainer, the Chairman of the Compensation Committee receives a $4,000 annual retainer, and any non-chairman committee member participating on the Audit Committee or Compensation Committee receives a $2,000 annual retainer, paid quarterly, at the end of the period. Additionally, the Company’s outside Directors each receive annually options to purchase 12,000 shares of the Company’s common stock. Each outside Director who is newly elected to the Board automatically receives an option to purchase 12,000 shares of the Company’s common stock.

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

COMPENSATION COMMITTEE REPORT

The Compensation Committee of our Board of Directors has reviewed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-X, which appears elsewhere in this Report and has discussed it with management. Based on this review and discussion, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis section be included in the Company's 2007 Annual Report on Form 10-K.

Members of the Compensation Committee:

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

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.

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, 2002. 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

	2002	2003	2004	2005	2006	2007
TUTOGEN MEDICAL	100.00	179.58	105.28	160.56	158.45	404.93
PEER GROUP INDEX	100.00	135.37	157.23	178.46	183.11	242.37
AMEX MARKET INDEX	100.00	123.58	142.66	172.69	179.78	221.51

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

The following table sets forth certain information regarding the beneficial ownership of the Company's common stock as of November 30, 2007, 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. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of November 30, 2007 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 19,376,939 shares of common stock issued and outstanding as of November 30, 2007.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner (1)(2)	Percentage of Class (3)
Zimmer CEP (formerly Centerpulse) USA Holding Co. Subsidiary of Zimmer Holdings, Inc. 345 East Main Street Warsaw, IN 46580	5,297,124	27.3%
Millenco, LLC (4) 666 Fifth Avenue New York, New York	1,003,189	5.2%
G. Russell Cleveland (5)	124,300	*
Roy D. Crowninshield, Ph.D. (6)	62,000	*
Neal B. Freeman (7)	24,500	*
Dr. J. Harold Helderman (8)	67,000	*
Udo Henseler, Ph.D. (9)	24,500	*
L. Robert Johnston, Jr. (9)	62,500	*
Guy L. Mayer (9)	168,750	*
Claude Pering (9)	46,200	*
Clifton Seliga (10)	44,750	*
Adrian J. R. Smith (9)	24,500	*
Carlton E. Turner (11)	24,500	*

All directors and officers as a group (11 persons)	673,500	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) According to a Schedule 13D filed with the Securities and Exchange Commission. Millennium Management, LLC is the manager of Millenco, LLC and Mr. Israel A. Englander is the managing member of Millennium Management, LLC.

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

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

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

(8) Includes 37,000 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

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

(10) Includes 43,750 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

(11) Includes 14,500 shares of common stock issuable upon exercise of options exercisable within sixty (60) days.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth certain information regarding the Company's equity compensation plans in effect as of September 30, 2007.

Plan Category	Number of securities to be Issued upon exercise of Outstanding options, warrants and rights (a)	Weighted-average Exercise price of Outstanding options, Warrants and rights	Number of securities remaining available for future issuance under Equity compensation plans (excluding securities reflected in coulumn (a))
Equity compensation plan approved by Securities holders - 1996 Plan (1)	1,407,700	$2.66	-0-
Equity compensation plan approved by	590,000	$7.07	910,000

Securities holders - 2006 Plan (1)			
Equity compensation plan not approved by Securties holders	-0-	-0-	-0-
Total	1,997,700	$3.97	910,000

(1) Reflects options to purchase shares of the Company's stock and shares available for issuance under the Company's stock options plans

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

As of September 30, 2007, Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer is a 28% owner of the Company's outstanding shares of Common Stock.

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, 2007, 2006 and 2005 product sales to Zimmer spine totaled $5.5 million, $2.9 million and $3.1 million, respectively. Accounts receivable from Zimmer Spine were $209,000 and $952,000 at September 30, 2007 and September 30, 2006, 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, 2007, 2006 and 2005, Zimmer Dental was paid commissions aggregating approximately $9.8 million, $7.2 million and $6.1 million, respectively. Accounts payable to Zimmer Dental total $2.5 million and $1.9 million at September 30, 2007 and September 30, 2006, respectively.

In August 2007, the Company entered into an exclusive distribution agreement with Zimmer Dental, Inc., whereby Zimmer Dental will distribute dental products internationally. For the year ended September 30, 2007, product sales under this new relationship totaled $983,000. Accounts receivable from Zimmer Dental totaled $292,000 at September 30, 2007.

Our Board has determined that the following members of the Board qualify as independent under the definition promulgated by the American Stock Exchange: All members except Mr. Mayer.

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, 2007 and 2006, and all fees billed for other services by Deloitte & Touche LLP during those periods:

Year Ended September 30,	2007	2006
Audit fees (1)	$ 609,000	$ 515,000
Audit-related fees (2)	0	44,000
Tax fees (3)	0	33,000
All other fees (4)	0	39,000
Total Accounting Fees and Services	$ 609,000	$ 631,000

(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 2007, total audit fees include $241,000 related to the 2006 audit, $132,000 related to quarterly reviews in 2007, $106,000 for interim and planning procedures relating to the 2007 year-end audit and $101,000 related to Sarbanes-Oxley. 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, 2007 and 2006 were approved by the Audit Committee.

The Company has established pre-approval policies and procedures for all future engagements of the Company's accountants. In accordance with the rules and regulations of the SEC relating to the independence of auditors, the Company's policies and procedures require that the Audit Committee be informed of each service, and prohibit the delegation of any pre-approval responsibilities to the Company's management.

The Company's pre-approval policies and procedures 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 policies also provide that all additional engagements of the auditor that were not approved in the annual pre-approval process, 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.

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 SEC.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Regeneration Technologies, Inc., Rockets FL Corp. and Tutogen Medical, Inc. dated as of November 12, 2007 (m)
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 (c)
3.2	Amended and Restated Bylaws (a)
4.1	Rights Agreement between Tutogen Medical, Inc. and Computershare Trust Company, Inc. dated as of July 16, 2002 (i)
4.2	Amendment Agreement, dated as of November 12, 2007, by and between Tutogen Medical, Inc. and Computershare Trust Company, N.A., a federally chartered trust company, as successor rights agent to Computershare Investor Services, LLC (l)
10.1	1996 Incentive and Non-Statutory Option Plan (e)
10.2	2006 Incentive and Non-Statutory Option Plan (f)
10.3	Employment Agreement of Guy L. Mayer, dated December 6, 2004 (g)
10.4	Registration Rights Agreement dated June 30, 2006, by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd. (h)
10.5	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. (h)
10.6	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. (h)
10.7	Securities Purchase Agreement dated June 30, 006 by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd. (h)
10.8	Copy of Distribution Agreement between Tutogen Medical, Inc. and Zimmer Dental, Inc. (a)(j)
10.9	Copy of Distribution Agreement between Tutogen Medical, Inc. and Zimmer Spine, Inc. (a)(j)
10.10	Copy of Assignment Agreement between Centerpulse France S.A.S., Zimmer GmbH, and Tutogen Medical GmbH, effective July 12, 2005 (a)
10.11	Copy of Distribution Agreement between Tutogen Medical, Inc. and Zimmer Dental, Inc. (j)(n)
10.12	Copy of Tissue Agreement between Tutogen Medical, Inc. and AlloSource (j)(n)
10.13	Securities Purchase Agreement dated April 10, 2007 by and between Tutogen Medical, Inc. and those purchasers executing the Securities Purchase Agreement (k)
10.14	Registration Rights Agreement dated April 10, 2007 by and between Tutogen Medical, Inc. and those purchasers executing the Securities Purchase Agreement (k)

21.1 Subsidiaries of the Registrant: Tutogen Medical GMbH – Germany – wholly owned
Tutogen Medical, S.A.R.L. - France - subsidiary of Tutogen Medial GmbH

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

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

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 (n)

(a) Filed as Exhibits to the Company Form S-1 Registration Statement, File No. 333-139738.
(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, 1997.
(d) Filed as Exhibit to Form 8-K Report August 16, 2006.
(e) Filed as Exhibit to Form S-8 filed October 31, 1996.
(f) Filed as Exhibit to Proxy Statement filed in connection with the Company's 2006 annual meeting of shareholders.
(g) Filed as Exhibit to Form 10-K Report for year ended September 30, 2005.
(h) Filed as Exhibit to Form 8-K Report July 6, 2006.
(i) Filed as Exhibit to Form 8-K Report July 17, 2002.
(j) Portions of this Exhibit have been omitted pursuant to Rule 406, are filed separately with the SEC, and are subject to a confidential treatment request.
(k) Filed as Exhibit to Form 8-K, April 10, 2007.
(l) Filed as Exhibit to Form 8-K, November 13, 2007.
(m) Filed as Exhibit to Form 8-K, November 19, 2007.
(n) Filed herewith.

(b) FINANCIAL STATEMENT SCHEDULES

Schedule II – Valuation and Qualifying Accounts for the years ended September 30, 2007, 2006 and 2005.

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 14, 2007

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 14, 2007
/s/ ROY D. CROWNINSHIELD Roy D. Crowninshield	Director	December 14, 2007
/s/ NEAL B. FREEMAN Neal B. Freeman	Director	December 14, 2007
/s/ J. HAROLD HELDERMAN Dr. J. Harold Helderman	Director	December 14, 2007
/s/ UDO HENSELER Dr. Udo Henseler	Director	December 14, 2007
/s/ GUY L. MAYER Guy L. Mayer	Director	December 14, 2007
/s/ ADRIAN J. R. SMITH Adrian J. R. Smith	Director	December 14, 2007
/s/ CARLTON E. TURNER Carlton E. Turner	Director	December 14, 2007

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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, 2007 and 2006, and the related consolidated statements of income (loss) and comprehensive income (loss), shareholders' equity, and cash flows for each of the three years in the period ended September 30, 2007. Our audits also included the financial statement schedule listed in the Index at Item 15(b). We also have audited the Company's internal control over financial reporting as of September 30, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these financial statements and the financial statement schedule, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and financial statement schedules and an opinion on the Company's internal control over financial reporting 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 and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Tutogen Medical Inc. and subsidiaries as of September 30, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2007, 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, presents fairly, in all material respects, the information set forth therein. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2007, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ DELOITTE & TOUCHE LLP

Orlando, Florida
December 14, 2007

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2007 AND 2006
(In Thousands, Except for Share and Per Share Data)

	2007	2006
ASSETS		
Current Assets		
Cash and cash equivalents	$ 7,849	$ 3,463
Short term marketable securities	5,000	-
Accounts receivable - net of allowance for doubtful accounts of $777 in 2007 and $483 in 2006	6,477	6,202
Inventories - net	17,390	12,678
Deferred tax assets - net	3,792	471
Prepaids and other current assets	1,550	1,436
	42,058	24,250
Property, plant, and equipment - net	14,429	12,940
Other assets	387	424
Deferred tax asset - net	2,376	1,303
TOTAL ASSETS	$ 59,250	$ 38,917
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,720	$ 1,346
Accrued expenses and other current liabilities	5,266	4,314
Accrued commissions	2,532	1,918
Short-term borrowings	356	5,783
Current portion of deferred distribution fees	1,817	1,577
Current portion of long-term debt	1,281	1,097
	12,972	16,035
Noncurrent Liabilities		
Deferred distribution fees and other	2,641	3,988
Long-term debt	3,278	3,673
Total Liabilities	18,891	23,696
Shareholders' Equity		
Common stock, $0.01 par value, 30,000,000 shares authorized; 19,167,939 and 16,197,235 issued and outstanding	192	162
Additional paid-in capital	54,812	37,751
Accumulated other comprehensive income	3,682	2,393
Accumulated deficit	(18,327)	(25,085)

Total shareholders' equity	40,359	15,221
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 59,250	$ 38,917

See Accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)
YEARS ENDED SEPTEMBER 30, 2007, 2006 AND 2005
(In Thousands, Except for Share and Per Share Data)

	2007	2006	2005
Revenue	$ 53,819	$ 37,947	$ 31,860
Cost of revenue	23,009	16,336	20,129
Gross profit	30,810	21,611	11,731
Operating Expenses			
General and administrative	9,277	7,803	5,790
Distribution and marketing	15,795	12,261	11,509
Research and development	2,203	1,834	1,659
Total Operating Expenses	27,275	21,898	18,958
Operating income (loss)	3,535	(287)	(7,227)
Foreign exchange loss	(118)	(311)	(173)
Interest and other income	367	108	77
Interest and other expense	(1,198)	(293)	(130)
	(949)	(496)	(226)
Income (loss) before taxes	2,586	(783)	(7,453)
Income tax benefit	(4,172)	(194)	(436)
Net income (loss)	6,758	(589)	(7,017)
Other comprehensive income			
Foreign currency translation adjustments	1,289	715	(570)
Comprehensive income (loss)	$ 8,047	$ 126	$ (7,587)
Average shares outstanding for basic earnings per share	17,682,750	16,027,469	15,919,286
Basic earnings (loss) per share	$ 0.38	$ (0.04)	$ (0.44)
Average shares outstanding for diluted earnings per share	19,080,164	16,027,469	15,919,286
Diluted earnings (loss) per share	$ 0.36	$ (0.04)	$ (0.44)

See Accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2007, 2006 AND 2005
(In Thousands)

	2007	2006	2005
Cash flows provided by (used in) operating activities			
Net income (loss)	$ 6,758	$ (589)	$ (7,017)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,056	778	984
Amortization of deferred distribution fees revenue	(1,648)	(835)	(640)
Severance costs	-	437	-
Amortization of debt discount and debt issuance costs	206	69	-
Provision for bad debts	295	19	308
Provision for inventory write-downs	173	246	889
Share-based compensation	762	451	-
Deferred income taxes	(4,268)	797	(505)
Changes in assets and liabilities:			
Accounts receivable	(309)	(2,632)	1,106
Inventories	(4,386)	(3,394)	3,771
Other assets	174	(513)	798
Accounts payable and other accrued expenses	762	(292)	(497)
Accrued commissions	614	153	244
Deferred distribution fees	500	3,550	-
Net cash provided by (used in) operating activities	1,689	(1,755)	(559)
Cash flows used in investing activities			
Purchase of investment securities	(5,000)	-	-
Deposits on purchase of property and equipment	-	(300)	-
Purchase of property and equipment	(2,296)	(5,690)	(1,682)
Net cash used in investing activities	(7,296)	(5,990)	(1,682)
Cash flows provided by financing activities			
Proceeds from issuances of common stock	12,000	-	-
Fees associated with issuance of common stock	(506)	-	-
Exercise of stock options	1,835	647	36
Debt and equity issuance costs	(152)	(263)	-
Proceeds from issuance of convertible debt and warrants	-	3,000	-
Proceeds from long-term borrowings	494	2,365	-
Change in short-term borrowings	(2,600)	2,747	1,108
Repayment of long-term debt	(1,235)	(593)	(164)
Net cash provided by financing activities	9,836	7,903	980
Effect of exchange rate changes on cash and cash equivalents	157	(257)	(240)
Net increase (decrease) in cash and cash equivalents	4,386	(99)	(1,501)

Cash and cash equivalents at beginning of year	3,463	3,562	5,063
Cash and equivalents at end of year	$ 7,849	$ 3,463	$ 3,562
Supplemental cash flow disclosures			
Interest paid	$ 368	$ 578	$ 127
Income taxes paid	$ 8	$ -	$ 149
Non-cash investing and financial activities:			
Capital lease arrangements	$ -	$ 987	$ -
Conversion of debenture	$ 3,000	$ -	$ -

See Accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
YEARS ENDED SEPTEMBER 30, 2007, 2006 AND 2005
(In Thousands, Except for Share Data)

	Common Stock ($.01 Par)	Additional Paid In Capital	Accumulated Other Comprehensive Income (1)	Accumulated Deficit	Total	Common Shares Issued and Outstanding
BALANCE, OCTOBER 1, 2004	$ 159	$ 36,345	$ 2,248	$ (17,479)	$ 21,273	15,915,960
Stock issued on exercise of options	-	36	-	-	36	17,000
Warrants issued	-	-	-	-	-	-
Stock issued on conversion of debt	-	-	-	-	-	-
Stock issued for private offering	-	-	-	-	-	-
Share-based compensation	-	-	-	-	-	-
Net income (loss)	-	-	-	(7,017)	(7,017)	-
Foreign currency translation adjustment	-	-	(570)	-	(570)	-
BALANCE, SEPTEMBER 30, 2005	$ 159	$ 36,381	$ 1,678	$ (24,496)	$ 13,722	15,932,960
Stock issued on exercise of options	3	644	-	-	647	264,275
Warrants issued	-	275	-	-	275	-
Stock issued on conversion of debt	-	-	-	-	-	-
Stock issued for private offering	-	-	-	-	-	-
Share-based compensation	-	451	-	-	451	-
	-	-	-	(589)	(589)	-

Net income (loss)						
Foreign currency translation adjustment	-	-	715	-	715	-
BALANCE, SEPTEMBER 30, 2006	$ 162	$ 37,751	$ 2,393	$ (25,085)	$ 15,221	$ 16,197,235
Stock issued on exercise of options	8	1,827	-	-	1,835	762,168
Warrants issued	-	-	-	-	-	-
Stock issued on conversion of debt	6	2,994	-	-	3,000	582,524
Stock issued for private offering	16	11,478	-	-	11,494	1,626,012
Share-based compensation	-	762	-	-	762	-
Net income	-	-	-	6,758	6,758	-
Foreign currency translation adjustment	-	-	1,289	-	1,289	-
BALANCE, SEPTEMBER 30, 2007	$ 192	$ 54,812	$ 3,682	$ (18,327)	$ 40,359	19,167,939

(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, 2007, 2006 AND 2005
(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® 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. The Company operates on a fiscal year ending September 30. References herein to 2007, 2006 and 2005 refer to years ended September 30, 2007, 2006 and 2005, respectively.

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 recorded and presented as a component of 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 Income (Loss) and Comprehensive Income (Loss). The Company recognized transaction losses of $118, $311, and $173 in 2007, 2006 and in 2005, 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.

Short Term Marketable Securities – Short term marketable securities consist of a certificate of deposit from a bank with an initial term of five-months.

Inventories - Inventories are stated at the lower of cost or market, with cost determined using the first-in, first-out method. 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 determined in part through periodic meetings 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. The adequacy of inventory 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, 2007 and 2006, unamortized debt issuance costs were $0 and $154, respectively, and are included in other assets in the accompanying consolidated balance sheets.

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
Equipment, furniture and fixtures	5 years
Computer hardware and software	3 years

Leasehold improvements are amortized over the shorter of five-years or the remaining life of the lease term. Amortization expense associated with assets financed by capital lease are included in depreciation and amortization in the accompanying consolidated financial 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.

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 provide for certain upfront lump sum payments in exchange for certain distribution rights. These payments are recorded to deferred distribution fees in the consolidated balance sheets. These payments are recognized as revenue over a straight-line basis, which approximates when services are provided under the contract. Recognition of revenue commences over the term of the distribution agreement upon delivery of initial products. These distribution agreements vary in amount and have terms from three to ten years. 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 had been paid to the Company. In July 2007, the Company met the required milestones needed to earn the second payment of $250. During 2007, Coloplast agreed to pay the Company $250 associated with an exclusive distribution agreement.

Revenue and Cost of Revenue - Revenue includes amounts from surgical product sales, tissue service processing, and distribution fees. Cost of revenue includes depreciation of $1,541, $529, and $686 for the years ended September 30, 2007, 2006 and 2005, respectively, as discussed above. Revenue on product sales and tissue processing 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 Statement of Financial Accounting Standards ("SFAS") No. 48, *"Revenue Recognition When Right of Return Exists"* ("SFAS 48"). 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. Certain shares are excluded from the computation of diluted earnings per share in periods where they have an anit-dilutive effect.

Share-Based Compensation - The Company estimates 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 No. 123, *"Accounting for Stock-Based Compensation"* (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 the Company's stock price as well as assumptions regarding a number of variables including the expected term of awards, expected stock price volatility, vesting periods 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 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 (loss) 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. If we 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 $160, $95, and $57 in 2007, 2006 and 2005, respectively.

3. NEW ACCOUNTING PRONOUNCEMENTS

In June of 2006, the FASB issued FASB Interpretation ("FIN") No. 48, *"Accounting for Uncertainty in Income Taxes"* ("FIN 48"). This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, *"Accounting for Income Taxes"* ("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 No. 157, *"Fair Value Measurements"* ("SFAS 157"). 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 February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities--Including an Amendment of FASB Statement No. 115*" which is effective for fiscal years beginning after November 15, 2007. This pronouncement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. We are currently evaluating the potential impact of this pronouncement on our consolidated 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. No shares of the Preferred Stock were issued or outstanding at September 30, 2007.

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 and for any subsequent issuances of its common stock. 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 (such exercise price was $35 per right at September 30, 2007), a number of the Company's common shares having a market value of twice such price. Subject to the terms of the Rights Agreement, the rights may be redeemed by the Company at a redemption price of $.001 per right or may be exchanged in whole or in part for Preferred Shares or shares of the Company's Common stock.

Stock Options 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 are generally subject to a three or four year vesting schedule and a contractual term of ten years from grant. This plan remains in effect for all options issued during its life. The Plan expired in February 2006 and no further options can be granted under the Plan

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. On December 11, 2006 an additional 500,000 shares authorized was adopted by the Board of Directors and ratified by the shareholders on March 19, 2007. The total shares authorized under the New Plan is 1,500,000. Under the New Plan, options may be granted at not less than the fair market value on the date of grant. Options are generally subject to a three or four year vesting schedule and a contractual term of ten years from grant.

Effective October 1, 2005, the Company adopted the provisions of SFAS No. 123R, *"Share-Based Payment"* ("SFAS 123R") which modified the financial accounting and reporting standards for stock-based compensation plans. SFAS 123R requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors. Under the provisions of SFAS 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 123R, the Company's net income (loss) before income taxes and net income (loss) for the years ended September 30, 2007 and 2006 was $762 and $451 more, respectively, 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 income (loss) per share for the years ended September 30, 2007 and 2006 was $.04 and $.03 more, respectively, than if the Company had continued to account for stock-based net compensation under APB 25. There is no net effect on the statement of cash flows related to the adoption of SFAS 123R. In 2006, there was no tax effect related to the adoption since the Company had recorded a full valuation allowance. In 2007, the valuation allowance was reversed and the Company recorded a deferred tax asset of $110 associated with the expense for non-qualified stock options.

The Company elected to use the modified prospective transition method as permitted by SFAS 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, 2007 and 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 123, *"Accounting for Stock-Based Compensation"* as amended by SFAS 148, *"Accounting for Stock-Based Compensation – Transition and Disclosure"*. Since the adoption of SFAS 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 123R. During the years ended September 30, 2007 and 2006, the Company recognized compensation expense of $762 and $451, respectively, relating to stock options granted during the years ended September 30, 2007 and 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 Consolidated Statement of Income (Loss) and Comprehensive Income (Loss).

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 123. Under APB 25, the Company accounted for stock-based awards to employees and directors using the intrinsic value method as allowed under SFAS 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in the Company's Consolidated Statement of Income (Loss) and Comprehensive Income (Loss) 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 loss and basic and diluted loss per share, as reported, to pro-forma net loss and basic and diluted net loss per share, as if the Company had expensed the fair value of stock options.

	2005
Net loss	$ (7,017)
Deduct: Total stock-based employee compensation Expense determined under fair value based method,	102
Pro-forma net loss	$ (7,119)
Basic loss per share:	

As reported	$	(0.44)
Pro-forma	$	(0.45)
Diluted loss per share:		
As reported	$	(0.44)
Pro-forma	$	(0.45)

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:

	2007	**2006**	**2005**
Weighted-average volatility	52.3%	50.2%	47.0%
Expected term (in years)	5	5	5
Risk-free rate	4.3%-5.0%	4.5%-4.7%	2.3%-3.1%

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 20% 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 for the year ended September 30, 2007:

		Outstanding Shares		
Options	**Shares**	**Weighted-Average Exercise Price**	**Weighted Average Remaining Contractual Term**	**Aggregate Intrinsic Value**
Outstanding at October 1, 2006	2,238,868	$ 2.65		
Granted	607,500	7.08		
Exercised	(762,168)	2.40		
Forfeited or expired	(86,500)	5.35		
Outstanding at September 30, 2007	1,997,700	$ 3.97	5.91	$ 15,052
Exercisable at September 30, 2007	1,314,700	$ 2.95	4.41	$ 11,245

As of September 30, 2007, 910,000 stock options were available for grant. As of September 30, 2007, there was $1,199 of total unrecognized compensation cost related to nonvested stock options that is expected to be recognized over a weighted-average period of 1.96 years. The intrinsic value of options exercised during the years ended September 30, 2007, 2006 and 2005 were $1,834, $561, and $23, respectively. The fair value of options vested during the years ended September 30, 2007, 2006 and 2005 was $844, $507 and $507, respectively. The weighted average fair value of options granted during the years ended September 30, 2007, 2006 and 2005 was $3.58, $3.34 and $2.99, 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 48% and 10%, respectively, of the Company’s consolidated revenues during 2007. Zimmer Dental markets the Company’s products to the end user and the Company ships and bills the customer directly. Internationally, Zimmer Dental is a stocking distributor for the

Company. 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 and it would materially and adversely affect the results of operations..

Tissue Supply—The Company's business is dependent on the availability of donated human cadaver tissues supplied by donor recovery groups. The Company's four largest recovery groups together supplied approximately 91% of our total human tissue during 2007. 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, 2007 there were no customers representing more than 10% of the Company's outstanding trade receivables.

6. INVENTORIES

Major classes of inventory at September 30, 2007 and 2006 were as follows:

	2007	2006
Raw materials	$ 3,602	$ 2,017
Work in process	7,356	5,811
Finished goods	6,432	4,850
	$ 17,390	$ 12,678

For the years ended September 30, 2007, 2006 and 2005, the Company had inventory write-downs of $2,315, $3,278 and $2,450, respectively. These amounts include write-downs for slow moving, excess and obsolete inventories based on historical experience, current product demand, regulatory considerations, industry trends, changes and risks and the remaining shelf life.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at September 30, 2007 and 2006 consisted of the following:

	2007	2006
Land	$ 587	$ 522
Buildings and Improvements	10,092	6,275
Machinery and Equipment	8,220	5,174
Office Furniture and Other	1,081	1,284
Construction-In-Progress	260	3,981
	20,240	17,236
Less Accumulated Depreciation	(5,811)	(4,296)
	$ 14,429	$ 12,940

Depreciation expense, which includes amortization related to capital leases, for the years ended September 30, 2007, 2006 and 2005 was $2,056, $778 and $984, 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 were paid in twelve monthly equal payments during the period from July 1, 2006 through June 30, 2007.

9. ACCRUED EXPENSES

Accrued expenses at September 30 consisted of the following:

	2007	2006
Accrued compensation	$ 2,495	$ 1,828
Accrued professional services	875	1,039
Accrued purchases	765	562
Other	1,131	885
	$ 5,266	$ 4,314

10. 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 $2,141 for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 7.25% to 10.25%. At September 30, 2007, the Company had no borrowings under the revolving credit agreements. At September 30, 2006 the Company had outstanding borrowings of 819 Euros or $1,039. 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 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, 2008. At September 30, 2007, the company had no outstanding borrowings on this credit facility. At September 30, 2006, the Company had $1,500 outstanding 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, 2007, the Company was in compliance with this covenant. In addition, the Company maintains a lock box arrangement and merchant credit card program 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, 2007, short term borrowings on the consolidated balance sheet included an outstanding balance of $340 related to such activity. The term of the outstanding borrowing at September 30, 2007 is 12-months with an interest rate of 7.5%.

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, was due upon the earlier of August 1, 2007, or upon a change of control of the Company and was convertible into common stock at a price of $5.15 per share at any time at the election of the holder. The warrants were 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. In April and May of 2007, the $3,000 debenture had fully converted into common stock. In November 2007, the 175,000 warrants had been fully exercised into common stock.

Under the Registration Rights Agreement, which requires common shares to be registered for the convertible debenture and warrants, the Company was required to file a Form S-1 registration statement with the United States Securities and Exchange Commission ("S-1") the earlier of the day following the filing of the Company's 10-K or December 31, 2006. The Company was then required to have the shares registered within 60 days of the filing date of the S-1. In March 2007, the Securities and Exchange Commission approved the registration of the shares. These shares were registered during the second quarter of 2007.

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 three 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 was amortized to interest expense over the term of the debenture. The remaining unamortized balance of the warrants as of September 30, 2007 and 2006 was $0 and $205, respectively. The convertible debenture balance of $0 and $2,725, net of debt discount, is included in short-term borrowings at September 30, 2007 and 2006, respectively. 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, and was amortized to interest expense over the term of the debenture.

11. LONG-TERM DEBT

Long-term debt at September 30, 2007 and 2006 consisted of the following:

	2007	2006
Senior Debt	$ 3,934	$ 3,635
Unsecured Debt	113	-
Capital Leases	512	1,135
	4,559	4,770
Less Current Portion	(1,281)	(1,097)
	$ 3,278	$ 3,673

Aggregate maturities of senior debt are $728 in 2008; $728 in 2009; $728 in 2010; $684 in 2011; $359 in 2012; and $707 beyond 2012.

Senior debt consists of four loans with a German bank. The first loan ($516 as of September 30, 2007) has an interest rate of 5.75%, payable monthly, maturing March of 2011. The second loan ($1,606 as of September 30, 2007) has an interest rate of 5.15%, payable quarterly, maturing March of 2012. The third loan ($1,491 as of September 30, 2007) payable semi-annually at a fixed rate of 5.6% maturing December 2016. The fourth loan ($321 as of September 30, 2007) is payable quarterly at a fixed rate of 5.75% maturing September 2012.

The Senior debt 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 million Euros ($5,709 as of September 30, 2007) by the parent company. There are no financial covenants under this debt.

The Capital lease debt consists of two leases. The first lease (initial cost of $1,300, with $470 of accumulated amortization as of September 30, 2007) 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 $240, with $157 of accumulated amortization as of September 30, 2007) is payable at $21 per quarter and matures March of 2008. The lease is secured by equipment located at the Company’s Florida tissue processing facility. The leases each contain fair market value purchase options at the end of the lease terms that are included in the capital lease obligation balance at September 30, 2007. As of September 30, 2007, 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. Future minimum capital lease payments of $512 for principal and $29 for interest are due in 2008.

For the year ended September 30, 2006, $987 related to a capital lease agreement has been presented as a non-cash investing and financing activity 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. During 2005 and 2007, no interest expense was capitalized.

12. 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 second senior debt loan with a balance of $1,606 at September 30, 2007 (see Note 10) is based on dealer quotes and was not significant as of September 30, 2007. This loan is payable in monthly installments of approximately $90 (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.

13. 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 Note 2. 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, 2007, 2006 and 2005 are as follows:

2007	International	United States	Consolidated
Gross revenue	$ 22,632	$ 37,984	$ 60,616
Less - intercompany	(6,797)	-	(6,797)
Total revenue - third party	15,835	37,984	53,819
Depreciation and amortization	1,011	1,045	2,056
Operating income	2,360	1,175	3,535
Interest expense	291	907	1,198
Interest Income	48	319	367
Income tax expense (benefit)	1,198	(5,370)	(4,172)
Net income	931	5,827	6,758
Capital expenditures	1,516	780	2,296
Fixed assets	10,790	3,639	14,429

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	-	(194)
Net income (loss)	332	(921)	(589)
Capital expenditures	3,248	2,742	5,990
Fixed assets	8,995	3,830	12,824

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)	-	(436)
Net loss	(1,037)	(5,980)	(7,017)
Capital expenditures	1,468	213	1,682
Fixed assets	5,912	699	6,611

A summary of revenues by segment for the years ended September 30, 2007, 2006 and 2005 are as follows:

	2007	2006	2005

Dental	$ 24,329	$ 17,616	$ 13,785
Spine	5,516	2,877	3,128
Surgical Specialties	8,139	4,937	4,839
Total U.S.	37,984	25,430	21,752
Gemany	4,667	2,851	1,980
Rest of World	9,179	7,472	6,220
France	1,425	1,672	1,337
Other - Distribution Fees	564	522	571
Total International	15,835	12,517	10,108
Total Consolidated	$ 53,819	$ 37,947	$ 31,860

14. INCOME TAXES

Income tax (benefit) expense consisted of the following components for the years ended September 30:

	2007	2006	2005
Current			
Federal	$ 79	$ 8	$ -
State	-	-	-
Foreign	-	(953)	-
Total	79	(945)	
Deferred			
Federal	1,171	116	(2,260)
State	(425)	19	(194)
Foreign	1,198	759	(571)
Total	1,944	894	(3,025)
Valuation allowance	(6,194)	(143)	2,589
Total income tax benefit	$ (4,172)	$ (194)	$ (436)

The differences between the U.S. statutory rates and those in the consolidated statements of income (loss) and comprehensive income (loss) are as follows.

	2007	2006	2005
Statutory federal rate	$ 852	$ (250)	$ (2,536)
State income tax - net of federal taxes	38	10	(194)
Foreign tax differential	99	(3)	(303)
Ineligibility of state net operating losses	387	-	-
Expense due to jurisdictional rate changes	334	-	-
Stock options	189	124	-
Tax return adjustments	120	-	-
Valuation allowance	(6,194)	(143)	2,589
Tax credits	(25)	-	-
Foreign exchange loss	-	(364)	-
Foreign dividend income	-	423	-
Other	29	9	8
Total income tax benefit	$ (4,172)	$ (194)	$ (436)

The tax effect of the temporary differences that give rise to the Company's net deferred taxes as of September 30, 2007, and 2006 are as follows:

	2007	2006
Current		
Deferred Tax Assets		
Net operating loss carryforward	$ 2,698	$ -
Inventory write-down	568	545
Distribution fees	291	19
Intercompany profits	172	-
Insurance reserve	113	117
Vacation pay	57	53
Management fee	-	576
Bad debt allowance	-	53
Stock options	-	34
Other	72	2
Valuation allowance	-	(928)
Subtotal	3,971	471
Deferred Tax Liabilities		
Bad debt allowance	(179)	-
Net Deferred Tax Asset - Current	**$ 3,792**	**$ 471**
Long Term		
Deferred Tax Assets		
Net operating loss carryforward	1,592	6,737
Distribution fees	618	38
Fixed assets	-	-
Stock options	109	-
Other	65	18
Valuation allowance	-	(5,238)
Subtotal	2,384	1,555
Deferred Tax Liabilities		
Fixed assets	(8)	(252)
Net Deferred Tax Asset - Long Term	**$ 2,376**	**$ 1,303**

The Company recorded in 2007 a tax benefit of $6,194 due to the reversal of a previously recorded valuation allowance related to our U.S. operations since we have determined that it is more likely than not that our existing deferred tax assets will be realized.

As of September 30, 2007, the Company has approximately $10,526 of federal net operating loss carry forwards expiring beginning in 2011, a $79 AMT credit carry forward, and a $46 credit on research and development that will begin to expire in 2013 if unused. The Company also has state net operating loss carry forwards of approximately $3,820 that will begin to expire in 2021. At September 30, 2007, the Company had approximately $795 ($299 tax effected) related to current year excess tax deductions from the exercise of non-qualified stock options. Since the

Company has elected the ordering rule as prescribed by SFAS 109, and because the Company has net operating loss carry forwards, the Company has not yet recorded the tax benefit from this deduction.

As of September 30, 2007, the Company has a corporate net operating loss carry forward for German income tax purposes of approximately $5,712 (4,002 Euros), and a trade net operation loss carry forward for German income tax purposes of approximately $3,387 (2,373 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 109. The Company does not have a valuation allowance against deferred tax assets as of September 30, 2007, because management believes that it is more likely than not that these tax benefits will be realized through the generation of future taxable income. At September 30, 2007, the Company had approximately $1,551 (1,087 Euros) related to current year excess tax deductions from disqualified incentive stock options. Since the Company has elected the ordering rule as prescribed by SFAS 109, and because the Company has net operating loss carry forwards, the Company has not yet recorded the tax benefit from this deduction which approximates $425K (298 Euros).

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. 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.

15. EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings (loss) per share computations for the years ended September 30, 2007, 2006 and 2005. The Company has excluded 170,000, 1,457,000 and 419,000 shares of stock as such shares are anti-dilutive to the calculation at September 30, 2007, 2006 and 2005, respectively:

	2007	2006	2005
Numerator			
Net income (loss)	$ 6,758	$ (589)	$ (7,017)
Interest on convertible debentures	57	-	-
Net income (loss) used in calculation of diluted earings per share	$ 6,815	$ (589)	$ (7,017)
Denominator			
Weighted-average shares of common stock outstanding used in calculation of basic earnings per share	17,682,750	16,027,469	15,919,286
Effect of dilutive securites - stock options, warrants and convertible debentures	1,397,414	-	-
Weighted-average shares of common stock outstanding used in calculation of diluted earnings per share	19,080,164	16,027,469	15,919,286
Basic earnings (loss) per share	$ 0.38	$ (0.04)	$ (0.44)
Diluted earnings (loss) per share	$ 0.36	$ (0.04)	$ (0.44)

16. COMMITMENTS AND CONTINGENCIES

The Company currently has operating leases for its corporate offices in the U.S., as well as several leases related to office equipment and automobiles. The U.S. Corporate office lease expires in January 2009, with two one-year renewal options. Total rental expense was $1,153, 959, and $1,212 for the years ended September 30, 2007, 2006 and 2005, 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, 2007 are as follows:

2008	$ 1,336
2009	691
2010	162
2011	83

2012	21
Thereafter	2
	$ 2,295

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. At September 30, 2005, the Company had an accrual recorded of $476 (approximately 395 Euros) related to a dispute with a former international distributor. During 2006, the dispute was settled for $360 (approximately 280 Euros) and the Company recorded a change in estimate and reduced the accrual by approximately $91 (approximately 71 Euros), which also reduced general and administrative expense. The settlement amount and outstanding legal costs were paid in 2007.

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 $861 for quarantined inventory 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 the total recall 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. The Company intends to vigorously defend this matter and does not believe that the outcome of this class action will have an adverse material effect on the Company's operations, cash flows, financial position, or financial statement disclosures.

17. RELATED PARTY

As of September 30, 2007, Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc. ("Zimmer") is a 28% owner of the Company's outstanding shares of common stock.

The Company has an exclusive license and distribution agreement with Zimmer Spine, Inc., a wholly owned subsidiary of Zimmer, 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, 2007, 2006 and 2005 product sales to Zimmer Spine totaled $5,516, $2,877, and $3,128, respectively. Accounts receivable from Zimmer Spine were $209 and $952 at September 30, 2007 and 2006, respectively.

The Company has also engaged Zimmer Dental, Inc. ("Zimmer Dental") a wholly owned subsidiary of Zimmer to act as an exclusive sales and marketing representative for the Company's bone tissue for dental applications in the United States and certain international markets. Under this distribution agreement, the Company ships directly to Zimmer Dental's customers (see Note 5). For the years ended September 30, 2007, 2006 and 2005, Zimmer Dental was paid commissions aggregating approximately $9,796, $7,200, and $6,055 respectively. Accounts payable to Zimmer Dental total $2,532 and $1,918 at September 30, 2007 and 2006, respectively.

In August 2007, the Company entered into an exclusive distribution agreement with Zimmer Dental, Inc., whereby Zimmer Dental will distribute dental products internationally. For the year ended September 30, 2007, product sales under this new relationship totaled $983. Accounts receivable from Zimmer Dental totaled $292 at September 30, 2007.

18. SUBSEQUENT EVENT

On November 12, 2007, the Company entered into an Agreement and Plan of Merger among Regeneration Technologies, Inc. ("Parent"), Rockets FL Corp.("Merger Sub") and the Company. The proposed merger transaction is structured as a tax free stock-for-stock exchange pursuant to which the Company's shareholders will receive 1.22 shares of the Parent's common stock for each share of the Company's common stock. As a result, the Company will become a wholly-owned subsidiary of the Parent. Upon completion of the proposed merger, Parent stockholders will own approximately 55 percent of the combined company and the Company's shareholders will own approximately 45 percent of the combined company, on a fully diluted basis. The proposed merger is subject to approval by the respective shareholders of the Parent and the Company, as well as customary closing conditions and regulatory approvals. If the Company terminates the proposed Agreement and Plan of Merger, under certain limited conditions, the Company could owe a termination fee of $6.5 million. The proposed merger is estimated to be completed during the second quarter of the Company's 2008 fiscal year.

In October 2007, the Company entered into a new five year Tissue Procurement, Processing and Supply Agreement with Allosource, Inc. whereby Allosource will provide the Company with various human tissues used in the Company's dental and spinal product lines.

19. SELECTED QUARTERLY FINANCIAL DATA *(Unaudited)*

The following is a summary of unaudited quarterly financial results for the year ended September 30, 2007:
(In Thousands, Except Per Share Data)

	2007 QUARTER ENDED			
	12/31/06	**03/31/07**	**06/30/07**	**09/30/07**
Revenues	$ 11,463	$ 13,017	$ 14,163	$ 15,176
Gross Profit	7,042	7,745	8,426	7,597
Operating Expenses	6,330	6,372	6,763	7,810
Operating income (loss)	712	1,373	1,663	(213)
Income tax expense (benefit)	73	87	(4,516)	184
Net income (loss)	361	930	5,907	(440)
Comprehensive income	763	1,039	6,015	230
Earnings (loss) per share				
Basic	$ 0.02	$ 0.06	$ 0.32	$ (0.02)
Diluted	$ 0.02	$ 0.05	$ 0.30	$ (0.02)

	2006 QUARTER ENDED			
	12/31/05	**03/31/06**	**06/30/06**	**09/30/06**
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)	$ -	$ (0.07)	$ 0.04
Diluted	$ (0.01)	$ -	$ (0.07)	$ 0.04

Tutogen Medical, Inc.
Schedule II — Valuation and Qualifying Accounts
Years ended September 30, 2007, 2006 and 2005

	Balance at Beginning of Period	Additions (Reversals) Charged to (Credited) to Costs and Expenses	Deductions *(1)*	Balance at End of Period
Allowance for doubtful accounts:				
Year ended September 30, 2007	**$ 483**	**$ 295**	**$ (1)**	**$ 777**
Year ended September 30, 2006	462	19	(2)	483
Year ended September 30, 2005	192	308	38	462
Allowance for product returns				
Year ended September 30, 2007	**$ 0**	**$ 71**	**$ 25**	**$ 46**
Year ended September 30, 2006	244	0	244	0
Year ended September 30, 2005	241	183	180	244
Valuation allowance for net deferred tax assets:				
Year ended September 30, 2007	**$ 6,166**	**$ 0**	**$ 6,166**	**$ 0**
Year ended September 30, 2006	6,309	(143)	0	6,166
Year ended September 30, 2005	4,523	1,786	0	6,309

(1) Net write-offs, recoveries and adjustments for foreign currency translation.