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TUTOGEN MEDICAL INC  
Form 10-Q  
February 14, 2005

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the period ended December 31, 2004.

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 January 31, 2005 there were outstanding 15,915,960 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) DECEMBER 31, 2004 -----	SEPTEMBER 30, 2004 -----
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 3,199	\$ 5,063
Marketable security	491	-

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Accounts receivable - net of allowance for doubtful accounts of \$203 in December 2004 and \$192 in September 2004	4,711	4,922
Inventories - net	15,167	15,072
Deferred income taxes	603	425
Other current assets	856	1,409
	-----	-----
	25,027	26,891
PROPERTY, PLANT AND EQUIPMENT, NET	6,337	6,138
DEFERRED INCOME TAXES	1,288	1,318
	-----	-----
TOTAL ASSETS	\$ 32,652	\$ 34,347
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and other accrued expenses	\$ 5,690	\$ 6,521
Accrued commissions	1,629	1,521
Current portion of deferred distribution fees	704	642
Current portion of long-term debt	183	173
	-----	-----
	8,206	8,857
OTHER LIABILITIES		
Deferred distribution fees	2,617	2,580
Long-term debt	842	827
SHAREHOLDERS' EQUITY	20,987	22,083
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 32,652	\$ 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 DECEMBER 31,	
	2004	2003
	----	----
REVENUE	\$ 7,073	\$ 7,485
COST OF REVENUE	3,760	2,989
	-----	-----

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Gross margin	3,313	4,496
OPERATING EXPENSES		
General and administrative	1,142	1,229
Distribution and marketing	2,711	2,070
Research and development	390	339
	-----	-----
	4,243	3,638
OPERATING (LOSS) INCOME	(930)	858
FOREIGN EXCHANGE LOSS	(579)	(40)
OTHER (EXPENSE) INCOME	(4)	21
INTEREST EXPENSE	(17)	(14)
	-----	-----
	(600)	(33)
(LOSS) INCOME BEFORE INCOME TAX EXPENSE	(1,530)	825
Income (benefit) tax expense	(148)	243
	-----	-----
NET (LOSS) INCOME	\$ (1,382)	\$ 582
	=====	=====
Comprehensive Income:		
Foreign currency translation adjustments	286	190
	-----	-----
COMPREHENSIVE (LOSS) INCOME	\$ (1,096)	\$ 772
	=====	=====
AVERAGE SHARES OUTSTANDING FOR BASIC (LOSS) EARNINGS PER SHARE	15,915,960	15,667,195
	=====	=====
BASIC (LOSS) EARNINGS PER SHARE	\$ (0.09)	\$ 0.04
	=====	=====
AVERAGE SHARES OUTSTANDING FOR DILUTED (LOSS) EARNINGS PER SHARE	15,915,960	16,682,431
	=====	=====
DILUTED (LOSS) EARNINGS PER SHARE	\$ (0.09)	\$ 0.04
	=====	=====

See accompanying Notes to Consolidated Financial Statements

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	2004 -----	2003 -----
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) income	\$ (1,382)	\$ 582
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	190	189
Deferred distribution fees revenue	(172)	(157)
Deferred income taxes	(148)	41
Reserve for obsolescence	(62)	-
Changes in assets and liabilities:		
Accounts receivable	469	1,009
Inventories	359	(909)
Other current assets	633	500
Accounts payable and other accrued expenses	(1,737)	(558)
Accrued commissions	107	28
	-----	-----
Net cash (used in) provided by operating activities	(1,743)	725
CASH FLOWS USED IN INVESTING ACTIVITIES		
Investment in a marketable security	(491)	-
Purchase of property and equipment	(389)	(194)
	-----	-----
Net cash used in investing activities	(880)	(194)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	-	2
Repayment of long-term debt	(34)	(15)
	-----	-----
Net cash provided by financing activities	(34)	(13)
EFFECT OF EXCHANGE RATE CHANGES ON CASH	793	64
	-----	-----
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,864)	582
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,063	5,049
	-----	-----
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 3,199	\$ 5,631
	=====	=====
SUPPLEMENTAL CASH FLOW DISCLOSURES		
Interest paid	\$ 17	\$ 14
	=====	=====
Income taxes paid	\$ 61	\$ -
	=====	=====

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 THREE MONTHS ENDED DECEMBER 31, 2004  
 (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) income	-	-	-	(1,38)
Foreign currency translation adjustment	-	-	286	
BALANCE, June 30, 2004	\$ 159	\$ 36,345	\$ 2,534	\$ (18,05)

(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)  
 DECEMBER 31, 2004  
 (IN THOUSANDS, EXCEPT SHARE DATA)

(1) OPERATIONS AND ORGANIZATION

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

(2) BASIS OF PRESENTATION

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The accompanying unaudited consolidated balance sheet of the of the Company as of December 31, 2004 and the unaudited results of operations for the three months ended December 31, 2004 and 2003 and the unaudited cash flows for the three months ended December 31, 2004 and 2003 have been prepared in conformity with accounting principles generally accepted in the United States of America for interim financial reporting. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments necessary in order to make the financial statements not misleading have been made. Operating results for the three months ended December 31, 2004 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), SHARE-BASED PAYMENT, that will require compensation costs related to share-based payment transactions to be recognized in the financial statements. This statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. 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 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 enterprise

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must consolidate a variable interest entity. This interpretation applies immediately to 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 December 31, 2004.

### (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

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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 December 31,	
	2004	2003
	----	----
Net (loss) income, as reported:	(\$1,382)	\$582
Pro-forma expense as if stock options were charged against net (loss) income	10	16
Pro-forma net (loss) income using the fair value method	(\$1,392)	\$566
Basic EPS:		
As reported	(\$0.09)	\$0.04
Pro forma using the fair value method	(\$0.09)	\$0.04
Diluted EPS:		
As reported	(\$0.09)	\$0.04
Pro forma using the fair value method	(\$0.09)	\$0.03

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(5) MARKETABLE SECURITY

The marketable security represents one U.S. Treasury Note with a face value of \$490 and a coupon rate of 1.875% maturing on December 31, 2005.

(6) INVENTORIES

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

	December 31, 2004	September 30, 2004
	----	----
Raw materials	\$ 2,462	\$ 2,171
Work in process	6,692	6,560
Finished goods	8,540	8,791
	17,694	17,522
Less reserves for obsolescence	2,527	2,450



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\$ 15,167                      \$ 15,072  
 =====                      =====

(7) INCOME TAXES

The Company has incurred cumulative net operating losses ("NOL's") through December 31, 2004 of approximately \$12 million, generated from its U.S. and German operations of \$9 million and \$3 million, respectively. These net operating losses are the primary component of the Company's net deferred tax asset of \$1.9 million as of December 31, 2004, 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 establishes valuation allowances in accordance with the provisions of FASB Statement No. 109, ACCOUNTING FOR INCOME TAXES. The Company continually reviews the adequacy and necessity of the valuation allowance and recognizes these benefits only as reassessment, based on recent developments including income from new contracts, indicates that it is more likely than not that the benefits will be realized. As of December 31, 2004 the Company continues to record the existing valuation allowance on its U.S. operations and has not provided a valuation allowance on its German operations based upon future taxable income projections and the NOL's in the German operation have no expiration date.

(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 intersegment sales and transfers at contractually agreed-upon prices.

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

A summary of the operations and assets by segment as of and for the three months ended December 31, 2004 and 2003, respectively areas follows:

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 3,964	\$ 4,916	\$ 8,880
Less - intercompany	(1,807)	-	(1,807)
	-----	-----	-----
Total revenue - third party	\$ 2,157	\$ 4,916	\$ 7,073
	=====	=====	=====
Depreciation and amortization	\$ 126	\$ 64	\$ 190

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	=====	=====	=====
Operating (loss)	\$ (405)	\$ (525)	\$ (930)
	=====	=====	=====
Interest expense	\$ 12	\$ 5	\$ 17
	=====	=====	=====
Net (loss)	\$ (438)	\$ (944)	\$ (1,382)
	=====	=====	=====
Capital expenditures	\$ 355	\$ 34	\$ 389
	=====	=====	=====
Identifiable assets	\$ 11,062	\$ 21,590	\$ 32,652
	=====	=====	=====

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2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 5,695	\$ 5,063	\$ 10,758
Less - intercompany	(3,273)	-	(3,273)
	-----	-----	-----
Total revenue - third party	\$ 2,422	\$ 5,063	\$ 7,485
	=====	=====	=====
Operating income	\$ 765	\$ 93	\$ 858
	=====	=====	=====
Depreciation and amortization	\$ 134	\$ 55	\$ 189
	=====	=====	=====
Interest expense	\$ 12	\$ 2	\$ 14
	=====	=====	=====
Net income	\$ 446	\$ 136	\$ 582
	=====	=====	=====
Capital expenditures	\$ 164	\$ 30	\$ 194
	=====	=====	=====
Identifiable assets	\$ 8,316	\$ 22,909	\$ 31,225
	=====	=====	=====

(9) SUBSEQUENT EVENT

In January 2005, the Company has entered into a foreign exchange hedging transaction of \$700 per month for a three-month period totaling \$2.1 million to purchase euros at a predetermined exchange rate. These amounts represent payments for intercompany purchase transactions with its German subsidiary.

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 December 31, 2004, decreased 5% to \$7,073 from \$7,485 in 2003. Foreign currency translations had the effect of increasing total revenues by \$320. The U.S. operation had a slight decrease in revenue of \$147 from \$5,063 to \$4,916 for this quarter or 3%. The spine revenues decreased \$1.0 million from \$2.1 to \$1.1 million this quarter due solely to the fulfillment of approximately \$1.0 million of backorders in 2003. The decrease in Spine business was offset by an 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. This product line contributed an increase of \$1.2 million or 85% from the comparable quarter. The urology business decreased \$194 as the demand has decreased due to competition from synthetic users. The International operation had an decrease in revenue of \$265 from \$2,422 to \$2,157. The decrease in International revenue was due to a temporary delay in the renewal of the CE marks ("European Conformity") on certain products, which have now been resolved.

Gross margin, for the three months ended December 31, 2004 was 47%, as compared to 60% for the comparable period last year. The lower gross margin was due to an unfavorable product mix of lower margin products from the dental product revenues versus the higher margin spine revenues and higher production costs due to the strengthening of the euro against the U.S. dollar. The spine revenues decreased to 15% of total revenues versus 27% a year ago.

GENERAL AND ADMINISTRATIVE

General and administrative expenses decreased 7% as the result cost control measures, despite an increase of \$48 due to the translation of the euro-based expenses as the result of the weakening of the U.S. dollar, for the three months ended December 31, 2004, from the comparable period last year. As a percentage of revenues, for the three months ended December 31, 2004, General and Administrative expenses remained at 16% for 2004 and 2003.

DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased from \$2,106 to \$2,711 or 29% for the three months ended December 31, 2004 from the comparable period last year. The increase was primarily due to higher marketing fees paid to Dental of \$1,252 versus \$649 a year ago as a result of an 85% increase in Dental sales. In addition, the translation of the euro-based expenses as the result of the weakening of the U.S. dollar had an unfavorable impact of \$103. For the three months ended December 31, 2004, as a percentage of revenues, Distribution and Marketing expenses increased from 28% in 2003 to 38% in 2004.

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### RESEARCH AND DEVELOPMENT

Research and development expenses increased 15% for the three months ended December 31, 2004, from the comparable period 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. For the three months ended December 31, 2004, as a percentage of revenues, Research and Development expenses increased from 5% in 2003 to 6% in 2004.

### FOREIGN EXCHANGE LOSSES

Foreign exchange losses increased to \$579 from \$40 for the three months ended December 31, 2004 and 2003, respectively. This was primarily the result of higher foreign exchange losses due to the weakness of the dollar versus the euro and higher inter-company balances at quarter-end.

### OTHER EXPENSE (INCOME)

Other expenses increased were \$4 compared to other income of \$21 a year ago due primarily to higher interest income in 2003.

### INTEREST EXPENSE

Interest expense was essentially flat from period to period.

### NET (LOSS) INCOME

As a result of the above, net loss for the three months ended December 31, 2004 totaled \$1,382 or \$0.09 basic and diluted loss per share, as compared to a net income of \$582 or \$0.04 basic and diluted earnings per share for the comparable period in 2003.

### INVENTORY

Inventory was essentially flat, from \$15.1 million at last fiscal year-end to \$15.2 million at December 31, 2004. The 9% weakening of the dollar against the Euro had the effect of increasing the inventory by \$419. Raw materials are up 13%, which reflects the receipt of higher than anticipated shipments of human tissue towards the end of the quarter, while work-in-process ("WIP") is up 2%. The increase in WIP is due solely to the increase in inventory to support the Dental product lines. Finished goods are down 2% reflecting the sell-through of the slow-moving inventory.

### CRITICAL ACCOUNTING POLICIES

The Company's significant accounting policies are more fully described in Note 2 to the consolidated financial statements in the annual report. However, certain of the accounting policies are particularly important to the portrayal of the financial position and results of operations and require the application of significant judgment by management; as a result, they are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be

used in the determination of certain estimates. Those estimates are based on historical experience, terms of existing contracts, observance of trends in the industry, information provided by customers and information available from other outside sources, as appropriate. The Company's significant accounting policies include:

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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 2004 and 2003. 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 currency losses of \$579 in 2004 and \$40 in 2003. The exchange rates at December 31, 2004 and December 31, 2003 were euro 0.77/U.S. dollar and euro 0.84/U.S. Dollar, respectively.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2004, the Company has working capital of \$16.8 million as compared to September 30, 2004 of \$18.0 million. The Company maintains current working capital credit lines totaling 1.5 million euros (approximately \$2.0 million) with several German banks and a \$1.0 million credit line with a U.S. bank. At December 31, 2004, the Company had no borrowings against these lines.

The Company has experienced a negative cash flow of \$1.4 million for the three months ended December 31, 2004 as compared to a positive cash flow of \$582 for the same period in 2003. The primary reason for the negative cash flow in 2004 was due to the net loss this quarter 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 December 31,

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2004 are as follows:

2005	\$	1,045
2006		492
2007		274
2008		164
2009		65
-----		
	\$	2,040
=====		

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, 2004 are as follows:

2005	\$	183
2006		193
2007		178
2008		471
-----		
	\$	1,025
=====		

### 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, Subsequent Event, of the Notes to the Consolidated Financial Statements.

### ITEM 4. CONTROLS AND PROCEDURES

Within 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13 a-14. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) that is required to be included in the Company's periodic filings with the Securities and Exchange Commission. There have been no significant changes in the Company's internal 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 6. REPORTS ON FORM 8-K

The Company filed no Reports on Form 8-K during the quarter ended December 31, 2004.

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SIGNATURES

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

TUTOGEN MEDICAL, INC.

Date: February 11, 2005

/s/ Guy L. Mayer

-----  
Chief Executive Officer

Date: February 11, 2005

/s/ George Lombardi

-----  
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 10QSB of Tutogen Medical, Inc. (the "Company") for the three months ended December 31, 2004 as filed with the

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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: February 11, 2005

TUTOGEN MEDICAL, INC.

/s/ George Lombardi

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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 10QSB of Tutogen Medical, Inc. (the "Company") for the three months ended December 31, 2004 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: February 11, 2005

TUTOGEN MEDICAL, INC.

/s/ Guy L. Mayer

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Chief Executive Officer

### CERTIFICATION

I GEORGE LOMBARDI CERTIFY THAT:

1. I HAVE REVIEWED THIS QUARTERLY REPORT ON FORM 10-Q OF TUTOGEN MEDICAL, INC.



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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-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: FEBRUARY 11, 2005

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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-QSB 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.

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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):

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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: FEBRUARY 11, 2005

BY:  
NAME: /S/ GUY L. MAYER

TITLE: CHIEF EXECUTIVE OFFICER