TUTOGEN MEDICAL INC
Form 10QSB
August 04, 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 June 30, 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 Incorporation or Organization)	(I.R.S. Employer 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 July 31, 2004 there were outstanding 15,888,960 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) JUNE 30, 2004	SEPTEMBER 30, 2003
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,255	$ 5,049
Accounts receivable - net of allowance for doubtful accounts of $202 in 2004 and $283 in 2003	3,851	5,526

Inventories - net	16,552	11,992
Deferred income taxes	736	709
Other current assets	1,294	1,098
	27,688	24,374
PROPERTY, PLANT AND EQUIPMENT, NET	5,422	4,842
DEFERRED INCOME TAXES	1,316	1,187
TOTAL ASSETS	$ 34,426	$ 30,403
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and other accrued expenses	$ 7,564	$ 6,926
Accrued commissions	1,186	957
Current portion of deferred distribution fees	641	617
Current portion of long-term debt	99	91
	9,490	8,591
OTHER LIABILITIES		
Deferred distribution fees	2,684	3,038
Long-term debt	694	728
SHAREHOLDERS' EQUITY	21,558	18,046
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 34,426	$ 30,403

See accompanying Notes to Consolidated Financial Statements.

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

	THREE MONTHS ENDED JUNE 30,		NINE MONTHS
	2004	2003	2004
REVENUE	$ 6,823	$ 8,933	$ 21,397
COST OF REVENUE	2,287	3,621	7,274

Gross margin	4,536	5,312	14,123
OPERATING EXPENSES			
General and administrative	1,127	1,176	3,551
Distribution and marketing	2,408	2,431	6,797
Research and development	336	275	1,061
Litigation Contingency	(405)	-	(405)
	3,466	3,882	11,004
OPERATING INCOME	1,070	1,430	3,119
OTHER EXPENSE	(19)	(70)	(99)
INTEREST EXPENSE	(17)	(13)	(44)
	(36)	(83)	(143)
INCOME BEFORE INCOME TAX EXPENSE	1,034	1,347	2,976
Income tax expense	399	529	1,105
NET INCOME	$ 635	$ 818	$ 1,871
Comprehensive Income:			
Foreign currency translation adjustments	(72)	205	1,317
COMPREHENSIVE INCOME	$ 563	$ 1,023	$ 3,188
AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS PER SHARE	15,758,053	15,647,110	15,720,959
BASIC EARNINGS PER SHARE	$ 0.04	$ 0.05	$ 0.12
AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS PER SHARE	16,468,810	16,265,537	16,515,915
DILUTED EARNINGS PER SHARE	$ 0.04	$ 0.05	$ 0.11

See accompanying Notes to Consolidated Financial Statements

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

	NINE MONTHS ENDED JUNE 30, 2004	NINE MONTHS ENDED JUNE 30, 2003
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	$ 1,871	$ 1,084
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	602	402
Deferred distribution fees revenue	(479)	(429)
Deferred income taxes	1,105	692
Reserve for bad debts	-	90
Reserve for obsolesence	(121)	(31)
Changes in assets and liabilities:		
Accounts receivable	1,733	(1,990)
Inventories	(4,213)	(214)
Other current assets	(151)	(771)
Accounts payable and other accrued expenses	(424)	1,641
Accrued commissions	741	336
Net cash provided by operating activities	664	810
CASH FLOWS USED IN INVESTING ACTIVITIES		
Purchase of property and equipment	(988)	(423)
Increase in patents and trade marks	-	(36)
Net cash used in investing activities	(988)	(459)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	324	829
Proceeds from revolving credit arrangements	-	338
Repayment of revolving credit arrangements	-	(338)
Repayment of long-term debt	(63)	(52)
Net cash provided by financing activities	261	777
EFFECT OF EXCHANGE RATE CHANGES ON CASH	269	286
NET INCREASE IN CASH AND CASH EQUIVALENTS	206	1,414
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,049	3,083
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,255	$ 4,497
SUPPLEMENTAL CASH FLOW DISCLOSURES		
Interest paid	$ 44	$ 39

See accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
YEAR ENDED SEPTEMBER 30, 2003 AND SIX MONTHS ENDED JUNE 30, 2004
(Unaudited)
(In Thousands, Except for Share Data)

	COMMON STOCK ($.01 PAR)	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE INCOME (1)	ACCUMU DEFI
BALANCE, OCTOBER 1, 2002	$ 152	$ 35,135	$ (925)	$ (20
Stock issued on exercise of options	5	845	-	
Net income	-	-	-	2
Foreign currency translation adjustment	-	-	1,006	
BALANCE, SEPTEMBER 30, 2003	157	35,980	81	(18
Stock issued on exercise of options	2	322	-	
Net income	-	-	-	1
Foreign currency translation adjustment	-	-	1,317	
BALANCE, June 30, 2004	$ 159	$ 36,302	$ 1,398	$ (16

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

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
JUNE 30, 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

The accompanying unaudited consolidated balance sheet of the of the Company as of June 30, 2004 and the unaudited results of operations for the three and nine months ended June 30, 2004 and 2003 and the unaudited cash flows for the nine months ended June 30, 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 nine months ended June 30, 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. 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 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 June 30,		Nine Months Ended June 30,	
	2004	2003	2004	2003
Net Income, as reported:	$635	$818	$1,871	$1,08
Pro-forma expense as if stock options were charged against net income	81	29	101	8

Pro-forma net income using the fair value method	$554	$789	$1,770	$99
	====	====	======	=====
Basic EPS:				
As reported	$0.04	$0.05	$0.12	$0.0
Pro forma using the fair value method	$0.04	$0.05	$0.11	$0.0
Diluted EPS:				
As reported	$0.04	$0.05	$0.11	$0.0
Pro forma using the fair value method	$0.03	$0.05	$0.11	$0.0

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 June 30, 2004.

(3) INVENTORIES

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

	June 30, 2004	September 30, 2003
Raw materials	$ 2,395	$ 2,439
Work in process	5,454	3,316
Finished goods	11,818	9,335
	19,668	15,090

Less reserves for obsolescence	3,116	3,098
	$ 16,552	$ 11,992

(4) INCOME TAXES

The Company has incurred cumulative net operating losses through June 30, 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 June 30, 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 June 30, 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.

A summary of the operations and assets by segment as of and for the three months ended June 30, 2004 and 2003, respectively are as follows:

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 5,440	$ 3,998	$ 9,438
Less - intercompany	(2,615)	-	(2,615)
Total revenue - third party	$ 2,825	$ 3,998	$ 6,823
Operating income (loss)	$ 1,414	$ (344)	$ 1,070

Depreciation and amortization	$ 127	$ 60	$ 187
Interest expense	$ 11	$ 6	$ 17
Net income (loss)	$ 883	$ (248)	$ 635
Capital expenditures	$ 318	$ 182	$ 500
Total assets	$ 11,903	$ 34,421	$ 46,324
Less intercompany advances	-	(11,898)	(11,898)
	$ 11,903	$ 22,523	$ 34,426

2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 5,151	$ 6,700	$ 11,851
Less - intercompany	(2,918)	-	(2,918)
Total revenue - third party	$ 2,233	$ 6,700	$ 8,933
Operating income (loss)	$ 1,607	$ (177)	$ 1,430
Depreciation and amortization	$ 122	$ 60	$ 182
Interest expense	$ 12	$ 1	$ 13
Net income	$ 807	$ 11	$ 818
Capital expenditures	$ 201	$ 73	$ 274
Total assets	$ 11,953	$ 31,956	$ 43,909
Less intercompany advances	-	(14,934)	(14,934)
	$ 11,953	$ 17,022	$ 28,975

A summary of the operations and assets by segment as of and for the nine months ended June 30, 2004 and 2003, respectively are as follows:

2004	INTERNATIONAL	UNITED STATES	CONSOLIDATED

Gross revenue	$ 17,371	$ 13,078	$ 30,449
Less - intercompany	(9,052)	-	(9,052)
Total revenue - third party	$ 8,319	$ 13,078	$ 21,397
Operating income (loss)	$ 3,581	$ (462)	$ 3,119
Depreciation and amortization	$ 376	$ 226	$ 602
Interest expense	$ 35	$ 9	$ 44
Net income (loss)	$ 2,110	$ (239)	$ 1,871
Capital expenditures	$ 664	$ 324	$ 988
Total assets	$ 11,903	$ 34,421	$ 46,324
Less intercompany advances	-	(11,898)	(11,898)
	$ 11,903	$ 22,523	$ 34,426

2003	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	$ 11,431	$ 15,508	$ 26,939
Less - intercompany	(4,689)	-	(4,689)
Total revenue - third party	$ 6,742	$ 15,508	$ 22,250
Operating income (loss)	$ 2,058	$ (130)	$ 1,928
Depreciation and amortization	$ 277	$ 125	$ 402
Interest expense	$ 36	$ 3	$ 39
Net income	$ 956	$ 128	$ 1,084
Capital expenditures	$ 301	$ 122	$ 423
Total assets	$ 11,953	$ 31,956	$ 43,909
Less intercompany advances	-	(14,934)	(14,934)
	$ 11,953	$ 17,022	$ 28,975

(6) LITIGATION CONTINGENCY

A partial decision by the court of appeal in Germany has resulted in a reduction of the original judgment received against the Company regarding a dispute between the Company and a former international distributor in the amount of $405. At June 30, 2004, $465 is accrued with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and the final settlement will not have a material impact on its results of operations or financial opinion.

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

RESULTS OF OPERATIONS

REVENUE AND GROSS MARGIN

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 June 30, 2004, decreased 24% to $6,823 from $8,933 for the comparable period. However, if we would compare this quarter with 2003 considering the new arrangement with Spine, as mentioned above, the comparable quarter would have been $7,171 or a decrease in revenue from 2003 of 5%. The U.S. operation had a decrease in revenue of $2,702 from $6,700 to $3,998 for this quarter or 40%. The U.S. revenues decreased primarily, as pointed out above, as a result of the new agreement with Spine. The Company's U.S. revenues for the prior year quarter would have been $1,762 lower under the new agreement with Spine, therefore, resulting in a decrease of U.S. revenue for this quarter of 5%. The Spine business, after considering the new arrangement, decreased by $1,000, which is the direct result of over-buying by Spine at the end of the previous year. This decrease in Spine business was partially 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 $800 from the comparable quarter. The International operation had an increase in revenue of $592 ($250 of the increase was due to currency translation) from $2,233 to $2,825. The increase in International revenue was due to an overall increase in the European and international distributor business.

Revenues for the nine months ended June 30, 2004 decreased 4% to $21,397 from

$22,250 for the comparable period. Adjusting for the new agreement with Spine, the sales for the comparable period in 2003 would have been $18,788. Therefore, revenues for the nine months ended June 30, 2004 actually increased 14% over the comparable period in 2003. Revenues from the U.S. operation increased 9% to $13,078 from $11,946 (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 23% from $6,742 in 2003 to $8,319 in 2004.

Gross margins, for the three and nine months ended June 30, 2004 were 66%, as compared to 59% and 60%, respectively for the comparable periods last year. The higher gross 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 decreased 4% and increased 8% for the three and nine months ended June 30, 2004, respectively, from the comparable periods last year. Third quarter expenses decreased $49. Year-to-date expenses increased $271, due to foreign exchange variance ($88), expenditures

related to the hiring of an investor relations/banker firms ($108), higher legal expenses related to merger opportunities ($88) and other ($67). As a percentage of revenues, for the three and nine months ended June 30, 2004, General and Administrative expenses increased from 13% and 14% in 2003, respectively to 16% in 2004.

DISTRIBUTION AND MARKETING

Distribution and marketing expenses were essentially flat from $2,431 to $2,408 and decreased 6% to $6,797 from $7,245 for the three and nine months ended June 30, 2004, respectively, 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 $294 for the quarter and $1,850 for the nine months ended June 30, 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 $404 and $1,040 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 nine months ended June 30, 2004, as a percentage of revenues, Distribution and Marketing expenses increased from 27% in 2003 to 35% in 2004 and decreased from 33% to 32%, respectively.

RESEARCH AND DEVELOPMENT

Research and development expenses increased 22% and 29%, respectively, for the three and nine months ended June 30, 2004, from the comparable periods last year. The increase was due to increased development efforts in the spine, dental and ligament product areas. For the three and nine months ended June 30, 2004, as a percentage of revenues, Research and Development expenses increased from 3% in 2003 to 5% in 2004 and 4% to 5%, respectively.

LITIGATION CONTINGENCY

A partial decision by the court of appeal in Germany has resulted in a reduction of the original judgment received against the Company regarding a dispute between the Company and a former international distributor in the amount of $405. At June 30, 2004, $465 is accrued with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and the final settlement will not have a material impact on its results of operations or financial opinion.

DEPRECIATION AND AMORTIZATION

Depreciation and amortization was essentially flat for the three months ended June 30, 2004 as compared to the same period last year, but for the nine months ended June 30, 2004, depreciation increased from $153 to $197, primarily due to the foreign exchange impact and additions to fixed assets.

OTHER EXPENSE

Other expenses decreased 73% and 23%, respectively, for the three and nine months ended June 30, 2004, from the comparable periods last year as a result of lower foreign exchange losses.

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 nine months ended June 30, 2004 totaled $635 or $0.04 basic and diluted earnings per share and $1,871 or $0.12 basic and $0.11 diluted earnings per share, respectively, as compared to a net income of $818 or $0.05 basic and diluted earnings per and net income of $1,084 or $0.07 basic and diluted earnings per share for the same periods in 2003.

INVENTORY

Inventory has increased from $12.0 million at last year-end to $16.6 million at June 30, 2004, a $4.6 million or 38% increase. Raw materials are down 2%, which reflects the curtailment of incoming tissue, while work-in-process ("WIP") is up 64% or $2.1 million from last year-end to the end of this quarter. The increase in WIP is due solely to the increase in the inventory to support the Dental product lines. Finished goods are up 26% or $2.5 million. Here again, $1.3 million is due to the significant increase in the Dental business. The Dental business is expected to increase by approximately 90% this year versus 2003. Fascia inventories are higher than normal by $720 due to reduced demand and the anticipation of the launch of a new product line. The 4% weakening of the dollar against the Euro had the effect of increasing the inventory by $226.

CRITICAL ACCOUNTING POLICIES

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

INVENTORIES. Inventories are valued at the lower of cost (weighted average basis) or market. Work in process and finished goods include costs attributable 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 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 rated 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 June 30, 2004, the Company has working capital of $18.2 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 June 30, 2004, the Company had no borrowings against these lines.

The Company has experienced a positive cash flow of $206 for the nine months ended June 30, 2004 as compared to a positive cash flow of $1,414 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 and equipment. The primary reason for the positive cash flow in 2004 was due to cash provided by operating activities, cash from financing activities and the effect of exchange rate changes on cash, partially offset by higher purchases of property and equipment. 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 June 30, 2004 are as follows:

2005	624
2006	282
2007	136
2008	74
	$ 1,586

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 June 30, 2004 are as follows:

2004	$ 99
2005	101
2006	106
2007	113
2008	376
	$ 795

NEW ACCOUNTING PRONOUNCEMENTS

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 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. 148amends 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.

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 June 30, 2004.

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.

PART II. OTHER INFORMATION

ITEM 6. REPORTS ON FORM 8-K

The Company filed no Reports on Form 8-K during the quarter ended June 30, 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: August 4, 2004

/s/ Manfred Kruger

President and
Chief Operating Officer

Date: August 4, 2004

/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 June 30, 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: August 4, 2004

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 10QSB of Tutogen Medical, Inc. (the "Company") for the three months ended June 30, 2004 as filed with the Securities and Exchange commission on the date hereof (the "Report"), I Manfred Krueger, as the 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: August 4, 2004

TUTOGEN MEDICAL, INC.

/s/ Manfred Krueger

Manfred Krueger
President and
Chief Operating Officer

CERTIFICATION

I GEORGE LOMBARDI 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-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: AUGUST 4, 2004

BY:
NAME: /S/ GEORGE LOMBARDI

TITLE: CHIEF FINANCIAL OFFICER,
TREASURER AND SECRETARY

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

   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: AUGUST 4, 2004

BY:
NAME: /S/ MANFRED KRUEGER

TITLE: CEO, PRESIDENT AND CHIEF OPERATING OFFICER