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TUTOGEN MEDICAL INC  
Form 10QSB  
August 12, 2003

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, 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 July 31, 2003 there were outstanding 15,647,110 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. FINANC

ITEM 1. FINANCIAL STATEMENTS.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS)

(UNAUDITED)  
JUNE 30,  
2003  
-----

ASSETS

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CURRENT ASSETS	
Cash and cash equivalents	\$ 4,497
Accounts receivable - net	5,283
Inventories - net	10,859
Deferred income taxes	1,033
Other current assets	1,216
	-----
	22,888
PROPERTY, PLANT AND EQUIPMENT, NET	4,730
INTANGIBLE AND OTHER ASSETS, NET	33
DEFERRED INCOME TAXES	1,324
	-----
TOTAL ASSETS	\$ 28,975
	=====
LIABILITIES AND SHAREHOLDERS' EQUITY	
CURRENT LIABILITIES	
Accounts payable and other accrued expenses	\$ 6,215
Accrued commissions	1,726
Current portion of deferred distribution fees	610
Current portion of long-term debt	88
	-----
	8,639
OTHER LIABILITIES	
Deferred distribution fees	3,155
Long-term debt	749
SHAREHOLDERS' EQUITY	16,432
	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 28,975
	=====

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 JUNE 30,	
-----	
2003	2002
----	----

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REVENUE	\$	8,933	\$	5,400
Cost of revenue		3,621		2,182
		-----		-----
GROSS MARGIN		5,312		3,218
OPERATING EXPENSES				
General and administrative		1,156		787
Distribution and marketing		2,384		1,823
Research and development		275		237
Depreciation and amortization		67		34
		-----		-----
		3,882		2,881
OPERATING INCOME		1,430		337
OTHER (EXPENSE) INCOME		(70)		21
INTEREST EXPENSE		(13)		(12)
		-----		-----
		(83)		9
INCOME BEFORE PROVISION FOR INCOME TAXES		1,347		346
Income taxes		529		134
		-----		-----
NET INCOME	\$	818	\$	212
		=====		=====
AVERAGE SHARES OUTSTANDING FOR BASIC EARNINGS PER SHARE		15,647,110		15,122,693
		=====		=====
BASIC EARNINGS PER SHARE	\$	0.05	\$	0.01
		=====		=====
AVERAGE SHARES OUTSTANDING FOR DILUTED EARNINGS PER SHARE		16,265,537		16,170,808
		=====		=====
DILUTED EARNINGS PER SHARE	\$	0.05	\$	0.01
		=====		=====

See accompanying Notes to Consolidated Financial Statements

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(UNAUDITED)

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

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See accompanying Notes to Consolidated Financial Statements

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
JUNE 30, 2003  
(IN THOUSANDS, EXCEPT SHARE DATA)

(1) OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. along with its consolidated subsidiaries ("the Company") is a international precision-tooled biological implant manufacturer specializing in the sourcing, processing, marketing, and distribution of human ("allografts") and bovine ("xenograft") tissue implants for neuro, orthopedic, cardiovascular, reconstructive and general surgical applications utilizing its patented Tutoplast(R) process of tissue preservation and viral inactivation.

(2) SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited consolidated balance sheets of the Company as of June 30, 2003 and the unaudited results of operations for the three and nine months ended June 30, 2003 and 2002 and the unaudited cash flows for the nine months ended June 30, 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 and nine months ended June 30, 2003 are not necessarily indicative of the results, which may be expected for the fiscal year ending September 30, 2003. The interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended September 30, 2002.

NEW ACCOUNTING PRONOUNCEMENTS - In July 2001, the FASB issued SFAS No. 141, "Business Combinations," and No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 supercedes APB Opinion No. 16, "Business Combinations" and amends or supercedes a number of related interpretations of APB 16. SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations, and changes the criteria to recognize intangible assets apart from goodwill. SFAS No. 142 supercedes APB Opinion No. 17, "Intangible Assets." Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually, or more frequently if impairment indicators arise, for impairment. The Company adopted the provisions of SFAS No. 141 for any business combination that was initiated after June 30, 2001. The Company adopted SFAS No. 142 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 142 did not have an impact on its results of operations or financial position.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 requires entities to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred. The provisions of SFAS No. 143 are effective for fiscal years beginning after June 15, 2002. The Company adopted SFAS No.

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143 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 143 did not have a material impact on its results of operations or financial position.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal

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of Long-Lived Assets". SFAS No. 144 supercedes SFAS No. 121, "Accounting for the impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of". The primary objectives of SFAS No. 144 were to develop one accounting model based on the framework established in SFAS No. 121, and to address significant implementation issues. The provisions of SFAS No. 144 are effective for fiscal years beginning after December 15, 2001. The Company adopted SFAS No. 144 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 144 did not have a material impact on its results of operations or financial position.

In April 2002, the FASB issued SFAS No. 145, "RESCISSION OF FASB STATEMENTS 4, 44 AND 64, AMENDMENT OF FASB STATEMENT 13, AND TECHNICAL CORRECTIONS". SFAS No. 145 rescinds the provisions of SFAS No. 4 that requires companies to classify certain gains and losses from debt extinguishments as extraordinary items, eliminates the provisions of SFAS No. 44 regarding transition to the Motor Carrier Act of 1980 and amends the provisions of SFAS No. 13 to require that certain lease modifications be treated as sale leaseback transactions. The provisions of SFAS No. 145 related to classification of debt extinguishment are effective for fiscal years beginning after May 15, 2002. Commencing January 1, 2003, the Company will classify debt extinguishment costs within income from operations and will reclassify previously reported debt extinguishments as such. The provisions of SFAS No. 145 related to lease modification are effective for transactions occurring after May 15, 2002. The adoption of SFAS No. 145 did not have a material impact on its results of operations.

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 is 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 transition guidance and annual disclosure provisions of

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SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing financial statements for interim periods beginning after December 15, 2002. The Company adopted SFAS No. 148 beginning in the second fiscal quarter of fiscal 2003 and such disclosures are included 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

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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 Company believes that the adoption of SFAS No. 149 will 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 June 15, 2003. The Company believes that the adoption of SFAS No. 150 will not have a material impact on the results of operations or financial position.

### (3) PRO FORMA NET INCOME

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - TRANSITION AND DISCLOSURE, an amendment of SFAS No. 123." SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

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.

	Nine Months Ended June 30,	
	2003	2002
	----	----
Net Income, as reported:	\$1,084	\$567
Pro-forma, expense as if stock options were charged against net income	86	45
	-----	----
Pro-forma net income using the fair value method	\$998	\$522

Basic EPS:



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As reported	0.07	0.04
Pro forma using the fair value method	0.06	0.03
 Diluted EPS:		
As Reported	0.07	0.04
Pro forma using the fair value method	0.06	0.03

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions; expected volatility of 45% and 10% for 2003 and 2002 respectively, risk-free interest rate of 1.13% and 4.69% for 2003 and 2002 respectively, and an expected life of three years. A dividend yield of zero has been assumed.

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### (4) INVENTORIES

Major classes of inventory at June 30, 2003 and September 30, 2002 were as follows:

	June 30, 2003	September 30, 2002
Raw materials	\$ 2,365	\$ 1,868
Work in process	2,664	3,209
Finished goods	7,560	6,630
	-----	-----
	12,589	11,707
Less reserves for obsolescence	1,730	1,757
	-----	-----
	\$ 10,859	\$ 9,950
	=====	=====

### (5) INCOME TAXES

The Company has incurred net operating losses through June 30, 2003 of approximately \$17 million, generated from its U.S. and German operations of \$8 million and \$9 million, respectively. These net operating losses are the primary component of the Company's net deferred tax asset of \$2.4 million as of June 30, 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 June 30, 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.

### (6) 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

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("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 inter-segment sales and transfers at contractually agreed-upon prices.

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

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A summary of the operations and assets by segment as of and for the three months ended June 30, 2003 and 2002, respectively are as follows:

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

2002	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 3,872	\$ 3,565	\$ 7,437
Less - intercompany	(2,037)	-	(2,037)
	-----	-----	-----
Total revenue - third party	\$ 1,835	\$ 3,565	\$ 5,400
	=====	=====	=====
Depreciation and amortization	\$ 140	\$ 170	\$ 310
	=====	=====	=====
Interest expense	\$ 11	\$ 1	\$ 12
	=====	=====	=====

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Net income	\$ 266	\$ (54)	\$ 212
	=====	=====	=====
Capital expenditures	\$ 67	\$ 56	\$ 123
	=====	=====	=====
Total assets	\$ 10,991	\$ 30,257	\$ 41,248
Less intercompany advances	-	(17,952)	(17,952)
	-----	-----	-----
	\$ 10,991	\$ 12,305	\$ 23,296
	=====	=====	=====

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A summary of the operations and assets by segment as of and for the nine months ended June 30, 2003 and 2002, respectively are as follows:

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
	=====	=====	=====
Depreciation and amortization	\$ 277	\$ 125	\$ 402
	=====	=====	=====
Interest expense	\$ 36	\$ 3	\$ 39
	=====	=====	=====
Net income	\$ 956	\$ 128	\$ 1,804
	=====	=====	=====
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
	=====	=====	=====
2002	INTERNATIONAL	UNITED STATES	CONSOLIDATED
Gross revenue	\$ 9,950	\$ 10,559	\$ 20,509
Less - intercompany	(4,765)	-	(4,765)
	-----	-----	-----
Total revenue - third party	\$ 5,185	\$ 10,559	\$ 15,744
	=====	=====	=====
Depreciation and amortization	\$ 73	\$ 61	\$ 134
	=====	=====	=====
Interest expense	\$ 45	\$ 4	\$ 49
	=====	=====	=====

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Net income	\$ 443	\$ 124	\$ 567
	=====	=====	=====
Capital expenditures	\$ 138	\$ 134	\$ 272
	=====	=====	=====
Total assets	\$ 10,991	\$ 30,257	\$ 41,248
Less intercompany advances	-	(17,952)	(17,952)
	-----	-----	-----
	\$ 10,991	\$ 12,305	\$ 23,296
	=====	=====	=====

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(7) RECLASSIFICATION

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

(8) EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT

In April 2003, the Company entered into an Exclusive License and Distribution Agreement ("Agreement") with Centerpulse Spine-Tech ("CST") redefining the terms governing its relationship. Effective with this agreement, CST will continue to market the Tutoplast(R) products for the spine market, however, CST will become a "stocking distributor", whereby CST will purchase the spine products from the Company and invoice the customers directly. It is expected that the impact of the terms of this Agreement will not have a material effect on revenues or net income for this fiscal year.

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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 June 30, 2003, increased 65% to \$8,933 from \$5,400 for the comparable period. The increase in revenue was partially attributable to the one-time shipment of \$1.9 million of inventory as the result of a renegotiated U.S. Distribution Agreement with Centerpulse Spine-Tech ("CST"), signed in April 2003 whereby Spine-Tech has become a "stocking distributor". This new arrangement is expected to have a negative near-term effect on the Company's annual revenues of approximately \$5.0 to \$6.0 million as CST is now purchasing the Company's spine products and invoicing the customer directly. Previously, the Company invoiced the customer and paid CST a significant marketing fee included in operating expenses. However, the new arrangement will significantly reduce the Company's risk of inventory (excess production and obsolescence) and the risk of slow accounts receivable collections (slow-paying class of customer, i.e., hospitals and doctors). The new agreement also eliminates all marketing fees paid to CST currently included in operating expenses. The end result should be a reduction in gross margins of approximately 8% to 10% (as a result of invoicing CST directly versus the

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end-user customer), the elimination of all marketing fees paid to CST, and an expected improvement in operating efficiencies. All of these effects are expected to result in an improvement in net income and cash flow.

The U.S. revenue increased to \$6,700 from \$3,565 or 88% for the same period last year. The revenue increase was primarily due to the aforementioned one-time shipment of inventory of \$1.9 million and an increase in the demand for the Company's Tutoplast(R) bone products for spinal and dental applications sold by Centerpulse Spine-Tech and Centerpulse Dental, the Company's marketing partners. These products contributed to an additional \$1.0 million of revenue. This increase was fueled by the improved sales of the Tutoplast(R) specialty graft, the Puros(TM) Symmetry(TM) PLIF Allograft System and the C-graft. International revenue increased to \$2,233 from \$1,835 or 22% for the same period last year. 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, 2003 increased 41% to \$22,250 from \$15,744 for the comparable period. The increase in revenue primarily occurred from the U.S. operation as its revenue increased 47% to 15,508 from \$10,559 for the same period last year. Incremental Centerpulse revenues and the one-time shipment of inventory of \$1.9 million contributed the entire increase in revenue. International revenue increased to \$6,742 from \$5,185 or 30% for the same period last year.

Gross margin for the three and nine months ended June 30, 2003 were 59% and 60%, respectively as compared to 60% and 53%, respectively for the comparable periods last year. The higher gross 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 47% and 42% for the three and nine months ended

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June 30, 2003, from the comparable periods last year. Third quarter expenses increased due to a higher provision for bad debts (\$90), foreign exchange variance (\$75), added staffing at the Alachua, Florida facility (\$69), travel expenses (\$58), and other expenses (\$77). Year-to-date expenses increased due to added staffing at the Alachua, Florida facility (\$253), foreign exchange variance (\$235), higher travel (\$101), higher provision for bad debts (\$90), telephone expenses (\$47), legal fees (\$28), rent (\$26), investor relations/banker (\$24) and other expenses (\$145). As a percentage of revenues for year-to-date, General and Administrative expenses remained relatively constant at 14% in 2003 and 2002.

### DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased 31% and 57% for the three and nine months ended June 30, 2003, from the comparable periods last year. The increase was primarily due to marketing fees due under the agreements with Centerpulse Spine and Dental as a result of the increase in revenues of the Company's Tutoplast bone products for spinal and dental applications. Such fees increased \$48 and \$1,478 for the three and nine months ended June 30, 2003, respectively. The balance of the increase was due to increased sales efforts Internationally. As a percentage of revenues for year-to-date, Distribution and Marketing expenses increased from 29% in 2002 to 32% in 2003.

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### RESEARCH AND DEVELOPMENT

Research and development expenses increased 16% and 34% for the three and nine months ended June 30, 2003, 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 remained relatively constant at 4% in 2003 and 2002.

### DEPRECIATION AND AMORTIZATION

Depreciation and amortization expense, for the three months ended June 30, 2003 increased from \$34 to \$67. This is mainly because of the new addition of new technical equipments in our international operation. As a percentage of revenues, Depreciation and Amortization expenses remained relatively constant at less than 1% compared in 2003 and 2002.

### OTHER (EXPENSE) INCOME

Other expense increased for the three and nine months ended June 30, 2003, due to unfavorable foreign exchange losses as the result of the continued weakening of the dollar against the euro.

### INTEREST EXPENSE

Interest expense remained flat for the quarter ended June 30, 2003 and decreased 20% for the nine months ended June 30, 2003 for the comparable period last year. The decrease was due to lower revolving credit balances from the International operation.

### INCOME TAXES

The effective tax rate remained at 39% for the three months ended June 30, 2003 and 2002. For the nine months ended June 30, 2003 and 2002, the effective tax rate was 38% and 29% due to a higher proportion of income from the International operation.

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### NET INCOME

Net income for the three and nine months ended June 30, 2003 totaled \$818 or \$0.05 basic and diluted earnings per share and \$1,084 or \$0.07 basic and diluted earnings per share as compared to a net income of \$212 or \$0.01 basic and diluted earnings per share and net income of \$567 or \$0.04 basic and diluted earnings per share for the same periods last year.

For the nine-month period ended June 30, 2003, the dollar (average for nine months) has weakened against the euro approximately 19% as compared to the comparable period last year. In view of our European manufacturing operations, the weakening of the dollar has unfavorably impacted earnings year-to-date by approximately \$665.

### 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

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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 critical accounting policies include:

**INVENTORIES.** Inventories are valued at the lower of cost (weighted average basis) or market. Work in process and finished goods includes 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. Customers are provided with a limited right of return. 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 June 30, 2003, the Company has working capital of \$14.2 million as compared to September 30,

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2002 of \$10.9 million. The Company maintains current working capital credit lines totaling (euro)1.8 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, 2003, the Company had no borrowings against these lines.

The Company has experienced a positive cash flow of \$1,414 for the nine months ended June 30, 2003 as compared to a negative cash flow of \$1,075 for the same period in 2002.

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.

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Future minimum rental payments required under leases that have initial or remaining noncancelable lease terms in excess of one year as of June 30, 2003 are as follows:

2004	\$	357
2005		125
2006		33
2007		7
		-----
	\$	522
		=====

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, 2003 are as follows:

2004	\$	88
2005		88
2006		88
2007		88
2008		485
		-----
	\$	837
		=====

### NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the FASB issued SFAS No. 141, "Business Combinations," and No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 supercedes APB Opinion No. 16, "Business Combinations" and amends or supercedes a number of related interpretations of APB 16. SFAS No. 141 eliminates the pooling-of-interests method of accounting for business combinations, and changes the criteria to recognize intangible assets apart from goodwill. SFAS No. 142 supercedes APB Opinion No. 17, "Intangible Assets." Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized but are reviewed annually, or more frequently if impairment indicators arise, for impairment. The Company adopted the provisions of SFAS No. 141 for any business combination that is initiated after June 30, 2001. The provisions of SFAS No.

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142 are effective for fiscal years beginning after December 15, 2001. The Company adopted SFAS No. 142 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 142 did not have a material impact on its results of operations or financial position. In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations". SFAS No. 143 requires entities to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred. The provisions of SFAS No. 143 are effective for fiscal years beginning after June 15, 2002. The Company adopted SFAS No. 143 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 143 did not have a material impact on its results of operations or financial position.

SFAS No. 144, "ACCOUNTING FOR THE IMPAIRMENT OR DISPOSAL OF LONG LIVED ASSETS" was to develop one accounting model based on the framework established in SFAS No. 121, and to address significant implementation issues. The provisions of SFAS No. 144 are effective for fiscal years beginning after December 15, 2001.



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The Company adopted SFAS No. 144 beginning in the first fiscal quarter of fiscal 2003. The adoption of SFAS No. 144 did not have a material impact on its results of operations or financial position.

In April 2002, the FASB issued SFAS No. 145, "RESCISSION OF FASB STATEMENTS 4, 44 AND 64, AMENDMENT OF FASB STATEMENT 13, AND TECHNICAL CORRECTIONS". SFAS No. 145 rescinds the provisions of SFAS No. 4 that requires companies to classify certain gains and losses from debt extinguishments as extraordinary items, eliminates the provisions of SFAS No. 44 regarding transition to the Motor Carrier Act of 1980 and amends the provisions of SFAS No. 13 to require that certain lease modifications is treated as sale leaseback transactions. The provisions of SFAS No. 145 related to classification of debt extinguishment are effective for fiscal years beginning after May 15, 2002. Commencing January 1, 2003, the Company will classify debt extinguishment costs within income from operations and will reclassify previously reported debt extinguishments as such. The provisions of SFAS No. 145 related to lease modification are effective for transactions occurring after May 15, 2002. The adoption of SFAS No. 145 did not have a material impact on its results of operations.

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)". Provisions of SFAS No. 146 related to lease modification are effective for transactions occurring after May 15, 2002. The adoption of SFAS No. 146 did not have a material impact on its results of operations.

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 is 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

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prominent and more frequent disclosures in financial statements of the effects of stock-based compensation. The transition guidance and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing financial statements for interim periods beginning after December 15, 2002. The Company adopted SFAS No. 148 beginning in the second fiscal quarter of fiscal 2003 and such disclosures are included 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

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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 Company believes that the adoption of SFAS No. 149 will 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 June 15, 2003. The Company believes that the adoption of SFAS No. 150 will not have a material impact on the results of operations or financial position.

### 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, 2003.

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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 June 30, 2003 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.

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Date: August 8, 2003

/s/ Manfred Krueger

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President and Chief Executive Officer

Date: August 8, 2003

/s/ George Lombardi

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Chief Financial Officer  
(Principal Financial and Accounting Officer)

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CERTIFICATION

I 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 STATEMENT 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 (S) AND I ARE 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, OR CAUSED SUCH DISCLOSURE CONTROLS AND PROCEDURES TO BE DESIGNED UNDER OUR SUPERVISION, 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 REPORT IS BEING PREPARED;
  - B) EVALUATED THE EFFECTIVENESS OF THE REGISTRANT'S DISCLOSURE CONTROLS AND PROCEDURES AND PRESENTED IN THIS REPORT OUR CONCLUSIONS ABOUT THE EFFECTIVENESS OF THE DISCLOSURE CONTROLS AND PROCEDURES, AS OF THE END OF THE PERIOD COVERED BY THIS REPORT BASED ON SUCH EVALUATION AND;
  - C) DISCLOSED IN THIS REPORT ANY CHANGE IN THE REGISTRANT'S INTERNAL CONTROL OVER FINANCIAL REPORTING THAT OCCURRED DURING THE REGISTRANT'S MOST RECENT FISCAL QUARTER (THE REGISTRANT'S FOURTH FISCAL QUARTER IN THE CASE OF AN ANNUAL REPORT) THAT HAS MATERIALLY AFFECTED, OR IS REASONABLY LIKELY TO MATERIALLY AFFECT THE REGISTRANT'S INTERNAL CONTROL OVER FINANCIAL REPORTING; AND

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5. THE REGISTRANT'S OTHER CERTIFYING OFFICERS AND I HAVE DISCLOSED, BASED ON OUR MOST RECENT EVALUATION OF INTERNAL CONTROL OVER FINANCIAL REPORTING, TO THE REGISTRANT'S AUDITORS AND THE AUDIT COMMITTEE OF REGISTRANT'S BOARD OF DIRECTORS (OR PERSONS PERFORMING THE EQUIVALENT FUNCTION):
- A) ALL SIGNIFICANT DEFICIENCIES AND MATERIAL WEAKNESSES 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.

CERTIFICATION

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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.

DATE: AUGUST 8, 2003

BY:

NAME: /S/ GEORGE LOMBARDI

TITLE: CHIEF FINANCIAL OFFICER,  
TREASURER AND SECRETARY

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CERTIFICATION

I 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 STATEMENT 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 (S) AND I ARE 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:
  - C) DESIGNED SUCH DISCLOSURE CONTROLS AND PROCEDURES, OR CAUSED SUCH

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DISCLOSURE CONTROLS AND PROCEDURES TO BE DESIGNED UNDER OUR SUPERVISION, 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 REPORT IS BEING PREPARED;

- D) EVALUATED THE EFFECTIVENESS OF THE REGISTRANT'S DISCLOSURE CONTROLS AND PROCEDURES AND PRESENTED IN THIS REPORT OUR CONCLUSIONS ABOUT THE EFFECTIVENESS OF THE DISCLOSURE CONTROLS AND PROCEDURES, AS OF THE END OF THE PERIOD COVERED BY THIS REPORT BASED ON SUCH EVALUATION AND;
  - C) DISCLOSED IN THIS REPORT ANY CHANGE IN THE REGISTRANT'S INTERNAL CONTROL OVER FINANCIAL REPORTING THAT OCCURRED DURING THE REGISTRANT'S MOST RECENT FISCAL QUARTER (THE REGISTRANT'S FOURTH FISCAL QUARTER IN THE CASE OF AN ANNUAL REPORT) THAT HAS MATERIALLY AFFECTED, OR IS REASONABLY LIKELY TO MATERIALLY AFFECT THE REGISTRANT'S INTERNAL CONTROL OVER FINANCIAL REPORTING; AND
5. THE REGISTRANT'S OTHER CERTIFYING OFFICERS AND I HAVE DISCLOSED, BASED ON OUR MOST RECENT EVALUATION OF INTERNAL CONTROL OVER FINANCIAL REPORTING, TO THE REGISTRANT'S AUDITORS AND THE AUDIT COMMITTEE OF REGISTRANT'S BOARD OF DIRECTORS (OR PERSONS PERFORMING THE EQUIVALENT FUNCTION):
- A) ALL SIGNIFICANT DEFICIENCIES AND MATERIAL WEAKNESSES 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.

CERTIFICATION

PAGE 2

- C) ANY FRAUD, WHETHER OR NOT MATERIAL, THAT INVOLVES MANAGEMENT OR OTHER EMPLOYEES WHO HAVE A SIGNIFICANT ROLE IN THE REGISTRANT'S INTERNAL CONTROLS.

DATE: AUGUST 8, 2003

BY:

NAME: /S/ MANFRED K. KRUEGER

TITLE: PRESIDENT AND CEO

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