TUTOGEN MEDICAL INC
Form S-1/A
February 20, 2007

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As filed with the Securities and Exchange Commission on February 20, 2007
Registration No. 333-139738

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
AMENDMENT NO. 1
FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
TUTOGEN MEDICAL, INC.

(Name of small business issuer in its charter)

Florida	**5047 8731**	**59-3100165**
(State or jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

13709 Progress Boulevard, Alachua, Florida 32615
Telephone: (386) 462-0402

(Address and telephone number of principal executive offices)
13709 Progress Boulevard, Alachua, Florida 32615

(Address and principal place of business or intended principal place of business)
Guy Mayer, President
13709 Progress Boulevard
Alachua, Florida 32615
Telephone: (386) 462-0402

(Name, address and telephone number of agent for service)
Copy of Communications to:
Williams Schifino Mangione & Steady, P.A.
Attn: William J. Schifino, Sr., Esq.
One Tampa City Center, Suite 3200, Tampa, Florida 33602
Telephone: (813) 221-2626

Approximate date of proposed sale to the public: From time to time after the effective date of this registration statement.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered[1]	Proposed maximum offering price per unit[2]	Proposed maximum aggregate offering price	Amount of registration fee[2]
Common Stock	582,524 shs.[3]	$7.15	$4,165,047	$446
	175,000 shs.[4]	$7.15	$1,251,250	$134
Total	757,524 shs.		$5,416,297	$580

(1) An indeterminate number of additional shares of common stock shall be issuable pursuant to Rule 416 to prevent dilution resulting from stock splits, stock dividends or similar transactions and in such an event the number of shares registered shall automatically be increased to cover the additional shares in accordance with Rule 416 under the Securities Act.

(2) Estimated for the sole purpose of calculating the registration fee pursuant to Rule 457(c) of the Securities Act of 1933, as amended and based upon the

closing price of our common stock on December 21, 2006, as reported on the American Stock Exchange.

(3) Represents shares issuable upon conversion of a subordinated convertible debenture. In accordance with the terms of the debenture, the number of shares included herein was determined assuming: (i) conversion of the entire $3,000,000 principal amount under the convertible debenture at a conversion price of $5.15 per share.

(4) Represents shares issuable upon exercise of warrants.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON THE DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON THE DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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PROSPECTUS **Subject to Completion**
February 20, 2007

703,535 SHARES
TUTOGEN MEDICAL, INC.
COMMON STOCK

This prospectus relates to the resale by the Azimuth Opportunity, Ltd., a British Virgin Islands corporation, (Azimuth or the Selling Stockholder) of up to 757,524 shares of our common stock. Of the shares being offered hereby, up to 582,524 shares are issuable upon conversion of a $3,000,000 subordinated convertible debenture held by Azimuth and 175,000 shares are issuable upon the exercise of warrants granted to Azimuth in connection with a loan of $3,000,000 made to the Company in June 2006. We will not receive any proceeds from the sale of shares of common stock by the Selling Stockholder. We will, however, receive proceeds from the exercise, if any, of the warrants to purchase 175,000 shares. All costs associated with the registration of the shares will be borne by us.

Azimuth may be deemed an underwriter within the meaning of the Securities Act of 1933 in connection with the sale of the common stock covered hereby. With the exception of Azimuth, no other underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. The Selling Stockholder may offer to sell the shares of common stock at fixed prices, at prevailing market prices at the time of sale, at varying prices or at negotiated prices.

Our common stock is quoted on the American Stock Exchange (AMEX) under the symbol TTG . On February 16, 2007, the closing price for our common stock was $8.40 per share.

Our business is subject to many risks and an investment in our common stock will involve a high degree of risk. You should carefully consider the various risk factors described herein beginning on page 5 before investing in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

The date of this prospectus is February ___, 2007

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FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, which relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as may, should, expects, plans, anticipates, believes, estimates, predicts or potential or the negative of these terms or other terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled Risk Factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We base our forward-looking statements on information currently available to us, and we assume no obligation to update them. Statements contained in this Prospectus 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.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the entire prospectus carefully; including the section entitled Risk Factors before deciding to invest in our common stock. As used in this prospectus, Tutogen Medical, Inc. may be referred to as we, us, our, Company and Tutogen.

Our Company

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 throughout the United States and in over twenty (20) other countries.

The Company contracts with independent tissue banks and procurement organizations to provide donated human tissue for processing under the Company s proprietary *Tutoplast*® process. The *Tutoplast*® process utilizes solvent dehydration and chemical inactivation which is applied to two types of preserved allografts: soft tissue; consisting of fascia lata, fascia temporalis, pericardium, dermis, sclera and bone tissue; consisting of various configurations of cancellous and cortical bone material. The *Tutoplast*® processed allografts have been used successfully in more than 1,500,000 procedures performed over the last thirty (30) years.

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, Inc. (Zimmer Dental) and Zimmer Spine, Inc. (Zimmer Spine), subsidiaries of Zimmer Holdings, Inc. (Zimmer Holdings) for the dental and spine markets, Mentor Corporation for breast reconstruction, IOP, Inc. for ophthalmology, Davol, Inc. for hernia, Coloplast Corporation for urology and Sense Medical LLC for ears, nose and throat. In the international markets that we serve, we use a network of independent distributors.

We estimate the worldwide market for our present products exceeds $1.25 billion, including all procedures in the field of use. The Company s existing tissue supply network, established processing facilities and proven *Tutoplast*® technology provide the foundation for continued revenue growth into fiscal 2007 and beyond. The future growth may be aided by new sources of tissue, new applications and products and expansion into new markets.

The Company operates two (2) tissue processing facilities: a 26,000 square foot facility in Alachua, Florida and a 33,000 square foot facility in Neunkirchen, Germany. The Alachua, Florida facility is a U.S. Food and Drug Administration registered medical device and biological establishment and is accredited by and a member of the American Association of Tissue Banks. The Neunkirchen, Germany facility is certified according to ISO9001 and EN4600, and is registered as a biological establishment with the U.S. Food and Drug Administration

The Company s executive officers are located at 13709 Progress Boulevard, Alachua, Florida 32615, telephone number (386) 462-0402.

The Offering

On June 30, 2006, the Company issued to Azimuth, an institutional investor, a $3.0 million convertible debenture and warrants for the purchase up to 175,000 shares of common stock for gross proceeds of $3.0 million.

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Pursuant to the terms of the securities purchase agreement, the debenture is convertible into shares of common stock at $5.15 per share, or 582,524 shares, at any time prior to August 1, 2007. In addition, the warrants are exercisable at a price of $5.15 per share at any time at the election of the holder until the earlier of the third anniversary of the date of issuance or upon a change in control of the Company. The debenture, which bears interest at the rate of five percent (5.0%) per year (payable quarterly in arrears), is due August 1, 2007 or upon a change in control of the Company. The debenture is unsecured and ranks junior to all of the Company s existing indebtedness and senior to any additional indebtedness. In addition, the terms of the debenture and warrants provide for anti-dilution adjustments to the conversion and exercise prices in the event that the Company issues equity securities at a price below $5.15 within twelve (12) months from the date of issuance, other than in connection with specified exempt issuances. The $5.15 conversion and exercise prices represent a premium to the market price of Tutogen s common stock on the day prior to the closing of the loan. The Company used the proceeds from the financing for general corporate purposes.

In connection with the financing, the Company entered into a registration rights agreement, under which the Company agreed to file a registration statement with the Securities and Exchange Commission for the resale of the shares of common stock underlying the debenture and the warrant sold in the private placement upon the earlier of December 31, 2006 or the day following the filing of the Company s Annual Report on Form 10-K for the fiscal year ending September 30, 2006. The registration was filed in a timely manner but as a further condition, it must be ordered effective by February 27, 2007. Failure to become effective as required results in payment by the Company to Azimuth for all or part of each thirty (30) calendar day period until cured $45,000 as partial liquidated damages, subject to certain limitations. Such penalties are also payable if sales cannot be made pursuant to the registration statement following its effectiveness.

Number of Shares to be Outstanding after the Offering

As of February 5, 2007, 16,655,855 shares of our common stock were outstanding. Assuming the issuance of all of the shares covered by this offering, there will be 17,413,379 shares of our common stock issued and outstanding.

Estimated Use of Proceeds

The shares of common stock offered by this prospectus are being registered for the account of Azimuth. As a result, all proceeds from the sale of the common stock by Azimuth will go to the Selling Stockholder and we will not receive any proceeds from such sale. We will, however, receive proceeds from the exercise, if any, of the warrant to purchase 175,000 shares of common stock. Any proceeds we receive from the exercise of the warrants will be used for working capital purposes.

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Summary of Financial Data

The summarized financial data presented below is derived from and should be read in conjunction with our audited financial statements for the fiscal years set forth below. The following data should also be read in conjunction with the information contained in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Year Ended September 30,					Three Months Ended December 31, (Unaudited)	
	2002	2003	2004	2005	2006	2005	2006
	(In thousands, except per share data)						
Statement of Operations Data:							
Revenue	$20,747	$30,260	$29,330	$31,860	$37,947	$ 8,034	$11,463
Gross margin %	60%	67%	60%	37%	57%	59%	61%
Operating (loss) income	1,666	5,265	3,158	(7,227)	(287)	(243)	712
Net (loss) income	901	3,707	1,133	(7,017)	(589)	(81)	361
Basic earnings (loss) per share	0.06	0.24	0.07	(0.44)	(0.04)	(0.01)	0.02
Diluted earnings (loss) per share	0.06	0.23	0.07	(0.44)	(0.04)	(0.01)	0.02
Average shares outstanding for basic (loss) earnings per share	15,114	15,495	15,734	15,919	16,027	15,945	16,390
Average shares outstanding for diluted (loss) earnings per share	15,960	16,095	16,469	15,919	16,027	15,945	18,025

	September 30,					December 31, (Unaudited)	
	2002	2003	2004	2005	2006	2005	2006
Balance Sheet Data:							
Working capital	$10,856	$15,342	$17,471	$ 8,433	$ 8,215	$ 7,768	$ 8,485
Total assets	23,748	29,962	33,536	26,205	38,917	26,413	41,424
Long-term debt	693	728	827	814	4,770	769	4,744
Stockholders equity	13,928	17,606	21,272	13,722	15,221	13,579	17,227

The Company adopted SFAS No. 123R in the year ended September 30, 2006. The impact of this adoption is discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations below within the General and Administrative Expenses section.

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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 prospectus in evaluating our Company and its business before purchasing shares of our Company s common stock. Our business, operating results and financial condition could seriously be harmed due to any of the following risks. The risks described below are not the only ones facing our Company. Additional risks not presently known to us may also impair our business operations. You could lose all or part of your investment due to any of these risks.

We depend heavily upon a limited number of sources of human tissue, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to process and distribute allografts.

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

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

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

We are highly dependent upon independent distributors to generate our revenues.

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

Zimmer Dental and Zimmer Spine each provide nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for our line of dental and spinal allografts. If our relationship with such companies is terminated or further 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.

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

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

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

The National Organ Transplant Act (NOTA) could be interpreted in a way that could reduce our revenues and income in the future.

Some aspects of our business are subject to additional local, state, federal or international regulation. Changes in the laws or new interpretations of existing laws could negatively affect our business, revenues or prospects, and increase the costs associated with conducting our business. The procurement and transplantation of allograft tissue is subject to federal regulation under the National Organ Transplant Act, or NOTA, a criminal statute that prohibits the purchase and sale of

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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 allograft and xenograft 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.

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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.

THE OFFERING

This prospectus relates to the resale by Azimuth of up to 757,524 shares of our common stock as follows:

(a) Up to 582,524 shares of common stock which are issuable upon conversion of $3,000,000 subordinated convertible debentures.

(b) Up to 175,000 shares of common stock to which are issuable upon exercise of warrants.

The Selling Stockholder may offer to sell the shares of common stock covered by this prospectus on the trading market of the American Stock Exchange or in private transactions or any other method permitted under applicable law. These sales may be at fixed or negotiated prices. We will not receive any proceeds from the resale of shares of our common stock by the Selling Stockholder.

USE OF PROCEEDS

The shares of common stock offered by this prospectus are being registered for the account of the Selling Stockholder named in this prospectus. As a result, all proceeds from the sales of the common stock will go to the Selling Stockholder and we will not receive any proceeds from the resale of the common shares by the Selling Stockholders. We will, however, receive proceeds from the exercise, if any, of the warrants held by Azimuth. All costs associated with this registration statement and prospectus will be incurred by us.

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MARKET FOR COMMON STOCK

The Company s common stock is traded on AMEX, under the symbol TTG . The quotations set forth below reflect inter-dealer prices, without retail mark-up, markdown, or commission, and do not necessarily reflect actual transactions. Set forth below is the range high and low closing price information for the Company s common stock for the periods indicated.

	High	Low
Fiscal 2005		
Quarter Ended December 31, 2004	$3.13	$2.24
Quarter Ended March 31, 2005	$2.60	$2.30
Quarter Ended June 30, 2005	$2.42	$2.11
Quarter Ended September 30, 2005	$4.56	$2.35
Fiscal 2006		
Quarter Ended December 31, 2005	$4.40	$2.62
Quarter Ended March 31, 2006	$5.00	$2.92
Quarter Ended June 30, 2006	$5.20	$4.55
Quarter Ended September 30, 2006	$6.24	$4.21
Fiscal 2007		
Quarter Ended December 31, 2006	$7.20	$4.32
Quarter (through February 16, 2007)	$8.40	$6.24

On February 16, 2007, the closing price of our common stock was $8.40 per share.

As of February 16, 2007, there were approximately 710 stockholders of record of the Company s common stock. Our registrar and transfer agent is Computershare Investor Services, 7530 Lucerne Drive, Suite 100, Cleveland, Ohio 44130.

Dividends

We have not paid any cash dividends to date and do not anticipate or contemplate paying cash dividends in the foreseeable future. We currently intend to retain any future earnings to fund the development and growth of our business.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated statements of operations and balance sheets for the periods indicated and have been derived from our consolidated financial statements included elsewhere in this prospectus. The selected financial data is qualified by reference to and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year Ended September 30,					Three Months Ended December 31, (Unaudited)	
	2002	2003	2004	2005	2006	2005	2006
	(In thousands, except per share data)						
Statement of Operations Data:							
Revenue	$20,747	$30,260	$29,330	$31,860	$37,947	$ 8,034	$11,463
Cost of revenue	8,434	10,195	11,852	20,129	16,336	3,329	4,421
Gross profit	12,313	20,065	17,478	11,731	21,611	4,705	7,042
Operating expenses:							
General and administrative	3,287	4,482	4,151	5,790	7,803	1,662	2,362
Distribution and marketing	6,294	8,835	8,737	11,509	12,261	2,859	3,441
Research and development	886	826	1,432	1,659	1,834	427	527
Litigation		657	(406)				
Total operating expenses	10,467	14,800	13,914	18,958	21,898	4,948	6,330
Provisions for (benefit of) income taxes	778	1,137	1,306	(436)	(194)	(106)	73
Net income (loss)	901	3,707	1,133	(7,017)	(589)	(81)	361
Comprehensive income (loss):							
Foreign currency translation gain (loss)	253	1,006	2,167	(570)	715	(203)	402
Comprehensive income (loss)	1,154	4,713	3,300	(7,587)	126	(284)	763
Average shares outstanding for	15,114	15,495	15,734	15,919	16,027	15,945	16,390

basic earnings (loss) per share							
Basic earnings (loss) per share	0.06	0.24	0.07	(0.44)	(.04)	(0.01)	0.02
Average shares outstanding for Diluted earnings (loss) per share	15,960	16,095	16,469	15,919	16,027	15,945	18,025
Diluted earnings (loss) per share	0.06	0.23	0.07	(0.44)	(.04)	(0.01)	0.02

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	September 30,				December 31, (Unaudited)	
	2002	2003	2004	2005	2006	2005	2006
Balance Sheet Data:							
Working capital	$ 10,856	$ 15,342	$ 17,471	$ 8,433	$ 8,215	$ 7,768	$ 8,485
Total assets	23,748	29,962	33,536	26,205	38,917	26,413	41,424
Long-term debt	693	728	827	814	4,770	769	4,744
Stockholders equity	13,928	17,606	21,272	13,722	15,221	13,579	17,227

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion together with Selected Consolidated Financial Data and our consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements about our business and operations, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those we currently anticipate as a result of many important factors, including the factors we described under Risk Factors, and Forward-Looking Statements elsewhere in this prospectus.

General Background

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 throughout 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 for the dental and spine markets, Mentor, Inc. for breast reconstruction, IOP, Inc. for ophthalmology, Davol for hernia, Coloplast for urology and Sense Medical for ears, nose and throat. In all other markets that we serve, we use a network of independent distributors.

Critical Accounting Policies

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

Share-Based Compensation

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

Prior to the first quarter of fiscal year 2006, we used historical stock price volatility in preparing our pro forma information under SFAS 123. Under SFAS 123R, we use a combination of historical and implied volatility to

establish the expected volatility assumption based upon our assessment that such information is more reflective of current market conditions and a better indicator of expected future volatility. SFAS 123R also requires forfeitures to be estimated at the

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time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate expected forfeitures, as well as the expected term of awards, based on historical experience. Future changes in these assumptions, our stock price or certain other factors could result in changes in our share-based compensation expense in future periods.

Inventories

Inventories are valued at the lower of cost or market. Work in process and finished goods includes costs attributable to direct labor and overhead. Impairment charges for slow moving, excess and obsolete inventories are recorded based on historical experience, current product demand including meeting periodically with distributors, regulatory considerations, industry trends, changes and risks and the remaining shelf life. As a result of this analysis, the Company records an allowance to reduce the carrying value of any impaired inventory to its fair value, which becomes its new cost basis. If the actual product life cycles, demand or general market conditions are less favorable than those projected by management, additional inventory impairment charges may be required which would affect future operating results due to increases costs from the resulting adjustment. The adequacy of these impairment charges is evaluated quarterly.

Revenue Recognition and Accounts Receivable

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. Oral or written purchase authorizations are generally obtained from customers for a specified amount of product at a specified price. Title transfers at the time of shipment. Customers are provided with a limited right of return. Revenue is recognized at shipment. Reasonable and reliable estimates of product returns are made in accordance with the Financial Accounting Standards Board Statement of Financial Accounting Standard (SFAS) No. 48 and allowances for doubtful accounts are based on significant historical experience. Revenue from distribution fees includes nonrefundable payments received as a result of exclusive distribution agreements between the Company and independent distributors. Distribution fees under these arrangements are recognized as revenue notably to approximate services provided under the contract. Recognition of revenue commenced over the term of the distribution agreement upon delivery of initial products.

Valuation of Deferred Tax Asset

We record valuation allowances to reduce the deferred tax assets to the amounts estimated to be recognized. While we consider taxable income in assessing the need for a valuation allowance, in the event we determine it is more likely than not that 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. We recorded a deferred tax asset valuation allowance of $6.1 million and $6.3 million at September 30, 2006 and 2005, respectively; representing 100% of existing U.S. net deferred tax assets.

Three Months Ended December 31, 2006 Compared to Three Months Ended December 31, 2005 (Unaudited)

Revenue and Gross Margin

Revenue for the quarter end December 31, 2006 increased to $11.5 million from $8.0 million in 2005, or 43%. The U.S. revenues were $8.1 million or 50% higher than the 2005 revenues of $5.4 million. The increase in U.S. revenues was fueled by the continuing increase in the demand for the Company s TUTOPLAST(R) bone products for dental applications sold by Zimmer Dental, the Company s distributor. In February 2006, the Company developed, in association with Zimmer Dental, a new pericardium product, and in September 2006, a new dermis product to augment ridge restoration. Sales of dental products increased 36% from a year ago. Spine revenues increased by $.9 million as the Company continues to supply Zimmer Spine with two new Spine products, Puros C and Puros A, launched at the end of the last fiscal year. Surgical specialties (primarily urology, ophthalmology, hernia, breast reconstruction and ENT) increased by 35% for 2006 compared to 2005 due to the new hernia and breast reconstruction products. The International

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operation had revenues of $3.3 million for the three months ended December 31, 2006, an increase of 27% from the 2005 revenues of $2.6 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 quarter ended December 31, 2006 increased to 61.4% from 58.6% in 2005. The higher margins were due to (1) efficiencies obtained from higher sales and production volume; and (2) the introduction of new products with higher margins.

General and Administrative

General and administrative expenses increased $.7 million for the three months ended December 31, 2006 over the comparable period last year. The increase was due primarily to: 1) an increase of $318,000 in stock option expenses under the Statement of Financial Accounting Standards No. 123R associated with year end grants to employees and the Board of Directors for performance; and, 2) an increase of $200,000 for accounting and other professional costs associated with the Company s year end 10-K filing and an S-1 filing to register shares under the convertible debenture. As a result of the above and as a result of increased revenues, General and Administrative expenses, as a percentage of revenues, remained flat at 21%.

Distribution and Marketing

Distribution and Marketing expenses increased to $3.4 million for the three months ended December 31, 2006 from $2.9 million of the comparable period last year. The increase was due mainly to higher marketing fees paid to Zimmer Dental of $2.2 million in 2006 versus $1.6 million a year ago as dental revenues increased to $5.3 million in 2006 up from $3.9 million in 2005. As a percentage of revenues, Distribution and Marketing expenses decreased from 36% to 30% for the three months ended December 31, 2005 and 2006, respectively. The decrease as a percentage of revenue is due to the 43% revenue growth; partially offset by the increased marketing fees paid to Zimmer Dental.

Research and Development

Research and Development expenses of $.5 million were similar for the three months ended December 31, 2006 to $.4 million for the comparable period last year. As a percentage of revenues, Research and Development expenses remained at 5%.

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. At December 31, 2006, the Company maintained an accrual of $28,000 with respect to final legal costs.

Other Income

Other income increased to $34,000 for the three months ended December 31, 2006 compared to $15,000 for the comparable period last year. This was primarily the result of higher interest income on bank balances.

Interest Expense

Interest expense for the three months ended December 31, 2006 increased to $274,000 from $78,000 for the comparable period last year due to increased borrowings for capital expenditures related to the facility expansion programs in Florida and Germany, interest expense associated with a $3.0 million convertible debenture issued in June 2006 and other short-term borrowings.

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Income Tax Expense

Income tax expense for the three months ended December 31, 2006 totaled $73,000 compared to an income tax benefit of $106,000 for the comparable period last year. The Company continues to record a full valuation allowance on its U.S. operations.

Net Income (Loss)

Net income for the three months ended December 31, 2006 totaled $.4 million, $.02 basic and diluted earnings per share as compared to a net loss of $.1 million or $.01 basic and diluted loss per share for the comparable period last year. The move to profitability between the periods is directly attributable to higher revenues and improved gross margins.

Accounts Receivable

The accounts receivable balance decreased at December 31, 2006 to $5.5 million, down from $6.2 million at September 30, 2006 due to increased collection efforts.

Inventory

The inventory balance increased to $15.0 million at December 31, 2006 from $12.7 million at September 30, 2006. The increase was primarily due to increased inventories associated with the recent introduction of new spine products to meet increasing purchase orders.

Foreign Currency Loss

The Company had a foreign exchange loss for the three months ended December 31, 2006 of $38,000 due to the declining exchange rate of the U.S. dollar against the Euro, coupled with the lower Euro denominated invoices outstanding compared to the three months ended December 31, 2005.

Year Ended September 30, 2006 Compared to Year Ended September 30, 2005

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.

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General and Administrative

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

Distribution and Marketing

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

Research and Development

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

Litigation Contingency

In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company by $406,000 between the Company and a former international distributor. At September 30, 2005, the Company maintained an accrual of $476,000 with respect to the remaining appeal and legal costs. At September 30, 2006, the Company agreed to a settlement of $360,000 resulting from a dispute between the Company and a former international distributor and recorded a change in estimate of approximately $91,000 as a reduction of accrued expenses, which reduced the general and administrative expense for the year. The remaining accrual will be used to settle final nominal legal and court costs.

Other Income

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

Interest Expense

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

Income Tax (Benefit) Expense

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

Net (Loss) Income

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

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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.

Year Ended September 30, 2005 Compared to Year Ended September 30, 2004

Revenue and Gross Margin

Revenue for the year ended September 30, 2005 increased $2.6 million or 9% to $31.9 million from $29.3 million in 2004. The U.S. revenues were $21.8 million or 27% higher than the 2004 revenues of $17.1 million. The increase in U.S. revenues was fueled by the continuing increase in the demand for the company s *Tutoplast*® bone products for dental applications sold by Zimmer Dental (Dental), the Company s marketing distributor. In January 2005, the Company developed, in association with Zimmer Dental, a new bone block to augment ridge restoration. The Dental business increased 100% from a year ago. The spine revenues decreased 36%, primarily due to significant purchases by Zimmer Spine in 2004. The urology business was essentially flat with a decrease of 6% from a year ago as this business is decreasing due to the increased reliance on synthetics for incontinence. However, Mentor continues to do well in the pelvic floor reconstruction market, with a slight increase in revenues for this product line. The ophthalmic business was essentially flat as this is a mature and niche business.

The international operation had revenues of $10.1 million for the year ended September 30, 2005, a decrease of $2.1 million or 17% from the 2004 revenues of $12.2 million. The decrease in revenues was primarily due to the temporary delay in the renewal of the CE marks (European Conformity) on certain products, which was resolved at the end of the first quarter of 2005, the resolution of certain regulatory issues in France and the temporary backlog of xenograft product lines.

Gross margins for the year ended September 30, 2005 decreased to 37% from 60% in 2004. The lower margins were due to several factors, (1), an unfavorable mix of lower margin products from the dental product revenues versus the spine revenues (dental revenues as a percentage of total revenues increased to 43% of total revenues versus 24% a year ago) (2), initial start-up manufacturing costs of $1.6 million, expensed in the third quarter, associated with shifting production of the dental product lines from Germany to the U.S. (the production transfer has been fully completed), (3), the recording in the fourth quarter of $1.0 million for the inventory reserve impact of the voluntary recall of products during fiscal year 2005, (4), the estimated patient testing and other related expenses of $250,000 as a result of the product recall recorded in the fourth quarter of fiscal year 2005.

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Voluntary Recall

On October 12, 2005, the Company issued a voluntary recall of all product units which utilized donor tissue received from BioMedical Tissue Services/BioTissue Recovery Services (BioMedical). This action was taken because the Company was unable to satisfactorily confirm that BioMedical had properly obtained donor consent. The Company quarantined all BioMedical products in its inventory, having a value of $1,035,000 and has notified all customers and distributors of record regarding this action. In connection with this recall, the Company wrote off $1,035,00 of inventory and accrued $250,000 of other related costs during the year ended September 30, 2005.

General and Administrative

General and administrative expenses increased 38% in 2005 to $5.8 million from $4.2 million in 2004. The increase was due to higher compensation costs related to new personnel ($534,000), expenses related to the closing of the New Jersey Corporate Offices ($444,000), expenses related to Sarbanes-Oxley compliance ($118,000), unfavorable translation of Euro-based expenses ($84,000), and other expenses ($26,000). As a result, General and Administrative expenses, as a percentage of revenues, increased from 14% in 2004 to 18% in 2005.

Distribution and Marketing

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

Research and Development

Research and Development expenses increased 16% or $0.3 million in 2005 to $1.7 million. The increase was due to increased development efforts in the dental and spine product areas. As a percentage of revenues, Research and Development expenses remained at 5% in 2005 and 2004.

Litigation Contingency

In 2004, a decision by the court of appeal in Germany resulted in a reduction of the original proposed judgment received against the Company by $406,000 between the Company and a former international distributor. At September 30, 2005 and 2004, the Company maintained an accrual of $476,000 with respect to the remaining appeal and legal costs.

Other Income/Expense

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

Interest Expense

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

Income Tax (Benefit) Expense

Income Tax (Benefit) Expense is mainly due to the income tax benefit on the loss from the Company s foreign operations. The Company continues to record a full valuation allowance on its U.S. operations.

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Net (Loss) Income

As a result of the above, net loss for the year ended September 30, 2005 totaled $7.0 million, $0.44 basic and diluted loss per share as compared to a net income of $1.1 million, $0.07 basic and diluted earnings per share for 2004. As a percentage of revenues, net income decreased from 3.9% in 2004 to a net loss of twenty-two percent (22%) in 2005.

Concentration of Risk

Distribution

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

Tissue Supply

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

Trade Receivables

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

Foreign Currency

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

Liquidity and Capital Resources

At September 30, 2006 and 2005 the Company had working capital of $8.2 million and $8.4 million, respectively. At December 31, 2006, the Company had working capital of $8.5 million.

Cash and cash equivalents remained consistent from $3.6 million in 2005 to $3.5 million in 2006. Cash and cash equivalents increased to $3.8 million at December 31, 2006.

The Company had $1.8 million and $559,000 in cash used by operating activities for the years ended September 30, 2006 and 2005, respectively. The primary reason for the increased use of cash was due to building inventory for new products. The Company had $83,000 in cash provided by operating activities for the three months ended December 31, 2006 compared to a negative cash flow from operations of $1.5 million for the comparable period last year. The primary reason for the positive cash flow was net income provided by operating activities and increased collection efforts in accounts receivable offset by an increase in inventory associated with new spine products.

Net cash used in investing activities, representing purchases of capital expenditures, was $6 million in 2006 and $1.7 million in 2005. The continued spending on capital expenditures is due to the facility expansion in the Florida and German manufacturing locations and manufacturing equipment. Net cash used in investing activities, representing

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purchases of capital expenditures, was $1.0 million for the three months ended December 31, 2006 and $.6 million for the comparable period for the prior year. The continued spending on capital expenditures is due to final costs associated with the new facility expansion for the German manufacturing location and an increase in manufacturing equipment to support increased sales. The capital expenditures were offset by proceeds from the exercise of stock options during the quarter.

Net cash from financing activities in 2006 and 2005 totaled $7.9 million and $1.0 million, respectively, from proceeds related to revolving credit facilities, a $3.0 million convertible debenture, additional long-term debt and capital leases. Net cash from financing activities increased to $1.2 million from $413,000 for the three months ending December 31, 2006 and 2005, respectively. The increase was primarily due to proceeds from the exercise of stock options during the quarter.

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 million for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 8.05% to 9.5%. At December 31, 2006 the Company had outstanding borrowings of 1.4 million Euros or $1.8 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, 2007. At December 31, 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 December 31, 2006, the Company was in compliance with this covenant.

On June 30, 2006, the Company issued a $3 million convertible debenture with detachable warrants to purchase up to 175,000 shares of its common stock. The debenture bears interest at 5.0% per year, is due upon the earlier of 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 condensed consolidated balance sheet at December 31, 2006. In addition, $205,000 of direct costs incurred at inception relating to the issuance of the convertible debenture was recorded as debt issuance costs in prepaids and other current assets, which will be amortized to interest expense over the one-year term of the debenture. As of December 31, 2006, the Company was in compliance with the terms and conditions of the convertible debenture.

Senior debt consists of three loans with a German bank. The first loan ($569,000 as of December 31, 2006) has an interest rate of 5.75%, payable monthly, maturing March of 2011. The second loan ($1,733,000 as of December 31, 2006) has an interest rate of 5.15%, payable quarterly, maturing March of 2012. The third loan ($1,452,000 as of December 31, 2006) has an interest rate of 5.6%, payable semi-annually, maturing November of 2018.

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, $.9 million as of December 31, 2006) is payable monthly at $55,000 per month and matures April of 2008. The lease is secured by leasehold improvements and equipment located at the Company s Florida tissue processing facility. The second lease (initially $224,000 and $64,000 as of December 31, 2006) is payable at $22,000 quarterly and matures September of 2007. The lease is secured by equipment located at the Company s Florida tissue processing facility. As of December 31, 2006, the Company is in compliance with the terms and conditions of the Capital lease debt.

The Company s future minimum commitments and obligations under current operating leases for its offices and manufacturing facilities in the U.S. and Germany, as well as several leases related to office equipment and automobiles through 2010 total $2,111,000. The Company considers these commitments and obligations to be reasonable in order to maintain the current and future business requirements.

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The following table summarizes the Company s contractual obligations as of September 30, 2006:

	Total	2007	2008	2009	2010	2011	2012+
				(In thousands)			
Long Term debt (1)	$ 4,770	$ 1,097	$ 1,033	$ 533	$ 545	$ 482	$ 1,080
Operating Lease obligations	$ 2,111	$ 988	$ 748	$ 343	$ 32	$ 0	$ 0
Short-term borrowings (1)	$ 5,783	$ 5,783	$ 0	$ 0	$ 0	$ 0	$ 0
	$ 12,664	$ 7,868	$ 1,781	$ 876	$ 577	$ 482	$ 1,080

(1) Does not include interest

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 2011 total $2,649,000. 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 December 31, 2006:

	Total	2007	2008	2009	2010	2011	2012+
				(In thousands) (Unaudited)			
Long Term debt (1)	$ 4,744	$ 1,001	$ 920	$ 560	$ 572	$ 507	$ 1,184
Operating Lease obligations	$ 2,649	$ 1,207	$ 868	$ 431	$ 97	$ 46	$ 0
Short-term borrowings (1)	$ 6,459	$ 6,459	$ 0	$ 0	$ 0	$ 0	$ 0
	$ 13,852	$ 8,667	$ 1,788	$ 991	$ 669	$ 553	$ 1,184

(1) Does not include interest

The Company maintains current working capital credit lines totaling 1.5 million Euros (approximately $2 million) with two German banks and a $1.5 million credit line with a U.S. bank. At September 30, 2006, the Company had outstanding balances of $1.0 million and $1.5 million for the working capital lines in Germany and the U.S., respectively. At December 31, 2006, the Company had outstanding balances of $1.8 million and $1.5 million for the working capital lines in Germany and the U.S., respectively. Management believes that the working capital as of December 31, 2006, together with the revolving lines of credit, will be adequate to fund ongoing operations. While the Company believes that it continues to make progress in these areas, there can be no assurances that changing governmental regulations will not have a material adverse effect on results of operations or cash flow. The Company may seek additional financing to meet the needs of its long-term strategic plan. The Company can provide no assurance that such additional financing will be available, or if available, that such funds will be available on favorable terms. The Company s ability to generate positive operational cash flow is dependent upon increasing processing revenue through increased recoveries by tissue banks in the U.S. and Europe, controlling costs, and the development of additional markets and surgical applications for its products worldwide.

Off Balance Sheet Arrangement

Guarantees In October 2005, the Parent Company agreed to provide a guarantee up to 4 million Euros for the Company s German subsidiary s debt to a German bank. At September 30, 2006, total debt outstanding to the German bank was 3.2 million Euros. At December 31, 2006, total debt outstanding to the German bank was 3.7 million Euros. The Company has no other off-balance sheet arrangements.

DESCRIPTION OF BUSINESS

Tutogen Medical, Inc., a Florida corporation, was formed in 1985, and with its consolidated subsidiaries (collectively, the Company or Tutogen), develops, manufactures and markets sterile biological implant products made from human (allograft) and animal (xenograft) tissue. Surgeons use our products to repair and promote the healing of a

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wide variety of bone and other tissue defects, including dental, spinal, urology, ophthalmology, head, neck and general surgery procedures. Our products are distributed throughout the United States and in over twenty (20) other countries.

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, and 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.

In contrast to other processors using freeze-drying, deep freezing or cryopreservation for human tissues, the *Tutoplast*® process utilizes a technique in which tissues are soaked and washed in a series of aqueous solutions and organic solvents, removing water and substances that could cause rejection or allergic reaction. This technique dehydrates the tissue, while maintaining its structure and allowing it to act as a scaffold after implantation, which is subsequently replaced by newly formed autologous tissue. During processing, the tissues are treated with agents shown to inactivate viruses such as hepatitis and HIV (the virus responsible for AIDS), rendering the allografts safe for the recipient. Soft tissue is also treated with chemicals shown to be effective against prions, the agent causing Creutzfeldt-Jakob Disease (CJD). Once packaged, tissues are terminally sterilized by low dosage gamma radiation.

An analysis of our revenues is as follow:

	Year Ended September 30,			Three Months Ended December 31, (Unaudited)	
	2004	2005	2006	2005	2006
			(In thousands)		
Dental	$ 6,893	$ 13,785	$ 17,616	$ 3,885	$ 5,286
Spine	4,850	3,128	2,877	374	1,293
Surgical Specialties	5,383	4,839	4,937	1,150	1,554
Total U.S.	$ 17,126	$ 21,752	$ 25,430	$ 5,409	$ 8,133
Germany	$ 3,521	$ 1,980	$ 2,851	$ 795	$ 891
France	2,121	1,337	1,672	274	403
Rest of World (ROW)	6,001	6,220	7,472	1,430	1,899
Other Distribution Fees	561	571	522	126	137
Total International	$ 12,204	$ 10,108	$ 12,517	$ 2,625	$ 3,330
Total Consolidated	$ 29,330	$ 31,860	$ 37,947	$ 8,034	$ 11,463

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

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

Following assignment to a manufacturing work order, tissue materials go through appropriate preprocessing operations and into the multi-stage *Tutoplast*® process. This process removes blood, lipids and extraneous materials, inactivates viruses and prions, and breaks down RNA and DNA into fragments not capable of replication and disease transmission while preserving the biological and mechanical properties. The *Tutoplast*® process yields a dehydrated, semi-processed product that may be stored at room temperature for extended periods of time. This tissue is subsequently processed to size and/or shape and packaged for terminal sterilization. All Tutogen packaged products are subjected to low dose gamma irradiation, which further enhances tissue safety and eliminates ancillary contamination that may be present from pre-sterilization handling. This terminal sterilization is performed by a third-party contractor utilizing a validated cycle.

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

Tutogen operates two tissue processing facilities; a 26,000 square foot facility in Alachua, Florida and a 33,000 square foot facility in Neunkirchen, Germany. Major expansion projects were recently completed at both facilities, and will be in service by the first calendar quarter of 2007. These expansion projects are intended to ensure the availability of sufficient production capacity to address the increasing demand for the Company s allograft and xenograft products in the foreseeable future. The Alachua, Florida facility is a U.S. Food and Drug Administration registered medical device and biological establishment and is accredited by and a member of the American Association of Tissue Banks. The Neunkirchen, Germany facility is certified according to ISO9001 and EN4600, and is registered as a biological establishment with the U.S. Food and Drug Administration

Quality Assurance and Regulatory Affairs

The Company maintains comprehensive quality assurance and regulatory compliance programs that provide oversight for all pertinent aspects of the Company s day-to-day operational activities. Among the responsibilities of the QA/RA organizations are:

- Maintenance of an extensive documentation and change-control system (specifications, standard operating procedures and engineering drawings)
- Internal and external auditing for compliance with international and domestic regulatory body or accrediting organization regulations or requirements
- Review and approval of donor medical record information and screening/test documentation
- Product and process document review and release for distribution
- Evaluation and follow-up of all Tutogen-related product complaints
- Management of Corrective and Preventive Action programs to reduce or eliminate any identified non-conformances

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

Marketing and Distribution

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Tutogen s products and processing services are provided globally through a combination of worldwide distributors, direct representatives and local distributors. Tutogen s personnel, along with distributors and their representatives, conduct product training sessions, make joint customer calls, set objectives and evaluate their representatives performance. Personnel also call on select physicians and key hospital accounts in order to provide needed clinical and technical information services. The overall strategy is to work with each global distributor to expand penetration into currently covered regions, develop additional global opportunities, and to broaden the product portfolio with procedure-specific products. In markets not covered by its global distributors, Tutogen s focus is on adding local distributors or direct operations capable of market penetration.

Approximately 70% of the Company s revenues are derived within the United States while the remaining international sales are derived primarily from Europe. Since Tutogen s foreign donor procurement practices are in full compliance with the donor suitability standards of the AATB and the U.S. Food and Drug Administration (FDA), the Company has worked closely with its distributors to expand into numerous market opportunities world wide. Tissue grafts are used in dental, spine, urology, ophthalmology, hernia, general surgery, head and neck applications, and plastic and reconstructive surgeries. Future objectives are to match this penetration into additional international and specialty markets, using either *Tutoplast*® processed human allograft or xenograft tissue implants.

The Company s U.S. marketing efforts have concentrated on building a marketing and distribution organization, capable of supporting its various distributors. The Company has entered into several exclusive marketing and distribution agreements with global medical device companies. These agreements have established exclusive distribution for *Tutoplast*® processed implants in specialized indications and surgical applications, for select international markets.

Zimmer Dental and Zimmer Spine, subsidiaries of Zimmer Holdings, 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 46% of total consolidated and 69% of total U.S. revenues for the fiscal year ended September 30, 2006. Zimmer Dental represents the products to the end user and the Company ships and bills the customer directly. Distribution fees earned pursuant to the agreements are recognized ratably over the terms of these respective agreements. During 2006, the Company expanded its relationship with Zimmer Dental by adding pericardium and dermis soft tissue grafts for dental applications. The additions of these new products provide Zimmer Dental with a full line of products for the dental surgeons. During 2006, the Company extended Zimmer Dental s exclusivity into select international markets.

Also starting September 2000, Zimmer Spine began representing Tutogen bone products for applications in the spine market. Initially, Tutogen shipped and billed the customers directly, but in April 2003 the Company entered into an exclusive license and distribution agreement with Zimmer Spine. Effective with this agreement Zimmer Spine became a stocking distributor , therefore Zimmer Spine now purchases the Company s products and distributes and invoices the customer directly. Zimmer Spine distributes both traditional bone and specialized bone products processed with the Company s *Tutoplast*® process. Revenues from Zimmer Spine for 2006 represented 8% and 11%, of total consolidated and U.S. revenues, respectively.

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

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

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

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

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

Internationally, the Company concentrates on an in-depth penetration of markets with major needs not covered by Tutogen s global distributors. In Europe, the specific focus is on countries such as Germany, France, Italy, Spain and the U.K., and in major specialty areas, such as dental, orthopedics and tissue processing. Approximately 40% of the total international sales are xenograft products. The Company believes that through a combination of international distribution strategies, Tutogen can increase its penetration of the international markets for processed tissue.

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

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)	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
Sense Medical	ENT	$55.0 million	Fascia lata Fascia temporalis Pericardium	Tympnoplasty Rhinoplasty Septoplasty

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Tissue Procurement

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

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

The Company embarked on a program in 1993 to develop xenografts (tissue derived from animals) as an allograft substitute. As with allografts, xenografts processed using the Company s proprietary *Tutoplast*® process have their biomechanical properties and remodeling capacity preserved with removal of antigenicity and infection risk. Studies have shown that *Tutoplast*® processed xenografts are at least equivalent to allografts as demonstrated by actual clinical use and laboratory studies. To date, the Company has received CE-Marks, the European equivalent to an FDA medical device approval, for bovine pericardium (1998), bovine cancellous bone (1997) and bovine compact (cortical) bone (1999), which permits distribution throughout Europe of products derived from such tissues. Approximately 40% of the total products sold internationally are bovine. Tutogen Germany currently obtains bovine material from a closed herd in an internationally approved source country. In the US, the Company received FDA 510(k) clearance for bovine pericardium in 2000, allowing the Company to market the first xenograft tissues (Tutopatch®) domestically, for indications of general and plastic surgery. Based on such approvals, Tutogen Germany will be able to supply bovine products in the US. The Company is currently evaluating the introduction and timing of bovine products in the US. The unique biomechanical properties of bovine tissue, combined with the absence of the supply constraints associated with allografts, permits the use of xenograft tissues in areas that cannot be optimally addressed with human tissue.

Tutogen allograft tissue recovery providers are FDA registered, state licensed and accredited by the AATB, as appropriate. Tissues are not purchased from these companies, but rather the providers are reimbursed for the costs incurred in the tissue recovery process itself, at the time of delivery. Due to the growing demand for and the limited supply of allograft tissue, the Company is continually seeking to form additional alliances with reputable hospital, tissue bank and organ procurement organization tissue recovery firms and entered into multiple new arrangements during 2006.

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

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

Competition

Tutogen considers itself a leader in safe bioimplants for tissue repair. Tutogen s competitive advantage is based

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on its *Tutoplast*® process of tissue preservation and viral inactivation. The *Tutoplast*® process consists of multiple steps that assure a safe, viable product and, at the same time, preserves the tissue structure, biomechanics and remodeling characteristics. The *Tutoplast*® process is very robust, and has been proven effective in removing antigenicity and inactivating conventional and unconventional viruses and prions. The implants are terminally sterilized, have a five (5) year shelf life, and can be stored at room temperature. The *Tutoplast*® process has an outstanding safety record. Since its introduction over thirty (30) years ago, more than 1,500,000 procedures have been successfully performed using *Tutoplast*® processed tissues, with no known complications from disease transmission or tissue rejection attributable to the implants. *Tutoplast*® processed implants have been described in more than 400 published scientific papers and peer-reviewed articles.

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

The industry in which the Company operates is highly competitive. Processors of allograft tissue for transplantation in the U.S. include commercial manufacturers such as Osteotech, Inc., RTI and LifeCell, Inc., companies well established in the fields of processing and distribution of bone and soft tissue implants, which have substantially greater financial resources than the Company. Not-for-profit tissue banks that procure and process tissue for distribution are considered competitors for certain applications in certain markets. Management believes that the *Tutoplast*® process, with its impressive record for safety in the surgical community, gives the Company a marked advantage over its competitors. However, due to government regulation, disrupted sources of tissue supply and increasing competition, there can be no assurance that the Company will be able to continue to compete successfully. In addition, there can be no assurance that in the future the Company s allografts will be able to compete successfully with new tissue substitutes being developed by other companies.

Growth Strategy

The Company estimates the worldwide market for its present products to be over $1.25 billion including all procedures in the various fields of use. The Company s existing tissue supply network, established processing facilities and proven *Tutoplast*® technology provides the foundation for continued growth into the foreseeable future. Future growth will be aided by new sources of tissue, new procedures and products, and expansion into new markets. The Company will focus on applications for both human allograft and xenograft tissue implants.

Besides the Company s internally developed new products and technology, a major component of the Company s growth strategy will be expanding its collaborations with each global distributor. Tutogen will continue to work with each organization to evaluate opportunities for new products and applications, and to determine the potential for international expansion. The ultimate goal is to provide each distributor with a full line of procedure specific implants, for their respective fields of use, and to leverage their sales strength in select international markets.

Currently, the Company s focus is on the introduction of new products and applications for *Tutoplast*® processed tissues. In January 2005, the Company developed, in association with Zimmer Dental, a new bone block to augment ridge restoration. In the U.S. the Puros block graft has been well accepted and is highlighted in various Zimmer Dental training courses. Globally, similar products processed from xenograft tissue, has helped generate growth as the Company focuses on expanding the international market for dental products. Additionally, the Company has developed membranes from *Tutoplast*® processed dermis and pericardium for use as a barrier in dental applications. These products have been used in Europe, and the U.S. launch for pericardium was in February 2006 and for dermis in September 2006. The addition of these new products in the U.S. will provide Zimmer Dental with a full line of products for the dental surgeons.

The spine market for biologic materials was estimated at approximately $656 million in 2005. This allograft market is split between traditional allograft bone (19%), machined specialty grafts (49%), and demineralized bone

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(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 will release these products to the market during 2007. The Company will explore expanding its spinal products internationally during 2007.

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

Internationally, the Company has internally developed a line of *Tutoplast*® machined bone implants for the repair of orthopaedic fractures and soft tissue ruptures. The Tutofix® line of implants was released in Europe in 2004. The current strategy is to broaden its release internationally.

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

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

International Operations

The Company currently has sales in more than 20 countries located primarily in Europe. For the periods set forth below, consolidated sales were derived from outside the United States as follows:

	Year Ended September 30,			Three Months ended December 31, (Unaudited)	
	2004	**2005**	**2006**	**2005**	**2006**
United States	$ 17,126	$ 21,752	$ 25,430	$ 5,409	$ 8,133
International	12,204	10,108	12,517	2,625	3,330