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TUTOGEN MEDICAL INC  
Form 10-Q  
May 12, 2005

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 March 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.)

1130 MCBRIDE AVENUE, WEST PATERSON, NEW JERSEY 07424  
(Address of Principal Executive Offices) (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (973) 785-0004

SECURITIES REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:

COMMON STOCK, PAR VALUE \$.01  
(Title of Class) (Name of Each Exchange on Which Registered)

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 .  
--- ---

As of April 30, 2005 there were outstanding 15,920,960 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 CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

	(UNAUDITED)	
	MARCH 31,	SEPTEMBER 30,
	2005	2004
	-----	-----
ASSETS		

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CURRENT ASSETS		
Cash and cash equivalents	\$ 2,551	\$ 5,063
Marketable security	491	-
Accounts receivable - net of allowance for doubtful accounts of \$221 in March 2005 and \$192 in September 2004	4,534	4,922
Inventories - net	13,459	15,072
Deferred income taxes	582	425
Other current assets	1,331	1,409
	-----	-----
	22,948	26,891
PROPERTY, PLANT AND EQUIPMENT, NET	6,374	6,138
DEFERRED INCOME TAXES	1,653	1,318
	-----	-----
TOTAL ASSETS	\$ 30,975	\$ 34,347
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and other accrued expenses	\$ 5,639	\$ 6,521
Accrued commissions	1,944	1,521
Current portion of deferred distribution fees	676	642
Current portion of long-term debt	186	173
	-----	-----
	8,445	8,857
OTHER LIABILITIES		
Deferred distribution fees	2,346	2,580
Long-term debt	780	827
SHAREHOLDERS' EQUITY	19,404	22,083
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 30,975	\$ 34,347
	=====	=====

See accompanying Notes to Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS EXCEPT PER SHARE DATA)  
(UNAUDITED)

THREE MONTHS ENDED MARCH 31,		SIX MONTHS
2005	2004	2005
----	----	----

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REVENUE	\$ 7,554	\$ 7,089	\$ 14,62
COST OF REVENUE	4,801	1,998	8,56
	-----	-----	-----
Gross margin	2,753	5,091	6,06
OPERATING EXPENSES			
General and administrative	1,289	1,238	2,43
Distribution and marketing	2,786	2,275	5,49
Research and development	452	386	84
	-----	-----	-----
	4,527	3,899	8,77
OPERATING (LOSS) INCOME	(1,774)	1,192	(2,70)
FOREIGN EXCHANGE GAIN (LOSS)	183	(72)	(39)
OTHER INCOME	24	9	2
INTEREST EXPENSE	(16)	(13)	(3)
	-----	-----	-----
	191	(76)	(40)
(LOSS) INCOME BEFORE INCOME TAX EXPENSE	(1,583)	1,116	(3,11)
Income (benefit) tax expense	(344)	463	(49)
	-----	-----	-----
NET (LOSS) INCOME	\$ (1,239)	\$ 653	\$ (2,62)
	=====	=====	=====
Comprehensive Income:			
Foreign currency translation adjustments	(344)	1,189	(5)
	-----	-----	-----
COMPREHENSIVE (LOSS) INCOME	\$ (1,583)	\$ 1,842	\$ (2,67)
	=====	=====	=====
AVERAGE SHARES OUTSTANDING FOR BASIC (LOSS) EARNINGS PER SHARE	15,915,960	15,738,218	15,915,96
	=====	=====	=====
BASIC (LOSS) EARNINGS PER SHARE	\$ (0.08)	\$ 0.04	\$ (0.1
	=====	=====	=====
AVERAGE SHARES OUTSTANDING FOR DILUTED (LOSS) EARNINGS PER SHARE	15,915,960	16,566,237	15,915,96
	=====	=====	=====
DILUTED (LOSS) EARNINGS PER SHARE	\$ (0.08)	\$ 0.03	\$ (0.1
	=====	=====	=====

See accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)  
(UNAUDITED)

	SIX MONTHS ENDED MARCH 31,	
	2005	2004
	----	----
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net (loss) income	\$ (2,621)	\$ 1,236
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	382	473
Deferred distribution fees revenue	(326)	(321)
Deferred income taxes	(492)	706
Reserve for obsolescence	115	-
Changes in assets and liabilities:		
Accounts receivable	520	1,187
Inventories	1,672	(3,165)
Other current assets	134	274
Accounts payable and other accrued expenses	(1,568)	49
Accrued commissions	423	76
	(1,761)	515
<b>CASH FLOWS USED IN INVESTING ACTIVITIES</b>		
Investment in a marketable security	(491)	-
Purchase of property and equipment	(617)	(542)
	(1,108)	(542)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Issuance of common stock	-	153
Repayment of long-term debt	(67)	(39)
	(67)	114
EFFECT OF EXCHANGE RATE CHANGES ON CASH	424	302
	(2,512)	389
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS		
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,063	5,049
	\$ 2,551	\$ 5,438
	=====	=====
<b>SUPPLEMENTAL CASH FLOW DISCLOSURES</b>		
Interest paid	\$ 32	\$ 27
	=====	=====
Income taxes paid	\$ 61	\$ -
	=====	=====

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See accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
 YEAR ENDED SEPTEMBER 30, 2004 AND SIX MONTHS ENDED MARCH 31, 2005  
 (Unaudited)  
 (In Thousands, Except for Share Data)

	COMMON STOCK (\$ .01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (1)	ACCUMULATED DEFICIT
BALANCE, OCTOBER 1, 2003	\$ 157	\$ 35,980	\$ 81	\$ (18,17)
Stock issued on exercise of options	2	365	-	
Net income	-	-	-	1,50
Foreign currency translation adjustment	-	-	2,167	
BALANCE, SEPTEMBER 30, 2004	159	36,345	2,248	(16,66)
Net loss	-	-	-	(2,62)
Foreign currency translation adjustment	-	-	(58)	
BALANCE, March 31, 2005	\$ 159	\$ 36,345	\$ 2,190	\$ (19,29)

(1) Represents foreign currency translation adjustments.  
 See accompanying Notes to Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
 MARCH 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

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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

The accompanying unaudited consolidated balance sheet of the of the Company as of March 31, 2005 and the unaudited results of operations for the three and six months ended March 31, 2005 and 2004 and the unaudited cash flows for the six months ended March 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 and six months ended March 31, 2005 are not necessarily indicative of the results, which may be expected for the fiscal year ending September 30, 2005. The interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended September 30, 2004.

### (3) NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement 123 (Revised, "SFAS 123R"), SHARE-BASED PAYMENT, that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. On April 14, 2005, the compliance date for SFAS 123R was extended. The Company will be required to comply with SFAS 123R for the three months ended March 31, 2006. The adoption of FASB No. 123 (Revised) is not expected to have a material impact on the results of operations or financial position of the Company.

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. The Company is currently assessing the impact of SAB No. 107 on our implementation and adoption of SFAS No. 123R.

In November 2004, the FASB issued Statement 151, INVENTORY COSTS, AN AMENDMENT OF ARB NO. 43, CHAPTER 4 to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of FASB No. 151 is not expected to have a material impact on the results of operations or financial position of the Company.

In January 2003, the FASB issued FIN No. 46, as restated by FIN No. 46R, CONSOLIDATION OF VARIABLE INTEREST ENTITIES, AND AN INTERPRETATION OF ARB 51. FIN No. 46 defines when a business enterprisemust consolidate a variable interest entity. This interpretation applies immediately to

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variable interest entities created after January 31, 2003. It applies in the first fiscal year or interim period beginning after December 15, 2003, to entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The Company does not have variable interest entities as of March 31, 2005.

### (4) STOCK-BASED AWARDS

The FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. (Under the fair value based method, compensation cost for stock options is measured when options are issued). In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The Company adopted SFAS No. 148 beginning in the second fiscal quarter of fiscal 2003 and such disclosures are included as herein.

The following table reconciles net (loss) income and basic and diluted (loss) earnings per share ("EPS"), as reported, to pro-forma net (loss) income and basic and diluted EPS, as if the Company had expensed the fair value of stock options as permitted by SFAS No. 123, as amended by SFAS No. 148, since it permits alternative methods of adoption.

	Three Months Ended March 31,		Six Months Mar
	2005	2004	2005
	----	----	----
Net (loss) income, as reported:	(\$1,239)	\$653	(\$2,621)
Pro-forma expense as if stock options were charged against net (loss) income	22	5	31
Pro-forma net (loss) income using the fair value method	(\$1,261)	\$648	(\$2,652)
Basic EPS:			
As reported	(\$0.08)	\$0.04	(\$0.16)
Pro forma using the fair value method	(\$0.08)	\$0.04	(\$0.17)
Diluted EPS:			
As reported	(\$0.08)	\$0.03	(\$0.16)
Pro forma using the fair value method	(\$0.08)	\$0.03	(\$0.16)

### (5) MARKETABLE SECURITY

The marketable security represents one U.S. Treasury Note with a face value of \$491 and a coupon rate of 1.875% maturing on December 31, 2005.

### (6) INVENTORIES



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Major classes of inventory at March 31, 2005 and September 30, 2004 were as follows:

	March 31, 2005 ----	September 30, 2004 ----
Raw materials	\$ 1,744	\$ 2,171
Work in process	6,939	6,560
Finished goods	7,405	8,791
	-----	-----
	16,088	17,522
Less reserves for obsolescence	2,629	2,450
	-----	-----
	\$ 13,459	\$ 15,072
	=====	=====

(7) INCOME TAXES

The Company has approximately \$10,700 of federal net operating loss carryforwards expiring beginning in 2008 and state net operating loss carryforwards of approximately \$13,400 that will begin to expire in 2005.

The Company has a corporate net operating loss carryforward for German income tax purposes of approximately \$4,300 (3,210 Euros), and a trade net operation loss carryforward for German income tax purposes of approximately \$1,600 (1,186 Euros), which can be carried forward indefinitely. These net operating losses are the primary component of the Company's net deferred tax asset of \$2.2 million as of March 31, 2005, generated from its U.S. and German operations. A full valuation allowance had been provided on all but \$135 thousand of the U.S. deferred tax asset and no valuation allowance has been provided on its German operations in the Company's consolidated financial statements. 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 September 2002, the Company eliminated the full valuation allowance on its International operations based upon future taxable income projections and its ability, based on German tax law, to carryforward its net operating losses indefinitely. As of March 31, 2005 the Company continues to record the existing valuation allowance on its U.S. operations.

(8) 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 net profit or loss from operations, not including non-recurring and foreign exchange gains or losses. 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 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 March 31, 2005 and 2004, respectively areas follows:

2005	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 4,285	\$ 4,728	\$ 9,013
Less - intercompany	(1,459)	-	(1,459)
	-----	-----	-----
Total revenue - third party	\$ 2,826	\$ 4,728	\$ 7,554
	=====	=====	=====
Operating loss	\$ (778)	\$ (996)	\$ (1,774)
	=====	=====	=====
Depreciation and amortization	\$ 129	\$ 64	\$ 193
	=====	=====	=====
Interest expense	\$ 12	\$ 4	\$ 16
	=====	=====	=====
Net loss	\$ (586)	\$ (653)	\$ (1,239)
	=====	=====	=====
Capital expenditures	\$ 196	\$ 31	\$ 227
	=====	=====	=====
Total identifiable assets	\$ 17,220	\$ 13,755	\$ 30,975
	=====	=====	=====
2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 6,236	\$ 4,016	\$ 10,252
Less - intercompany	(3,163)	-	(3,163)
	-----	-----	-----
Total revenue - third party	\$ 3,073	\$ 4,016	\$ 7,089
	=====	=====	=====
Operating income (loss)	\$ 1,402	\$ (210)	\$ 1,192
	=====	=====	=====
Depreciation and amortization	\$ 113	\$ 60	\$ 173
	=====	=====	=====
Interest expense	\$ 12	\$ 1	\$ 13
	=====	=====	=====
Net income (loss)	\$ 780	\$ (127)	\$ 653
	=====	=====	=====
Capital expenditures	\$ 178	\$ 60	\$ 238
	=====	=====	=====
Total identifiable assets	\$ 18,455	\$ 15,166	\$ 33,621
	=====	=====	=====

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

2005	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 8,249	\$ 9,644	\$ 17,893
Less - intercompany	(3,266)	-	(3,266)
	-----	-----	-----
Total revenue - third party	\$ 4,983	\$ 9,644	\$ 14,627
	=====	=====	=====
Operating loss	\$ (1,183)	\$ (1,521)	\$ (2,704)
	=====	=====	=====
Depreciation and amortization	\$ 254	\$ 128	\$ 382
	=====	=====	=====
Interest expense	\$ 24	\$ 8	\$ 32
	=====	=====	=====
Net loss	\$ (1,024)	\$ (1,597)	\$ (2,621)
	=====	=====	=====
Capital expenditures	\$ 552	\$ 65	\$ 617
	=====	=====	=====
Total identifiable assets	\$ 17,220	\$ 13,755	\$ 30,975
	=====	=====	=====
2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 11,932	\$ 9,079	\$ 21,011
Less - intercompany	(6,437)	-	(6,437)
	-----	-----	-----
Total revenue - third party	\$ 5,495	\$ 9,079	\$ 14,574
	=====	=====	=====
Operating income (loss)	\$ 2,167	\$ (118)	\$ 2,049
	=====	=====	=====
Depreciation and amortization	\$ 247	\$ 226	\$ 473
	=====	=====	=====
Interest expense	\$ 24	\$ 3	\$ 27
	=====	=====	=====
Net income	\$ 1,226	\$ 10	\$ 1,236
	=====	=====	=====
Capital expenditures	\$ 341	\$ 201	\$ 542
	=====	=====	=====

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Total identifiable assets	\$ 18,455	\$ 15,166	\$ 33,621
	=====	=====	=====

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(9) HEDGING TRANSACTION

The Company entered into forward foreign exchange contracts as hedges to reduce the risk from exchange rate fluctuations on intercompany inventory purchases with its German subsidiary. At March 31, 2005, the Company had foreign exchange contracts of \$700 per month for a period through July 25, 2005, totaling \$2.8 million. At March 31, 2005, the fair value of these contracts resulted in immaterial unrealized losses.

(10) LEGAL PROCEEDINGS

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

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany has resulted in a reduction of the original proposed judgment received against the Company by \$406. At March 31, 2005 and September 30, 2004, the Company accrued \$476 with respect to the remaining appeal and legal costs.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS  
(IN THOUSANDS)

RESULTS OF OPERATIONS

REVENUE AND GROSS MARGIN

Revenues for the three months ended March 31, 2005, increased 7% to \$7,554 from \$7,089 in 2004. Foreign currency translations had the effect of increasing total revenues by \$204. The U.S. operation had an 18% increase in revenues from \$4,017 in 2004 to \$4,728 for this quarter. 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 90% 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 urology business continues to be flat due to competition from synthetic users. The International operation had a decrease in revenue of \$246 from \$3,072 to \$2,826. The decrease in International revenue was primarily due to the resolution of certain regulatory issues in France and a temporary backlog of xenograft product lines. An analysis of revenues by major business segment is as follows:

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(000's omitted)	Three Months	Three Months	Six Months	Six Months
	3/31/05	3/31/04	3/31/05	3/31/04
Spine	483	1,033	1,533	3,083
Dental	3,102	1,633	5,701	3,023
Urology	657	742	1,368	1,646
Ophthalmic	253	340	641	748
Other	233	269	401	579
Total - U.S.	4,728	4,017	9,644	9,079
Germany	579	747	899	1,474
France	212	622	627	1,002
ROW	1,884	1,559	3,157	2,739
Other	151	144	300	280
Total-International	2,826	3,072	4,983	5,495
Total Consolidated	7,554	7,089	14,627	14,574

Gross margin, for the three and six months ended March 31, 2005 was 36% and 41%, respectively, as compared to 72% and 66%, respectively for the comparable periods last year. The lower gross margin was due to an unfavorable product mix of lower margin products from the dental product revenues versus

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the higher margin spine revenues and higher production costs due to the strengthening of the euro against the U.S. dollar. Year-to-date spine revenues have decreased to 10% of total revenues versus 21% a year ago.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased 8% for the three months ended March 31, 2005 from the comparable period last year and remain flat at \$2,431 for the year-to-date versus \$2,420 for the comparable period last year. The increase for the quarter was primarily due to the translation of the euro-based expenses as the result of the weakening of the U.S. dollar. As a percentage of

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revenues, for the three and six months ended March 31, 2005, General and Administrative expenses remained at 17% for 2005 and 2004.

### DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased 20% and 25% for the three and six months ended March 31, 2005, respectively, from the comparable periods last year. The increase was primarily due to higher marketing fees paid to Dental of \$1,416 versus \$748 a year ago as a result of a 90% increase in Dental revenues, partially offset by a decrease in expenses as part of a reorganization of the international sales group. As a percentage of revenues, for the three and six months ended March 31, 2005, Distribution and Marketing expenses increased from 33% and 30%, respectively in 2004 to 37% for 2005.

### RESEARCH AND DEVELOPMENT

Research and development expenses increased 17% and 16% for the three and six months ended March 31, 2005, respectively, from the comparable periods last year. The increase was primarily due to the translation of the euro-based expenses as the result of the weakening of the U.S. dollar. As a percentage of revenues, for the three and six months ended March 31, 2005, Research and Development expenses increased from 5% to 6% for 2005 and 2004.

### FOREIGN EXCHANGE GAIN/(LOSS)

The Company had a foreign exchange gain for the quarter of \$183 as the dollar gained some ground against the euro at March 31, 2005. However, for the six months ended March 31, 2005, there is a foreign exchange loss of \$397. This was the result of the settlement of inter-company payments due to the weakness of the dollar versus the euro during this period.

### OTHER EXPENSE (INCOME)

Other expenses increased by \$19 and decreased by \$11, for the three and six months ended March 31 2005, respectively, from the comparable periods a year ago, primarily due to fluctuations in interest income.

### INTEREST EXPENSE

Interest expense was essentially flat from period to period.

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### NET (LOSS) INCOME

As a result of the above, net loss for the three and six months ended March 31, 2005 totaled \$1,239 or \$0.8 basic and diluted loss per share and \$2,621 or \$0.16 basic and diluted loss per share, as compared to a net income of \$653 or \$0.04 basic and \$0.03 diluted earnings per share and \$1,236 or \$0.08 basic and \$0.07 diluted earnings per share for the comparable periods in 2004.

### INVENTORY

Inventory decreased 11%, from \$15.1 million at last fiscal year-end to \$13.5 million at March 31, 2005. Raw materials are down 20%, which reflects the delay in the receipt of shipments of human tissue from the European procurement sites, while work-in-process ("WIP") is up 6%. The increase in WIP is due solely to the increase in inventory to support the Dental product lines. Finished goods are down 16% reflecting the sell-through of the slow-moving inventory.

### CRITICAL ACCOUNTING POLICIES

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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 to direct labor and overhead. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand. 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, 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 of 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.

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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 currency losses of \$397 in 2005 and \$111 in 2004. The exchange rates at March 31, 2005 and 2004 were dollar 1.34/euro and dollar 1.23/euro, respectively.

**DERIVATIVE INSTRUMENTS.** The Company has forward foreign exchange contracts, which have been designated as a cash flow hedge. The effective portion of the derivative's gain or loss is initially reported as a component of other comprehensive income (outside earnings) and subsequently reclassified into earnings when the forecasted transaction affects earnings. The ineffective portion of the gain or loss is reported in earnings immediately.

### LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2005, the Company has working capital of \$14.5 million as compared to September 30, 2004 of \$18.0 million. The Company maintains current working

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capital credit lines totaling 1.5 million euros (approximately \$1.9 million) with several German banks and a \$1.0 million credit line with a U.S. bank. At March 31, 2005, the Company had no borrowings against these lines.

The Company has experienced a negative cash flow of \$2,512 for the six months ended March 31, 2005 as compared to a positive cash flow of \$389 for the same period in 2004. The primary reason for the negative cash flow in 2005 was due to the net loss for the six-month period and the payments for capital expenditures associated with the completion of a new clean room at the German manufacturing facility. The Company's ability to generate positive operational cash flow is dependent upon increasing processing revenues through increased recoveries by tissue banks in the U.S. and Europe, and the development of additional markets and surgical applications worldwide. While the Company believes that it continues to make progress in both these areas, there can be no assurances that changing governmental regulations will not have a material adverse effect on the results of operations and cash flow.

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

2005	\$	967
2006		695
2007		575
2008		440
2009		68
		-----
	\$	2,745
		=====

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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 March 31, 2005 are as follows:

2005	\$	186
2006		195
2007		163
2008		422
		-----
	\$	966
Less current portion		186
		-----
	\$	780
		=====

### 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, 2004. There have been no significant changes in our market risk exposures from the fiscal 2004 year-end, except that in January 2005, the Company has now engaged in a hedging program as explained in Note 9, Hedging Transaction, of the Notes to the Consolidated Financial Statements.

### ITEM 4. CONTROLS AND PROCEDURES



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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 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY-HOLDERS

An annual Meeting of Stockholders was held on March 14, 2005. All management's nominees for director, as listed in the Proxy Statement for the Annual Meeting, were elected. Listed below are the matters voted on by stockholders and the number of votes cast at the Annual Meeting:

(a) ELECTION OF EIGHT MEMBERS OF THE BOARD OF DIRECTORS.

Name -----	Voted for -----	Voted Against -----	Votes Withheld -----	Broker Non-Votes and Abstentions -----
G. Russell Cleveland	11,072,426	0	2,589,145	0
Roy D. Crowninshield	11,460,311	0	2,201,260	0
Robert C. Farone	11,253,397	0	2,408,174	0
J. Harold Helderman	11,413,282	0	2,248,289	0
Richard J. May	11,437,209	0	2,224,362	0
Guy L. Mayer	11,465,897	0	2,195,674	0
Thomas W. Pauken	11,195,375	0	2,466,196	0
Carlton E. Turner	11,255,341	0	2,406,230	0

(b) AMENDMENT TO THE 1996 STOCK OPTION PLAN.

Voted For:	9,990,074
Voted Against:	766,048
Votes Abstained:	212,895
Broker Non-Votes	2,692,554

(c) RATIFICATION OF THE APPOINTMENT OF DELOITTE AND TOUCHE L.L.P. AS INDEPENDENT AUDITORS OF THE COMPANY FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2005.

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Voted For:	13,602,609
Voted Against:	17,019
Votes Abstained:	41,943

### ITEM 6. REPORTS ON FORM 8-K

The Company filed one report on Form 8-K during the quarter ended March 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: May 11, 2005

/s/ Guy L. Mayer

-----  
Chief Executive Officer

Date: May 11, 2005

/s/ George Lombardi

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Chief Financial Officer  
(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

In connection with the Quarterly Report on Form 10Q of Tutogen Medical, Inc. (the "Company") for the three and six months ended March 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 operations of the Company.

Date: May 11, 2005

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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 and six months ended March 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 operations of the Company.

Date: May 11, 2005

TUTOGEN MEDICAL, INC.

/s/ Guy L. Mayer

-----  
Chief Executive Officer

CERTIFICATION

I GEORGE LOMBARDI 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;

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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-14 AND 15D-14) FOR THE REGISTRANT AND HAVE:
- A) DESIGNED SUCH DISCLOSURE CONTROLS AND PROCEDURES 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 QUARTERLY REPORT IS BEING PREPARED;
  - B) EVALUATED THE EFFECTIVENESS OF THE REGISTRANT'S DISCLOSURE CONTROLS AND PROCEDURES AS OF A DATE WITHIN 90 DAYS PRIOR TO THE FILING DATE OF THIS QUARTERLY REPORT (THE "EVALUATION DATE"); AND
  - C) PRESENTED IN THIS QUARTERLY REPORT OUR CONCLUSIONS ABOUT THE EFFECTIVENESS OF THE DISCLOSURE CONTROLS AND PROCEDURES BASED ON OUR EVALUATION AS OF THE EVALUATION DATE.
5. THE REGISTRANT'S OTHER CERTIFYING OFFICER AND I HAVE DISCLOSED, BASED ON OUR MOST RECENT EVALUATION, 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 IN THE DESIGN OR OPERATION OF INTERNAL CONTROLS WHICH COULD ADVERSELY AFFECT THE REGISTRANT'S ABILITY TO RECORD, PROCESS, SUMMARIZE AND REPORT FINANCIAL DATA AND HAVE IDENTIFIED FOR THE REGISTRANT'S AUDITORS ANY MATERIAL WEAKNESSES IN INTERNAL CONTROLS; 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.

CERTIFICATION

6. THE REGISTRANT'S OTHER CERTIFYING OFFICERS AND I HAVE INDICATED IN THIS QUARTERLY REPORT WHETHER THERE WERE SIGNIFICANT CHANGES IN INTERNAL CONTROLS OR IN OTHER FACTORS THAT COULD SIGNIFICANTLY AFFECT INTERNAL CONTROLS SUBSEQUENT TO THE DATE OF OUR MOST RECENT EVALUATION, INCLUDING ANY CORRECTIVE ACTIONS WITH REGARD TO SIGNIFICANT DEFICIENCIES AND MATERIAL WEAKNESSES.

DATE: MAY 11, 2005

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-15 (E) AND 15D-15(E)) FOR THE REGISTRANT AND HAVE:
  - A) DESIGNED SUCH DISCLOSURE CONTROLS AND PROCEDURES 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 QUARTERLY REPORT IS BEING PREPARED;
  - B) EVALUATED THE EFFECTIVENESS OF THE REGISTRANT'S DISCLOSURE CONTROLS AND PROCEDURES AS OF A DATE WITHIN 90 DAYS PRIOR TO THE FILING DATE OF THIS QUARTERLY REPORT (THE "EVALUATION DATE"); AND
  - C) PRESENTED IN THIS QUARTERLY REPORT OUR CONCLUSIONS ABOUT THE EFFECTIVENESS OF THE DISCLOSURE CONTROLS AND PROCEDURES BASED ON OUR EVALUATION AS OF THE EVALUATION DATE.
5. THE REGISTRANT'S OTHER CERTIFYING OFFICER AND I HAVE DISCLOSED, BASED ON OUR MOST RECENT EVALUATION, 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 IN THE DESIGN OR OPERATION OF INTERNAL CONTROLS WHICH COULD ADVERSELY AFFECT THE REGISTRANT'S ABILITY TO RECORD, PROCESS, SUMMARIZE AND REPORT FINANCIAL DATA AND HAVE IDENTIFIED FOR THE REGISTRANT'S AUDITORS ANY MATERIAL WEAKNESSES IN INTERNAL CONTROLS; 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.

### CERTIFICATION

6. THE REGISTRANT'S OTHER CERTIFYING OFFICERS AND I HAVE INDICATED IN THIS

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QUARTERLY REPORT WHETHER THERE WERE SIGNIFICANT CHANGES IN INTERNAL CONTROLS OR IN OTHER FACTORS THAT COULD SIGNIFICANTLY AFFECT INTERNAL CONTROLS SUBSEQUENT TO THE DATE OF OUR MOST RECENT EVALUATION, INCLUDING ANY CORRECTIVE ACTIONS WITH REGARD TO SIGNIFICANT DEFICIENCIES AND MATERIAL WEAKNESSES.

DATE: MAY 11, 2005

BY:  
NAME: /S/ GUY L. MAYER

TITLE: CHIEF EXECUTIVE OFFICER

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