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TUTOGEN MEDICAL INC
Form 10-Q
August 14, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(MARK ONE)

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

For the period ended June 30, 2006.

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.)

13709 PROGRESS BOULEVARD ALACHUA, FLORIDA 32615
(Address of Principal Executive Offices) (Zip Code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (386) 462-0402

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 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 .

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

As of July 31, 2006 there were outstanding 16,093,135 shares of Tutogen Medical, Inc. Common Stock, par value \$0.01.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

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

| | JUNE 30, 2006 | SEPTEMBER 2005 |
|---|------------------|-------------------|
| | ----- | ----- |
| ASSETS | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 3,795 | \$ 3,5 |
| Accounts receivable - net of allowance for doubtful accounts of \$507 in June 2006 and \$462 in September 2005 | 4,883 | 3,4 |
| Inventories - net | 11,874 | 9,5 |
| Deferred tax asset | 639 | 1,1 |
| Other current assets | 1,331 | 6 |
| | ----- | ----- |
| Total current assets | 22,522 | 18,3 |
| Property, plant and equipment, net | 11,509 | 6,6 |
| Deposits | 300 | |
| Deferred tax asset | 2,435 | 1,2 |
| | ----- | ----- |
| TOTAL ASSETS | \$ 36,766 | \$ 26,2 |
| | ===== | ===== |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | \$ 2,148 | \$ 1,3 |
| Accrued expenses | 3,303 | 3,3 |
| Other current liabilities | 1,067 | 1,2 |
| Accrued commissions | 1,936 | 1,7 |
| Short-term borrowings | 6,331 | 1,0 |
| Current portion of deferred distribution fees | 996 | 5 |
| Current portion of long-term debt | 1,063 | 1 |
| | ----- | ----- |
| Total current liabilities | 16,844 | 9,5 |
| Noncurrent Liabilities | | |
| Other noncurrent liabilities | 3,145 | 2,3 |
| Long-term debt | 2,709 | 6 |
| | ----- | ----- |
| TOTAL LIABILITIES | 22,698 | 12,4 |
| Shareholders' Equity: | | |
| Common stock, \$0.01 par value, 30,000,000 authorized; 16,083,135 and 15,932,960 issued and outstanding | 161 | 1 |
| Additional paid-in capital | 37,340 | 36,3 |

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| | | |
|--|-----------|---------|
| Accumulated other comprehensive income | 2,251 | 1,6 |
| Accumulated deficit | (25,684) | (24,4 |
| | ----- | ----- |
| Total shareholders' equity | 14,068 | 13,7 |
| | ----- | ----- |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY | \$ 36,766 | \$ 26,2 |
| | ===== | ===== |

See accompanying Notes to Condensed Consolidated Financial Statements.

1

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

| | THREE MONTHS ENDED JUNE 30, | | NINE M |
|--|-----------------------------|-------------------------------|--------|
| | 2006 | 2005 | 2006 |
| | | (AS RESTATED, SEE NOTE 14) | |
| | ----- | ----- | ----- |
| REVENUE | \$ 10,000 | \$ 9,281 | \$ 27 |
| COST OF REVENUE | 5,317 | 6,101 | 12 |
| | ----- | ----- | ----- |
| Gross profit | 4,683 | 3,180 | 14 |
| OPERATING EXPENSES | | | |
| General and administrative | 2,134 | 1,206 | 5 |
| Distribution and marketing | 3,342 | 3,071 | 9 |
| Research and development | 453 | 406 | 1 |
| | ----- | ----- | ----- |
| | 5,929 | 4,683 | 15 |
| | ----- | ----- | ----- |
| OPERATING LOSS | (1,246) | (1,503) | (1 |
| FOREIGN EXCHANGE (LOSS) GAIN | (233) | 317 | |
| OTHER INCOME | 12 | 16 | |
| INTEREST EXPENSE | (75) | (19) | |
| | ----- | ----- | ----- |
| | (296) | 314 | |
| | ----- | ----- | ----- |
| LOSS BEFORE INCOME TAX (BENEFIT) EXPENSE | (1,542) | (1,189) | (1 |
| | ----- | ----- | ----- |
| Income tax (benefit) expense | (413) | 88 | |
| | ----- | ----- | ----- |
| NET LOSS | \$ (1,129) | \$ (1,277) | \$ (1 |

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| | | | |
|---|------------|------------|--------|
| Comprehensive Income: | | | |
| Foreign currency translation gain | 377 | 455 | |
| COMPREHENSIVE LOSS | \$ (752) | \$ (822) | \$ |
| AVERAGE SHARES OUTSTANDING FOR BASIC AND DILUTED LOSS PER SHARE | 16,058,724 | 15,917,755 | 15,993 |
| BASIC AND DILUTED LOSS PER SHARE | \$ (0.07) | \$ (0.08) | \$ |

See accompanying Notes to Condensed Consolidated Financial Statements.

2

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

| | NINE MONTHS ENDED JUNE 30, | |
|---|----------------------------|-------------------------------|
| | 2006 | 2005 |
| | | (AS RESTATED, SEE NOTE 14) |
| CASH FLOWS USED IN OPERATING ACTIVITIES | | |
| Net loss | \$ (1,188) | \$ (4,320) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 688 | 771 |
| Amortization of deferred distribution fees revenue | (407) | (479) |
| Severance costs | 437 | 0 |
| Deferred income taxes | (693) | (404) |
| Provision for inventory write-downs | 741 | 201 |
| Share-based compensation | 303 | 0 |
| Changes in assets and liabilities: | | |
| Accounts receivable | (1,410) | 13 |
| Inventories | (3,061) | 3,632 |
| Other current assets | (503) | 20 |
| Accounts payable | 477 | (1,006) |
| Accrued expenses | (517) | (103) |
| Other current liabilities | (143) | 710 |
| Accrued commissions | 171 | 325 |
| Other noncurrent liabilities | 1,650 | 0 |
| Net cash used in operating activities | (3,455) | (640) |
| CASH FLOWS USED IN INVESTING ACTIVITIES | | |
| Investment in a marketable security | 0 | (140) |
| Deposits on purchase of property and equipment | (300) | 0 |

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| | | |
|---|----------|----------|
| Purchase of property and equipment | (5,280) | (1,144) |
| Net cash used in investing activities | (5,580) | (1,284) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Issuance of common stock | 383 | 6 |
| Proceeds from long-term borrowings | 3,186 | (200) |
| Proceeds from short-term borrowings | 2,669 | 626 |
| Proceeds from issuance of convertible debt and warrants | 3,000 | 0 |
| Debt issuance costs | (205) | 0 |
| Repayment of short-term borrowings | (110) | 0 |
| Repayment of long-term debt | (228) | (130) |
| Net cash provided by financing activities | 8,695 | 302 |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH | 573 | (147) |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 233 | (1,769) |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 3,562 | 5,063 |
| CASH AND EQUIVALENTS AT END OF PERIOD | \$ 3,795 | \$ 3,294 |
| ----- | | |
| SUPPLEMENTAL CASH FLOW DISCLOSURES: | | |
| Interest paid | \$ 231 | \$ 51 |
| Income taxes paid | \$ 0 | \$ 151 |

See accompanying Notes to Condensed Consolidated Financial Statements.

3

TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
NINE MONTHS ENDED JUNE 30, 2006
(Unaudited)
(In Thousands, Except for Share Data)

| | COMMON STOCK (\$.01 PAR) | ADDITIONAL PAID-IN CAPITAL | ACCUMULATED OTHER COMPREHENSIVE INCOME | ACCUMULATED DEFICIT |
|-------------------------------------|---------------------------------|----------------------------------|---|------------------------|
| | ----- | ----- | ----- | ----- |
| BALANCE, SEPTEMBER 30, 2005 | \$ 159 | \$ 36,381 | \$ 1,678 | \$ (24,4 |
| Stock issued on exercise of options | 2 | 381 | -- | |
| Warrants issued | -- | 275 | -- | |
| Share-based compensation | -- | 303 | -- | |
| Net loss | -- | -- | -- | (1,1 |

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| | | | | |
|---|--------|-----------|----------|----------|
| Foreign currency translation adjustment | -- | -- | 573 | |
| | ----- | ----- | ----- | ----- |
| BALANCE, June 30, 2006 | \$ 161 | \$ 37,340 | \$ 2,251 | \$ (25,6 |
| | ===== | ===== | ===== | ===== |

See accompanying Notes to Condensed Consolidated Financial Statements.

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TUTOGEN MEDICAL, INC. AND SUBSIDIARIES
 NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
 JUNE 30, 2006
 (IN THOUSANDS, EXCEPT SHARE DATA)

(1) OPERATIONS AND ORGANIZATION

Tutogen Medical, Inc. with its consolidated subsidiaries (the "Company") processes, manufactures and distributes worldwide, specialty surgical products and performs tissue processing services for neuro, orthopedic, reconstructive and general surgical applications. The Company's core business is processing human donor tissue, utilizing its patented Tutoplast(R) process, for distribution to hospitals and surgeons. The Company processes tissue at its two manufacturing facilities in Germany and the United States and distributes its products and services to over 30 countries worldwide.

(2) BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in conformity with accounting principles generally accepted in the United States 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 and nine months ended June 30, 2006 are not necessarily indicative of the results which may be expected for the fiscal year ending September 30, 2006. The 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/A for the year ended September 30, 2005. Certain amounts for prior periods have been reclassified to be consistent with the current period presentation.

(3) NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board ("FASB") issued Statement No. 123R "SFAS No. 123R", SHARE-BASED PAYMENT, that requires compensation costs related to share-based payment transactions to be recognized in the financial statements. The Company began complying with SFAS No. 123R for the three months ended December 31, 2005. In March 2005, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin ("SAB") No. 107, SHARE-BASED PAYMENT ("SAB No. 107"), which provides interpretive guidance related to the interaction between SFAS No. 123R and certain SEC rules and regulations, as well as provides the SEC staff's views regarding the valuation of share-based payment arrangements. See Note 4, "Stock-Based Awards", regarding the impact of these pronouncements on the Company's financial statements.

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In November 2004, the FASB issued SFAS No. 151, INVENTORY COSTS, AN AMENDMENT OF ARB NO. 43. SFAS No. 151 requires idle facility expenses, freight, handling costs, and wasted material (spoilage) costs to be excluded from the cost of inventory and expensed when incurred. It also requires that allocation of fixed overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151, effective at the beginning of year ended September 30, 2006, had no material impact on the Company's financial statements.

In May of 2005, the FASB issued SFAS 154, ACCOUNTING CHANGES AND ERROR CORRECTIONS. This statement replaces APB Opinion 20, ACCOUNTING CHANGES, and SFAS 3, REPORTING ACCOUNTING CHANGES IN INTERIM FINANCIAL STATEMENTS. This statement changes the requirements for the accounting for and reporting of a change in accounting principle, and applies to all voluntary changes in accounting principle. This statement also applies to changes required by an accounting pronouncement in the unusual instance that the

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pronouncement does not include specific transition provisions. Previously, APB Opinion 20 required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. This statement is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In June of 2006, the FASB issued FASB Interpretation (FIN) No. 48 ACCOUNTING FOR UNCERTAINTY IN INCOME TAXES ("FIN 48"). This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 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. Under this interpretation, the evaluation of a tax position is a two-step process. First, the enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, based on the technical merits of the position. The second step is measuring the benefit to be recorded from tax positions that meet the more-likely-than-not recognition threshold, whereby the enterprise determines the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement, and recognizes that benefit in its financial statements. FIN 48 also provides guidance on recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. Management does not believe the adoption of this standard will have a material impact on the Company's financial statements.

(4) STOCK-BASED AWARDS

The Company maintains the 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,

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options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant. This 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. Under the New Plan, options may be granted at not less than the fair market value on the date of grant. Options may be subject to a vesting schedule and expire four, five or ten years from grant.

Effective October 1, 2005, the Company adopted the provisions of SFAS No. 123R which establishes the financial accounting and reporting standards for stock-based compensation plans. SFAS No. 123R requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors. Under the provisions of SFAS No. 123R, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the requisite service period of the entire award (generally the vesting period of the award). As a result of adopting SFAS No. 123R, the Company's net loss before income taxes and net loss for the three and nine months ended June 30, 2006 was \$68 and \$303, respectively, more than if the Company had continued to account for stock-based compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and its related interpretations. Basic and diluted net loss per share for the three months ended June 30, 2006 was not affected by the adoption of SFAS No. 123R. Basic and diluted net loss per share for the nine months ended June 30, 2006 was \$0.02 more than if the Company had continued to account for stock-based compensation under APB 25. In addition, there was no tax effect related to the adoption of SFAS No. 123R due to the recording of a full valuation allowance against U.S. net deferred tax assets.

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The Company elected to use the modified prospective transition method as permitted by SFAS No. 123R and, therefore, financial results for prior periods have not been restated. Under this transition method, stock-based compensation expense for the three and nine months ended June 30, 2006 includes expense for all equity awards granted prior to, but not yet vested as of October 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123,") as amended by SFAS No. 148, "Accounting for Stock-Based Compensation--Transition and Disclosure." Since the adoption of SFAS No. 123R, there have been no changes to the Company's stock compensation plans or modifications to outstanding stock-based awards which would increase the value of any awards outstanding. Compensation expense for all stock-based compensation awards granted subsequent to October 1, 2005 was based on the grant-date fair value determined in accordance with the provisions of SFAS No. 123R. During the three and nine months ended June 30, 2006, the Company recognized compensation expense of \$68 and \$303, respectively relating to stock options granted during the three and nine months ended June 30, 2006 in addition to the vesting of options outstanding as of October 1, 2005. All such expense was recognized within "General and administrative expense" in the Statement of Operations. There were no significant capitalized stock-based compensation costs at June 30, 2006.

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Prior to October 1, 2005, the Company accounted for stock-based compensation in accordance with APB 25 and also followed the disclosure requirements of SFAS No. 123. Under APB 25, the Company accounted for stock-based awards to employees and directors using the intrinsic value method as allowed under SFAS No. 123. Under the intrinsic value method, no stock-based compensation expense had been recognized in the Company's Statement of Operations because the exercise price of the Company's stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant. The following table illustrates the effect on net loss and loss per share for the three and nine months ended June 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to its stock plans:

| | Three Months ended June 30, 2005 | Nine Months ended June 30, 2005 |
|--|--|---------------------------------------|
| | ----- | ----- |
| Net loss: | \$ (1,277) | \$ (4,320) |
| Deduct: | | |
| Total stock-based employee compensation expense determined under fair-value-based method, net of related tax effects | 2 | 34 |
| | ----- | ----- |
| Pro-forma net loss | \$ (1,279) | \$ (4,354) |
| | ===== | ===== |
| Basic and diluted loss per share: | | |
| As reported | \$ (0.08) | \$ (0.27) |
| Pro-forma using the fair value method | \$ (0.08) | \$ (0.27) |

The fair value of each stock option grant is estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

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| | June 30, 2006 | June 30, 2005 |
|---------------------------------|---------------|---------------|
| | ----- | ----- |
| Expected Volatility | 50.5% | 48.6% |
| Risk-free interest rate (range) | 3.7 - 3.9% | 4.1 - 4.7% |
| Expected term (in years) | 5 | 5 |

EXPECTED VOLATILITY. The Company's methodology for computing the expected volatility is based solely on the Company's historical volatility.

EXPECTED TERM. The expected term is based on employee exercise patterns during the Company's history and expectations of employee exercise behavior in the future giving consideration to the contractual terms of the stock-based awards.

RISK-FREE INTEREST RATE. The interest rate used in valuing awards is based on the yield at the time of grant of a U.S. Treasury security with an equivalent remaining term.

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DIVIDEND YIELD. The Company has never paid cash dividends, and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield.

PRE-VESTING FORFEITURES. Estimates of pre-vesting option forfeitures of 10% are based on Company experience and industry trends. The Company will adjust its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of compensation expense to be recognized in future periods.

Presented below is a summary of the status of the Company's stock options as of June 30, 2006, and related transactions for the quarter then ended:

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| STOCK OPTIONS | NUMBER OF COMMON SHARES (000's) | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVERAGE REMAINING CONTRACTURAL LIFE | AGGREGATE INTRINSIC VALUE |
|-----------------------------------|--|--|--|---------------------------------|
| | ----- | ----- | ----- | ----- |
| Outstanding at September 30, 2005 | 2,481 | \$ 2.64 | 5.1 | \$ -- |
| Granted | 28 | 3.12 | 10.0 | -- |
| Canceled | -- | -- | -- | -- |
| Exercised | (18) | 2.53 | -- | -- |
| | ----- | ----- | ----- | ----- |
| Outstanding at December 31, 2005 | 2,491 | \$ 2.65 | 5.3 | \$ -- |
| Granted | 88 | 3.22 | 10.0 | -- |
| Canceled | (6) | 3.58 | -- | -- |
| Exercised | (88) | 2.70 | -- | -- |
| | ----- | ----- | ----- | ----- |
| Outstanding at March 31, 2006 | 2,485 | \$ 2.66 | 4.9 | \$ -- |
| Granted | -- | -- | -- | -- |
| Canceled | (53) | 3.66 | -- | -- |
| Exercised | (45) | 2.21 | -- | -- |
| | ----- | ----- | ----- | ----- |
| Outstanding at June 30, 2006 | 2,387 | \$ 2.64 | 4.9 | \$ -- |
| Vested or expected to vest | 2,149 | \$ 2.64 | 4.2 | \$ -- |
| Fully vested at June 30, 2006 | 1,854 | \$ 2.49 | 2.0 | \$ -- |

As of June 30, 2006, 291,728 stock options were available for grant. The weighted-average grant-date fair value of options granted during the nine months ended June 30, 2006 and June 30, 2005 was \$1.63 and \$1.18, respectively. Cash received from option exercises for the nine months ended June 30, 2006 and June 30, 2005, was \$383 and \$6 respectively.

As of June 30, 2006, there was \$355 of total unrecognized compensation cost

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related to nonvested stock options. That cost is expected to be recognized over a weighted-average period of 1.7 years.

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(5) INVENTORIES

Major classes of inventory at June 30, 2006 and September 30, 2005 were as follows:

| | June 30, 2006 | September 30, 2005 |
|--------------------------------|------------------|-----------------------|
| | ----- | ----- |
| Raw materials | \$ 2,818 | \$ 1,753 |
| Work in process | 5,587 | 4,219 |
| Finished goods | 7,489 | 6,860 |
| | ----- | ----- |
| | 15,894 | 12,832 |
| Less reserves for obsolescence | 4,020 | 3,278 |
| | ----- | ----- |
| | \$ 11,874 | \$ 9,554 |
| | ===== | ===== |

(6) INCOME TAXES

The Company has approximately \$16,801 of federal net operating loss carryforwards expiring beginning in 2008 and state net operating loss carryforwards of approximately \$16,304 that will begin to expire in September 2006.

The Company has a corporate net operating loss carryforward for German income tax purposes of approximately \$4,793 (3,818 Euros), and a trade net operating loss carryforward for German income tax purposes of approximately \$2,883 (2,297 Euros), which can both be carried forward indefinitely.

The Company continually reviews the adequacy and necessity of the valuation allowance in accordance with the provisions of FASB Statement No. 109, ACCOUNTING FOR INCOME TAXES. As of June 30, 2006, the Company continues to maintain a full valuation allowance on the net deferred tax assets attributable to its domestic operations. The Company does not maintain a valuation allowance on its international deferred tax assets, because management believes it is more-likely-than-not that these tax benefits will be realized through the generation of future international taxable income.

The Company has not recorded deferred income taxes on the 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.

(7) SEVERANCE COSTS

During the three months ended June 30, 2006, the Company accrued compensation expense of \$437 for severance costs upon the termination of the Managing Director of the Company's German subsidiary. These costs are a component of General and Administrative expenses in the Condensed Consolidated Statement of Operations and Comprehensive Loss for the three and nine months ended June 30, 2006, and the accrual for these costs is

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included in Accrued Expenses in the Condensed Consolidated Balance Sheet as of June 30, 2006. These severance costs are being paid in twelve monthly equal payments during the period from July 1, 2006 through June 30, 2007.

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(8) DEBT AND SHORT-TERM BORROWINGS

As of March 31, 2006, the Company had a \$1,300 construction loan with a financing company which has provided funding for the expansion of its U.S. manufacturing facility. With the completion of the manufacturing facility during the quarter ended June 30, 2006, the construction loan converted into a long-term capital lease. During the three months ended June 30, 2006, the Company commenced lease payments of \$55 per month over 24 months. At the end of the term, the Company has the option to purchase the property for a price determined by the Company and the lessor or continue to extend the lease for additional time periods.

On March 31, 2006, the Company refinanced a \$1,800 construction loan which provided funding for the expansion of its German manufacturing facility. The loan has a term of six years, to be repaid at approximately \$78 per quarter beginning in June 2006, and an interest rate of 5.15% which was fixed by an interest rate swap entered into on March 31, 2006 (See Note 9 for hedging activities).

The Company maintains current working capital credit lines totaling 1,500 euros (approximately \$1,883) with three German banks and a \$1,500 credit line with a U.S. bank. At September 30, 2005 the Company had no borrowings against these lines. During the nine months ended June 30, 2006, the Company made draws on these lines of credit totaling \$6,611 and repaid \$4,655. As of June 30, 2006, the Company had an outstanding balance of \$2,934 on these lines.

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 bears interest at 5.0% per year, is due upon the earlier of 12 months or upon a change of control of the Company and is convertible into common stock at a price of \$5.15 per share at any time at the election of the holder. The warrants are 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. For purposes of interim reporting, convertible debt is included in short-term borrowings on the balance sheet at June 30, 2006.

The relative fair value of the detachable warrants is \$275 and was computed using the Black-Scholes pricing model under the following assumptions: (1) expected life of 3 years; (2) volatility of 53.5%, (3) risk free interest of 5.13% and dividend yield of 0%. The proceeds of the convertible debenture were allocated to debt and warrants based on their relative fair values. The relative fair value of the warrants was recorded to additional paid-in capital and resulted in a discount on the convertible debenture, which will be amortized to interest expense over the one-year term of the debenture. The convertible debenture balance of \$2,725, net of debt discount, is included in short-term borrowings. In addition, \$205 of direct costs incurred relating to the issuance of the convertible debenture was recorded as debt issuance costs in other current assets, which will also be amortized to interest expense over the one-year term of the debenture.

(9) HEDGING ACTIVITIES

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The Company accounts for its hedging activities in accordance with SFAS No. 133, "Accounting for Derivatives and Hedging Activities", 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 \$1,800 construction loan is based on dealer quotes and was not significant as of June 30, 2006. The construction loan payable is due on March 30, 2012 in monthly installments of approximately \$78 (63 Euros) 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.

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(10) 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 accounting policies of these segments are consistent with prior periods. The Company evaluates performance based on the operating income of each segment. 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 unique regulatory and marketing differences in these markets as well as their physical location.

A summary of the operations and assets by segment as of and for the three months ended June 30, 2006 and 2005, respectively are as follows:

| | THREE MONTHS - 2006 | | |
|-----------------------------|---------------------|-----------|------------|
| SEGMENT DATA | INTERNATIONAL | US | TOTAL |
| | ----- | ----- | ----- |
| GROSS REVENUE | \$ 3,975 | \$ 6,492 | \$ 10,467 |
| LESS: INTERCOMPANY | \$ (467) | \$ 0 | \$ (467) |
| | ===== | ===== | ===== |
| TOTAL REVENUE - THIRD PARTY | \$ 3,508 | \$ 6,492 | \$ 10,000 |
| OPERATING LOSS | \$ (919) | \$ (327) | \$ (1,246) |
| NET LOSS | \$ (712) | \$ (417) | \$ (1,129) |
| TOTAL IDENTIFIABLE ASSETS | \$ 18,239 | \$ 18,527 | \$ 36,766 |
| | ===== | ===== | ===== |

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THREE MONTHS - 2005

| SEGMENT DATA | INTERNATIONAL | US | TOTAL |
|-----------------------------|---------------|------------|------------|
| GROSS REVENUE | \$ 5,042 | \$ 6,529 | \$ 11,571 |
| LESS: INTERCOMPANY | \$ (2,290) | \$ 0 | \$ (2,290) |
| | ===== | ===== | ===== |
| TOTAL REVENUE - THIRD PARTY | \$ 2,752 | \$ 6,529 | \$ 9,281 |
| OPERATING INCOME (LOSS) | \$ 537 | \$ (2,040) | \$ (1,503) |
| NET INCOME (LOSS) | \$ 291 | \$ (1,568) | \$ (1,277) |
| TOTAL IDENTIFIABLE ASSETS | \$ 17,181 | \$ 11,460 | \$ 28,641 |
| | ===== | ===== | ===== |

A summary of the operations and assets by segment as of and for the nine months ended June 30, 2006 and 2005, respectively are as follows:

NINE MONTHS - 2006

| SEGMENT DATA | INTERNATIONAL | US | TOTAL |
|-----------------------------|---------------|-----------|------------|
| GROSS REVENUE | \$ 11,533 | \$ 17,874 | \$ 29,407 |
| LESS: INTERCOMPANY | \$ (2,258) | \$ 0 | \$ (2,258) |
| | ===== | ===== | ===== |
| TOTAL REVENUE - THIRD PARTY | \$ 9,275 | \$ 17,874 | \$ 27,149 |
| OPERATING LOSS | \$ (742) | \$ (885) | \$ (1,627) |
| NET LOSS | \$ (575) | \$ (613) | \$ (1,188) |
| TOTAL IDENTIFIABLE ASSETS | \$ 18,239 | \$ 18,527 | \$ 36,766 |
| | ===== | ===== | ===== |

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NINE MONTHS - 2005

| SEGMENT DATA | INTERNATIONAL | US | TOTAL |
|-----------------------------|---------------|------------|------------|
| GROSS REVENUE | \$ 13,292 | \$ 16,172 | \$ 29,464 |
| LESS: INTERCOMPANY | \$ (5,556) | \$ 0 | \$ (5,556) |
| | ===== | ===== | ===== |
| TOTAL REVENUE - THIRD PARTY | \$ 7,736 | \$ 16,172 | \$ 23,908 |
| OPERATING LOSS | \$ (1,068) | \$ (3,561) | \$ (4,629) |
| NET LOSS | \$ (1,155) | \$ (3,165) | \$ (4,320) |

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| | | | |
|---------------------------|-----------|-----------|-----------|
| TOTAL IDENTIFIABLE ASSETS | \$ 17,181 | \$ 11,460 | \$ 28,641 |
| | ===== | ===== | ===== |

(11) LEGAL PROCEEDINGS

In 2003, the Company received a proposed judgment in Germany as the result of a dispute between the Company and a former international distributor. The estimated settlement, including legal costs was accrued as a litigation contingency. In 2004, a decision by the court of appeal in Germany resulted in a reduction of the original proposed judgment received against the Company by \$406. At June 30, 2006 and September 30, 2005, the Company maintained an accrual of \$477 (380 euros) with respect to the remaining appeal and legal costs. Management believes that such accrual is sufficient and that the final settlement should not have a material impact on the results of operations.

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 \$1,046 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 reserved \$872 for quarantined inventory, which remains reserved at June 30, 2006. Additionally, as of September 30, 2005, the Company had accrued \$250 of related costs in connection with the recall. As of June 30, 2006, 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. It is management's opinion that it is too early in the process to determine the effect of this class action on the financial condition of the Company. However, the Company intends to vigorously defend this matter and does not believe that settlement of this class action will have an adverse material effect on the Company's operations, cash flow or financial position.

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

The Company has an exclusive license and distribution agreement with Zimmer Spine, a wholly owned subsidiary of Zimmer Holdings, Inc., 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 quarters ended June 30, 2006 and 2005, product sales to Zimmer spine totaled \$617 and \$1,260, respectively, representing 6.2% and 13.6% respectively of the Company's total revenues. For the nine months ended

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June 30, 2006 and 2005, product sales to Zimmer spine totaled \$1,416 and \$2,792, respectively, representing 5.2% and 11.7% respectively of the Company's total revenues. Accounts receivable from Zimmer Spine were \$410 and \$44 at June 30, 2006 and September 30, 2005, respectively.

The Company has also engaged Zimmer Dental, a wholly owned subsidiary of Zimmer Holdings, Inc., to act as an exclusive distributor for the Company's bone tissue for dental applications in the United States and certain international markets. Under this distribution agreement, the Company sells directly to Zimmer Dental's customers. For the quarters ended June 30, 2006 and 2005, Zimmer Dental was paid commissions aggregating approximately \$1,936 and \$1,735, respectively. For the nine months ended June 30, 2006 and 2005, Zimmer Dental was paid commissions aggregating approximately \$5,282 and \$4,404, respectively. Accounts payable to Zimmer Dental total \$1,936 and \$1,740 at June 30, 2006 and September 30, 2005, respectively.

Zimmer CEP (formerly Centerpulse) USA Holding Co., a subsidiary of Zimmer Holdings, Inc., is a 33% owner of the Company's outstanding shares of Common Stock.

On March 10, 2006, Zimmer Holdings Inc. ("Zimmer") filed an amended Schedule 13 (d) expressing its intention to initiate discussions with the Company which could possibly include further investment by Zimmer in securities of the Company or the acquisition by Zimmer of some or all of the outstanding common stock of the Company.

On August 9, 2006, representatives of Zimmer Holdings, Inc. ("Zimmer") contacted the management of the Company telephonically to propose to the Company a non-binding indication of interest ("the Indication of Interest") with respect to a proposed acquisition of the Company at an indicative price range of \$5.00 - \$6.00 per share of Common Stock. Later on the same day, the Company contacted Zimmer and rejected the Indication of Interest. Zimmer has determined not to pursue an acquisition of the Company at this time, but based on other factors deemed relevant by Zimmer, including, but not limited to, the price and availability of Common Stock, subsequent developments affecting Zimmer and the Company, the business prospects of Zimmer and the Company, general stock market and economic conditions and tax considerations, Zimmer may formulate other plans and/or make other proposals and take other actions with respect to its investment in the Company that it deems to be appropriate.

(13) SUBSEQUENT EVENTS

On August 8, 2006, the Company received the second milestone payment of \$1,650 from Davol, Inc. for the release of new hernia products.

(14) RESTATEMENT

As part of the financial review for the three and six months ended March 31, 2006, the Company became aware of misstatements in previously reported inventory and cost of revenue. The Company discovered that the misstatements were attributable to errors in the calculation of intercompany profit to be eliminated during the consolidation process for prior periods. While investigating the inventory errors, the Company also discovered other errors affecting the Company's deferred tax benefit, accrued expenses, general and administrative and distribution and marketing expenses for the fiscal year ended September 30, 2005. As a result, the Company has restated the accompanying condensed consolidated financial statements for the three and nine months ended June 30, 2005 to correct these errors.

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The impact of this restatement on the accompanying condensed consolidated financial statements is summarized below:

| FOR THE THREE MONTHS ENDED JUNE 30, 2005 ----- | As Previously Reported ----- | Adjustments ----- | As Restated ----- |
|---|---------------------------------------|----------------------|-------------------------|
| Cost of revenues | \$ 6,256 | \$ (155) | \$ 6,101 |
| Gross profit | 3,025 | 155 | 3,180 |
| Operating loss | (1,658) | 155 | (1,503) |
| Net loss | (1,432) | 155 | (1,277) |
| Comprehensive loss | (977) | 155 | (822) |
| Basic and diluted loss per share | (0.09) | 0.01 | (0.08) |

| FOR THE NINE MONTHS ENDED JUNE 30, 2005 ----- | As Previously Reported ----- | Adjustments ----- | As Restated ----- |
|--|---------------------------------------|----------------------|-------------------------|
| Cost of revenues | \$ 14,817 | \$ 267 | \$ 15,084 |
| Gross profit | 9,091 | (267) | 8,824 |
| Operating loss | (4,362) | (267) | (4,629) |
| Net loss | (4,053) | (267) | (4,320) |
| Comprehensive loss | (3,540) | (267) | (3,807) |
| Basic and diluted loss per share | (0.25) | (0.02) | (0.27) |
| Cash flows from operating activities | | | |
| Net loss | (4,053) | (267) | (4,320) |
| Inventories | 3,365 | 267 | 3,632 |

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

RESTATED FINANCIAL STATEMENTS

The accompanying management's discussion and analysis of the Company's financial condition and results of operations included in this report reflects the impact of the restatement described in Note 14 to the unaudited condensed consolidated financial statements.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements typically are identified by use of terms such as "may," "will," "should," "plan," "expect," "anticipate," "estimate," and similar

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words, although some forward-looking statements are expressed differently. Actual results could differ significantly from those discussed herein. Some of the matters described in the "Risk Factors" and "Description of Business" sections of its Form 10-K/A and other reports filed with the Securities and Exchange Commission, constitute cautionary statements, including certain risks and uncertainties, that could cause actual results to vary materially from the future results indicated in such forward-looking statements. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements. The following discussion of our results of operations should be read in conjunction with the Financial Statements and Notes included in Part I. "Financial Information".

BUSINESS

During the three months ended June 30, 2006, the Company generated \$10,000 in revenues which represented the highest quarterly revenue in the Company's history. The Company continues to experience growth in dental sales. By the end of the three months ended June 30, 2006, the Company launched new products in the important hernia repair market with Davol as the Company's distribution partner. A new cervical graft introduced near the end of the quarter ended June 30, 2006, coupled with additional new spine products to be released over the next six months are expected to contribute to continued growth in spinal sales. The expansion of the US facility was essentially completed during the three months ended June 30, 2006 to add flexibility and efficiencies to the manufacturing capabilities of the Company.

The international operations continue to grow at double-digit growth patterns. In conjunction with this, the Company is also expanding the physical plant in Neunkirchen, Germany in order to fully support the growing and important international segment.

During the three and nine months ended June 30, 2006, the Company had several large expenses totaling approximately \$864 principally associated with strategic discussions with Zimmer Holdings, Inc., the costs of restating the Company's financial statements for certain historical periods, and severance costs associated with the replacement of the Managing Director of the Company's German subsidiary. These expenses are described more fully in the Results of Operations.

We also experienced a foreign currency exchange loss of \$233 and \$261 for the three and nine months ended June 30, 2006, respectively due to the dollar's declining exchange rate against the euro. During the fourth quarter of 2006, the Company expects to substantially reduce its foreign currency exposure through the settlement of certain intercompany accounts.

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.

On March 10, 2006, Zimmer Holdings Inc. ("Zimmer") filed an amended Schedule 13 (d) expressing its intention to initiate discussions with the Company which could possibly include further investment by Zimmer in securities of the Company or the acquisition by Zimmer of some or all of the outstanding common stock of the Company.

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On August 9, 2006, representatives of Zimmer Holdings, Inc. ("Zimmer") contacted the management of the Company telephonically to propose to the Company a non-binding indication of interest ("the Indication of Interest") with respect to a proposed acquisition of the Company at an indicative price range of \$5.00 - \$6.00 per share of Common Stock. Later on the same day, the Company contacted Zimmer and rejected the Indication of Interest. Zimmer has determined not to pursue an acquisition of the Company at this time, but based on other factors deemed relevant by Zimmer, including, but not limited to, the price and availability of Common Stock, subsequent developments affecting Zimmer and the Company, the business prospects of Zimmer and the Company, general stock market and economic conditions and tax considerations, Zimmer may formulate other plans and/or make other proposals and take other actions with respect to its investment in the Company that it deems to be appropriate.

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RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2006 AND 2005

Revenues for the three months ended June 30, 2006, increased 8% to \$10,000 from \$9,281 for the same period in 2005. Revenues for the U.S. operations remained level at \$6,492 for the three months ended June 30, 2006 compared to \$6,529 for the same period last year. U.S. dental sales increased 19% from the three-month period a year ago offset by lower spine sales during the quarter. The international operations continued a favorable trend of increased sales growth of 27% from \$2,752 to \$3,508 for the three-month periods ended June 30, 2005 and 2006, respectively. The increase in international revenue was primarily due to increased sales in Germany and the rest of the world. An analysis of revenues by geographic region is as follows:

| (000'S OMITTED) | Three Months 06/30/06 | Three Months 06/30/05 |
|-----------------------|-----------------------------|-----------------------------|
| | ----- | ----- |
| Spine | \$ 617 | \$ 1,260 |
| Dental | 4,727 | 3,969 |
| Surgical Specialties | 1,148 | 1,300 |
| | ----- | ----- |
| Total - U.S. | 6,492 | 6,529 |
| | | |
| Germany | 785 | 594 |
| France | 318 | 329 |
| ROW | 2,258 | 1,688 |
| Other | 147 | 141 |
| | ----- | ----- |
| Total - International | 3,508 | 2,752 |
| | | |
| Total Consolidated | \$ 10,000 | \$ 9,281 |
| | ===== | ===== |

Gross margin for the three months ended June 30, 2006 was 47% as compared to 34% for the comparable period last year. The higher gross margin compared to the same period last year was due to greater efficiencies in the U.S. operations as more manufacturing capabilities have come on line.

General and administrative expenses increased \$928 for the three months ended

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June 30, 2006 over the comparable period last year. The increase from prior year quarter to this quarter was primarily due to \$437 in severance costs associated with the replacement of the Managing Director of the Company's German subsidiary, \$217 in legal, accounting and other professional costs associated with the restatement of prior-period financial results, \$210 related to the strategic discussions with Zimmer Holdings and increased costs of \$68 associated with stock option expenses. General and Administrative expenses were 21% and 13% of total revenues for the three months ended June 30, 2006 and 2005, respectively.

Distribution and marketing expenses increased 9% for the three months ended June 30, 2006 over the comparable period last year. The increase was primarily due to higher marketing fees paid to Zimmer Dental of \$1,936 versus \$1,735 a year ago as a result of the 19% increase in dental revenues in the U.S. As a percentage of revenues, distribution and marketing expenses were 33% for both three month periods ended June 30, 2006 and 2005.

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Research and development expenses remained at similar levels for the three months ended June 30, 2006, over the comparable period last year. As a percentage of revenues, research and development expenses increased from 4% for three months ended June 30, 2005 to 5% for the three months ended June 30, 2006.

The Company had a foreign exchange loss for the three months ended June 30, 2006 of \$233 due to the declining exchange rate of the U.S. dollar against the euro. During the fourth quarter of 2006, we expect to substantially reduce our foreign currency exposure through the settlement of certain intercompany accounts.

Interest expense increased \$56 for the three months ended June 30, 2006 compared to the same period last year. The increase in interest expense is primarily related to the increased debt used to fund the expansion of the manufacturing facilities in the U.S. and Germany and increased utilization of the Company's credit lines to support growth and operations.

Due to the several large general and administrative expenses and the foreign exchange loss identified above, the net loss for the three months ended June 30, 2006 totaled \$1,129 or \$0.07 basic and diluted loss per share as compared to a net loss of \$1,277 or \$0.08 basic and diluted loss per share for the comparable period in 2005.

NINE MONTHS ENDED JUNE 30, 2006 AND 2005

Revenues for the nine months ended June 30, 2006, increased 14% to \$27,149 from \$23,908 for the same period in 2005. The U.S. operation had an 11% increase in revenues from \$16,172 for the nine months ended June 30, 2005 to \$17,874 for the current nine-month period. This increase 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 marketing partner. U.S. dental sales increased 34% from the nine-month period a year ago. The International operation had an increase of 20% from \$7,736 for the nine months ended June 30, 2005 to \$9,275 for the nine-month period ended June 30, 2006. The increase in International revenue was primarily due to increased sales in Germany, France and the rest of the world through direct sales force efforts and favorable outcomes in the regulatory environment of these countries. An analysis of revenues for the nine months ended June 30, 2006 by geographic region follows:

| | |
|--------|--------|
| Nine | Nine |
| Months | Months |

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| (000'S OMITTED) | 06/30/06 | 06/30/05 |
|-----------------------|-----------|-----------|
| | ----- | ----- |
| Spine | \$ 1,416 | \$ 2,792 |
| Dental | 12,950 | 9,670 |
| Surgical Specialties | 3,508 | 3,710 |
| | ----- | ----- |
| Total - U.S. | 17,874 | 16,172 |
| Germany | 2,360 | 1,493 |
| France | 1,151 | 956 |
| ROW | 5,363 | 4,845 |
| Other | 401 | 442 |
| | ----- | ----- |
| Total - International | 9,275 | 7,736 |
| Total Consolidated | \$ 27,149 | \$ 23,908 |
| | ===== | ===== |

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Gross margin for the nine months ended June 30, 2006 was 53% as compared to 37% for the comparable period last year. The higher gross margin was due to greater efficiencies in the U.S. operations as more manufacturing capabilities have come on line.

General and administrative expenses increased 43% for the nine months ended June 30, 2006 over the comparable period last year. The increase for the nine-month period was primarily due to the increased costs of \$437 in severance costs associated with the replacement of the Managing Director of the Company's German subsidiary, \$303 associated with stock option expenses, \$217 associated with legal, accounting and other professional fees associated with the restatement of prior-period financial results, \$210 related to the strategic discussions with Zimmer Holdings, and costs related to new personnel. As a percentage of revenues general and administrative expenses were 19% and 15% for the nine months ended 2006 and 2005, respectively.

Distribution and marketing expenses increased 10% for the nine months ended June 30, 2006 over the comparable period last year. The increase was primarily due to higher distribution fees paid to Zimmer Dental of \$5,282 versus \$4,404 a year ago as a result of the 34% increase in dental revenues in the U.S. As a percentage of revenues, distribution and marketing expenses were 35% and 36% for the nine months ended June 30, 2006 and 2005, respectively.

Research and development expenses remained at similar levels for the nine months ended June 30, 2006 as compared to the comparable period last year. As a percentage of revenues, research and development expenses remained at 5% for the nine months ended June 30, 2006 and 2005.

The Company had a foreign exchange loss for the nine-month period of \$261 due to the declining exchange rate of the U.S.dollar against the euro. During the fourth quarter of 2006, we expect to substantially reduce our foreign currency exposure through the settlement of certain intercompany accounts.

Interest expense remained similar for the nine months ended June 30, 2006 compared to the same period last year.

Due to the several large general and administrative expenses identified above during the nine months ended June 30, 2006, net loss for the nine months ended June 30, 2006 totaled \$1,188 or \$0.07 basic and diluted loss per share as

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compared to a net loss of \$4,320 or \$0.27 basic and diluted loss per share for the comparable period in 2005. The reduced loss was primarily due to increased sales and improving gross margins.

PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment increased 74% during the nine months ended June 30, 2006 related to the costs associated with the expansion of both the U.S. and German facilities.

INVENTORY

Net Inventory increased 24%, from \$9,554 at last fiscal year-end to \$11,874 at June 30, 2006. Raw material levels increased 61% due to increased purchase orders for various new products during the period. For the same reason, work-in-process ("WIP") is up 32% and finished goods levels are up 9%.

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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, 2005. However, certain of the accounting policies are particularly important to the portrayal of the financial position and results of operations and require the application of significant judgment by management; as a result, they are subject to an inherent degree of uncertainty. In applying those policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on historical experience, terms of existing contracts, observance of trends in the industry, information provided by customers and information available from other outside sources, as appropriate. The Company's significant accounting policies include:

INVENTORIES. Inventories are valued at the lower of cost (weighted average basis) or market. Work in process and finished goods include costs attributable to direct labor and overhead. Reserves for slow moving and obsolete inventories are provided based on historical experience, current product demand and the estimated remaining shelf life. The adequacy of these reserves is evaluated quarterly.

REVENUE RECOGNITION AND ACCOUNTS RECEIVABLE. Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed, final, delivery has occurred, and there is a reasonable assurance of collection of the sales proceeds. Oral or written purchase authorizations are generally obtained from customers for a specified amount of product at a specified price. 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 and allowances for doubtful accounts is 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 ratably over the life of the contract.

FOREIGN CURRENCY TRANSLATION. The functional currency of the Company's German subsidiary is the Euro for the years 2006 and 2005. Assets and liabilities of foreign subsidiaries are translated at the period end exchange

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rate ("spot rate") while revenues and expenses are translated at the average exchange rate for the period. The resulting translation adjustments, representing unrealized, non-cash losses or gains are made directly to comprehensive income. Gains and losses resulting from transactions of the Company and its subsidiaries, which are made in currencies different from their own, are included in net income as they occur. The Company recognized a foreign exchange loss of \$233 for the three months ended June 30, 2006 as compared to a gain of \$317 for the three months ended June 30, 2005. The Company recognized a foreign exchange loss of \$261 for the nine months ended June 30, 2006 versus a loss of \$80 for the nine months ended June 30, 2005.

VALUATION OF DEFERRED TAX ASSET. The Company records valuation allowances to reduce the deferred tax assets to the amounts estimated to be recognized. 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 to the valuation allowance would be made and charged to income in the period of such determination.

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LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2006, the Company has working capital of \$5,678 as compared to \$8,817 at September 30, 2005. The Company maintains current working capital credit lines totaling 1,500 euros (approximately \$1,800) with two German banks and a \$1,500 credit line with a U.S. bank. At June 30, 2006, the Company had outstanding \$1,434 on the credit lines in Germany and \$1,500 outstanding on the U.S. credit line to support ongoing working capital initiatives. At September 30, 2005, the Company had no borrowings against these lines. During the nine months ended June 30, 2006, the Company made draws on these lines of credit totalling \$6,611 and repaid \$4,655. As of June 30, 2006, the Company had an outstanding balance of \$2,934 on these lines.

The Company had a negative cash flow from operations of \$3,770 for the nine months ended June 30, 2006 as compared to a negative cash flow from operations of \$640 for the same period in 2005. The primary reasons for the increased cash utilized for operating activities in 2006 was due mainly to increased inventory purchases and an increase in accounts receivable due to increased sales offset somewhat by the receipt of a deferred distribution payment and a reduced net loss for the nine-month period ended June 30, 2006. Cash flows used in investing activities increased to \$5,265 as the Company continued to expand its manufacturing facilities in the U.S. and Germany. The increase in investing activities has been financed by construction facilities of \$1,300 and \$1,800 in the U.S. and Germany, respectively, increasing cash from financing activities by \$3,186 in cash flow statement. In addition, the Company generated \$3,000 through the issuance of convertible debt and warrants during the nine months ended June 30, 2006. The Company's ability to generate positive operational cash flow is dependent upon increased 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.

Future minimum rental payments required under Company's operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of June 30, 2006 are as follows:

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| | | |
|------|----|-------|
| 2006 | \$ | 418 |
| 2007 | | 747 |
| 2008 | | 445 |
| 2009 | | 233 |
| 2010 | | 63 |
| | | ----- |
| | \$ | 1,906 |
| | | ===== |

Long-term debt consists of senior debt construction loans and capital leases. Future minimum payments as of June 30, 2006 are as follows (1):

| | | |
|-------------------------------|----|-------|
| 2006 | \$ | 257 |
| 2007 | | 1,087 |
| 2008 | | 989 |
| 2009 | | 444 |
| 2010 & beyond | | 995 |
| | | ----- |
| | | 3,772 |
| Less current portion | | 1,063 |
| | | ----- |
| Total future minimum payments | \$ | 2,709 |
| | | ===== |

(1) The above payments do not include interest.

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ITEM 3. QUANTITATIVE STATEMENTS AND SUPPLEMENTARY DATA

For information regarding the Company's exposure to certain market risks, see Item 7A, Quantitative Statements and Supplementary Data, in the Annual Report on Form 10K/A for the year ended September 30, 2005. There have been no significant changes in our market risk exposures.

We are subject to market risk from exposure to changes in interest rates based upon our financing, investing and cash management activities. A 1% increase in interest rates would not have a material effect on our results of operations.

ITEM 4. CONTROLS AND PROCEDURES

DISCLOSURE CONTROLS AND PROCEDURES

As part of the financial review for the three and six months ended March 31, 2006 under the direction of the Company's chief executive officer and new chief financial officer, the Company conducted an analysis of the Company's inventory on hand as of prior reporting periods, its policies and procedures over certain journal entries recorded in the financial close process, and the effectiveness of the design and operation of the Company's disclosure controls and procedures, (as defined in Rule 13(a) - 15(e) under the 34 Act). Accordingly, the Company concluded that as of September 30, 2005 and December 31, 2005 the Company's disclosure controls and procedures were not effective in ensuring that information required to be disclosed by us in the reports that we file under the Securities and Exchange Act is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission rules and forms.

As a result, the Company has restated the financial statements for prior periods. (See Note 14 to the accompanying unaudited interim condensed

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Consolidated Financial Statements.)

A material weakness in internal control is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the financial statements would not be prevented or detected on a timely basis by the Company. For the quarter ended March 31, 2006, the Company has subsequently taken steps to remediate this material weakness including designing and implementing a more effective and precise analytic model for calculating intercompany profit. Additionally, the Company has developed a system for assuring the accuracy of this model. This system includes an enhanced reporting process for determining actual costs and transfer prices used in the calculation of intercompany profit to be eliminated during the consolidation process. Also, the Company has designed and documented new policies and procedures to strengthen its controls over certain journal entries recorded in its financial close process.

Management believes that these subsequent changes in the design of internal controls have strengthened the Company's disclosure controls and procedures, as well as its internal control over financial reporting, and have remediated the material weakness that the Company identified in its internal control over financial reporting as of September 30, 2005 and December 31, 2005. The Company has discussed this material weakness and its remediation program with its Audit Committee. The Company recognizes that controls and procedures can provide only reasonable assurance of achieving the desired control objectives. Accordingly, the Company intends to continue to refine its internal control over financial reporting on an ongoing basis as it deems appropriate.

The Company instituted the changes noted above during its financial close process during the quarter ended March 31, 2006 to materially enhance its internal control over financial reporting of inventory, net revenues, cost of revenues and financial close process.

Based on their evaluation as of the filing date of this Form 10-Q, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act") are effective to ensure that information required to be disclosed in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

CHANGES IN CONTROL:

There has not been any change in the Company's internal control over financial reporting during the quarter ended June 30, 2006 that has materially affected, or is reasonably likely to materially affect, those controls.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Please refer to Note 11 of the Interim Financial Statements.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY-HOLDERS
None

ITEM 5. OTHER INFORMATION

The Company filed four reports on Form 8-K and one report on Form 8-K/A during the quarter ended June 30, 2006.

On August 14, 2006, the Company issued a press release announcing financial results for the fiscal quarter ended June 30, 2006. The full text of the press release is set forth in Exhibit 99.1 hereto. The exhibit is furnished under this Item 5 in lieu of its being furnished under cover of and pursuant to Item 2.02 of Form 8-K. This information furnished pursuant to this Item 5 (including the exhibits hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 6. EXHIBITS

- 4.1* Registration Rights Agreement dated June 30, 2006, by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd.
 - 4.2* 5.0% Subordinated Convertible Debenture of Tutogen Medical, Inc. dated June 30, 2006 in an aggregate principal amount of \$3,000,000 issued to Azimuth Opportunity, Ltd.
 - 4.3* Common Stock Purchase Warrant dated June 30, 2006 issued to Azimuth Opportunity, Ltd. for the purchase of up to 175,000 shares of the common stock of Tutogen Medical, Inc.
 - 10.1* Securities Purchase Agreement dated June 30, 2006 by and between Tutogen Medical, Inc. and Azimuth Opportunity, Ltd.
 - 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
 - 99.1*** Press release dated August 14, 2006
- * Previously filed and incorporated herein by reference from the Form 8-K filed on July 6, 2006.
- *** Filed herewith

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

TUTOGEN MEDICAL, INC.

Date: August 14, 2006

/s/ Guy L. Mayer

Chief Executive Officer

Date: August 14, 2006

/s/ L. Robert Johnston, Jr.

Chief Financial Officer

(Principal Financial and Accounting Officer)