TUTOGEN MEDICAL INC
Form 10-Q
May 14, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-QSB

(MARK ONE)

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

For the period ended March 31, 2001.

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.)
925 ALLWOOD ROAD, CLIFTON, NEW JERSEY	07012
(Address of Principal Executive Offices)	(Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (973) 365-2799

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   No_.

As of April 30, 2001 there were outstanding 14,883,275 shares of Tutogen Medical, Inc. Common Stock, par value $0.01.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) March 31, 2001	(audited) September 30, 2000
ASSETS		
Current Assets		
Cash and cash equivalents	$ 4,388	$ 3,835
Accounts receivable - net	1,786	1,559
Inventories - net	5,745	5,652
Deferred tax asset, current portion	605	135
Other current assets	744	585

	13,268	11,766
Property, plant and equipment, net	3,545	3,072
Intangible Assets - net	4	2
Deferred tax asset	2,380	-
TOTAL ASSETS	$ 19,197	$ 14,840
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued expenses	$ 2,446	$ 1,966
Revolving credit arrangements	258	333
Current portion of deferred distribution fees	296	-
Current portion of long-term debt	59	58
	3,059	2,357
Other Liabilities		
Long-term debt	717	745
Deferred distribution fees	2,192	-
Shareholders' Equity	13,229	11,738
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 19,197	$ 14,840

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 March 31,	
	2001	2000
OPERATING REVENUES		
Surgical products and related services	$ 2,925	$ 4,372
Distribution fees	77	1,000
Total revenues	3,002	5,372
Cost of revenue	2,259	2,477

Gross margin	743	2,895
OPERATING EXPENSES		
General and administrative	728	625
Distribution and marketing	664	610
Research and development	248	228
Depreciation and amortization	29	31
	1,669	1,494
OPERATING PROFIT (LOSS)	(926)	1,401
Other income	112	85
Interest expense	(15)	(54)
	97	31
INCOME (LOSS) BEFORE INCOME TAXES AND CUMULATIVE EFFECT OF ACCOUNTING CHANGE	(829)	1,432
Income tax (benefit) expense	-	36
INCOME (LOSS) BEFORE CUMULATIVE EFFECT OF ACCOUNTING CHANGE	(829)	1,396
Cumulative effect of accounting change	-	-
NET INCOME (LOSS)	$ (829)	$ 1,396
Average shares outstanding for basic earnings per share	14,857,750	11,290,023
Basic earnings (loss) per share	$ (0.06)	$ 0.12
Average shares outstanding for diluted earnings per share	14,857,750	15,085,380
Diluted earnings (loss) per share	$ (0.06)	$ 0.09

See accompanying Notes to Consolidated Financial Statements

TUTOGEN MEDICAL, INC. AND
SUBSIDIARIES
CONSOLIDATED STATEMENTS OF

CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended March 31, 2001	Six Months Ended March 31, 2000
Cash flows from operating activities		
Net income	$ 264	$ 1,920
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	98	203
Cumulative effect of accounting change	1,724	-
Changes in assets and liabilities:		
Accounts receivable	(231)	(439)
Inventories	(115)	197
Deferred tax asset	(2,850)	-
Other current assets	(163)	(80)
Accounts payable and accrued liabilities	497	770
Deferred distribution fees revenue	872	-
Net cash provided by in operating activities	96	2,571
Cash flows from investing activities		
Purchase of property, plant and equipment	(591)	(383)
Net cash used in investing activities	(591)	(383)
Cash flows from financing activities		
Issuance of stock	1,300	875
Proceeds from revolving credit arrangements	258	-
Repayment of revolving credit arrangements	(333)	(753)
Proceeds from long-term debt	1	580
Repayment of long-term debt	(27)	-
Net cash provided by financing activities	1,199	702
Effect of exchange rate changes on cash	(151)	(107)
Net increase in cash and cash equivalents	553	2,783
Cash and cash equivalents at beginning of period	3,835	376
Cash and cash equivalents at end of period	$ 4,388	$ 3,159
Supplemental cash flow disclosures		
Interest paid	$ 26	$ 109

See accompanying Notes to Consolidated Financial Statements

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For The Year Ended December 31, 2000 and Quarter Ended March 31, 2001

Amounts in Thousands (except per share and share data)	Shares Issued	Common Stock	Paid-in Capital	Retained Earnings	Treas Sto
Balance, December 31, 1999	4,819,002	$ 2,409	$ 26,674	$ 20,213	$
Comprehensive Income:					
Net income - 2000	-	-	-	7,010	
Other comprehensive income, net of income taxes					
Net unrealized appreciation in the fair value of securities available for sale	-	-	-	-	
Comprehensive Income:					
Cash dividends - $.55 per share	-	-	-	(2,964)	
Net proceeds from issuance of common stock	85,038	43	1,176	-	
5% Stock dividend	241,055	121	3,525	(3,652)	
Purchase of treasury stock	-	-	-	-	(
Retirement of treasury stock	(37,250)	(19)	(564)	-	
Deferred compensation	-	-	(29)	-	
Balance, December 31, 2000	5,107,845	$ 2,554	$ 30,782	$ 20,607	
Comprehensive Income:					
Net income - 2001	-	-	-	1,796	
Other comprehensive income, net of income taxes					
Net unrealized appreciation in the fair value of securities available for sale	-	-	-	-	
Comprehensive Income:					
Cash dividends - $.14 per share	-	-	-	(761)	
Net proceeds from issuance of common stock	18,570	9	325	-	
5% Stock dividend	254,916	127	5,392	(5,519)	
Purchase of treasury stock	-	-	-	-	(

Retirement of treasury stock	(28,100)	(14)	(532)	-
Balance, March 31, 2001	5,353,231	$ 2,676	$ 35,967	$ 16,123

The accompanying notes to consolidated financial statements are an integral part of these statements.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

Amounts in Thousands

Cash Flows From Operating Activities:

Net Income

Adjustments to reconcile net income to net cash

provided by operating activities:

Depreciation and amortization

Provision for loan losses

Decrease in accrued interest receivable

Increase in accrued interest payable

Net change in other assets and other liabilities

Net (accretion) amortization on securities

Net losses (gains) on sales of securities

Net gains on sales of loans

Net Cash Provided By Operating Activities

Cash Flows From Investing Activities:

Proceeds from maturities of securities available for sale

Proceeds from sales of securities available for sale

Purchases of securities available for sale

Net decrease (increase) in loans

Proceeds from sales of loans

Net capital expenditures

Net Cash Provided By (Used for) Investing Activities

Cash Flows From Financing Activities:

Net increase in demand and savings deposits

Net increase in time deposits

Net (decrease) increase in borrowed funds

Net increase in long-term debt

Net proceeds from issuance of common stock

Net treasury stock transactions

Cash dividends paid

Net Cash Provided By Financing Activities

Net Increase in Cash and Cash Equivalents

Cash and Cash Equivalents, Beginning of Period

Cash and Cash Equivalents, End of Period

Supplemental Disclosures of Cash Flow Information:

Interest paid

Income taxes paid

Supplemental Disclosures of Investing and Financing Activities:

Transfers from loans to other real estate owned

The accompanying notes to consolidated financial statements are an integral part of these statements.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2001
(IN THOUSANDS, EXCEPT SHARE DATA)

(1) OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. along with its consolidated subsidiaries ("the Company") processes, manufactures and distributes worldwide specialty surgical products and provides tissue processing services for neuro, orthopedic, cardiovascular, reconstructive and general surgical applications. The Company's core business is processing human donor tissue ("allografts") utilizing its patented Tutoplast(R) process for distribution to hospitals and surgeons.

(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 and six months ended March 31, 2001 and 2000 have been prepared in conformity with generally accepted accounting principles for interim financial reporting. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments necessary in order to make the financial statements not misleading have been made. Operating results for the three and six months ended March 31, 2001 are not necessarily indicative of the results, which may be expected for the fiscal year ending September 30, 2001. The interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended September 30, 2000.

(3) INVENTORIES

Major classes of inventory at March 31, 2001 and September 30, 2000 were as follows:

	March 31, 2001	September 30, 2000
Raw materials	$ 1,067	$ 820
Work in process	1,747	2,564
Finished goods	3,608	3,018
Less reserves for obsolescence	677	750
	$ 5,745	$ 5,652

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2001
(IN THOUSANDS, EXCEPT SHARE DATA)

(4) INCOME TAXES

The Company has incurred total net operating losses through December 31, 2000 of $14.8 million, generated from its U.S. and German operations of $8.3 million and $6.5 million, respectively. These net operating losses are the primary component of the Company's deferred tax asset of $5.5 million as of December 31, 2000, generated from its U.S. and German operation of $2.6 million and $2.9 million, respectively. A full valuation allowance had been provided on all but $135,000 of the U.S. deferred tax asset and a full valuation allowance had been provided for the German deferred tax asset in the Company's consolidated financial statements as of and for the year ended September 30, 2000. 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, 2000, the Company continues to record the existing valuation allowance on its U.S. operations and eliminated the full valuation allowance on its German operations based upon future taxable income projections.

(5) ACCOUNTING CHANGE

The company has entered into comprehensive long term agreements with various organizations, including Mentor Corporation, Sulzer Spin-Tech, Inc. and Calcitek, Inc. for the worldwide distribution of its patented Tutoplast(R) processed bone and soft tissue. Upon execution of these agreements, each of these organizations made initial non-refundable payments to the Company, which was recognized as distribution fees. During the quarter ended December 31, 2000, the Company has adopted the Securities and Exchange Commission Staff Accounting Bulletin No. 101 - REVENUE RECOGNITION IN FINANCIAL STATEMENTS ("SAB 101"). SAB101 provides that up front payments under these arrangements be recognized as revenue as products are delivered over the periods that the fees are earned. The cumulative effect of this accounting change was to decrease net income by $1.7 million or $0.12 per basic earnings per share.

(6) RECLASSIFICATION

Certain reclassifications have been made to the 2000 financial statements to conform to the 2001 presentation.

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

RESULTS OF OPERATIONS

REVENUE AND COST OF REVENUE

Revenue from surgical products and related services for the three months ended March 31, 2001 decreased 33% to $2,925 from $4,372 for the comparable period. The decrease in revenue primarily occurred from the US operation as its revenue decreased to $1,326 from $2,712 for the same period last year. In 1999, revenue was unusually high due to the fulfillment of significant backorders from the

Company's marketing and distribution alliance with Mentor Corporation. The revenue shortfall was partially offset by the continued rollout by Sulzer Spine-Tech, the Company's marketing partner, of the Company's Tutoplast(R) bone products for spinal applications, which contributed nearly $450 of revenue. International revenue decreased to $1,599 from $1,660 or less than 4% for the same period last year.

Revenue from surgical products and related services for the six months ended March 31, 2001 decreased 32% to $5,999 from $8,780 for the comparable period. Here again, the decrease in revenue primarily occurred from the US operation as its revenue decreased to $2,802 from $5,673 for the same period last year. The revenue shortfall from the Mentor product line of $3,008, and the lower US distribution revenue of $514, was partially offset by the incremental Sulzer Spine-Tech revenues of $837. International revenue increased slightly to $3,197 from $3,107 or 3% higher for the same period last year.

Revenue from distribution fees for the three and six months ended March 31, 2001 were $77 and $150, respectively compared to $1,000 for the comparable periods. In 1999, the Company entered into a long-term agreement with Sulzer Spine-Tech, Inc. whereby $1,000 represented an upfront payment under such agreement.

Cost of Revenue on surgical products revenue for the three and six months ended March 31, 2001 were 77% and 70%, respectively compared to 57% for the comparable periods. The higher cost of revenue margins were primarily due to inventory write-offs and rejected material of $640 and lower throughputs at the US operation.

GENERAL AND ADMINISTRATIVE

General and administrative expenses increased 16% and 21% for the three and six months ended March 31, 2001, respectively from the comparable periods last year. The higher expenses are due to additional staff of $124 and investor relations and banking program of $50, partially offset by cost savings in other areas. For the three months ended March 31, 2001, as a percentage of surgical products revenues, General and Administrative expenses increased from 14% in 2000 to 25% in 2001.

DISTRIBUTION AND MARKETING

Distribution and marketing expenses increased 9% and 14% for the three and six months ended March 31, 2001, from the comparable periods last year. The increase was solely due to marketing fees earned, under the agreement with Sulzer Spine-Tech as a result of the rollout of the Company's Tutoplast bone products for spinal application. For the three months ended March 31, 2001, as a percentage of surgical product revenues, Distribution and Marketing expenses increased from 14% in 2000 to 23% in 2001, primarily due to the lower revenue performance.

RESEARCH AND DEVELOPMENT

Research and development expenses increased 9% and decreased 10% for the three and six months ended March 31, 2001, from the comparable periods last year. The changes from quarter to quarter are due to the timing and completion of certain R & D projects. For the three months ended March 31, 2001, as a percentage of surgical product revenues, Research and Development increased from 5% in 2000 to 8% in 2001.

DEPRECIATION AND AMORTIZATION

Depreciation and amortization decreased 6% and 62% for the three and six months ended March 31, 2001, from the comparable periods last year. The reduction in depreciation and amortization was attributed to an increase in fully depreciated property, plant and equipment.

OTHER INCOME

Other income increased 32% and 192% for the three and six months ended March 31, 2001, from the comparable periods last year. Other income increased substantially due to favorable foreign exchange gains and interest income.

INTEREST EXPENSE

Interest expense decreased 72% and 76% for the three and six months ended March 31, 2001, from the comparable periods last year. The overall decrease in interest was due to the Company's strong cash position and its ability to maintain minimum revolving credit balances.

NET INCOME (LOSS)

Net loss for the three months ended March 31, 2001 totaled $829 or $0.06 basic and diluted loss per share compared to a net income of $1,396 or $0.12 basic earnings per share and $0.09 diluted earnings per share for the same period last year. Last years earnings included the upfront distribution fee of $1,000 as part of the Sulzer Spine-Tech partnership arrangement. The loss for the period is directly attributable to unanticipated production costs related to the rollout of the Sulzer product line and the decrease in revenues.

Net income this year was impacted by the one-time recognition of the tax benefit of net operating carryforward losses from the International operation of $2,850. In addition, the Company recorded a one-time cumulative effect of the Company's change in accounting for the income recognition of distribution fees of $1,724. The impact of these two accounting transactions resulted in net income for the six months ended March 31, 2001 of $264 or $0.02 basic and diluted earnings per share compared to a net income of $1,920 or $0.17 basic earnings per share and $0.14 diluted earnings per share for the same period a year ago.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001 and September 30, 2000 the Company had working capital of $10.2 million and $9.4 million, respectively. The Company maintains current working capital credit lines totaling DM 2.9 million (approximately $1.3 million) with several German banks and a $1.0 million credit line with a U.S. bank. At March 31, 2001 the Company had $258 borrowings against these lines.

The Company has experienced a positive cash flow during the year ended September 30, 2000 and the six months ended March 31, 2001, as indicated by the increase in cash and cash equivalents from $0.4 million at September 30, 1999 to $4.4 million at March 31, 2001.

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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PART II. OTHER INFORMATION

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

An annual Meeting of Stockholders was held on March 26, 2001. All management's nominees for director, as listed in the Proxy Statement for the Annual Meeting, were elected. Listed below are the matters voted on by stockholders and the number of votes cast at the Annual Meeting:

(a) ELECTION OF SEVEN MEMBERS OF THE BOARD OF DIRECTORS.

Name	Voted For	Voted Against	Votes Withheld	Broker Non-Votes and Abstentio
G. Russell Cleveland	13,668,364	0	5,007	0
Robert C. Farone	13,667,814	0	5.557	0
J. Harold Helderman	13,668,614	0	4,757	0
Manfred Kruger	13,668,364	0	5,007	0
Thomas W. Pauken	13,668,414	0	4,957	0
Theodore I. Malinin	13,668,602	0	4,769	0
Carlton E. Turner	13,668,364	0	9,207	0

(b) RATIFICATION OF THE APPOINTMENT OF DELOITTE AND TOUCHE L.L.P. AS INDEPENDENT AUDITORS OF THE COMPANY FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2001.

Voted For:	13,671,091
Voted Against:	1,520
Voted Abstained:	760
Broker Non-Votes	0

(c) TO APPROVE THE AMENDMENT TO THE 1996 INCENTIVE AND NON-STATUTORY STOCK OPTION PLAN

Voted For:	12,277,309
Voted Against:	48,462
Voted Abstained:	9,535
Broker Non-Votes	0

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ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

EXHIBITS

No. 27 Financial Data Schedule

No reports on Form 8-K were filed by the Company during the quarter ended March 31, 2001.

SIGNATURES

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

TUTOGEN MEDICAL, INC.

Date: May 4, 2001

/s/ Manfred Kruger

President and Chief Executive Officer

Date: May 4, 2001

/s/ George Lombardi

Chief Financial Officer
(Principal Financial and Accounting Officer)