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TUTOGEN MEDICAL INC  
Form 10-Q  
February 13, 2006

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.c. 20549

Form 10-Q

(Mark One)

XX Quarterly Report Pursuant to Section 13 or 15(d) of the Securities  
--- Exchange Act of 1934.

For the period ended December 31, 2005.

--- Transition Report Pursuant to Section 13 or 15(d) of the Securities  
Exchange Act of 1934.

For the transition period from\_\_ to\_\_.

Commission File Number: 0-16128

TUTOGEN MEDICAL, INC.  
(Exact name of registrant as specified in its charter)

Florida 59-3100165  
(State or other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) Identification No.)

13709 Progress Boulevard, Alachua, Florida 32615  
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (386) 462-0402

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No .  
--- ---

Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No X .  
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As of January 15 2006 there were outstanding 15,950,460 shares of Tutogen Medical, Inc. Common Stock, par value \$0.01.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

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### PART I. FINANCIAL INFORMATION

#### Item 1. Financial Statements.

#### TUTOGEN MEDICAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

	(unaudited) December 31, 2005	September 30, 2005
	-----	-----
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 1,834	\$ 3,562
Accounts receivable - net of allowance for doubtful accounts of \$467 in December 2005 and \$462 in September 2005	3,749	3,473
Inventories - net	11,465	10,558
Deferred income taxes	682	695

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Other current assets	622	623
	-----	-----
	18,352	18,911
Property, plant and equipment, net	6,904	6,612
Deferred income taxes	1,703	1,619
	-----	-----
TOTAL ASSETS	\$ 26,959	\$ 27,142
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and other liabilities	\$ 5,997	\$ 6,273
Accrued commissions	2,128	1,765
Short-term borrowing	1,436	1,048
Current portion of deferred distribution fees	558	589
Current portion of long-term debt	185	184
	-----	-----
	10,304	9,859
Other Liabilities		
Deferred distribution fees	1,784	1,925
Long-term debt	584	630
Shareholders' Equity	14,287	14,728
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 26,959	\$ 27,142
	=====	=====

See accompanying Notes to Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands except per share data)  
(unaudited)

	Three Months Ended	
	December 31,	
	2005	2004
	-----	-----
REVENUE	\$ 8,034	\$ 7,073
COST OF REVENUE	3,797	3,760
	-----	-----
Gross margin	4,237	3,313
OPERATING EXPENSES		

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General and administrative	1,489	1,142
Distribution and marketing	2,862	2,711
Research and development	427	390
	-----	-----
	4,778	4,243
OPERATING LOSS	(541)	(930)
FOREIGN EXCHANGE GAIN (LOSS)	119	(579)
OTHER INCOME (LOSS)	15	(4)
INTEREST EXPENSE	(78)	(17)
	-----	-----
	56	(600)
LOSS BEFORE INCOME TAX BENEFIT	(485)	(1,530)
Income tax benefit	(106)	(148)
	-----	-----
NET LOSS	\$ (379)	\$ (1,382)
	=====	=====
Comprehensive (loss) income:		
Foreign currency translation adjustments	(203)	286
	-----	-----
COMPREHENSIVE LOSS	\$ (582)	\$ (1,096)
	=====	=====
AVERAGE SHARES OUTSTANDING FOR BASIC AND DILUTED LOSS PER SHARE	15,945,243	15,915,960
	=====	=====
BASIC AND DILUTED LOSS PER SHARE	\$ (0.02)	\$ (0.09)
	=====	=====

See accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(in thousands)  
(unaudited)

	THREE MONTHS ENDED	
	-----	
	DECEMBER 31,	
	-----	
	2005	2004
	----	----
Cash flows from operating activities		
Net loss	\$ (379)	\$ (1,382)
Adjustments to reconcile net loss to net cash used in operating activities:		

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Depreciation and amortization	172	190
Amortization of deferred distribution fees revenue	(139)	(172)
Deferred income taxes	(106)	(148)
Provision for inventory write-downs	(58)	(62)
Share-based compensation	96	-
Changes in assets and liabilities:		
Accounts receivable	(303)	469
Inventories	(903)	359
Other current assets	(4)	633
Accounts payable and other liabilities	(214)	(1,737)
Accrued commissions	363	107
	-----	-----
Net cash used in operating activities	(1,475)	(1,743)
Cash flows used in investing activities		
Investment in a marketable security	-	(491)
Purchase of property and equipment	(554)	(389)
	-----	-----
Net cash used in investing activities	(554)	(880)
Cash flows from financing activities		
Proceeds from issuance of common stock	45	-
Proceeds from short-term borrowings	405	-
Repayment of long-term borrowings	(37)	(34)
	-----	-----
Net cash provided by (used in) financing activities	413	(34)
Effect of exchange rate changes on cash	(112)	793
	-----	-----
Net decrease in cash and cash equivalents	(1,728)	(1,864)
Cash and cash equivalents at beginning of period	3,562	5,063
	-----	-----
Cash and cash equivalents at end of period	\$ 1,834	\$ 3,199
	=====	=====
Supplemental cash flow disclosures		
Interest paid	\$ 41	\$ 17
	=====	=====
Income taxes paid	\$ -	\$ 61
	=====	=====

See accompanying Notes to Consolidated Financial Statements

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CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
YEAR ENDED SEPTEMBER 30, 2005 AND THREE MONTHS ENDED DECEMBER 31, 2005  
(In Thousands, Except for Share Data)

-----  
(Unaudited)  
-----

	Common Stock (\$ .01 par)	Additional Paid-in Capital	Accumulated Other Comprehensive Income (1)	Accu De
BALANCE, OCTOBER 1, 2004	\$ 159	\$ 36,345	\$ 2,248	\$ (
Stock issued on exercise of options	-	36	-	
Net loss	-	-	-	
Foreign currency translation adjustment	-	-	(770)	
	-----	-----	-----	---
BALANCE, SEPTEMBER 30, 2005	159	36,381	1,478	(
Stock issued on exercise of options	1	44	-	
Share-based compensation	-	96	-	
Net loss	-	-	-	
Foreign currency translation adjustment	-	-	(203)	
	-----	-----	-----	---
BALANCE, December 31, 2005	\$ 160	\$ 36,521	\$ 1,275	\$ (
	=====	=====	=====	=====

(1) Represents foreign currency translation adjustments.

See accompanying Notes to Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
December 31, 2005  
(in thousands, except share data)

(1) OPERATIONS AND ORGANIZATION

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

(2) BASIS OF PRESENTATION

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The accompanying unaudited consolidated balance sheet of the Company as of December 31, 2005 and September 30, 2005, the unaudited results of operations for the three months ended December 31, 2005 and 2004, and the unaudited cash flows for the three months ended December 31, 2005 and 2004 have been prepared in conformity with accounting principles generally accepted in the United States of America for interim financial reporting. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments necessary in order to make the financial statements not misleading have been made. Operating results for the three months ended December 31, 2005 are not necessarily indicative of the results, which may be expected for the fiscal year ending September 30, 2006. The interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company included in the Company's Annual Report on Form 10-K for the year ended September 30, 2005.

### (3) NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement No. 123R ("SFAS No. 123R"), Share-Based Payment, that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. The Company is required to comply with SFAS No. 123R for the three months ended December 31, 2005. In March 2005, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin ("SAB") No. 107, Share-Based Payment ("SAB No. 107"), which provides interpretive guidance related to the interaction between SFAS No. 123R and certain SEC rules and regulations, as well as provides the SEC staff's views regarding the valuation of share-based payment arrangements. See Footnote 4 regarding the impact of these pronouncements on the Company's financial statements.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43. SFAS No. 151 requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be excluded from the cost of inventory and expensed when incurred. It also requires that allocation of fixed overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 during the three months ended December 31, 2005 did not have a material impact on the results of operations or financial position of the Company.

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### (4) STOCK-BASED AWARDS

The Company maintains the 1996 Stock Option Plan (the "Plan") (4,000,000 shares authorized) under which incentive and nonqualified options have been granted to employees, directors and certain key affiliates. Under the Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

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

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fair value of the award, and is recognized as an expense over the requisite service period of the entire award (generally the vesting period of the award). As a result of adopting SFAS No. 123R, the Company's net loss before income taxes and net loss for the three months ended December 31, 2005 was \$96 more than if the Company had continued to account for stock-based compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and its related interpretations. Basic and diluted net loss per share for the three months ended December 31, 2005 was not affected by the adoption of SFAS No. 123R. In addition, there was no tax effect related to the adoption of SFAS No. 123R due to the recording of a full valuation allowance against U.S. net deferred tax assets.

The Company elected to use the modified prospective transition method as permitted by SFAS No. 123R and, therefore, financial results for prior periods have not been restated. Under this transition method, stock-based compensation expense for the three months ended December 31, 2005 includes expense for all equity awards granted prior to, but not yet vested as of October 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123,") as amended by SFAS No. 148, "Accounting for Stock-Based Compensation--Transition and Disclosure." Since the adoption of SFAS No. 123R, there have been no changes to the Company's stock compensation plans or modifications to outstanding stock-based awards which would increase the value of any awards outstanding. Compensation expense for all stock-based compensation awards granted subsequent to October 1, 2005 was based on the grant-date fair value determined in accordance with the provisions of SFAS No. 123R. During the quarter ended December 31, 2005, the Company recognized compensation expense of \$96 relating to stock options granted during the three months ended December 31, 2005 in addition to the vesting of options outstanding as of October 1, 2005. All such expense was recognized within "General and administrative expense" in the Statement of Operations. There were no significant capitalized stock-based compensation costs at December 31, 2005.

Prior to October 1, 2005, the Company accounted for stock-based compensation in accordance with APB 25 and also followed the disclosure requirements of SFAS No. 123. Under APB 25, the Company accounted for stock-based awards to employees and directors using the intrinsic value method as allowed under SFAS No. 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in the Company's Statement of Operations because the exercise price of the Company's stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant. The following table sets forth the computation of basic and diluted loss per share for the three months ended December 31, 2004 and illustrates the effect on net loss and loss per share as if the Company had applied the fair value recognition provisions of SFAS 123 to its stock plans:

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	Three Months Ended December 31, 2004 ----
Net loss as reported:	(\$1,382)
Pro-forma expense as if stock options were charged against net loss(1)	10



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	-----
Pro-forma net loss using the fair value method	(\$1,392)
	=====
Basic and diluted Loss per Share:	
As reported	(\$0.09)
Pro forma using the fair value method	(\$0.09)

- (1) The pro forma stock-based compensation expense was not tax-effected due to the recording of a full valuation allowance against U.S. net deferred tax assets.

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

	December 31,	
	2005	2004
	-----	-----
Dividend Yield	0.0%	0.0%
Expected Volatility	48.6%	48.6%
Risk-free interest rate (range)	4-4.1%	3.3-3.6%
Expected term (in years)	5.00	5.00

**Expected Volatility.** The Company's methodology for computing the expected volatility is based solely on the Company's historical volatility.

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

**Risk-Free Interest Rate.** The interest rate used in valuing awards is based on the yield at the time of grant of a U.S. Treasury security with an equivalent remaining term.

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

**Pre-Vesting Forfeitures.** Estimates of pre-vesting option forfeitures are based on Company experience and industry trends. The Company will adjust its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

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Presented below is a summary of the status of the Company's stock options as of December 31, 2005, and related transactions for the quarter then ended:

Weighted

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Stock Options -----	Shares (000'S) -----	Weighted Average Exercise Price -----	Average Remaining Contractual Life -----	Aggreg Intrin Val -----
Outstanding at September 30, 2005	2,481	\$ 2.64	5.1	\$
Granted	28	3.12	10.0	
Canceled	-			
Exercised	(18)	2.53	-	
-----				
Outstanding at December 31, 2005	2,491	\$ 2.65	5.3	\$
Vested or expected to vest	2,242	\$ 2.65	5.3	\$
Fully vested at December 31, 2005	1,877	\$ 2.50	2.4	\$

The weighted-average grant-date fair value of options granted during the fiscal quarters ended December 31, 2005 and December 31, 2004 was \$1.48 and \$1.43, respectively. Cash received from option exercises for the quarters ended December 31, 2005 and December 31, 2004, was \$45 and \$0, respectively.

As of December 31, 2005, there was \$473 of total unrecognized compensation cost related to nonvested stock options. That cost is expected to be recognized over a weighted-average period of 1.4 years.

(5) INVENTORIES

Major classes of inventory at December 31, 2005 and September 30, 2005 were as follows:

	December 31, 2005 -----	September 30, 2005 -----
Raw materials	\$ 1,835	\$ 1,753
Work in process	5,458	4,469
Finished goods	7,367	7,614
	-----	-----
	14,660	13,836
Less reserves for obsolescence	3,195	3,278
	-----	-----
	\$ 11,465	\$ 10,558
	=====	=====

(6) INCOME TAXES

The Company has approximately \$14,000 of federal net operating loss carryforwards expiring beginning in 2008 and state net operating loss carryforwards of approximately \$13,500 that will begin to expire in 2006.

The Company has a corporate net operating loss carryforward for German income tax purposes of approximately \$3,863 (3,262 Euros), and a trade net operation loss carryforward for German income tax purposes of approximately

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\$1,456 (1,229 Euros), which can be carried forward indefinitely. The Company continually reviews the adequacy and necessity of the valuation allowance in accordance with the provisions of FASB Statement No. 109, Accounting for Income Taxes. As of December 31, 2005, the Company continues to maintain a full valuation allowance on the net deferred tax assets attributable to its domestic operations. The Company does not maintain a valuation allowance on its International deferred tax assets, because management believes it is more likely than not that these tax benefits will be realized through the generation of future International taxable income.

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

### (7) SEGMENT DATA

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

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

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A summary of the operations and assets by segment as of and for the three months ended December 31, 2005 and 2004, respectively are as follows:

2005	International	United States	Consolidated
Gross revenue	\$ 3,816	\$ 5,409	\$ 9,225
Less - intercompany	(1,191)	-	(1,191)
	=====	=====	=====
Total revenue - third party	\$ 2,625	\$ 5,409	\$ 8,034
	=====	=====	=====
Operating loss	\$ (230)	\$ (311)	\$ (541)
	=====	=====	=====
Depreciation and amortization	\$ 113	\$ 59	\$ 172
	=====	=====	=====
Interest expense	\$ 28	\$ 50	\$ 78
	=====	=====	=====
Net Segment losses, net of taxes	\$ (312)	\$ (67)	\$ (379)

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Capital expenditures	\$ 388	\$ 166	\$ 554
Total identifiable assets	\$ 9,059	\$ 17,900	\$ 26,959
2004	International	United States	Consolidated
Gross revenue	\$ 3,964	\$ 4,916	\$ 8,880
Less - intercompany	(1,807)	-	(1,807)
Total revenue - third party	\$ 2,157	\$ 4,916	\$ 7,073
Operating loss	\$ (405)	\$ (525)	\$ (930)
Depreciation and amortization	\$ 126	\$ 64	\$ 190
Net Segment losses, net of taxes	\$ (438)	\$ (944)	\$ (1,382)
Capital expenditures	\$ 355	\$ 34	\$ 389
Total identifiable assets	\$ 11,062	\$ 21,590	\$ 32,652

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(8) LEGAL PROCEEDINGS

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany resulted in a reduction of the original proposed judgment received against the Company by \$406. At December 31, 2005 and September 30, 2005 the Company maintains an accrual of \$476 with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and that the final settlement will not have a material impact on results of operations.

On October 12, 2005, the Company issued a voluntary recall of all product units, which utilized donor tissue received from BioMedical Tissue Services/BioTissue Recovery Services ("BioMedical"). This action was taken because the Company was unable to satisfactorily confirm that BioMedical had properly obtained donor consent. The Company quarantined all BioMedical products in its inventory, having a value of \$1,035, and has notified all customers and distributors of record regarding this action. In connection with this recall, the Company has destroyed \$174 of the quarantined products and accrued \$872 of inventory write-downs and \$250 of other related costs at September 30, 2005 and December 31, 2005. In January 2006, the Company was named as one of several defendants in a class action suit related to this recall. It is management's opinion that it is too early in

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

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

### (9) SUBSEQUENT EVENT

In January 2006, the Company entered into a four-year exclusive worldwide distribution agreement with Davol Inc., 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 wall. Davol, in addition to purchasing the product is required to pay approximately \$3.3 million in up-front distribution fees, with the first payment in January 2006 and the final payment due in May 2006 as certain milestones are met.

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## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS December 31, 2005 (in thousands, except share data)

This report contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "anticipate," "estimate," and similar words, although some forward-looking statements are expressed differently. Actual results could differ significantly from those discussed herein. Some of the matters described in the "Risk Factors" and "Description of Business" sections of its Form 10-K and other reports filed with the Securities and Exchange Commission, constitute cautionary statements, including certain risks and uncertainties, that could cause actual results to vary materially from the future results indicated in such forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements.

Fiscal year 2005 for the Company was devoted to assembling an effective team of industry professionals, re-engaging our distribution partners and dramatically expanding our manufacturing capabilities. Product manufacturing capabilities to support growing sales within the United States have been transitioned from the Company's facility in Neunkirchen, Germany to Alachua, Florida. Tutogen now manufactures 80 percent of the U.S. product requirement in our facility in Alachua. This compares to 5 percent of the U.S. requirements at this time last year. Additionally, manufacturing and product management executives were added to the operations team in fiscal year 2005 with the goal of increasing revenues and improving operating efficiencies. The Company established a strategic goal to develop new products in the spine, dental, general surgery markets and to enter new markets for hernia repair.

Dental sales continue to grow. The Company has re-worked the fee agreement that

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governs the distribution relationship with Zimmer Dental. This, combined with the transfer of manufacturing for all dental products to the Alachua facility with improved costs, will have a positive impact on our dental operating margins. For spine sales, management believes that the second half of fiscal year 2006 will improve as it is anticipated that Zimmer will substantially work-off existing inventories during the first half of the year and commence new purchases during the second half of fiscal 2006. The Company is solidifying the product/market foundation in 2006 by entering, as planned, the important hernia repair market with Davol as the Company's distribution partner.

The Company is now positioned in Europe to return that business to more historical double-digit growth patterns, starting with the first quarter. In conjunction with this, the Company is also expanding the physical plant in Neunkirchen, Germany in order to fully support the growing and important international business.

The Company's ability to generate positive operational cash flow is dependent upon increasing revenues supported by increased raw tissue recoveries by tissue banks in the U.S. and Europe, controlling costs and the development of additional markets and surgical applications worldwide. While the Company believes that it continues to make progress in these areas, there can be no assurances.

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Results of Operations - Three months ended December 31, 2005 compared with the three months ended December 31, 2004

### Revenue

Revenues for the three months ended December 31, 2005, increased 14% to \$8,034 from \$7,073 in 2004. The U.S. operation had a 10% increase in revenues from \$4,916 in 2004 to \$5,409 for the quarter ended December 31, 2005. This increase was fueled by the continuing increase in the demand for the Company's Tutoplast(R) bone products for dental applications sold by Zimmer Dental ("Dental"), the Company's marketing partner. The Dental business increased 49% from a year ago. The spine revenues continue to be impacted by the high inventory levels at the Company's marketing partner, Zimmer Spine. The spine revenues decreased \$676 from the same quarter a year ago. The surgical specialties, consisting of urology, ophthalmic and ENT businesses decreased 10% compared to last year from \$1,266 in 2004 to \$1,150 this quarter, partially due to a backlog on certain product lines. The International revenues for the three months ended December 31, 2005 increased 22% this quarter to \$2,625 from \$2,157 in 2004. The International segment has increased its revenues primarily through improved product sales in Germany for the Company's Xenograft product lines, offset by decreased sales in Europe recovering from its regulatory compliance matters, which have since been resolved. An analysis of revenues by major business segment is as follows:

(000's omitted)	Three Months	Three Months
	12/30/05	12/31/04
Spine	\$ 374	\$ 1,050

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Dental	3,885	2,600
Surgical Specialties	1,150	1,266
Total - U.S.	\$ 5,409	\$ 4,916
Germany	795	320
France	274	418
ROW	1,430	1,266
Other	126	153
Total-International	\$ 2,625	\$ 2,157
Total Consolidated	\$ 8,034	\$ 7,073

### Margin

Gross margin, for the three months ended December 31, 2005 was 53% as compared to 47% for the three month comparable period last year. The increased gross margin for the three months was due primarily to the favorable impact of the manufacturing efficiencies realized in the U.S. operating segment as the result of transferring the manufacturing of the dental product lines from the German operation to the U.S.

### General and Administrative

General and administrative expenses increased 30% for the three months ended December 31, 2005 from the

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comparable period last year. The increase for the quarter was primarily due to higher compensation from new and unfilled positions (\$178), higher bank charges directly related to increased dental revenues as customers pay by credit card (\$30), stock compensation (\$96), compliance with Sarbanes Oxley (\$9) and other increases (\$34). As a percentage of revenues, for the three months ended December 31, 2005, General and Administrative expenses were 19% compared to 16% of revenues for the comparable period in 2004.

### Distribution and Marketing

Distribution and marketing expenses increased 6% for the three months ended December 31, 2005 from the comparable period last year. The increase was primarily due to an increase in U.S. sales and marketing expenses paid to Zimmer Dental of \$1,545 versus \$1,252 a year ago as a result of 49% increase in dental revenues offset partially by the benefits realized from the reorganization of the international sales group. As a percentage of revenues, for the three months ended December 31, 2005, Distribution and Marketing expenses decreased to 36% from 38% in 2004.

### Research and Development

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Research and development expenses increased 9% for the three months ended December 31, 2005, from the comparable period last year. The increase was primarily due to increased spending on new product developments for the upcoming year. As a percentage of revenues, for the three months ended December 31, 2005, Research and Development expenses decreased to 5% from 6% in 2004.

### Foreign Exchange Gain/(Loss)

The Company recognized a foreign currency exchange gain for the quarter ended December 31, 2005 of \$119 due to the dollars' improved exchange rate against the Euro.

### Other Income

Other income increased by \$19 for the three months ended December 31, 2005 from the comparable period a year ago, primarily due to favorable increases in the investment returns recognized in interest income.

### Interest Expense

Interest expense increased \$61 for the three months ended December 31, 2005 from the comparable period a year ago, primarily due to the leasing of costs associated with new equipment used to facilitate growth and the facility expansion programs in Florida and Germany.

### Net Loss

As a result of the above, net loss for the three months ended December 31, 2005 totaled \$379 or \$0.02 basic and diluted loss per share, as compared to a net loss of \$1,382 or \$0.09 basic and diluted earnings per share for the comparable period in 2004.

### Inventory

Inventory increased 8%, from \$10.6 million at last fiscal year-end to \$11.5 million at December 31, 2005. Raw materials and work-in-process ("WIP"), increased 5% and 22%, respectively, which reflects the plan to replace inventory quarantined or destroyed last year-end as a result of the voluntary recall of certain products. Finished goods inventory remained consistent with year end balances.

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### Critical Accounting Policies

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

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



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to direct labor and overhead. Reserves for slow moving and obsolete inventories are provided based on historical experience, current product demand and the remaining shelf life. The adequacy of these reserves 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. Delivery is to have occurred at the time of shipment. Customers are provided with a limited right of return. Revenue is recognized at shipment. Reasonable and reliable estimates of product returns are made in accordance with SFAS No. 48 and allowances for doubtful accounts based on significant historical experience. Revenue from service sales is recognized when the service procedures have been completed or applicable milestones have been achieved. Revenue from distribution fees includes nonrefundable payments received as a result of exclusive distribution agreements between the Company and independent distributors. Distribution fees under these arrangements are recognized as revenue as products are delivered.

Foreign Currency Translation. The functional currency of the Company's German subsidiary is the Euro for the years 2005 and 2004. Assets and liabilities of foreign subsidiaries are translated at the period end exchange rate while revenues and expenses are translated at the average exchange rate for the year. The resulting translation adjustments, representing unrealized, non-cash losses are made directly to comprehensive income. Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in income as they occur. The Company recognized a foreign currency translation loss of \$203 and a currency translation gain of \$286 for the three months ending December 31, 2005 and 2004, respectively.

### Liquidity and Capital Resources

At December 31, 2005, the Company has working capital of \$8.0 million as compared to September 30, 2005 of \$9.1 million. The Company maintains current working capital credit lines totaling 1.5 million euros (approximately \$1.8 million) with several German banks and a \$1.5 million credit line with a U.S. bank. At December 31, 2005, the Company had no borrowings against the German and U.S. credit lines.

The Company has experienced a negative cash flow of \$1.7 million for the three months ended December 31, 2005 as compared to a negative cash flow of \$1.9 million for the same period in 2004. The primary reasons for the negative cash flow during the quarter ended December 31, 2005 was due to a net loss for the three-

month period, higher inventory levels compared to year-end caused by a plan to manufacture and replace recalled products, increased capital spending levels associated with the expansion of the U.S. and German manufacturing facilities, partially offset by an increase in short-term borrowings.

The Company's ability to generate positive operational cash flow is dependent upon increasing revenues supported by increased raw tissue recoveries by tissue banks in the U.S. and Europe, controlling costs and the development of additional markets and surgical applications worldwide. While the Company believes that it continues to make progress in these areas, there can be no assurances.

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Future minimum rental payments required under the Company's leases that have initial or remaining non-cancelable lease terms in excess of one year as of December 31, 2005 are as follows:

2006	\$ 886
2007	616
2008	590
2009	338
2010	25
	-----
	\$ 2,455
	=====

Long-term debt consists of senior debt, 5.75% interest until March 30, 2008 when terms are renegotiable, due 2008. Future minimum payments as of December 31, 2005 are as follows:

2006	\$ 388
2007	196
2008	121
2009	60
2010	4
	-----
	769
Less current portion	185
	\$ 584
	=====

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### Item 3. QUANTITATIVE STATEMENTS AND SUPPLEMENTARY DATA

For information regarding the Company's exposure to certain market risks, see Item 7A, Quantitative Statements and Supplementary Data, in the Annual Report on Form 10K for the year ended September 30, 2005. There have been no significant changes in our market risk exposures from the fiscal 2005 year-end.

We are subject to market risk from exposure to changes in interest rates based upon our financing, investing and cash management activities. A 1% increase in interest rates would not have a material effect on our results of operations.

### Item 4. CONTROLS AND PROCEDURES

Within 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13 a-14. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) that is required to be included in the Company's periodic filings with the Securities and Exchange Commission. There have been no significant changes in the Company's internal

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controls or, to the Company's knowledge, in other factors that could significantly affect those internal controls subsequent to the date the Company carried out its evaluation.

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Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Footnote 8 of the Interim Financial Statements.

Item 6. Reports on Form 8-K

The Company filed no Reports on Form 8-K during the quarter ended December 31, 2005.

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SIGNATURES

Registrant has duly caused this report to be signed on its behalf by the Pursuant to the requirements of the Securities and Exchange Act of 1934, the undersigned, thereunto duly authorized.

TUTOGEN MEDICAL, INC.

Date: February 10, 2006

/s/ Guy L. Mayer

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Chief Executive Officer

Date: February 10, 2006

/s/ George Lombardi

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Chief Financial Officer, Treasurer  
and Secretary (Principal Financial  
and Accounting Officer)

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Certification of the Chief Financial Officer Pursuant to  
18 U.S.C. Section 1350, as Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002

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In connection with the Quarterly Report on Form 10Q of Tutogen Medical, Inc. (the "Company") for the three months ended December 31, 2005 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I George Lombardi, as the Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: February 10, 2006

TUTOGEN MEDICAL, INC.

/s/ George Lombardi

-----  
George Lombardi  
Chief Financial Officer, Treasurer  
and Secretary

Certification of the Chief Executive Officer Pursuant to  
18 U.S.C. Section 1350, as Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10Q of Tutogen Medical, Inc. (the "Company") for the three months ended December 31, 2005 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I Guy L. Mayer, as the Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: February 10, 2006

TUTOGEN MEDICAL, INC.

/s/ Guy L. Mayer

-----  
Guy L. Mayer  
Chief Executive Officer

CERTIFICATION

I, George Lombardi certify that:

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1. I have reviewed this Quarterly Report on Form 10-Q of Tutogen Medical, Inc.
2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;
3. Based on my knowledge, the financial statements and other financial information included in the Quarterly Report fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;
4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15e and 15d-15e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15f and 15d-15f) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

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Date: February 10, 2006

BY:

Name: /s/ George Lombardi

Title: Chief Financial Officer, Treasurer and Secretary

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CERTIFICATION

I, Guy L. Mayer certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tutogen Medical, Inc.
2. Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;
3. Based on my knowledge, the financial statements and other financial information included in the Quarterly Report fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;
4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15e and 15d-15e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15f and 15d-15f) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's

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most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal controls which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 10, 2006  
BY:  
Name: /s/ Guy L. Mayer  
Title: Chief Executive Officer

