

TUTOGEN MEDICAL INC  
Form 10-Q  
February 07, 2008

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the period ended December 31, 2007

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  
(State of Incorporation)

59-3100165  
(IRS Employer Identification Number)

13709 Progress Boulevard, Box 19, Alachua, Florida 32615  
(Address of Principal Executive Offices)

Registrant's telephone number, including area code (386) 462-0402

Indicate by check mark whether the registrant: (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 12 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

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company (as defined in Rule 12b-2 of the Act). Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

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As of January 30, 2008, there were 19,421,289 shares outstanding of the issuer's common stock, par value \$.01 per share.

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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  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (IN THOUSANDS EXCEPT FOR SHARE DATA)  
 (UNAUDITED)

	December 31, 2007	September 30, 2007
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 6,145	\$ 7,849
Short-term marketable securities	5,000	5,000
Accounts receivable - net of allowance for doubtful accounts of \$813 at Dec. 31, 2007 and \$777 at Sept. 30, 2007	7,492	6,477
Inventories - net	19,012	17,390
Deferred tax assets - net	3,170	3,792
Prepays and other current assets	1,115	1,550
	41,934	42,058
Property, plant, and equipment - net	14,812	14,429
Other assets	433	387
Deferred tax asset - net	2,645	2,376
<b>TOTAL ASSETS</b>	<b>\$ 59,824</b>	<b>\$ 59,250</b>
 <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 3,388	\$ 1,720
Accrued expenses and other current liabilities	4,301	5,266
Accrued commissions	2,799	2,532
Short-term borrowings	351	356
Current portion of deferred distribution fees	1,836	1,817
Current portion of long-term debt	1,138	1,281
	13,813	12,972
Noncurrent Liabilities		
Deferred distribution fees and other	2,495	2,641
Long-term debt	3,192	3,278
<b>Total Liabilities</b>	<b>19,500</b>	<b>18,891</b>
Shareholders' Equity		

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Common stock, \$0.01 par value, 30,000,000 shares authorized; 19,390,289 and 19,167,939 issued and outstanding, respectively	194	192
Additional paid-in capital	56,306	54,812
Accumulated other comprehensive income	4,077	3,682
Accumulated deficit	(20,253)	(18,327)
Total shareholders' equity	40,324	40,359
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 59,824</b>	<b>\$ 59,250</b>

See accompanying Notes to Condensed Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF (LOSS) INCOME AND COMPREHENSIVE (LOSS)  
INCOME  
(IN THOUSANDS EXCEPT PER SHARE DATA)  
(UNAUDITED)

	Three Months Ended December 31,	
	2007	2006
Revenue	\$ 14,955	\$ 11,463
Cost of revenue	6,888	4,421
Gross profit	8,067	7,042
Operating Expenses		
General and administrative	4,210	2,362
Distribution and marketing	4,553	3,441
Research and development	617	527
Total Operating Expenses	9,380	6,330
Operating (loss) income	(1,313)	712
Foreign exchange loss	(3)	(38)
Interest and other income	130	34
Interest and other expense	(86)	(274)
	41	(278)
(Loss) income before taxes	(1,272)	434
Income tax expense	-	73
Net (loss) income	(1,272)	361
Other comprehensive income		
Foreign currency translation adjustments	395	402
Comprehensive (loss) income	\$ (877)	\$ 763
Average shares outstanding for basic earnings per share	19,281,684	16,390,100
Basic (loss) earnings per share	\$ (0.07)	\$ 0.02
Average shares outstanding for diluted earnings per share	19,281,684	18,025,289
Diluted (loss) earnings per share	\$ (0.07)	\$ 0.02

See accompanying Notes to Condensed Consolidated Financial Statements.



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

	Three Months Ended December 31,	
	2007	2006
Cash flows (used in) provided by operating activities		
Net (loss) income	\$ (1,272)	\$ 361
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	489	368
Amortization of deferred distribution fees revenue	(457)	(384)
Amortization of debt discount and debt issuance costs	-	69
Provision for bad debts	19	83
Provision for inventory write-downs	258	171
Share-based compensation	445	414
Deferred income taxes	(3)	73
Changes in assets and liabilities:		
Accounts receivable	(1,205)	715
Inventories	(1,730)	(2,228)
Other assets	385	470
Accounts payable and other accrued expenses	592	(276)
Accrued commissions	267	247
Deferred distribution fees	250	-
Net cash (used in) provided by operating activities	(1,962)	83
Cash flows used in investing activities		
Purchase of property and equipment	(471)	(950)
Net cash used in investing activities	(471)	(950)
Cash flows provided by financing activities		
Exercise of stock warrants	901	-
Exercise of stock options	150	829
Proceeds from long-term borrowings	52	-
Repayment of long-term debt	(402)	(133)
Change in short-term borrowings	(8)	548
Net cash provided by financing activities	693	1,244
Effect of exchange rate changes on cash and cash equivalents	36	(11)
Net (decrease) increase in cash and cash equivalents	(1,704)	366
Cash and cash equivalents at beginning of period	7,849	3,463
Cash and equivalents at end of period	\$ 6,145	\$ 3,829

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Supplemental cash flow disclosures

Interest paid	\$	84	\$	154
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Income taxes paid	\$	-	\$	8
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See accompanying Notes to Condensed Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
 THREE-MONTHS ENDED DECEMBER 31, 2007  
 (Unaudited)

(In Thousands, Except for Share Data)

	Common Stock (\$01 Par)	Additional Paid In Capital	Accumulated Other Comprehensive Income (1)	Accumulated Deficit	Total	Common Shares Issued and Outstanding
BALANCE, SEPTEMBER 30, 2007	\$ 192	\$ 54,812	\$ 3,682	\$ (18,327)	\$ 40,359	19,167,939
Stock issued on exercise of options	1	149	-	-	150	47,350
Stock issued on exercise of warrants	1	900	-	-	901	175,000
Share-based compensation	-	445	-	-	445	-
Cumulative effect of adopting new accounting principal	-	-	-	(654)	(654)	-
Net loss	-	-	-	(1,272)	(1,272)	-
Foreign currency translation adjustment	-	-	395	-	395	-
BALANCE, DECEMBER 31, 2007	\$ 194	\$ 56,306	\$ 4,077	\$ (20,253)	\$ 40,324	19,390,289

(1) Represents foreign currency translation adjustments.

See accompanying Notes to Condensed Consolidated Financial Statements.

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE THREE-MONTH PERIODS ENDED DECEMBER 31, 2007 AND 2006  
(UNAUDITED)  
(IN THOUSANDS, EXCEPT FOR SHARE DATA)

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## 1. OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. with its consolidated subsidiaries (the "Company") processes, manufactures and distributes worldwide, specialty surgical products and performs tissue processing services for neuro, orthopedic, reconstructive and general surgical applications. The Company's core business is processing human donor tissue, utilizing its patented TUTOPLAST(R) process, for distribution to hospitals and surgeons. The Company processes at its two manufacturing facilities in Germany and the United States and distributes its products and services in over 20 countries worldwide.

## 2. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial reporting. 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-month period ended December 31, 2007 are not necessarily indicative of the results for the fiscal year ending September 30, 2008. The unaudited condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements of the Company included in the Company's Annual Report on Form 10-K for the year ended September 30, 2007.

## 3. NEW ACCOUNTING PRONOUNCEMENTS

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS 157"). This standard defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. This standard is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the requirements of SFAS 157 and has not yet determined the impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities-Including an Amendment of FASB Statement No. 115" which is effective for fiscal years beginning after November 15, 2007. This pronouncement permits an entity to choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. Management is currently evaluating the potential impact of this pronouncement on our consolidated financial statements.

In December 2007, the FASB issued SFAS 160 "Noncontrolling Interests in Consolidated Financial Statements - An Amendment of ARB No. 51" ("SFAS 160"). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. Earlier adoption is prohibited. The Company does not have any noncontrolling interests in subsidiaries and believes that SFAS 160 will not have a material impact on its financial statements.

In December 2007, the FASB issued SFAS 141 (Revised 2007) "Business Combinations" ("SFAS 141R"). SFAS 141R establishes principles and requirements for the reporting entity in a business combination, including recognition and measurement in the financial statements of the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also establishes disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years.

#### 4. STOCK-BASED AWARDS

The Company maintains a 1996 Stock Option Plan (the "Plan") (4,000,000 shares authorized) under which incentive and nonqualified options have been granted to employees, directors and certain key affiliates. Under the Plan, options may be granted at not less than the fair market value of the underlying common stock on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant. The Plan remains in effect for all options issued during its life.

The Plan was superseded by the Tutogen Medical, Inc. Incentive and Non-Statutory Stock Option Plan (the "New Plan") (1,000,000 shares authorized), adopted by the Board of Directors on December 5, 2005 and ratified by the shareholders on March 13, 2006. On March 19, 2007, the shareholders approved increasing the shares authorized under the New Plan from 1,000,000 to 1,500,000. Under the New Plan, options may be granted at not less than the fair market value of the underlying common stock on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

Presented below is a summary of the activity of the Company's stock options for the three-month period ending December 31, 2007:

Options	Shares	Outstanding Shares		
		Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at October 1, 2007	1,997,700	\$ 2.95		
Granted	453,000	11.60		
Exercised	(47,350)	2.15		
Forfeited or expired	(5,000)	10.60		
Outstanding at December 31, 2007	2,398,350	\$ 5.43	6.53	\$ 12,041
Exercisable at December 31, 2007	1,425,725	\$ 3.56	4.79	\$ 9,828

As of December 31, 2007, 462,000 stock options were available for grant. As of December 31, 2007, there was \$2,524 of total unrecognized compensation cost related to nonvested stock options that is expected to be recognized over a weighted-average period of 2.24 years. The intrinsic value of options exercised during the three-month period ended December 31, 2007 was \$102. The fair value of options vested during the three-month period ended December 31, 2007 was \$457. The weighted average fair value of options granted during the three-month period ended December 31, 2007 was \$5.00.

During the quarters ended December 31, 2007 and 2006, stock-based compensation expense of \$350 and \$414, respectively, is included in our Condensed Consolidated Statements of (Loss) Income and Comprehensive (Loss) Income. The Company also capitalized \$95 of compensation expense to inventory at December 31, 2007.

## 5. INVENTORIES

Major classes of inventory were as follows:

	December 31, 2007	September 30, 2007
Raw materials	\$ 4,676	\$ 3,602
Work in process	9,908	7,356
Finished goods	4,428	6,432
	\$ 19,012	\$ 17,390

The increase in inventory from September 30, 2007 to December 31, 2007 was primarily due to higher inventory levels to support increased demand for the Company's products. At December 31, 2007 and September 30, 2007, the Company had inventory reserves of \$2,660 and \$2,315, respectively. These amounts include write-downs for slow-moving, excess and obsolete inventories based on historical experience, current product demand, regulatory considerations, industry trends, changes and risks and the remaining shelf life.

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## 6. INCOME TAXES

The deferred tax asset balances consist primarily of net operating loss carry forwards, deferred distribution fees and inventory reserves. As of December 31, 2007, the Company had approximately \$11,323 of federal net operating loss carry forwards expiring beginning in 2012, a \$79 alternative minimum tax credit carry forward, and a \$60 credit on research and development that will begin to expire in 2013. The Company also had state net operating loss carry forwards of approximately \$4,617 that will begin to expire in 2025.

As of December 31, 2007, the Company had a corporate net operating loss carry forward for German income tax purposes of approximately \$3,033 (2,059 Euros), and a trade net operating loss carry forward for German income tax purposes of approximately \$613 (416 Euros), both of which can be carried forward indefinitely. The Company continually reviews the adequacy and necessity of the valuation allowance in accordance with the provisions of SFAS No. 109, "Accounting for Income Taxes".

Historically, the Company has not recorded deferred income taxes on the undistributed earnings of its foreign subsidiaries because it was management's intent to indefinitely reinvest such earnings. During the 2006 fiscal year, the Company reduced certain intercompany accounts, which resulted in a taxable dividend of \$82 from Germany to the U.S. The Company does not intend to record deferred income taxes on future undistributed earnings of its foreign subsidiaries because it is management's intent to indefinitely reinvest such earnings. Upon distribution of these earnings, the Company may be subject to U.S. income taxes and/or foreign withholding taxes.

In June 2006, the FASB issued Interpretation No. 48 ("FIN 48"), "Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109". FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109. This Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. In connection with the Company's adoption of FIN 48 on October 1, 2007, the Company reported a net decrease to retained earnings of \$654 related to German taxes. Unrecognized tax benefits were \$654 at adoption. If these unrecognized tax benefits were recognized, approximately \$654 would impact the effective tax rate.

During the quarter ended December 31, 2007, the Company increased its FIN 48 liability by \$22. Unrecognized tax benefits were \$676 at December 31, 2007. If these unrecognized tax benefits were recognized, approximately \$676 would impact the effective tax rate.

The Company's primary tax jurisdictions are U.S. federal, the state of Florida, Germany and France. The Company is not currently under examination by the U.S. federal government or the state of Florida and fiscal years ended September 30, 2004 to September 30, 2007 remain open under the statute of limitations. In Germany, tax years ending September 30, 2002 to September 30, 2007 remain open, although the Company is currently under examination for the fiscal years ended September 30, 2002 to September 30, 2005. The fiscal years ended September 30, 2003 to September 30, 2007 remain open in France. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. Given the Company's current net operating loss positions in each of the tax jurisdictions, there has never been interest or penalties recognized for tax matters. The Company does not believe that its FIN 48 liability will change materially in the next twelve-months.

## 7. REVOLVING CREDIT ARRANGEMENTS AND SHORT TERM BORROWINGS

Under the terms of revolving credit facilities with two German banks, the Company may borrow up to 1,500 Euros (1,000 Euros and 500 Euros, respectively) or \$2,209 for working capital needs. These renewable credit lines allow the Company to borrow at interest rates ranging from 7.5% to 10.25%. At December 31, 2007, the Company had



outstanding borrowings of 129 Euros or \$190 in the aggregate. At September 30, 2007, the Company had no outstanding borrowings under the revolving credit agreements. The 500 Euro revolving credit facility is secured by accounts receivable of the German subsidiary. The 1,000 Euros revolving credit facility is collateralized by a mortgage on the Company's German facility and a guarantee of up to 4,000 Euros or \$5,892 by the Parent Company.

In November 2005, the Company entered into a revolving credit facility in the U.S. for up to \$1,500, expiring on November 18, 2008. At December 31, 2007 and September 30, 2007, the Company had no outstanding borrowings on this credit facility. The U.S. accounts receivable and inventory assets collateralize the borrowing under the revolving credit facility. The Company is required to maintain a maximum senior debt to tangible net worth ratio of 2.0 to 1.0. As of December 31, 2007, the Company was in compliance with this covenant. In addition, the Company maintains a lock box arrangement with the bank.

On June 30, 2006, the Company issued a \$3,000 convertible debenture with detachable warrants to purchase up to 175,000 shares of its common stock. The debenture bore interest at 5.0% per year, was due upon the earlier of August 1, 2007, or upon a change of control of the Company and was convertible into common stock at a price of \$5.15 per share at any time at the election of the holder. The warrants were exercisable at \$5.15 per share at any time at the election of the shareholder until the earlier of the third anniversary of the date of issuance or upon a change in control of the Company. In April and May of 2007, the \$3,000 debenture was fully converted into common stock. In November 2007, the 175,000 warrants were fully exercised into common stock.

## 8. DERIVATIVE INSTRUMENTS

The Company accounts for its hedging activities in accordance with SFAS No. 133, "Accounting for Derivatives and Hedging Activities" ("SFAS No. 133") as amended. SFAS No. 133 requires that all hedging activities be recognized in the balance sheet as assets or liabilities and be measured at fair value. Gains or losses from the change in fair value of hedging instruments that qualify for hedge accounting are recorded in other comprehensive income. The Company's policy is to specifically identify the assets, liabilities or future commitments being hedged and monitor the hedge to determine if it continues to be effective. The Company does not enter into or hold derivative instruments for trading or speculative purposes. The fair value of the Company's interest rate swap agreement for its 1,500 Euro or \$2,209 long-term loan is based on dealer quotes and was not significant as of December 31, 2007. The loan is due on March 30, 2012 in monthly installments of approximately 63 Euros or \$93 including principal and interest based on an adjustable rate as determined by one-month EURIBOR, fixed by a swap agreement for the life of the loan with the lender at 3.7% as a cash flow hedge. The proceeds were used to construct new facilities.

## 9. 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 International. The Company evaluates performance based on the operating income of each segment. The accounting policies of these segments are consistent with prior periods. The Company accounts for intersegment sales and transfers at contractually agreed-upon prices.

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

A summary of the operations and assets by segment as of and for the quarters ended December 31, 2007 and 2006 are as follows:

December 31, 2007	International	United States	Consolidated
Gross revenue	\$ 5,611	\$ 10,553	\$ 16,164
Less - intercompany	(1,209)	-	(1,209)
Total revenue - third party	4,402	10,553	14,955
Net income (loss) before taxes	1,043	(2,315)	(1,272)
Net income (loss)	677	(1,949)	(1,272)
Total assets	20,639	39,185	59,824
Property, Plant and Equipment	11,137	3,675	14,812
December 31, 2006	International	United States	Consolidated
Gross revenue	\$ 5,031	\$ 8,133	\$ 13,164
Less - intercompany	(1,701)	-	(1,701)
Total revenue - third party	3,330	8,133	11,463

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Net income before taxes	225	209	434
Net income	152	209	361
Total assets	18,885	22,539	41,424
Property, Plant and Equipment	10,196	3,803	13,999

## 10. (LOSS) EARNINGS PER SHARE

The following is a reconciliation of the numerators and denominators of the basic and diluted (loss) earnings per share computations for the three-month periods ended December 31, 2007 and 2006. The Company has excluded 1,738,964 and 423,000 of stock options for the three-month periods ended December 31, 2007 and 2006, respectively, as such stock options are anti-dilutive to the calculation.

Numerator	Three Months Ended	
	2007	December 31, 2006
Net (loss) income used in calculation of basic and diluted earnings per share	\$ (1,272)	\$ 361
Denominator		
Weighted-average shares of common stock outstanding used in calculation of basic earnings per share	19,281,684	16,390,100
Effect of dilutive securities - stock options, warrants and convertible debentures	-	1,635,189
Weighted-average shares of common stock outstanding used in calculation of diluted earnings per share	19,281,684	18,025,289
Basic (loss) earnings per share	\$ (0.07)	\$ 0.02
Diluted (loss) earnings per share	\$ (0.07)	\$ 0.02

## 11. LEGAL PROCEEDINGS

On October 12, 2005, the Company issued a voluntary recall of all product units which utilized donor tissue received from BioMedical Tissue Services/BioTissue Recovery Services ("BioMedical"). This action was taken because the Company was unable to satisfactorily confirm that BioMedical had properly obtained donor consent. The Company quarantined all BioMedical products in its inventory, having a value of \$1,035 and notified all customers and distributors of record regarding this action. In connection with the recall, the Company wrote off \$174 of inventory during 2005, and \$861 for quarantined inventory at September 30, 2006. Additionally, as of September 30, 2005, the Company had accrued \$250 of related costs in connection with the recall. As of December 31, 2007 and September 30, 2007, the accrual for these costs was \$0, due in part to actual payments made for such costs and in part to an adjustment made by management during the three-months ended March 31, 2006 to reduce the accrual by approximately \$150 as a result of a change in management's estimate of other related costs. The effect of this adjustment was to reduce cost of revenue by approximately \$150.

In January 2006, the Company was named as one of several defendants in a class action suit related to the BioMedical recall. The Company intends to vigorously defend this matter and does not believe that the outcome of this class action will have a material adverse effect on the Company's operations, cash flows, financial position or financial statement disclosures.

The Company is party to various claims, legal actions, complaints and administrative proceedings arising in the ordinary course of business. In management's opinion, the ultimate disposition of these matters will not have a material adverse effect on its financial condition, cash flows or results of operations.

## 12. RELATED PARTY TRANSACTIONS

As of December 31, 2007, Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc. ("Zimmer") was the owner of 27% of the Company's outstanding shares of common stock.

The Company has an exclusive license and distribution agreement with Zimmer Spine, Inc., a wholly owned subsidiary of Zimmer, whereby Zimmer Spine has been granted the right to act as the Company's exclusive distributor of bone tissue for spinal applications in the United States. For the three-months ended December 31, 2007 and 2006 product sales to Zimmer Spine totaled \$1,150 and \$1,293, respectively. Accounts receivable from Zimmer Spine were \$171 and \$209 at December 31, 2007 and September 30, 2007.

The Company has also engaged Zimmer Dental, Inc. (“Zimmer Dental”) a wholly owned subsidiary of Zimmer to act as an exclusive sales and marketing representative for the Company's bone tissue for dental applications in the United States and certain international markets. Under this distribution agreement, the Company ships directly to Zimmer Dental’s customers. For the three-month periods ended December 31, 2007 and 2006, Zimmer Dental was paid commissions aggregating approximately \$2,532 and \$1,918 respectively. Accounts payable to Zimmer Dental total \$2,779 and \$2,532 at December 31, 2007 and September 30, 2007, respectively. Accounts receivable from Zimmer Dental totaled \$238 at December 31, 2007 and \$292 at September 30, 2007.

In August 2007, the Company entered into an exclusive distribution agreement with Zimmer Dental, whereby Zimmer Dental will distribute dental products internationally. For the three-month period ending December 31, 2007, product sales under this new relationship totaled \$61.

### 13. SUBSEQUENT EVENTS

On November 12, 2007, the Company entered into an Agreement and Plan of Merger among Regeneration Technologies, Inc. (“Parent”), Rockets FL Corp. (“Merger Sub”) and the Company. The proposed merger transaction is structured as a tax free stock-for-stock exchange pursuant to which the Company’s shareholders will receive 1.22 shares of the Parent’s common stock for each share of the Company’s common stock. As a result, the Company will become a wholly-owned subsidiary of the Parent. Upon completion of the proposed merger, Parent stockholders will own approximately 55% of the combined company and the Company’s shareholders will own approximately 45% of the combined company, on a fully diluted basis. The proposed merger is subject to approval by the respective shareholders of the Parent and the Company, as well as customary closing conditions and regulatory approvals. If the Company terminates the Agreement and Plan of Merger, under certain limited conditions, the Company could owe a termination fee of \$6.5 million. The proposed merger is estimated to be completed during the second quarter of the Company’s 2008 fiscal year. Information about the proposed merger is set forth in the joint proxy statement/prospectus filed with the Securities and Exchange Commission on January 23, 2008.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (In Thousands, except for share data).

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

The discussion contained in this report under Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), contains forward-looking statements that involve risks and uncertainties. The issuer's actual results could differ significantly from those discussed herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" as well as those discussed elsewhere in this Report. Statements contained in this Report that are not historical facts are forward-looking statements that are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. A number of important factors could cause the issuer's actual results for 2008 and beyond to differ materially from those expressed in any forward-looking statement made by or on behalf of the issuer.

BUSINESS

During the three months ended December 31, 2007, the Company generated \$14,955 in revenues. The Company continues to experience strong growth in U.S. dental sales, which totaled \$6,720 up 27% from the same quarter last year. The Company continued to grow the hernia market with Davol Inc., a subsidiary of C.R. Bard, Inc., and the breast reconstruction market with Mentor Corporation with Surgical Specialties sales (which includes urology, ophthalmology, hernia, breast reconstruction and ear, nose and throat, or ENT) up 73% over the same period in the prior year. The increase was due primarily to sales of the new hernia repair and breast reconstruction products.

International sales increased 32% over the same quarter last year.

In October 2007, the Company entered into a new five year Tissue Procurement, Processing and Supply Agreement with Allosource, Inc. whereby Allosource will provide the Company with various human tissues used in the Company's dental and spinal product lines.

On November 12, 2007, the Company entered into an Agreement and Plan of Merger among Regeneration Technologies, Inc. ("Parent"), Rockets FL Corp. ("Merger Sub") and the Company. The proposed merger transaction is structured as a tax free stock-for-stock exchange pursuant to which the Company's shareholders will receive 1.22 shares of the Parent's common stock for each share of the Company's common stock. As a result, the Company will become a wholly-owned subsidiary of the Parent. Upon completion of the proposed merger, Parent stockholders will own approximately 55% of the combined company and the Company's shareholders will own approximately 45% of the combined company, on a fully diluted basis. The proposed merger is subject to approval by the respective shareholders of the Parent and the Company, as well as customary closing conditions and regulatory approvals. If the Company terminates the Agreement and Plan of Merger, under certain limited conditions, the Company could owe a termination fee of \$6.5 million. The proposed merger is estimated to be completed during the second quarter of the Company's 2008 fiscal year.

Statements in the following discussion and analysis relating to the Company's business strategies, operating plans, planned expenditures, expected capital requirements and other forward-looking statements regarding the Company's business do not take into account potential future impacts of the Company's proposed merger with Regeneration Technologies.

The Company's ability to generate positive operational cash flow is dependent upon increasing revenues supported by increased tissue procurement, controlling costs and the development of additional markets and surgical applications worldwide. While the Company believes that it continues to make progress in these areas, there can be no assurances.





## RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED DECEMBER 31, 2007 AND 2006

## REVENUE

An analysis of revenue is as follows:

	1st Qtr FY 2008	1st Qtr FY 2007	Growth Rates 1st Qtr FY 2008
Dental	\$ 6,720	\$ 5,286	27%
Spine	1,150	1,293	-11%
Surgical Specialties	2,683	1,554	73%
Total U.S.	10,553	8,133	30%
Gemany	1,231	891	38%
Rest of World	2,608	1,899	37%
France	409	403	1%
Other - Distribution Fees	154	137	12%
Total International	4,402	3,330	32%
Total Consolidated	\$ 14,955	\$ 11,463	30%

Revenue for the three-month period ended December 30, 2007 totaled \$14,955 compared to \$11,463 for the same period last year or a 30% increase. U.S. revenues for the three-month period ended December 31, 2007 increased by \$2,420 (\$8,133 to \$10,553) or 30%. The increase in U.S. revenues was fueled by the continuing increase in the demand for the Company's TUTOPLAST(R) bone products for dental applications sold by Zimmer Dental, the Company's sales and marketing representative, and increased demand for the Company's new hernia repair and breast reconstruction products. Dental revenues totaled \$6,720, which was a record quarter for the Company. Spine revenues for the quarter decreased slightly by \$143 (\$1,293 to \$1,150) or 11% compared to the same period last year as the Company had multiple new product stocking orders during the first quarter of 2007. Surgical Specialties revenues (primarily urology, ophthalmology, hernia, breast reconstruction and ENT) for the three-month period ended December 31, 2007 increased by \$1,129 (\$1,554 to \$2,683) or 73% compared to the same period last year due primarily to the new hernia and breast reconstruction products. International revenues for the three-month period ended December 31, 2007 increased \$1,072 (\$3,330 to \$4,402) or 32% compared to the same period last year. The increases are primarily due to increased sales efforts by several key distributors in various countries. In addition, international revenues received a positive impact during the first quarter of 2008 due to the declining exchange rate of the U.S. dollar against the Euro.

## GROSS MARGIN

The Company's gross margin for three-month period ended December 31, 2007 decreased from 61% to 54% over the same period in the prior year. The lower margin was due to unfavorable product mix and yields and backorders of certain higher margin products.

## GENERAL AND ADMINISTRATIVE

General and administrative expenses for the three-month period increased over the prior year period by \$1,848 (\$2,362 to \$4,210). Included in this increase are expenses of \$1,615 associated with the proposed merger. Excluding the merger expenses, general and administrative expenses for the three-month period increased over the prior year period by \$233. The increase was primarily due to \$227 associated with costs for the quarter related to the compliance with the Sarbanes Oxley Act of 2002. The Company does not expect to incur any additional material Sarbanes Oxley costs in fiscal year 2008. During the quarter, the Company incurred \$445 in stock option expenses under SFAS 123(R) associated with stock option grants to employees, of which \$256 was charged to general and administrative expenses or \$158 lower than the same period last year. The decrease in stock option expense in general and administrative expenses was offset by increased personnel costs. Exclusive of the merger expenses, general and administrative expenses as a percentage of sales declined from 21% to 17 % for the three months ended December 31, 2007 compared to the same period last year.

## DISTRIBUTION AND MARKETING

Distribution and marketing expenses for the three-month period ended December 31, 2007 increased over the prior year period by \$1,112 (\$3,441 to \$4,553) or 32%. The increase was primarily due to higher marketing fees earned by Zimmer Dental of \$580 (\$2,164 to \$2,744) which is consistent with overall increased dental sales. The increase is also due to increased personnel costs of \$193, stock option expense of \$77 and charges related to the declining exchange rate of the U.S. dollar to the Euro of \$142. As a percentage of sales, distribution and marketing expenses remained at 30% for the three-months ended December 31, 2007 compared to the same period last year.

## RESEARCH AND DEVELOPMENT

Research and development expenses for the three-month period ended December 31, 2007 increased over the prior year period by \$90. As a percentage of revenues, research and development expenses decreased from 5% to 4% for the three months ended December 31, 2007 when compared to the same period last year.

## INTEREST AND OTHER INCOME

Interest and other income, which primarily represents interest income, increased to \$130 for the three months ended December 31, 2007 compared to \$34 for the prior year period. This increase is related to interest income earned on the \$11,494 net proceeds from the equity financing completed in April 2007.

## INTEREST EXPENSE

Interest expense for the three-month period ended December 31, 2007 decreased over the prior year period by \$188 (\$274 to \$86). The decrease was primarily due to full conversion of the \$3,000 convertible debenture into common shares during the three months ended June 30, 2007 and the Company paying off substantially all outstanding balances on the lines of credit with the U.S. and German banks.

## FOREIGN CURRENCY LOSS

The Company had nominal foreign currency exchange losses for the three-month period ended December 31, 2007.

## INCOME TAX EXPENSE

Income tax expense for the three-month period ending December 31, 2007 was \$0. The Company did not receive a tax benefit for losses during the quarter due primarily to certain non-deductible merger related costs.

## NET LOSS

Net loss for the three-month period ended December 31, 2007, totaled \$1,272, or \$.07 basic and diluted loss per share. Exclusive of the expenses associated with the proposed merger of \$1,615, net income for the three-month period ended December 31, 2007, totaled \$343, or \$.02 basic and diluted earnings per share compared to \$361 or \$.02 basic and diluted earnings per share for the same period last year.

## ACCOUNTS RECEIVABLE

The accounts receivable balance increased by \$1,015 from the September 30, 2007 balance of \$6,477 to the December 31, 2007 balance of \$7,492. The increase relates directly to the increased growth in revenues, exclusive of the Zimmer Dental stocking order in Germany last quarter that was paid early.

INVENTORY

The inventory balance increased by \$1,622 from the September 30, 2007 balance of \$17,390 to the December 31, 2007 balance of \$19,012. The increase was primarily due to higher inventory levels to support additional increased demand for the Company's products.

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## 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 for the year ended September 30, 2007. However, certain of the accounting policies are particularly important to the portrayal of the Company's 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:

**Share-Based Compensation.** We adopted SFAS No. 123(R) in the first quarter of fiscal year 2006. SFAS 123(R) requires the measurement and recognition of compensation expense for all share-based payment awards including employee stock options based on estimated fair values. Under SFAS 123(R), we estimate the value of share-based payments on the date of grant using the Black-Scholes model, which was also used previously for the purpose of providing pro forma financial information as required under SFAS 123. The determination of the fair value of, and the timing of expense relating to, share-based payment awards on the date of grant using the Black-Scholes model is affected by our stock price as well as assumptions regarding a number of variables including the expected term of awards, expected stock price volatility, vesting periods and expected forfeitures.

Prior to the first quarter of fiscal year 2006, we used historical stock price volatility in preparing our pro forma information under SFAS 123. Under SFAS 123(R), we use a combination of historical and implied volatility to establish the expected volatility assumption based upon our assessment that such information is more reflective of current market conditions and a better indicator of expected future volatility. SFAS 123(R) also requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate expected forfeitures, as well as the expected term of awards, based on historical experience. Future changes in these assumptions, our stock price or certain other factors could result in changes in our share-based compensation expense in future periods.

**Inventories.** Inventories are valued at the lower of cost or market, with cost determined using the first-in-first-out method. Work in process and finished goods includes costs attributable to direct labor and overhead. Impairment charges for slow moving, excess and obsolete inventories are recorded based on historical experience, current product demand determined in part through periodic meetings with distributors, regulatory considerations, industry trends, changes and risks and the remaining shelf life. As a result of this analysis, the Company records an allowance to reduce the carrying value of any impaired inventory to its fair value, which becomes its new cost basis. If the actual product life cycles, demand or general market conditions are less favorable than those projected by management, additional inventory impairment charges may be required which would affect future operating results. The adequacy of these inventory impairment charges is evaluated quarterly.

**Revenue Recognition and Accounts Receivable.** Revenue on product sales and tissue processing 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. Title transfers 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 "Revenue Recognition When Right of Return Exists" ("SFAS 48") and allowances for doubtful accounts are based on significant historical experience. Revenue from distribution fees includes 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 ratably to approximate services provided under the contract. Recognition of revenue commenced over the term of the distribution agreement upon delivery of initial products.

Valuation of Deferred Tax Assets. We record valuation allowances to reduce the net deferred tax assets to the amounts estimated to be realizable. While we consider taxable income in assessing the need for a valuation allowance, in the event we determine it is more likely than not we would be able to realize our deferred tax assets in the future, an adjustment to the valuation allowance would be made and income increased in the period of such determination. Likewise, in the event we determine we would not be able to realize all or part of our deferred tax assets in the future, an adjustment would be made to the valuation allowance and charged to income in the period of such determination.

Valuation of Long-Lived Assets. Long-lived assets on our balance sheet are stated at the lower of cost, net of depreciation and amortization, or fair value. The factors in this valuation which require significant estimates and judgments are: (1) determination of the estimated useful life of each asset, which determines expense per period, number of periods of expense, and the carrying value of each asset at any time; and (2) determination of the fair value of assets, which may result in other than temporary impairment charges when fair value is lower than the carrying value of assets, which we would recognize as a charge to earnings during the period in which we made the determination. If we overestimate the useful life of an asset, or overestimate the fair value of an asset, and at some time in the future we dispose of that asset for a lower amount than its carrying value, our historically reported total assets and net income would have been higher than they would have been during periods prior to our recognition of the loss on disposal of assets, and lower during the period when we recognize the loss.

## LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2007 and September 30, 2007, the Company had working capital of \$28,121 and \$29,086, respectively.

Cash and cash equivalents decreased from \$7,849 at September 30, 2007 to \$6,145 at December 31, 2007 due to \$961 of fees paid related to the proposed merger, with the remaining amount primarily due to investments in inventory to support demand.

The Company used \$1,962 of cash for operating activities for the three-month period ended December 31, 2007 compared to cash flow provided by operating activities of \$83 for the comparable period last year. Exclusive of the payments associated with the proposed merger of \$962, cash used in operating activities was \$1,000. The primary reason for the use of cash for the three months ended December 31, 2007 was an increase in inventory levels to support additional increased demand for the Company's products.

Net cash used in investing activities, representing purchases of capital expenditures, was \$471 for the three months ended December 31, 2007 and \$950 for the comparable prior year period. The purchases represented primarily capital expenditures associated with the new equipment for the U.S. and German manufacturing plants.

Net cash provided by financing activities was \$693 for the three-month period ended December 31, 2007 compared to \$1,244 for the three-month period ended December 31, 2006. During the three-month period ended December 31, 2007, the Company received \$901 of proceeds from the full exercise of the warrants related to the \$3,000 debenture, offset by payments on long-term debt.

Future minimum rental payments required under the Company's operating leases that have initial or remaining non-cancelable lease terms in excess of one year on a fiscal year basis are as follows:

1/1/08 - 9/30/08	\$	1,168
2009		760
2010		283
2011		186
2012		121
	\$	2,518

Long-term debt consists of senior debt construction loans and capital leases. Future minimum payments on a fiscal year basis are as follows (1):

1/1/08 - 9/30/08	\$	1,138
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2009		798
2010		770
2011		664
2012		312
Thereafter		648
		4,330
Less current portion		1,138
Total future minimum payments	\$	3,192

(1) does not include interest

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The Company maintains current working capital credit lines totaling 1,500 Euros or \$2,209 with two German banks and a \$1,500 credit line with a U.S. bank. At December 31, 2007, the Company had outstanding balances of \$190 and \$0 for the working capital lines in Germany and the U.S., respectively. Management believes that the working capital as of December 31, 2007 will be adequate to fund ongoing operations. The Company may seek additional financing to meet the needs of its long-term strategic plan. The Company can provide no assurance that such additional financing will be available, or if available, that such funds will be available on favorable terms. The Company's ability to generate positive operational cash flow is dependent upon increasing processing revenue through increased recoveries by tissue banks in the U.S. and Europe, controlling costs, and the development of additional markets and surgical applications for its products worldwide. While the Company believes that it continues to make progress in these areas, there can be no assurances.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For information regarding the Company's exposure to certain market risks, see the Annual Report on Form 10-K for the year ended September 30, 2007. There have been no significant changes to our market risk exposures.

In the United States and in Germany, the Company is exposed to interest rate risk. Changes in interest rates affect interest income earned on cash and cash equivalents and interest expense on revolving credit arrangements. Except for an interest rate swap associated with \$2,209 of long term debt over six years starting March 31, 2006, the Company does not enter into derivative transactions related to cash and cash equivalents or debt. Accordingly, the Company is subject to changes in interest rates. Based on December 31, 2007 cash and cash equivalents and long-term debt balances, a 1% change in interest rates would have a de-minimus impact on the Company's results of operations.

The value of the U.S. dollar compared to the Euro affects our financial results. Changes in exchange rates may positively or negatively affect revenues, gross margins, operating expenses and net income. The international operation currently transacts business primarily in the Euro. Intercompany transactions translate from the Euro to the U.S. dollar. Based on December 31, 2007 outstanding intercompany balances, a 1% change in currency rates would have a de-minimus impact on our results of operations.

### ITEM 4. CONTROLS AND PROCEDURES

#### DISCLOSURE CONTROLS AND PROCEDURES

The Company maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 as amended) that are designed to provide reasonable assurance that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In connection with the filing of this Form 10-Q, management evaluated, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2007. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2007.

#### CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There has not been any change in the Company's internal control over financial reporting during the three-month period ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, those controls.



PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Refer to Note 11 of the Unaudited Condensed Consolidated Interim Financial Statements.

ITEM 1A. RISK FACTORS.

Refer to the section entitled "Risk Factors" contained in the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on January 23, 2008. Such section is incorporated herein by reference.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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

None.

ITEM 5. OTHER INFORMATION.

None.

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ITEM 6. EXHIBITS.

- 10.1\* Severance Agreement by and between Tutogen Medical, Inc. and L. Robert Johnston, Jr. dated January 22, 2008
- 10.2\* Severance Agreement by and between Tutogen Medical, Inc. and Claude Pering dated January 22, 2008
- 10.3\* Severance Agreement by and between Tutogen Medical, Inc. and Clifton J. Seliga dated January 22, 2008
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 -- Chief Executive Officer
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 -- Chief Financial Officer
- 32.1 Certifications Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Management contract or compensating plan or arrangement

SIGNATURES

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

TUTOGEN MEDICAL,  
INC.

Date: February 7, 2008

/s/ Guy L. Mayer  
Chief Executive Officer

Date: February 7, 2008

/s/ L. Robert Johnston, Jr.  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)