

Edgar Filing: TUTOGEN MEDICAL INC - Form 10-Q/A

TUTOGEN MEDICAL INC  
Form 10-Q/A  
July 06, 2006

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.c. 20549

FORM 10-Q/A  
(AMENDMENT NO. 1)

(Mark One)

X 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 No X .  
--- ---

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2of the Exchange Act).  
(Check one): Large accelerated filer Yes No  
--- ---

Accelerated filer Yes No Non-accelerated filer Yes X No  
--- ---

Indicate by check mark whether the registrant is a shell company (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

#### EXPLANATORY NOTE

Tutogen Medical, Inc. ("the Company") is filing this Amendment to its Quarterly report on Form 10-Q for the Company's fiscal quarter ended December 31, 2005, which was originally filed with the Securities and Exchange Commission (the "SEC") on February 13, 2006 (the "Original Filing"), to reflect the restatement of the Company's audited consolidated financial statements for the fiscal year ended September 30, 2005, the unaudited condensed consolidated financial statements for the three months ended December 31, 2005 and 2004, as well as the notes related thereto, as described in Note 11 ("Restatement") to the accompanying unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q/A.

As part of the financial review for the three and six months ended March 31, 2006, the Company became aware of misstatements in previously reported inventory and cost of revenue. The Company discovered that the misstatements were attributable to errors in the calculation of intercompany profit to be eliminated during the consolidation process in prior periods. While investigating the inventory errors, the Company also discovered other errors affecting the Company's deferred tax benefit, accrued expenses, general and administrative and distribution and marketing expenses for the fiscal year ended September 30, 2005 and the three months ended December 31, 2005. As a result, the Company has restated the accompanying consolidated financial statements for the years ended September 30, 2005, and the three months ended December 31, 2005 and 2004 to correct these errors with this Form 10-Q/A.

In addition, the Company's management has determined that the accounting errors referenced above were the result of a material weakness in the Company's internal control over financial reporting related to its inventory valuation and certain journal entries recorded in the financial close process. The Company has taken steps to remediate the weakness as of the date of this report. See Item 4 "Controls and Procedures".

This Form 10-Q/A sets forth the Original Filing in its entirety. However, this Form 10-Q/A amends and restates certain information in Items 1, 2, and 4 of Part I and Part II of the Original filing, in each case, solely as a result of, and to reflect, the restatement. No other information in the Original Filing is amended hereby.

Except for the amended information referred to above, this Form 10-Q/A continues to describe conditions as of the date of the Original Filing and the company has not modified or updated other disclosures presented in the Original Filing. This Form 10-Q/A does not reflect events occurring after the date of the Original Filing or modify or update disclosures (including, except as otherwise provided herein, the exhibits to the Original Filing) affected by subsequent events. Accordingly, this Form 10-Q/A includes updated certifications from the Company's Chief Executive Officer and Chief Financial Officer at Exhibits 31.1, 31.2, and 32.

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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
	-----	-----
	(AS RESTATED, SEE NOTE 11)	
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

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Inventories - net	10,852	9,554
Deferred tax asset	1,177	1,149
Other current assets	622	623
	-----	-----
Total current assets	18,234	18,361
Property, plant and equipment, net	6,904	6,612
Deferred tax asset	1,275	1,232
	-----	-----
TOTAL ASSETS	\$ 26,413	\$ 26,205
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and other liabilities	\$ 6,159	\$ 6,342
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
	-----	-----
Total current liabilities	10,466	9,928
Noncurrent Liabilities		
Deferred distribution fees	1,784	1,925
Long-term debt	584	630
	-----	-----
TOTAL LIABILITIES	12,834	12,483
SHAREHOLDERS' EQUITY:		
Common stock, \$0.01 par value, 30,000,000 authorized; 15,932,960 and 15,950,460 shares issued and outstanding	160	159
Additional paid-in capital	36,521	36,381
Accumulated other comprehensive income	1,475	1,678
Accumulated deficit	(24,577)	(24,496)
	-----	-----
Total shareholders' equity	13,579	13,722
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 26,413	\$ 26,205
	=====	=====

See accompanying Notes to Condensed 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

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	-----	-----
	(AS RESTATED, SEE NOTE 11)	
REVENUE	\$ 8,034	\$ 7,073
COST OF REVENUE	3,415	4,292
	-----	-----
Gross profit	4,619	2,781
OPERATING EXPENSES		
General and administrative	1,576	1,142
Distribution and marketing	2,859	2,711
Research and development	427	390
	-----	-----
	4,862	4,243
OPERATING LOSS	(243)	(1,462)
FOREIGN EXCHANGE GAIN (LOSS)	119	(579)
OTHER INCOME (EXPENSE)	15	(4)
INTEREST EXPENSE	(78)	(17)
	-----	-----
	56	(600)
LOSS BEFORE INCOME TAX BENEFIT	(187)	(2,062)
Income tax benefit	(106)	(148)
	-----	-----
NET LOSS	\$ (81)	\$ (1,914)
	=====	=====
Comprehensive (loss) income:		
Foreign currency translation (loss) gain	(203)	286
	-----	-----
COMPREHENSIVE LOSS	\$ (284)	\$ (1,628)
	=====	=====
AVERAGE SHARES OUTSTANDING FOR BASIC AND DILUTED LOSS PER SHARE	15,945,243	15,915,960
	=====	=====
BASIC AND DILUTED LOSS PER SHARE	\$ (0.01)	\$ (0.12)
	=====	=====

See accompanying Notes to Condensed Consolidated Financial Statements

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	----- DECEMBER 31, -----	
	2005	2004
	-----	-----
	(AS RESTATED, SEE NOTE 11)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (81)	\$ (1,914)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	172	190
Amortization of deferred distribution fees revenue	(139)	(172)
Deferred income taxes	(173)	(148)
Provision for inventory write-downs	(58)	(62)
Share-based compensation	96	-
Changes in assets and liabilities:		
Accounts receivable	(303)	469
Inventories	(1,296)	891
Other current assets	(4)	633
Accounts payable and other liabilities	(52)	(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	44	-
Proceeds from short-term borrowings	406	-
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
	=====	=====

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See accompanying Notes to Condensed Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
 THREE MONTHS ENDED DECEMBER 31, 2005  
 (Unaudited)  
 (In Thousands, Except for Share Data)

	COMMON STOCK (\$ .01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (1)	ACCU DE
BALANCE, SEPTEMBER 30, 2005	\$ 159	\$ 36,381	\$ 1,478	\$ (
Prior period adjustment	-	-	200	
	-----	-----	-----	---
BALANCE, SEPTEMBER 30, 2005 (as restated, see Note 11)	\$ 159	\$ 36,381	\$ 1,678	\$ (
Stock issued on exercise of options	1	44	-	
Share-based compensation	-	96	-	
Net loss (as restated, see Note 11)	-	-	-	
Foreign currency translation adjustment	-	-	(203)	
	-----	-----	-----	---
BALANCE, December 31, 2005	\$ 160	\$ 36,521	\$ 1,475	\$ (
	=====	=====	=====	====

(1) Represents foreign currency translation adjustments. See accompanying Notes to Condensed 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.

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### (2) BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America for interim financial reporting. 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/A 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 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, STOCK-BASED Awards 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 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



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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 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 per share as if the Company had applied the fair value recognition provisions of SFAS 123 to its stock plans:

	Three Months Ended December 31, 2004
Net loss:	(\$1,914)
Deduct: Total stock-based employee compensation expense determined under fair value based method, net of related tax effects	10 -----
Pro forma net loss	(\$1,924)

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Basic and diluted loss per share:	
As reported	(\$0.12)
Pro forma using the fair value method	(\$0.13)

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:

STOCK OPTIONS	NUMBER OF COMMON SHARES ('000'S)	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	AGGREGATE INTRINSIC VALUE
	-----	-----	-----	-----

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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	\$

As of December 31, 2005, 320,803 stock options were available for grant. 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 \$44 and \$ 0.0 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	5,344	4,219
Finished goods	6,868	6,860
	-----	-----
	14,047	12,832
Less reserves for obsolescence	3,195	3,278
	-----	-----
	\$ 10,852	\$ 9,554
	=====	=====

(6) INCOME TAXES

The Company has approximately \$15,100 of federal net operating loss carryforwards expiring beginning in 2008 and state net operating loss carryforwards of approximately \$14,600 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

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operation loss carryforward for German income tax purposes of approximately \$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 SFAS 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 consistent with prior periods. 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.

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:

DECEMBER 31, 2005

SEGMENT DATA	INTERNATIONAL	US	TOTAL
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 INCOME (LOSS)	\$ 224	\$ (467)	\$ (243)
DEPRECIATION & AMORTIZATION	\$ 113	\$ 59	\$ 172
INTEREST EXPENSE	\$ 28	\$ 50	\$ 78
NET SEGMENT INCOME (LOSS)	\$ 142	\$ (223)	\$ (81)
CAPITAL EXPENDITURE	\$ 388	\$ 166	\$ 554
TOTAL IDENTIFIABLE ASSETS	\$ 15,425	\$ 10,988	\$ 26,413

DECEMBER 31, 2004

SEGMENT DATA	INTERNATIONAL	US	TOTAL
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	\$ (936)	\$ (526)	\$ (1,462)
DEPRECIATION & AMORTIZATION	\$ 126	\$ 64	\$ 190
INTEREST EXPENSE	\$ 12	\$ 5	\$ 17
NET SEGMENT LOSS	\$ (970)	\$ (944)	\$ (1,914)
CAPITAL EXPENDITURE	\$ 355	\$ 34	\$ 389
TOTAL IDENTIFIABLE ASSETS	\$ 17,761	\$ 13,548	\$ 31,309

## (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 maintained 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 \$1,046, and has notified all customers and distributors of record regarding this action. In connection with this recall, the Company wrote off \$174 of inventory during 2005. At September 30, 2005 and December 31, 2005, \$872 of inventory and \$250 of other related costs were reserved. 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 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

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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.

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### (9) RELATED PARTY

The Company has an exclusive license and distribution agreement with Zimmer Spine, a wholly owned subsidiary of Zimmer Holdings, Inc., whereby Zimmer Spine has been granted the right to act as the Company's exclusive distributor of bone tissue for spinal applications in the United States. For the quarters ended December 31, 2005 and 2004 product sales to Zimmer spine totaled \$374, and \$1,050, respectively, representing 4.7% and 14.8% respectively of our total revenues. Accounts receivable from Zimmer Spine were \$176 and \$44 at December 31, 2005 and September 30, 2005, respectively.

The Company has also engaged Zimmer Dental, a wholly owned subsidiary of Zimmer Holdings, Inc., to act as an exclusive distributor for the Company's bone tissue for dental applications in the United States and certain international markets. Under this distribution agreement, the Company sells directly to Zimmer Dental's customers. For the quarters ended December 31, 2005 and 2004, Zimmer Dental was paid commissions aggregating approximately \$1,565 and \$1,194, respectively. Accounts payable to Zimmer Dental total \$2,123 and \$1,740 at December 31, 2005 and September 30, 2005, respectively.

Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc., is a significant owner of the Company's outstanding shares of Common Stock.

### (10) 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 \$3,300 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. These payments will be deferred and recognized as revenue over the term of the distribution agreement when product begins to ship.

### (11) RESTATEMENT

As part of the financial review for the three and six months ended March 31, 2006, the Company became aware of misstatements in previously reported inventory and cost of revenue. The Company discovered that the misstatements were attributable to errors in the calculation of intercompany profit to be eliminated during the consolidation process for prior periods. While investigating the inventory errors, the Company also

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discovered other errors affecting the Company's deferred tax benefit, accrued expenses, general and administrative and distribution and marketing expenses for the fiscal year ended September 30, 2005 and the three months ended December 31, 2005. As a result, the Company has restated the accompanying consolidated financial statements for the fiscal year ended September 30, 2005, for the three months ended December 31, 2005 and for the three months ended December 31, 2004, to correct these errors.

The impact of this restatement on the accompanying consolidated financial statements is summarized below:

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FOR THE QUARTER ENDED DECEMBER 31, 2005	As Previously Reported	Adjustments	As Restated
Cost of revenues	\$ 3,797	\$ (382)	\$ 3,415
Gross profit	4,237	382	4,619
General and administrative	1,489	87	1,576
Distribution and marketing expenses	2,862	(3)	2,859
Operating loss	(541)	298	(243)
Net loss	(379)	298	(81)
Comprehensive loss	(582)	298	(284)
Basic and diluted loss per share	(0.02)	0.01	(0.01)
Cash flows from operating activities			
Net loss	(379)	298	(81)
Deferred income taxes	(106)	(67)	(173)
Inventories	(903)	(393)	(1,296)
Accounts payable and other accrued expenses	(214)	162	(52)
As of December 31, 2005:			
Inventories	11,465	(613)	10,852
Deferred tax asset	2,385	67	2,452
Accounts payable and other accrued expenses	5,997	162	6,159
Accumulated other comprehensive income	1,275	200	1,475
Accumulated deficit	(23,669)	(908)	(24,577)
Shareholders' equity	14,287	(708)	13,579
AS OF SEPTEMBER 30, 2005:	As Previously Reported	Adjustments	As Restated
Inventories, net	10,558	(1,003)	9,555
Deferred tax asset	2,314	67	2,381
Accounts payable and other accrued expenses	6,273	69	6,342
Accumulated other comprehensive income	1,478	200	1,678
Accumulated deficit	(23,290)	(1,206)	(24,496)
Shareholders' equity	14,728	(1,006)	13,722
FOR THE QUARTER ENDED DECEMBER 31, 2004	As Previously Reported	Adjustments	As Restated

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Cost of revenues	\$ 3,760	\$ 532	\$ 4,292
Gross profit	3,313	(532)	2,781
Net loss	(1,382)	(532)	(1,914)
Operating loss	(930)	(532)	(1,462)
Comprehensive loss	(1,096)	(532)	(1,628)
Basic and diluted loss per share	(0.09)	(0.03)	(0.12)
Cash flows from operating activities			
Net loss	(1,382)	(532)	(1,914)
Inventories	359	532	891

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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)

RESTATED FINANCIAL STATEMENTS

The Company is filing this amended report to reflect the restatement of the Company's unaudited condensed consolidated financial statements for the three months ended December 31, 2005 and 2004 as well as the restatement of the Company's audited consolidated financial statements for the fiscal year ended September 30, 2005, including the notes related thereto, as more fully described in Note 11 ("Restatement") to the accompanying unaudited consolidated financial statements included with this Form 10-Q/A. The determination to restate these financial statements was made as a result of management's identification of misstatements in previously reported inventory and cost of revenue attributable to errors in the calculation of intercompany profit to be eliminated during the consolidation process in prior periods as well as other errors affecting the Company's deferred tax benefit, accrued expenses, general and administrative and distribution and marketing expenses for the fiscal year ended September 30, 2005 and the three months ended December 31, 2005. Management's discussion and analysis of the Company's financial condition and results of operations included in this report has been revised to reflect the impact of the restatement.

CAUTIONARY STATEMENT RELATING TO FORWARD-LOOKING STATEMENTS

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 this Form 10-Q/A 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.

MANAGEMENT'S OVERVIEW

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



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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.

With regards to these product lines, the dental product sales continue to grow. The Company has re-worked the fee agreement that 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 the 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

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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.

### 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 for the same period during 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 continued 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	Three
	Months	Months
	12/30/05	12/31/04
Spine	\$ 374	\$ 1,050
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 58% as compared to 39% 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 38% for the three months ended December 31, 2005 from the comparable period last year. The increase for the quarter was primarily due to higher compensation from cost related to new personnel (\$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 20% compared to 16% of revenues for the comparable period in 2004.

## DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased 5% for the three months ended

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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

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.

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### 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 borrowings for 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 \$81 or \$0.01 basic and diluted loss per share, as compared to a net loss of \$1,914 or \$0.12 basic and diluted earnings per share for the comparable period in 2004.

### INVENTORY

Inventory increased 13.6%, from \$9,555 at last fiscal year-end to \$10,852 at December 31, 2005. Raw materials and work-in-process ("WIP"), increased 5% and 27%, respectively, which reflects the plan to replace inventory quarantined or destroyed last year-end as a result of the voluntary recall of certain products (see Note 8 to condensed consolidated financial statements). Finished goods inventory remained consistent with year end balances.

### 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

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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 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. 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

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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.

**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 we would be able to realize our deferred tax assets in the future, it is more likely than not that an adjustment would be made and income increased in the period of such determination. Likewise, in the event we determine we would not be able to realize all or part of our deferred tax assets in the future, an adjustment would be made and charged to income in the period of such determination.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2005, the Company has working capital of \$7,768 as compared to September 30, 2005 of \$8,434. The Company maintains current working capital credit lines totaling 1,500euros (approximately \$1,800) with several German

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banks and a \$1,500 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 \$1,728 for the three months ended December 31, 2005 as compared to a negative cash flow of \$1,864 for the same period in 2004. The primary reasons for the negative cash flow during the quarter ended December 31, 2005 was due to 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.

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:

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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:(1)

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

(1) The above payments do not include interest.

### 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 10-K/A for the year ended September 30, 2005. There have been no significant changes in our market risk exposures from the fiscal 2005 year-end.

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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

#### DISCLOSURE CONTROLS AND PROCEDURES

In the Form 10-Q for the Company's fiscal quarter ended December 31, 2005, initially filed with the SEC on February 13, 2006, the Company's management, with the participation of the Company's chief executive officer and former chief financial officer, evaluated the Company's disclosure controls and procedures (as defined in Rule 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended (the "34 Act")) as of December 31, 2005, (the "Evaluation Date"). Based on that evaluation, the chief executive officer and former chief financial officer of the Company concluded that, as of the Evaluation Date, the disclosure controls and procedures established by the Company were adequate to ensure that information required to be disclosed by the Company in reports that the Company files under the Exchange Act, was recorded, processed, summarized and reported on a timely basis in accordance with applicable rules and regulations.

Subsequent to that filing (and as part of the financial review for the three and six months ended March 31, 2006) under the direction of the Company's chief executive officer and new chief financial officer, the Company conducted an analysis of the Company's inventory on hand as of prior reporting periods, its policies and procedures over certain journal entries recorded in the financial close process, and the effectiveness of the design and operation of the Company's disclosure controls and procedures, (as defined in Rule 13(a) - 15(e) under the 34 Act). The evaluation led the Company to conclude that as of September 30, 2005, the Company's controls and procedures relating to the calculation of intercompany profit and certain journal entries recorded in the financial close process were deficient, resulting in a material weakness in internal control over financial reporting. Accordingly, the Company concluded that as of December 31, 2005 the Company's disclosure controls and procedures

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were not effective in ensuring that information required to be disclosed by us in the reports that we file under the Securities and Exchange Act is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission rules and forms.

As a result, the Company has restated the financial statements for the periods covered in the Company's quarterly report on Form 10-Q/A for the quarter ended December 31, 2005. (See Note 11 to the accompanying unaudited interim Condensed Consolidated Financial Statements.)

A material weakness in internal control is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the financial statements would not be prevented or detected on a timely basis by the Company. The Company has subsequently taken steps to remediate this material weakness including designing and implementing a more effective and precise analytic model for calculating intercompany profit. Additionally, the Company has developed a system for assuring the accuracy of this model. This system includes an enhanced reporting process for determining actual costs and transfer prices used in the calculation of intercompany profit to be eliminated during the consolidation process. Also,

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the Company has designed and documented new policies and procedures to strengthen its controls over certain journal entries recorded in its financial close process.

Management believes that these subsequent changes in the design of internal controls will strengthen the Company's disclosure controls and procedures, as well as its internal control over financial reporting, and will remediate the material weakness that the Company identified in its internal control over financial reporting as of December 31, 2005. The Company has discussed this material weakness and its remediation program with its Audit Committee. The Company recognizes that controls and procedures can provide only reasonable assurance of achieving the desired control objectives. Accordingly, the Company intends to continue to refine its internal control over financial reporting on an ongoing basis as it deems appropriate.

The Company instituted the changes noted above during its financial close process during the quarter ended March 31, 2006 to materially enhance its internal control over financial reporting of inventory, net revenues, cost of revenues and financial close process.

### CHANGES IN CONTROL:

Except as described above, there has not been any change in our internal control over financial reporting during the quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, those controls.

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## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

Please refer to Footnote 8 of the Interim Financial Statements.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS

None.

### ITEM 5. OTHER INFORMATION

### ITEM 6. EXHIBITS

31.1 Certification of Chief Executive Officer, pursuant to Rule 13a-14. \*\*\*

31.2 Certification of Chief Financial Officer, pursuant to Rule 13a-14. \*\*\*

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

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\*\*\* Filed herewith

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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: July 6, 2006

/s/ Guy L. Mayer

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Chief Executive Officer

Date: July 6, 2006

/s/ L. Robert Johnston, Jr.

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Chief Financial Officer  
(Principal Financial  
and Accounting Officer)

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