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TUTOGEN MEDICAL INC
Form 10QSB
February 13, 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 December 31, 2003.

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, 2004 there were outstanding 15,690,210 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)
DECEMBER 31,
2003

SEPTEMBER 30,
2003

ASSETS

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| | | |
|---|-----------|-----------|
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 5,631 | \$ 5,049 |
| Accounts receivable - net | 4,777 | 5,526 |
| Inventories - net | 13,132 | 11,992 |
| Deferred income taxes | 755 | 709 |
| Other current assets | 649 | 1,098 |
| | ----- | ----- |
| | 24,944 | 24,374 |
| PROPERTY, PLANT AND EQUIPMENT, NET | 5,180 | 4,842 |
| DEFERRED INCOME TAXES | 1,101 | 1,187 |
| | ----- | ----- |
| TOTAL ASSETS | \$ 31,225 | \$ 30,403 |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable and other accrued expenses | \$ 7,315 | \$ 7,438 |
| Accrued commissions | 473 | 445 |
| Current portion of deferred distribution fees | 659 | 617 |
| Current portion of long-term debt | 99 | 91 |
| | ----- | ----- |
| | 8,546 | 8,591 |
| OTHER LIABILITIES | | |
| Deferred distribution fees | 3,091 | 3,038 |
| Long-term debt | 768 | 728 |
| SHAREHOLDERS' EQUITY | 18,820 | 18,046 |
| | ----- | ----- |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 31,225 | \$ 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 DECEMBER 31, | |
|-----------------|---------------------------------|----------|
| | 2003 | 2002 |
| | ---- | ---- |
| REVENUE | \$ 7,485 | \$ 6,574 |
| COST OF REVENUE | 2,989 | 2,846 |
| | ----- | ----- |

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| | | |
|---|------------|------------|
| Gross margin | 4,496 | 3,728 |
| OPERATING EXPENSES | | |
| General and administrative | 1,158 | 929 |
| Distribution and marketing | 2,070 | 2,342 |
| Research and development | 339 | 248 |
| Depreciation and amortization | 71 | 41 |
| | ----- | ----- |
| | 3,638 | 3,560 |
| OPERATING INCOME | 858 | 168 |
| OTHER EXPENSE | (19) | (25) |
| INTEREST EXPENSE | (14) | (13) |
| | ----- | ----- |
| | (33) | (38) |
| INCOME BEFORE INCOME TAX EXPENSE (BENEFIT) | 825 | 130 |
| Income tax expense (benefit) | 243 | (1) |
| | ----- | ----- |
| NET INCOME | \$ 582 | \$ 131 |
| | ===== | ===== |
| | | |
| AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS PER SHARE | 15,667,195 | 15,158,110 |
| | ===== | ===== |
| BASIC EARNINGS PER SHARE | \$ 0.04 | \$ 0.01 |
| | ===== | ===== |
| | | |
| AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS PER SHARE | 16,682,431 | 15,884,927 |
| | ===== | ===== |
| DILUTED EARNINGS PER SHARE | \$ 0.04 | \$ 0.01 |
| | ===== | ===== |

See accompanying Notes to Consolidated Financial Statements

2

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

THREE
2003

CASH FLOWS FROM OPERATING ACTIVITIES

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| | |
|---|-------------|
| Net income | \$ |
| Adjustments to reconcile net income to net cash provided by (used in) operating activities: | |
| Depreciation and amortization | |
| Deferred distribution fees revenue | |
| Deferred income taxes | |
| Changes in assets and liabilities: | |
| Accounts receivable | |
| Inventories | |
| Other current assets | |
| Accounts payable and other accrued expenses | |
| Accrued commissions | |
| Net cash provided by (used in) operating activities | ----- |
| | |
| CASH FLOWS USED IN INVESTING ACTIVITIES | |
| Purchase of property and equipment | ----- |
| | |
| CASH FLOWS FROM FINANCING ACTIVITIES | |
| Issuance of common stock | |
| Repayment of long-term debt | ----- |
| Net cash used in financing activities | ----- |
| | |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH | ----- |
| | |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | |
| | |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | ----- |
| | |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD | \$ ===== |
| | |
| SUPPLEMENTAL CASH FLOW DISCLOSURES | |
| Interest paid | \$ ===== |

See accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
DECEMBER 31, 2003
(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

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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 financial statements of the Company and the unaudited results of operations and cash flows for the three months ended December 31, 2003 and 2002 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, 2003 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 - 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 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 December 31, | |
|---------------------------------|------|
| 2003 | 2002 |
| ---- | ---- |

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| | | |
|--|--------|--------|
| Net Income, as reported: | \$582 | \$131 |
| Pro-forma expense as if stock options were charged against net income | 16 | 15 |
| | ---- | ---- |
| Pro-forma net income using the fair value method | \$566 | \$116 |
| | ==== | ==== |
| Basic EPS: | | |
| As reported | \$0.04 | \$0.01 |
| Pro forma using the fair value method | \$0.04 | \$0.01 |
| Diluted EPS: | | |
| As reported | \$0.04 | \$0.01 |
| Pro forma using the fair value method | \$0.03 | \$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.

In January 2003, the FASB issued FIN No. 46, 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 December 31, 2003.

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(3) INVENTORIES

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

| | December 31, 2003 | September 30, 2003 |
|--|----------------------|-----------------------|
| | ---- | ---- |

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| | | |
|--------------------------------|-----------|-----------|
| Raw materials | \$ 2,623 | \$ 2,439 |
| Work in process | 3,230 | 3,316 |
| Finished goods | 10,724 | 9,335 |
| | ----- | ----- |
| | 16,577 | 15,090 |
| Less reserves for obsolescence | 3,445 | 3,098 |
| | ----- | ----- |
| | \$ 13,132 | \$ 11,992 |
| | ===== | ===== |

(4) INCOME TAXES

The Company has incurred net operating losses through December 31, 2003 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 December 31, 2003, generated from its U.S. and German operations. A full valuation allowance had been provided on all but \$135,000 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, 2003 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 profit or loss from operations before income taxes, 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 December 31, 2003 and 2002, respectively are as follows:

| 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 |
| | ===== | ===== | ===== |

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| | | | |
|-------------------------------|-------------------|--------------------|--------------------|
| Depreciation and amortization | \$ 134 ===== | \$ 55 ===== | \$ 189 ===== |
| Interest expense | \$ 12 ===== | \$ 2 ===== | \$ 14 ===== |
| Net income | \$ 446 ===== | \$ 136 ===== | \$ 582 ===== |
| Capital expenditures | \$ 164 ===== | \$ 30 ===== | \$ 194 ===== |
| Total assets | \$ 8,316 | \$ 34,014 | \$ 42,330 |
| Less intercompany advances | - ----- | (11,105) ----- | (11,105) ----- |
| | \$ 8,316 ===== | \$ 22,909 ===== | \$ 31,225 ===== |

| 2002 | INTERNATIONAL | UNITED STATES | CONSOLIDATED |
|-------------------------------|--------------------|--------------------|--------------------|
| Gross revenue | \$ 2,707 | \$ 4,525 | \$ 7,232 |
| Less - intercompany | (658) ----- | - ----- | (658) ----- |
| Total revenue - third party | \$ 2,049 ===== | \$ 4,525 ===== | \$ 6,574 ===== |
| Depreciation and amortization | \$ 78 ===== | \$ 63 ===== | \$ 141 ===== |
| Interest expense | \$ 11 ===== | \$ 2 ===== | \$ 13 ===== |
| Net income (loss) | \$ (131) ===== | \$ 262 ===== | \$ 131 ===== |
| Capital expenditures | \$ 59 ===== | \$ 50 ===== | \$ 109 ===== |
| Total assets | \$ 11,173 | \$ 29,923 | \$ 41,096 |
| Less intercompany advances | - ----- | (16,066) ----- | (16,066) ----- |
| | \$ 11,173 ===== | \$ 13,857 ===== | \$ 25,030 ===== |

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(6) RECLASSIFICATION

Certain reclassifications have been made to the 2002 financial statements to conform to the 2003 presentation.

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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

Revenues for the three months ended December 31, 2003, increased 14% to \$7,485 from \$6,574 for the comparable period. The \$911 increase in revenue was almost equally derived from the Company's U.S. operation, as its revenue increased to \$5,063 from \$4,525 or 12% for the same period last year and from the International operation, as its revenue increased to \$2,422 from \$2,049. It should be pointed out that as a result of the new distribution agreement signed with Zimmer Spine in April 2003, whereby Zimmer Spine became a "stocking distributor" which means among other things that they would invoice the end customer direct, the Company's revenues would have been \$3,200 higher for this quarter or \$10,685 or an increase of 63% over the comparable period. The U.S. revenue increase was primarily due to an increase in the demand for the Company's Tutoplast(R) bone products for dental applications sold by Zimmer Dental (formerly Centerpulse Dental), the Company's marketing partner. This product line contributed \$600 of the increase in revenue. The increase in international revenue was due to an overall increase in the European and international distributor business.

Cost of revenue, for the three months ended December 31, 2003 was 40% as compared to 43% for the comparable period. The lower cost of revenue margin was primarily due to a favorable mix of low cost of revenue on the spinal revenues and a decrease in product development and manufacturing costs from a year ago.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased 25% for the three months ended December 31, 2003, from the comparable period last year. Expenses increased due to foreign exchange impact (\$86), merger transaction expenses (\$75) and higher travel (\$68). As a percentage of revenues, General and Administrative expenses were 15% and 14% in 2003 and 2002, respectively.

DISTRIBUTION AND MARKETING

Distribution and marketing expenses decreased 12% from \$2,342 in 2002 to \$2,070 in 2003 for the three months ended December 31, 2003, from the comparable period last year. The decrease was primarily due to lower marketing fees due under the agreement with Zimmer Spine as a result of the new agreement whereby Zimmer is invoicing the end customer direct and therefore the marketing fee is eliminated. Such fees decreased from \$1,476 in 2002 to \$649 in 2003. The partial offset to the decrease in marketing fees was due to higher expenditures as a result of increased sales efforts Internationally. As a percentage of revenues, Distribution and Marketing expenses decreased from 36% in 2002 to 28% in 2003.

RESEARCH AND DEVELOPMENT

Research and development expenses increased 37% for the three months ended December 31, 2003, from the comparable period 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 2002 to 5% in 2003.

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DEPRECIATION AND AMORTIZATION

Depreciation and amortization was essentially flat from period to period.

OTHER EXPENSE

Other expenses were essentially flat from period to period.

INTEREST EXPENSE

Interest expense was essentially flat from period to period.

NET INCOME

Net income for the three months ended December 31, 2003 totaled \$582 or \$0.04 basic and diluted earnings per share as compared to a net income of \$131 or \$0.01 basic and diluted earnings per share for the same period last year.

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 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

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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 December 31, 2003, the Company has working capital of \$16.5 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 December 31, 2003, the Company had no borrowings against these lines.

The Company has experienced a positive cash flow of \$582 for the three months ended December 31, 2003 as compared to a negative cash flow of \$585 for the same period in 2002. The primary reason for the positive cash flow is 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 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, 2003 are as follows:

| | |
|------|--------|
| 2004 | \$ 389 |
| 2005 | 208 |
| 2006 | 130 |
| 2007 | 50 |
| | ----- |
| | \$ 777 |
| | ===== |

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, 2003 are as follows:

| | |
|------|--------|
| 2004 | \$ 99 |
| 2005 | 104 |
| 2006 | 109 |
| 2007 | 117 |
| 2008 | 438 |
| | ----- |
| | \$ 867 |
| | ===== |

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

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("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 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 December 31, | |
|---|---------------------------------|--------|
| | 2003 | 2002 |
| | ---- | ---- |
| Net Income, as reported: | \$582 | \$131 |
| Pro-forma expense as if stock options were charged against net income | 16 | 15 |
| | ---- | ---- |
| Pro-forma net income using the fair value method | \$566 | \$116 |
| | ==== | ==== |
| Basic EPS: | | |
| As reported | \$0.04 | \$0.01 |
| Pro forma using the fair value method | \$0.04 | \$0.01 |
| Diluted EPS: | | |
| As reported | \$0.04 | \$0.01 |
| Pro forma using the fair value method | \$0.03 | \$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

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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, 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 December 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 6. REPORTS ON FORM 8-K

The Company filed Reports on Form 8-K on November 4, 2003 and December 29, 2003 during the quarter ended December 31, 2003.

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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, 2003 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 12, 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 December 31, 2003 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: February 12, 2004

TUTOGEN MEDICAL, INC.

/s/ Manfred Krueger
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: FEBRUARY 12, 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: FEBRUARY 12, 2004

BY:
NAME: /S/ MANFRED KRUEGER

TITLE: CEO, PRESIDENT AND CHIEF OPERATING OFFICER

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