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TUTOGEN MEDICAL INC  
Form 10QSB  
May 14, 2004

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-QSB

(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, 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 April 30, 2004 there were outstanding 15,778,960 shares of Tutogen Medical, Inc. Common Stock, par value \$0.01.

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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, 2004 -----	SEPTEMBER 30, 2003 -----
ASSETS		
CURRENT ASSETS		

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Cash and cash equivalents	\$ 5,438	\$ 5,049
Accounts receivable - net	4,415	5,526
Inventories - net	15,430	11,992
Deferred income taxes	741	709
Other current assets	875	1,098
	-----	-----
	26,899	24,374
PROPERTY, PLANT AND EQUIPMENT, NET	5,144	4,842
DEFERRED INCOME TAXES	1,578	1,187
	-----	-----
TOTAL ASSETS	\$ 33,621	\$ 30,403
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and other accrued expenses	\$ 7,939	\$ 7,438
Accrued commissions	520	445
Current portion of deferred distribution fees	646	617
Current portion of long-term debt	98	91
	-----	-----
	9,203	8,591
OTHER LIABILITIES		
Deferred distribution fees	2,867	3,038
Long-term debt	728	728
SHAREHOLDERS' EQUITY	20,823	18,046
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 33,621	\$ 30,403
	=====	=====

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
	2004	2003	2
	----	----	---
REVENUE	\$ 7,089	\$ 6,743	\$

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COST OF REVENUE	1,998	2,520	
	-----	-----	-----
Gross margin	5,091	4,223	
OPERATING EXPENSES			
General and administrative	1,221	1,130	
Distribution and marketing	2,236	2,419	
Research and development	386	298	
Depreciation and amortization	56	46	
	-----	-----	-----
	3,899	3,893	
OPERATING INCOME	1,192	330	
OTHER EXPENSE	(63)	(33)	
INTEREST EXPENSE	(13)	(13)	
	-----	-----	-----
	(76)	(46)	
INCOME BEFORE INCOME TAX EXPENSE	1,116	284	
Income tax expense	463	149	
	-----	-----	-----
NET INCOME	\$ 653	\$ 135	\$
	=====	=====	=====
Comprehensive Income:			
Foreign currency translation adjustments	1,189	189	
	-----	-----	-----
COMPREHENSIVE INCOME	\$ 1,842	\$ 324	\$
	=====	=====	=====
AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS PER SHARE	15,738,218	15,527,577	15,
	=====	=====	=====
BASIC EARNINGS PER SHARE	\$ 0.04	\$ 0.01	\$
	=====	=====	=====
AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS PER SHARE	16,566,237	16,070,210	16,
	=====	=====	=====
DILUTED EARNINGS PER SHARE	\$ 0.03	\$ 0.01	\$
	=====	=====	=====

See accompanying Notes to Consolidated Financial Statements

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(IN THOUSANDS)  
(UNAUDITED)

	SIX MONTHS ENDED MARCH 31,	
	2004	2003
	----	----
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 1,236	\$ 266
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	473	283
Deferred distribution fees revenue	(321)	(278)
Deferred income taxes	706	148
Changes in assets and liabilities:		
Accounts receivable	1,187	(1,416)
Inventories	(3,165)	(407)
Other current assets	274	(323)
Accounts payable and other accrued expenses	49	1,653
Accrued commissions	76	151
	-----	-----
Net cash provided by operating activities	515	77
CASH FLOWS USED IN INVESTING ACTIVITIES		
Purchase of property and equipment	(542)	(229)
Increase in patents and trade marks	-	(21)
	-----	-----
Net cash used in investing activities	(542)	(250)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	153	829
Repayment of long-term debt	(39)	(31)
	-----	-----
Net cash provided by financing activities	114	798
EFFECT OF EXCHANGE RATE CHANGES ON CASH	302	195
	-----	-----
NET INCREASE IN CASH AND CASH EQUIVALENTS	389	820
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,049	3,083
	-----	-----
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 5,438	\$ 3,903
	=====	=====
SUPPLEMENTAL CASH FLOW DISCLOSURES		
Interest paid	\$ 27	\$ 25
	=====	=====

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, 2003 AND SIX MONTHS ENDED MARCH 31, 2004  
 (IN THOUSANDS, EXCEPT FOR SHARE DATA)

	COMMON STOCK (\$ .01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (1)	ACCUMULATED DEFICIT
BALANCE, OCTOBER 1, 2002	\$ 152	\$ 35,135	\$ (925)	\$ (20,430)
Stock issued on exercise of options	5	845	-	
Net income	-	-	-	2,260
Foreign currency translation adjustment	-	-	1,006	
BALANCE, SEPTEMBER 30, 2003	157	35,980	81	(18,170)
Stock issued on exercise of options	1	152	-	
Net income	-	-	-	1,230
Foreign currency translation adjustment	-	-	1,389	
BALANCE, MARCH 31, 2004	\$ 158	\$ 36,132	\$ 1,470	\$ (16,930)

(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, 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) SIGNIFICANT ACCOUNTING POLICIES

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The accompanying unaudited consolidated balance sheet of the of the Company as of March 31, 2004 and the unaudited results of operations for the three and six months ended March 31, 2004 and 2003 and the unaudited cash flows for the six months ended March 31, 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, 2004 are not necessarily indicative of the results, which may be expected for the fiscal year ending September 30, 2004. The interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended September 30, 2003.

NEW ACCOUNTING PRONOUNCEMENTS - The FASB issued SFAS No. 146, ACCOUNTING FOR COSTS ASSOCIATED WITH EXIT OR DISPOSAL ACTIVITIES. SFAS NO. 146 NULLIFIES EMERGING ISSUES TASK FORCE ("EITF") NO. 94-3, LIABILITY RECOGNITION FOR CERTAIN EMPLOYEE TERMINATION BENEFITS AND OTHER COSTS TO EXIT AN ACTIVITY (INCLUDING CERTAIN COSTS INCURRED IN AS RESTRUCTURING). The principal difference between SFAS No. 146 and EITF No. 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of an entity's commitment to an exit plan. SFAS No. 146 was effective for exit and disposal activities that are initiated after December 31, 2002. The provisions of SFAS No. 146 did not have a material impact on its financial position or results of operations.

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.

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The following table reconciles net income and basic and diluted earnings pre share (EPS), as reported, to pro-forma net 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 En March 31,	
	2004	2003	2004	2003
	----	----	----	----
Net Income, as reported:	\$653	\$135	\$1,236	\$
Pro-forma expense as if stock options were				

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charged against net income	5	42	21	
	-----	-----	-----	-----
Pro-forma net income using the fair value method	\$648	\$93	\$1,215	\$
	=====	=====	=====	=====
 Basic EPS:				
As reported	\$0.04	\$0.01	\$0.08	\$0
Pro forma using the fair value method	\$0.04	\$0.01	\$0.07	\$0
 Diluted EPS:				
As reported	\$0.04	\$0.01	\$0.08	\$0
Pro forma using the fair value method	\$0.04	\$0.01	\$0.07	\$0

In April 2003, the FASB issued SFAS No. 149, AMENDMENT OF STATEMENT 133 ON DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES. SFAS No. 149 amends SFAS No. 133 for certain decisions made by the Board as part of the Derivatives Implementation Group ("DIG") process and is effective for contracts entered into or modified after June 30, 2003. In addition, SFAS No. 149 should be applied prospectively. The provisions of SFAS No. 149 that relate to SFAS No. 133 Implementation Issues that have been effective for fiscal quarters that began prior to June 15, 2003, should continue to be applied in accordance with their respective effective dates. The adoption of SFAS No. 149 did not have an impact on the results of operations or financial position.

In June 2003, the FASB issued SFAS No. 150, ACCOUNTING FOR CERTAIN FINANCIAL INSTRUMENTS WITH CHARACTERISTICS OF BOTH LIABILITIES AND EQUITY to improve the accuracy of securities issuers' accounting for such financial instruments. For earlier transactions, the provisions of SFAS No. 150 take effect at the start of the first interim period beginning after December 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the results of operations or financial position.

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 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 March 31, 2004.

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### (3) INVENTORIES

Major classes of inventory at March 31, 2004 and September 30, 2003 were as follows:

	March 31, 2004	September 30, 2003	
	----	----	
Raw materials	\$ 2,842	\$ 2,439	
Work in process	3,819	3,316	
Finished goods	12,112	9,335	
	-----	-----	



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	18,773	15,090
Less reserves for obsolescence	3,343	3,098
	-----	-----
	\$ 15,430	\$ 11,992
	=====	=====

(4) INCOME TAXES

The Company has incurred cumulative net operating losses through March 31, 2004 of approximately \$16 million, generated from its U.S. and German operations of \$8 million and \$8 million, respectively. These net operating losses are the primary component of the Company's net deferred tax asset of \$2.0 million as of March 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 March 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.

(5) 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.

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, 2004 and 2003, respectively are as follows:

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
	=====	=====	=====

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Depreciation and amortization	\$ 113	\$ 60	\$ 173
	=====	=====	=====
Interest expense	\$ 12	\$ 1	\$ 13
	=====	=====	=====
Net income	\$ 780	\$ (127)	\$ 653
	=====	=====	=====
Capital expenditures	\$ 178	\$ 60	\$ 238
	=====	=====	=====
Total assets	\$ 12,732	\$ 33,418	\$ 46,150
Less intercompany advances	-	(12,529)	(12,529)
	-----	-----	-----
	\$ 12,732	\$ 20,889	\$ 33,621
	=====	=====	=====

2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 3,573	\$ 4,283	\$ 7,856
Less - intercompany	(1,113)	-	(1,113)
	-----	-----	-----
Total revenue - third party	\$ 2,460	\$ 4,283	\$ 6,743
	=====	=====	=====
Depreciation and amortization	\$ 83	\$ 60	\$ 143
	=====	=====	=====
Interest expense	\$ 11	\$ 2	\$ 13
	=====	=====	=====
Net income (loss)	\$ 204	\$ (69)	\$ 135
	=====	=====	=====
Capital expenditures	\$ 85	\$ 56	\$ 141
	=====	=====	=====
Total assets	\$ 12,323	\$ 31,192	\$ 43,515
Less intercompany advances	-	(16,041)	(16,041)
	-----	-----	-----
	\$ 12,323	\$ 15,151	\$ 27,474
	=====	=====	=====

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A summary of the operations and assets by segment as of and for the six months ended March 31, 2004 and 2003, respectively are as follows:

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
------	---------------	---------------	--------------

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Gross revenue	\$ 11,932	\$ 9,079	\$ 21,011
Less - intercompany	(6,437)	-	(6,437)
	-----	-----	-----
Total revenue - third party	\$ 5,495	\$ 9,079	\$ 14,574
	=====	=====	=====
Depreciation and amortization	\$ 247	\$ 226	\$ 473
	=====	=====	=====
Interest expense	\$ 24	\$ 3	\$ 27
	=====	=====	=====
Net income	\$ 1,226	\$ 10	\$ 1,236
	=====	=====	=====
Capital expenditures	\$ 341	\$ 201	\$ 542
	=====	=====	=====
Total assets	\$ 12,732	\$ 33,418	\$ 46,150
Less intercompany advances	-	(12,529)	(12,529)
	-----	-----	-----
	\$ 12,732	\$ 20,889	\$ 33,621
	=====	=====	=====

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2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 6,280	\$ 8,808	\$ 15,088
Less - intercompany	(1,771)	-	(1,771)
	-----	-----	-----
Total revenue - third party	\$ 4,509	\$ 8,808	\$ 13,317
	=====	=====	=====
Depreciation and amortization	\$ 160	\$ 123	\$ 283
	=====	=====	=====
Interest expense	\$ 23	\$ 2	\$ 25
	=====	=====	=====
Net income	\$ 9	\$ 257	\$ 266
	=====	=====	=====
Capital expenditures	\$ 144	\$ 106	\$ 250
	=====	=====	=====
Total assets	\$ 12,323	\$ 31,192	\$ 43,515
Less intercompany advances	-	(16,041)	(16,041)

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-----	-----	-----
\$ 12,323	\$ 15,151	\$ 27,474
=====	=====	=====

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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 COST OF REVENUE

In April 2003, the Company signed a renegotiated U.S. Distribution Agreement with Centerpulse Spine-Tech, now known as Zimmer Spine ("Spine"), whereby Spine has become a "stocking distributor". The effect of this new arrangement means that Spine is now invoicing the end customer directly. The new agreement also eliminates marketing fees paid to Spine included in Distribution and Marketing.

Revenues for the three months ended March 31, 2004, increased 5% to \$7,089 from \$6,743 for the comparable period. The International operation generated an increase in revenue of \$613 (\$273 of the increase was due to currency translation) from \$2,460 to \$3,073. This was partially offset by a decrease in revenue from the U.S. operation of \$267 from \$4,283 to \$4,016 for this quarter. The U.S. revenue increased as a result of 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 \$700 of an increase in revenue. However, as pointed out above, the Company's revenues for the prior year quarter would have been \$800 lower under the new agreement with Spine, therefore, resulting in an increase of U.S. revenue for this quarter of 19%. The increase in international revenue was due to an overall increase in the European and international distributor business.

Revenues for the six months ended March 31, 2004 increased 9% to \$14,574 from \$13,317 for the comparable period. Adjusting for new agreement with Spine, the sales for the comparable period in 2003 would have been \$11,617. Therefore, revenues for the six months ended March 31, 2004 actually increased 25% over the comparable period in 2003. Revenues from the U.S. operation increased 28% to \$9,079 from \$7,108 (as adjusted for the change in the new distribution arrangement with Spine) for the same period last year and revenues from the international operations increased 21% from \$4,509 in 2003 to \$5,495 in 2004. Incremental Spine and Dental revenues contributed the entire increase in revenue.

Cost of revenue, for the three and six months ended March 31, 2004 were 28% and 34%, respectively, as compared to 37% and 40%, respectively for the comparable periods last year. The lower cost of revenue margin was primarily due to the significant reduction in scrap as the result of improved manufacturing efficiencies from the International operation, partially offset by start-up expenses related to the introduction of bone production in the U.S. operation. Historically, the U.S. operation solely manufactured membranes or soft tissue.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased 8% and 16% for the three and six

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months ended March 31, 2004, from the comparable periods last year. Second quarter expenses increased \$91, primarily due to the foreign exchange impact of \$81. Year-to-date expenses increased \$320, due to foreign exchange variance (\$161), expenditures related to the hiring of an investor relations/banker firms (\$57), higher legal expenses related to merger opportunities (\$40) and other (\$60). As a percentage of revenues, for year-to-date, General and Administrative expenses were flat in 2004 and 2003 at 16%.

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### DISTRIBUTION AND MARKETING

Distribution and marketing expenses decreased 8% from \$2,419 to \$2,236, and decreased 10% to \$4,306 from \$4,761 for the three and six months ended March 31, 2004, from the comparable periods last year. The decrease was primarily due to lower marketing fees as a result of the new agreement with Spine, whereby the Spine marketing fees have been eliminated. Such fees decreased \$1,053 for the quarter and \$2,166 for the six months ended March 31, 2004 as compared to the comparable periods in 2003. The partial offset to the decrease in the Spine marketing fees was due to higher marketing fees paid to Dental of \$323 and \$609 for the quarter and year-to-date, respectively as a result of increased Dental sales. The balance of the increase was due to increased sales efforts internationally and foreign exchange variances. For the three and six months ended March 31, 2004, as a percentage of revenues, Distribution and Marketing expenses decreased from 36% in 2003 to 32% in 2004 and from 36% to 30%, respectively.

### RESEARCH AND DEVELOPMENT

Research and development expenses increased 30% and 33%, respectively, for the three and six months ended March 31, 2004, from the comparable periods last year. The increase was due to increased development efforts in the spine, dental and ligament product areas. As a percentage of revenues, Research and Development expenses increased from 4% in 2003 to 5% in 2004.

### DEPRECIATION AND AMORTIZATION

Depreciation and amortization was essentially flat for the three months ended March 31, 2004 as compared to the same period last year, but for the six months ended the same period depreciation increased from \$87 to \$128, primarily due to the foreign exchange impact and additions to fixed assets.

### OTHER EXPENSE

Other expenses were essentially flat from period to period.

### INTEREST EXPENSE

Interest expense was essentially flat from period to period.

### NET INCOME

As a result of the above, net income for the three and six months ended March 31, 2004 totaled \$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, respectively, as compared to a net income of \$135 or \$0.01 basic and diluted earnings per and net income of \$266 or \$0.02 basic and diluted earnings per share for the same periods in 2003.

### 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

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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 are 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 and consider delivery 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 include 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 financial position and results of operations of the Company's foreign subsidiary is measured using local currency (Euro) as the functional currency. Assets and liabilities of the foreign subsidiary are translated at the rate of exchange in effect at the end of the period. Revenues and expenses are translated at the average exchange rate for the period. Foreign currency translation gains and losses not impacting cash flows are credited to or charged against other comprehensive income (loss). Foreign currency translation gains and losses arising from cash transactions are credited to or charged against current earnings.

### LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2004, the Company has working capital of \$17.7 million as compared to September 30, 2003 of \$15.8 million. The Company maintains current working capital credit lines totaling (euro)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, 2004, the Company had no borrowings against these lines.

The Company has experienced a positive cash flow of \$389 for the six months ended March 31, 2004 as compared to a positive cash flow of \$820 for the same period in 2003. In 2003, the cash flow was influenced by increased issuance of common shares from the exercise of stock options and lower purchases of property

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and equipment. The primary reason for the positive cash flow in 2004 was due to the increase in net income for the period.

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

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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, 2004 are as follows:

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, 2004 are as follows:

### NEW ACCOUNTING PRONOUNCEMENTS

In June 2002, the FASB issued SFAS No. 146, ACCOUNTING FOR COSTS ASSOCIATED WITH EXIT OR DISPOSAL ACTIVITIES. SFAS No. 146 nullifies Emerging Issues Task Force ("EITF") No. 94-3, LIABILITY RECOGNITION FOR CERTAIN EMPLOYEE TERMINATION BENEFITS AND OTHER COSTS TO EXIT AN ACTIVITY (INCLUDING CERTAIN COSTS INCURRED IN AS RESTRUCTURING). The principal difference between SFAS No. 146 and EITF No. 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under EITF No. 94-3, a liability for an exit cost was recognized at the date of an entity's commitment to an exit plan. SFAS No. 146 was effective for exit and disposal activities that are initiated after December 31, 2002. The provisions of SFAS No. 146 did not have a material impact on its financial position or results of operations.

On December 31, 2002, 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

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method of accounting for stock-based employee compensation. (Under the fair value based method, compensation cost for stock options is measured when options

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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 income and basic and diluted earnings per share (EPS), as reported, to pro-forma net 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 Ended March 31,	
	2004 ----	2003 ----	2004 ----	2003 ----
Net Income, as reported:	\$653	\$135	\$1,236	\$266
Pro-forma expense as if stock options were charged against net income	5 ----	42 --	21 --	57 ----
Pro-forma net income using the fair value method	\$648 =====	\$93 ===	\$1,215 =====	\$209 =====
 Basic EPS:				
As reported	\$0.04	\$0.01	\$0.08	\$0.02
Pro forma using the fair value method	\$0.04	\$0.01	\$0.07	\$0.01
 Diluted EPS:				
As reported	\$0.04	\$0.01	\$0.08	\$0.02
Pro forma using the fair value method	\$0.04	\$0.01	\$0.07	\$0.01

In April 2003, the FASB issued SFAS No. 149, AMENDMENT OF STATEMENT 133 ON DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES. SFAS No. 149 amends SFAS No. 133 for certain decisions made by the Board as part of the Derivatives Implementation Group ("DIG") process and is effective for contracts entered into or modified after June 30, 2003. In addition, SFAS No. 149 should be applied prospectively. The provisions of SFAS No. 149 that relate to SFAS No. 133 Implementation Issues that have been effective for fiscal quarters that began prior to June 15, 2003, should continue to be applied in accordance with their respective effective dates. The adoption of SFAS No. 149 did not have an impact on the results of operations or financial position.

In June 2003, the FASB issued SFAS No. 150, ACCOUNTING FOR CERTAIN FINANCIAL INSTRUMENTS WITH CHARACTERISTICS OF BOTH LIABILITIES AND EQUITY to improve the accuracy of securities issuers' accounting for such financial instruments. For earlier transactions, the provisions of SFAS No. 150 take effect at the start of the first interim period beginning after December 15, 2003. The adoption of SFAS No. 150 did not have a material impact on the results of operations or financial position.



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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 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 March 31, 2003.

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

An annual Meeting of Stockholders was held on April 20, 2004. 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	13,188,918	0	330,179	0
Roy D. Crowninshield	13,190,903	0	328,194	0
Robert C. Farone	13,219,875	0	299,222	0
J. Harold Helderman	13,223,875	0	295,222	0
Manfred K. Kruger	13,190,603	0	328,494	0
Richard J. May	13,222,875	0	296,222	0
Thomas W. Pauken	13,189,803	0	329,294	0
Carlton E. Turner	13,221,875	0	297,222	0

#### (B) RATIFICATION OF THE APPOINTMENT OF DELOITTE AND TOUCHE L.L.P. AS INDEPENDENT AUDITORS OF THE COMPANY FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2004.

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Voted For:	13,460,426
Voted Against:	54,591
Votes Abstained:	4,080
Broker Non-Votes	0

ITEM 6. REPORTS ON FORM 8-K

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

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CERTIFICATION

Each of the undersigned hereby certifies in his capacity as an officer of Tutogen Medical, Inc. (the "Company") that the Quarterly Report of the Company on Form 10-QSB for the periods ended March 31, 2004 fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition of the Company at the end of such periods and the results of operations of the Company for such periods.

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 13, 2004

/s/ Manfred Kruger

-----  
President and Chief Executive Officer

Date: May 13, 2004

/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 10QSB of Tutogen Medical, Inc.

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(the "Company") for the three months ended March 31, 2004 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 13, 2004

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 March 31, 2004 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I Manfred Krueger, as the Chief Executive Officer, President and Chief Operating 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 13, 2004

TUTOGEN MEDICAL, INC.

/s/ Manfred Krueger

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Manfred Krueger  
Chief Executive Officer, President and  
Chief Operating Officer

CERTIFICATION

I George Lombardi certify that:

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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-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 13, 2004

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BY:  
Name: /s/ George Lombardi  
Title: Chief Financial Officer,  
Treasurer and Secretary

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CERTIFICATION

I Manfred Krueger 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.
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

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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: May 13, 2004

BY:

Name: /s/ Manfred Krueger

Title: CEO, President and Chief Operating Officer