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PARADIGM MEDICAL INDUSTRIES INC
Form 10QSB
November 15, 2004

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

FORM 10-QSB

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For Quarter Ended September 30, 2004

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: 0-28498

PARADIGM MEDICAL INDUSTRIES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

87-0459536
(I.R.S. Employer
Identification No.)

2355 South 1070 West, Salt Lake City, Utah
(Address of principal executive office)

84119
(Zip Code)

Registrant's telephone number, including area code: (801) 977-8970

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for 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 check mark whether the small business issuer is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

| | |
|--|---|
| Common Stock, \$.001 par value | 25,509,868 |
| ----- | ----- |
| Title of Class | Number of Shares Outstanding as of September 30, 2004 |
| Class A Warrant to Purchase One Share of Common Stock | 1,000,000 |
| ----- | ----- |
| Title of Class | Number of Warrants Outstanding as of September 30, 2004 |

PARADIGM MEDICAL INDUSTRIES, INC.

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FOR THE QUARTER ENDED SEPTEMBER 30, 2004

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PARADIGM MEDICAL INDUSTRIES, INC.
CONDENSED BALANCE SHEET
(UNAUDITED)

September 30, 2004

ASSETS

Current Assets

| | | |
|-------------------------|----|---------|
| Cash & Cash Equivalents | \$ | 188,000 |
| Receivables, Net | | 726,000 |
| Inventory | | 770,000 |
| Prepaid Expenses | | 88,000 |

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| | |
|---|--------------|
| Total Current Assets | 1,772,000 |
| Intangibles, Net | 679,000 |
| Property and Equipment, Net | 135,000 |
| Total Assets | \$ 2,586,000 |
| <hr/> | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current Liabilities: | |
| Trade Accounts Payable | 653,000 |
| Accrued Expenses | 990,000 |
| Current Portion of Long-term Debt | 53,000 |
| Total Current Liabilities | 1,696,000 |
| Long-term Debt | 22,000 |
| Total Liabilities | 1,718,000 |
| <hr/> | |
| Stockholders' Equity: | |
| Preferred Stock, Authorized: | |
| 5,000,000 Shares, \$.001 par value | |
| Series A | |
| Authorized: 500,000 shares; issued and | |
| outstanding: 5,627 shares at September 30, 2004 | - |
| Series B | |
| Authorized: 500,000 shares; issued and | |
| outstanding: 8,986 shares at September 30, 2004 | - |
| Series C | |
| Authorized: 30,000 shares; issued and | |
| outstanding: zero shares at September 30, 2004 | - |
| Series D | |
| Authorized: 1,140,000 shares; issued and | |
| outstanding: 5,000 shares at September 30, 2004 | - |
| Series E | |
| Authorized: 50,000; issued and | |
| outstanding: 1,000 at September 30, 2004 | - |
| Series F | |
| Authorized: 50,000; issued and | |
| outstanding: 4,598.75 at September 30, 2004 | - |
| Series G | |
| Authorized: 2,000,000; issued and | |
| outstanding: 1,981,560 at September 30, 2004 | 2,000 |
| Common Stock, Authorized: | |
| 80,000,000 Shares, \$.001 par value; issued and | |
| outstanding: 25,509,868 at September 30, 2004 | 25,000 |
| Additional paid-in-capital | 57,470,000 |
| Accumulated Deficit | (56,629,000) |
| Total Stockholders' Equity | 868,000 |
| Total Liabilities and Stockholders' Equity | \$ 2,586,000 |

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PARADIGM MEDICAL INDUSTRIES, INC.
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

| | Three Months Ended September 30, | | Nine Sep |
|--|-------------------------------------|------------|--------------|
| | 2004 | 2003 | 2004 |
| Sales | \$ 899,000 | \$ 853,000 | \$ 2,288,000 |
| Cost of Sales | 358,000 | 354,000 | 859,000 |
| Gross Profit | 541,000 | 499,000 | 1,429,000 |
| Operating Expenses: | | | |
| Marketing and Selling | 198,000 | 171,000 | 547,000 |
| General and Administrative | 276,000 | 331,000 | 703,000 |
| Research, development and service | 163,000 | 203,000 | 543,000 |
| Impairment of assets | - | - | - |
| Total Operating Expenses | 637,000 | 705,000 | 1,793,000 |
| Operating Income (Loss) | (96,000) | (206,000) | (672,000) |
| Other Income and (Expense): | | | |
| Interest Income | - | - | - |
| Interest Expense | (11,000) | (4,000) | (40,000) |
| Other Income (Expense) | 588,000 | 247,000 | 592,000 |
| Total Other Income and (Expense) | 577,000 | 243,000 | 552,000 |
| Net income (loss) before provision for income taxes | 481,000 | 37,000 | 188,000 |
| Income taxes | - | - | - |
| Net income (loss) | \$ 481,000 | \$ 37,000 | \$ 188,000 |
| Net income (loss) Per Common Share | | | |
| - Basic and Diluted | \$ 0.02 | - | \$ 0.00 |
| Weighted Average Outstanding Shares - Basic | 25,373,000 | 23,668,000 | 25,373,000 |
| - Diluted | 27,675,000 | 26,752,000 | 27,675,000 |

See accompanying notes to condensed financial statements.

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PARADIGM MEDICAL INDUSTRIES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)

| | Nine Months Ended September 30, | |
|---|---------------------------------|----------------|
| | 2004 | 2003 |
| | (Unaudited) | (Unaudited) |
| Cash Flows from Operating Activities: | | |
| ----- | | |
| Net Income (Loss) | \$ 188,000 | \$ (2,305,000) |
| Adjustment to Reconcile Net Loss to Net Cash Used In Operating Activities: | | |
| ----- | | |
| Depreciation and Amortization | 112,000 | 268,000 |
| Issuance of Stock Option/Warrant for Services | - | 83,000 |
| Issuance of Common Stock for Settlement of potential litigation | - | 190,000 |
| Increase/decrease in Inventory Reserve | (226,000) | 382,000 |
| (Recovery of) provision for Losses on Receivables | (46,000) | 83,000 |
| Impairment of Intangible and other assets | - | 159,000 |
| Gain on sale of investment | (532,000) | |
| Gain on Settlement of obligations | (21,000) | (247,000) |
| Loss on disposal of assets | 6,000 | |
| (Increase) Decrease from Changes in: | | |
| Trade Accounts Receivable | 28,000 | 161,000 |
| Inventories | 459,000 | 402,000 |
| Prepaid Expenses | 53,000 | (215,000) |
| Increase (Decrease) from Changes in: | | |
| Trade Accounts Payable | (32,000) | (120,000) |
| Accrued Expenses and Deposits | ----- | ----- |
| Net Cash Used in Operating Activities | (440,000) | (712,000) |
| | ----- | ----- |
| Cash Flow from Investing Activities: | | |
| ----- | | |
| Purchase of Property and Equipment | - | (1,000) |
| Disposal of Property and Equipment | - | 6,000 |
| Proceeds from the sale of assets | 6,000 | |
| Proceeds from the sale of investment | 532,000 | |
| Net Cash Provided By Investing Activities | 538,000 | 5,000 |
| | ----- | ----- |
| Cash Flows from Financing Activities: | | |
| ----- | | |
| Additions to notes payable | - | |
| Principal Payments on Notes Payable | (42,000) | (63,000) |
| Proceeds from Short-Term Borrowing | - | 90,000 |
| Sale of stock and exercise of warrants | - | 429,000 |
| Sale of stock and exercise of warrants Series G | - | 270,000 |
| | ----- | ----- |
| Net Cash (Used In) Provided By Financing Activities | (42,000) | 726,000 |
| | ----- | ----- |

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| | | |
|---|------------|------------|
| Net increase in Cash and Cash Equivalents | 56,000 | 19,000 |
| Cash and Cash Equivalents at Beginning of Period | 132,000 | 194,000 |
| Cash and Cash Equivalents at End of Period | \$ 188,000 | \$ 213,000 |
| Supplemental Disclosure of Cash Flow Information: | | |
| Cash Paid for Interest | \$ 9,000 | \$ 17,000 |
| Cash Paid for Income Taxes | \$ - | \$ - |

See accompanying notes to condensed financial statements

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PARADIGM MEDICAL INDUSTRIES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(UNAUDITED)

Significant Accounting Policies

The accompanying condensed financial statements of the Company have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to such rules and regulations. These condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) that, in the opinion of management, are necessary to present fairly the results of operations of the Company for the periods presented. These condensed financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Form 10KSB for the year ended December 31, 2003. The results of operations for the three and nine months ended September 30, 2004, are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2004.

Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Historically, the Company has not demonstrated the ability to generate sufficient cash flows from operations to satisfy its liabilities and sustain operations, and the Company has incurred significant losses. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continuation as a going concern is dependent on its ability to generate sufficient income and cash flow to meet its obligations on a timely basis and/or obtain additional financing as may be required. The Company is

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actively seeking options to obtain additional capital and financing.

In addition, the Company has taken significant steps to reduce costs and increase operating efficiencies. Specifically, the Company has established procedures to more efficiently manage inventory purchases, reduced administrative personnel, and significantly reduced the use of consultants, all of which has resulted in large decreases in expenses. However, the sales force increased from three to five representatives in June, which has resulted in more payroll, travel and other selling expenses. Although these cost savings have significantly reduced the Company's losses and ongoing cash flow needs, if the Company is unable to obtain equity or debt financing, it may be unable to continue development of its products and may be required to substantially curtail or cease operations.

Net loss Per Share

Net loss per common share is computed on the weighted average number of common and common equivalent shares outstanding during each period. Common stock equivalents consist of convertible preferred stock, common stock options and warrants. Common equivalent shares are excluded from the computation when their effect is anti-dilutive. Other common stock equivalents consisting of options and warrants to purchase 6,427,000 and 5,704,000 shares of common stock and preferred stock convertible into 2,302,000 and 2,384,000 shares of common stock at September 30, 2004 and 2003, respectively, have not been included in loss periods because they are anti-dilutive.

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For the three months ended September 30, 2004 the options and warrants to purchase 6,427,000 shares of common stock were excluded because of the treasury stock method.

The following table is a reconciliation of the basic and diluted weighted average shares for the three and nine month periods ended September 30, 2004 and September 30, 2003:

| | Three Months Ended September 30, | | Nine Mont September |
|---|-------------------------------------|------------|------------------------|
| | 2004 | 2003 | 2004 |
| Basic weighted average shares outstanding | 25,373,000 | 23,668,000 | 25,373,000 |
| Common stock equivalents-convertible preferred stock | 2,302,000 | 2,384,000 | 2,302,000 |
| Dilutive effect of stock options | | 700,000 | |
| | | | |
| Diluted weighted average shares outstanding | 27,675,000 | 26,752,000 | 27,675,000 |
| | | | |

Preferred Stock Conversions

Under the Company's Articles of Incorporation, holders of the Company's Class A and Class B Preferred Stock have the right to convert such stock into shares of the Company's common stock at the rate of 1.2 shares of common stock for each share of preferred stock. During the nine months ended September 30, 2004, no

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shares of Series A Preferred Stock and no shares of Series B Preferred Stock were converted to the Company's Common Stock.

Holders of Series D Preferred have the right to convert such stock into shares of the Company's common stock at the rate of one share of common stock for each share of preferred stock. During the six months ended September 30, 2004, no shares of Series D Preferred Stock were converted to the Company's Common stock.

Holders of Series E Preferred have the right to convert such stock into shares of the Company's common stock at the rate of 53.3 shares of common stock for each share of preferred stock. During the six months ended September 30, 2004, no shares of Series E Preferred Stock were converted to the Company's Common stock.

Holders of Series F Preferred have the right to convert such stock into shares of the Company's common stock at the rate of 53.3 shares of common stock for each share of preferred stock. During the six months ended September 30, 2004, no shares of Series F Preferred Stock were converted to shares of the Company's Common stock.

Holders of Series G Preferred have the right to convert such stock into shares of the Company's common stock at the rate of one share of common stock for each share of preferred stock. During the six months ended September 30, 2004, no shares of Series G Preferred Stock were converted to shares of the Company's Common stock.

Stock - Based Compensation

For stock options and warrants granted to employees, the Company employs the footnote disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. SFAS No. 123 encourages entities to adopt a fair-value based method of accounting for stock options or similar equity instruments. However, it also allows an entity to continue measuring compensation cost for stock-based compensation using the intrinsic-value method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). The Company has elected to continue to apply the provisions of APB 25 and provide pro forma footnote disclosures required by SFAS No. 123. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

Stock options and warrants granted to non-employees for services are accounted for in accordance with SFAS 123 which requires expense recognition based on the fair value of the options/warrants granted. The Company calculates the fair value of options and warrants granted by use of the Black-Scholes pricing model. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation.

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| | Three Months Ended September 30, 2004 | 2003 | Nine Months Ended 2004 |
|---------------------------------|--|--------|---------------------------|
| | ----- | ----- | ----- |
| Net income (loss) - as reported | \$ 481,000 | 37,000 | 188,000 |

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| | | | |
|---|------------|----------|-----------|
| Deduct: total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects | (93,000) | (48,000) | (266,000) |
| Net income (loss) - pro forma | \$ 388,000 | (11,000) | (78,000) |
| | | | |
| Earnings per share: | | | |
| Basic and diluted - as reported | \$ 0.02 | - | 0.01 |
| Basic and diluted - pro forma | \$ 0.01 | - | (0.00) |

Related Party Transactions

Payments for legal services to the firm of which the chairman of the board of directors is a partner were approximately \$55,000 and \$23,000 for the three months ended September 30, 2004 and 2003, respectively.

Accrued Expenses

Accrued expenses consist of the following at September 30, 2004:

| | | |
|---|----|---------|
| Accrued consulting and litigation reserve | \$ | 498,000 |
| Accrued payroll and employee benefits | | 142,000 |
| Sales taxes payable | | 40,000 |
| Customer deposits | | 10,000 |
| Accrued royalties | | 17,000 |
| Deferred revenue | | 73,000 |
| Warranty and return allowance | | 154,000 |
| Other accrued expenses | | 56,000 |
| | | ----- |
| Total | \$ | 990,000 |
| | | ===== |

During the quarter ended June 30, 2004, the Company recorded a reduction in the warranty accrual of approximately \$308,000. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically the Company has recorded a monthly warranty expense and related increase to the warranty accrual, however in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$308,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued.

Sale of Investment

In July 2004, the Company sold its investment in International Bioimmune Systems, Inc. (IBS) for \$532,000 cash. Because, for book purposes, the Company's investment in IBS had previously been reduced to \$0, the full amount of \$532,000 was recorded as a gain in the quarter ended September 30, 2004.

Item 2: Management's Discussion and Analysis or Plan of Operation

This report contains forward-looking statements and information relating to the Company that is based on beliefs of management as well as assumptions made by, and information currently available to management. These statements reflect its current view respecting future events and are subject to risks, uncertainties and assumptions, including the risks and uncertainties

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noted throughout the document. Although the Company has attempted to identify important factors that could cause the actual results to differ materially, there may be other factors that cause the forward-looking statements not to come true as anticipated, believed, projected, expected or intended. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those described herein as anticipated, believed, projected, estimated, expected or intended.

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Critical Accounting Policies

Revenue Recognition. The Company recognizes revenue in compliance with Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101), as revised by Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104). SAB 101 and SAB 104 detail four criteria that must exist before revenue is recognized:

1. Persuasive evidence of an arrangement exists. Prior to shipment of product, the Company requires a signed purchase order and, depending upon the customer, a down payment toward the final invoiced price or full payment in advance with certain international product distributors.

2. Delivery and performance have occurred. Unless the purchase order requires specific installation or customer acceptance, the Company recognizes revenue when the product ships. If the purchase order requires specific installation or customer acceptance, the Company recognizes revenue when such installation or acceptance has occurred. Title to the product passes to the customer upon shipment. This revenue recognition policy does not differ among the various different product lines. The Company guarantees the functionality of its product. If its product does not function as marketed when received by the customer, the Company either makes the necessary repairs on site or has the product shipped to the Company for the repair work. Once the product has been repaired and retested for functionality, it is re-shipped to the customer. The Company provides warranties that generally extend for one year from the date of sale. Such warranties cover the necessary parts and labor to repair the product as well as any shipping costs that may be required. The Company maintains a reserve for estimated warranty costs based on its historical experience and management's current expectations.

3. The sales price is fixed or determinable. The purchase order received from the customer includes the agreed-upon sales price. The Company does not accept customer orders, and therefore do not recognize revenue, until the sales price is fixed.

4. Collectibility is reasonably assured. With limited exceptions, the Company requires down payments on product prior to shipment. In some cases the Company requires payment in full prior to shipment. The Company also performs credit checks on new customers and ongoing credit checks on existing customers. The Company maintains an allowance for doubtful accounts receivable based on historical experience and management's current expectations.

Recoverability of Inventory. Since its inception, the Company has purchased several complete lines of inventory. In some circumstances the Company has been able to utilize certain items acquired and others remain unused. On a quarterly basis, the Company attempts to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if the Company identifies products that have become obsolete due to product upgrades or

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enhancements, a reserve is established for such products. The Company intends to make efforts to sell these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced.

Recoverability of Goodwill and Other Intangible Assets. The Company's intangible assets consist of goodwill, product and technology rights, engineering and design costs, and patent costs. Intangibles with a determined life are amortized on a straight-line basis over their determined useful life and are also evaluated for potential impairment if events or circumstances indicate that the carrying amount may not be recoverable. Intangibles with an indefinite life, such as goodwill, are not amortized but are tested for impairment on an annual basis or when events and circumstances indicate that the asset may be impaired. Impairment tests include comparing the fair value of a reporting unit with its carrying net book value, including goodwill. To date, the Company's determination of the fair value of the reporting unit has been based on the estimated future cash flows of that reporting unit.

Allowance for Doubtful Accounts. The Company records an allowance for doubtful accounts to offset estimated uncollectible accounts receivable. Bad debt expense associated with the increases in the allowance for doubtful accounts is recorded as part of general and administrative expense. The Company's accounting policy generally is to record an allowance for receivables over 90 days past due unless there is significant evidence to support that the receivable is collectible.

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General

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements, which involve risks and uncertainty. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors discussed in this section. The Company's fiscal year is from January 1 through December 31.

The Company is engaged in the design, development, manufacture and sale of high technology diagnostic and surgical eye care products. Given the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow. As seen in the results for the three months ended September 30, 2004, diagnostic products have been the major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the Company's financial position improves. The Company does not focus on a specific diagnostic product or products but, instead, on this entire diagnostic product group.

Paradigm has improved its financial and operating performance through higher sales, improving margins, and a substantial reduction in our costs.

Paradigm has displayed improvement in its manufacturing efficiencies, as well as the timeliness and the quality of its services to its customers. For example, a great deal of the improvement is attributable to reforms in operations, which enabled dramatically improved availability of product and decreased lead times. Additional reorganization of services enabled substantially reduced 'wait times' and reserve requirements. Specifically, the Company was able to record an increase in income of approximately \$300,000 from a reduction in warranty reserves. This reduction was a result of a comprehensive

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analysis by management regarding historical warranty costs. Historically the Company has recorded a monthly warranty expense and related increase to the warranty accrual, however in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$300,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued.

The increase in sales was due primarily to the strength in the Company's diagnostic products, specifically the Perimetry and Topography lines, as well as strong growth in the Blood Flow Analyzer (BFA) line, where sales more than doubled from the year-ago period.

Results of Operations

Three Months Ended September 30, 2004, Compared to Three Months Ended September 30, 2003

Net sales for the three months ended September 30, 2004 increased by \$46,000, or 5.4%, to \$899,000 as compared to \$853,000 for the same period of 2003. This increase was primarily due to increased sales of the P40 and P45 UBM Ultrasound Biomicroscopes as well as continued strength in the sales of the Blood Flow Analyzer(TM).

For the three months ended September 30, 2004, sales from the Company's diagnostic products totaled \$833,000, or 93% of total revenues, compared to \$664,000, or 78% of total revenues for the same period of 2003. There were no sales from the surgical line consisting of the Precissionist Thirty Thousand(TM) and the Photon(TM) laser system for the three months ended September 30, 2004, compared to \$46,000, or 5% of total revenues, for the corresponding period of 2003. The remaining 7% of sales, or \$66,000, during the three months ended September 30, 2004 was from parts, disposables, and service revenue.

Sales of the P40 and P45 UBM Ultrasound Biomicroscopes increased to \$373,000 during the third quarter 2004, or 41% of total quarterly revenues, compared to \$211,000, or 25% of total revenues, for the same period last year. Sales of the Blood Flow Analyzer(TM) increased by \$130,000 to \$184,000, or 20% of total revenues, for the three months ended September 30, 2004, compared to net sales of \$54,000, or 6% of total revenues during the same period in 2003. Sales from the P37 A/B Scan Ocular Ultrasound Diagnostic increased to \$98,000, or 6% of total revenues, for the quarter ended September 30, 2004, up slightly compared to \$93,000, or 11% of total revenues, for the same period last year. Combined sales of the LD 400 and TKS 5000 Autoperimeters and the 200 Corneal Topographer were \$178,000, or 20% of the total revenues, for the three months ended September 30, 2004, compared to \$306,000, or 36% of total revenues, for the same quarter of 2003.

Sales have been higher for the Company despite, an industry slow down, due to the emphasis on the sales of the P40 and P45 Ultrasound Biomicroscopes, particularly in Asian markets as well as an increased focus on the sales of the Blood Flow Analyzer(TM) in the United States market.

For the three months ended September 30, 2004, gross profit increased slightly by 2%, to 60% of total revenues, compared to the 58% of total revenues for the comparable period of 2003.

Marketing and selling expenses increased by approximately \$27,000, or 16%, to \$198,000, for the three months ended September 30, 2004, from \$171,000 for the comparable period in 2003. This increase was due mainly to the Company's initiation of an advertising campaign as well as to prepayments for participation at the American Academy of Ophthalmologists annual show in New Orleans.

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General and administrative expenses decreased by \$55,000, or 17 %, to \$276,000 for the three months ended September 30, 2004, from \$331,000 for the comparable period in 2003. The general and administrative expense savings were the result of greater focus and cost containment measures and more aggressive budget management procedures implemented in the second quarter of 2004.

Research, development and service expenses decreased \$40,000, or 20%, for the three months ended September 30, 2004 to \$163,000, compared to \$203,000 recorded in the same period of 2003. Much of the improvement was from the continued benefit of the reorganization of the service department initiated in the second quarter of 2004, which is yielding not only cost improvement but dramatically lower response times and enabled clean up of the service unit backlogs.

Other income of mainly consists of a gain recorded from the sale of the Company's investment in International Bioimmune Systems, Inc. In July 2004, the Company sold its investment in International Bioimmune Systems, Inc. (IBS) for \$532,000 cash. Because, for book purposes, the Company's investment in IBS had previously been reduced to \$0, the full amount of \$532,000 was recorded as a gain in the quarter ended September 30, 2004.

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Nine Months Ended September 30, 2004, Compared to Nine Months Ended September 30, 2003

Net sales increased by \$63,000, or 3%, to \$2,288,000 for the nine months ended September 30, 2004, from \$2,225,000 for the comparable period in 2003. The Company's diagnostic products sales increased by \$336,000, or 19%, to \$2,085,000, or 91% of revenues, during the first nine months of 2004 compared with \$1,750,000, or 79% of total revenues, for the comparable period of 2003.

In the first nine months of 2004, sales of the Company's P40 and P45 UBM Ultrasound Biomicroscopes were \$639,000, or 28% of total revenues, compared to \$421,000, or 19% of total revenues, in the same period of 2003. Sales from the Blood Flow Analyzer(TM) increased by \$178,000 to \$475,000, or 21% of total revenues, during the first two quarters of 2004 compared with \$297,000, or 13% of total revenues, in the same period of last year.

During the first nine months of 2004, sales from P37 A/B Scan Ocular Ultrasound Diagnostic increased to \$229,000, or 10% of total revenue, slightly up from the \$222,000, or 10% of total revenues, in the same period last year. Sales of the LD 400 and TKS 5000 Autoperimeters and the CT 200 Corneal Topographer were slightly lower in the second quarter, with total revenue of \$741,000, or 32% of total revenues, in the first three quarters of 2004 compared with \$808,000, or 36% of total revenues, during the same period of 2003.

Sales of surgical products are at a standstill pending FDA approval of the Photon(TM) laser system. In the nine month period ended September 30 2004, the Company realized a loss of \$3,000 in the surgical line consisting of the Precisionist Thirty Thousand (TM) and the Photon(TM) laser system. This compared to \$94,000, for the comparable period of 2003.

Gross profit for the nine months ended September 30, 2004 increased by 18% to 62% of total revenues, compared to 44% of total revenues, for the same period in 2003. The increase was mainly due to an increase in the reserve for inventory obsolescence of \$382,000 in the nine months ended September 30, 2003. There was a decrease of \$226,000 in the reserve during the nine months ended September 30, 2004; however this decrease was the result of a write-off of

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inventory directly against the reserve. The \$382,000 increase in inventory reserve in 2003 resulted in an increase to cost of sales whereas the \$226,000 reduction in 2004 resulted in a corresponding reduction to inventory and did not have any effect on the statement of operations.

Marketing and selling expenses decreased by \$164,000, or 30%, to \$547,000 for the nine months ended September 30, 2004, from \$711,000 for the comparable period in 2003. This reduction was due primarily to more effective use of marketing programs. During this period two additional full-time salespersons were added, a print advertising campaign initiated, and plans were made to support a major trade show in the fourth quarter of 2004.

General and administrative expenses decreased by \$1,164,000, or 62%, to \$703,000 for the nine months ended September 30, 2004, from \$1,867,000 for the same period in 2003. The favorable reduction in general and administrative expense in 2004 also reflected the ongoing results of the Company's new budget management and cost reduction programs. In addition, during the quarter ended June 30, 2004, the Company recorded a reduction in the warranty accrual of approximately \$308,000. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically the Company has recorded a monthly warranty expense and related increase to the warranty accrual, however in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$308,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued. The general and administrative expenses during the nine months ended September 30, 2003 also included \$443,000 in accruals to settle outstanding disputes and \$83,000 for additional allowance for doubtful accounts receivable.

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Research, development and service expenses decreased by \$246,000, or 45%, to \$543,000 for the nine months ended September 30, 2004, from \$789,000 for the same period in 2003. Expenses associated with the development of new products during the first nine months of 2004 decreased compared to the same period in 2003, as a result of the Company's cost reduction program.

There was no impairment of assets for the nine months ended September 30, 2004, compared to \$159,000 in impairment of assets recorded in the same period of 2003.

Other income of mainly consists of a gain recorded from the sale of the Company's investment in International Bioimmune Systems, Inc. In July 2004, the Company sold its investment in International Bioimmune Systems, Inc. (IBS) for \$532,000 cash. Because, for book purposes, the Company's investment in IBS had previously been reduced to \$0, the full amount of \$532,000 was recorded as a gain in the quarter ended September 30, 2004.

Liquidity and Capital Resources

The Company used \$440,000 cash in operating activities for the nine months ended September 30, 2004, compared to \$712,000 for the nine months ended September 30, 2003. The increase in cash used by operating activities for the nine months ended September 30, 2004 was primarily attributable to reduction in accrued expenses and deposits. The Company's efforts to substantially reduce costs and manage current assets and current liabilities continued to minimize cash used for operating activities. Net cash used in financing activities was \$42,000 for the nine months ended September 30, 2004, versus cash provided of \$726,000 in the same period in 2003. During the nine months ended September 30,

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2004, the Company did not sell any shares of common or preferred stock. In the past, the Company has relied heavily upon sales of its common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to the Company in the future.

The Company had working capital of \$76,000 as of September 30, 2004. In the past, the Company has relied heavily upon sales of its common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to the Company in the future. The Company will continue to seek funding to meet its working capital requirements through collaborative arrangements and strategic alliances, additional public offerings and private placements of its securities; and bank borrowings. In July 2004, the Company sold its investment in International Bio-Immune Systems, Inc. (IBS) for \$532,000 cash. The Company is uncertain whether or not the combination of the cash received from the sale of IBS stock and the benefits from sales of its products will be sufficient to assure its operations through December 31, 2004. The Company will continue to seek funding through the sale of common and preferred stock.

As of September 30, 2004, the Company had net operating loss carry-forwards (NOLs) of approximately \$36 million. These carry-forwards are available to offset future taxable income, if any, and have begun to expire in 2001 and extend for twenty years. The Company's ability to use net operating loss carryforwards (NOLs) to offset future income is dependant upon certain limitations as a result of the pooling transaction with Vismed and the tax laws in effect at the time of the NOLs can be utilized. The Tax Reform Act of 1986 significantly limits the annual amount that can be utilized for certain of these carryforwards as a result of change of ownership.

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As of September 30, 2004, the Company had accounts payable of \$653,000, a significant portion of which is over 90 days past due. The Company has contacted many of the vendors or companies that have significant amounts of payables past due in an effort to delay payment, renegotiate a reduced settlement payment, or establish a longer-term payment plan. While some companies have been willing to renegotiate the outstanding amounts, others have demanded payment in full. Under certain conditions, including but not limited to judgments rendered against the Company in a court of law, a group of creditors could force the Company into bankruptcy due to its inability to pay the liabilities arising out of such judgments at that time. In addition to the accounts payable noted above, the Company also has non-cancelable capital lease obligations and operating lease obligations that require the payment of approximately \$172,000 in 2005, and \$14,000 in 2006.

The Company has taken numerous steps to reduce costs and increase operating efficiencies. These steps consist of the following:

1. The Company closed its San Diego facility. In so doing, numerous manufacturing, accounting and management responsibilities were consolidated. In addition, such closure resulted in significant headcount reductions as well as savings in rent and other overhead costs.

2. The Company has significantly reduced the use of consultants, which has resulted in a large decrease to these expenses.

3. The Company has reduced its direct sales force to five representatives, which has resulted in less payroll, travel and other selling expenses.

Because the Company has significantly fewer sales representatives, its

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ability to generate sales has been reduced.

The Company has taken measures to reduce the amount of uncollectible accounts receivable such as more thorough and stringent credit approval, improved training and instruction by sales personnel, and frequent direct communication with the customer subsequent to delivery of the system. The allowance for doubtful accounts was 37% of total outstanding receivables as of September 30, 2004 and 40% as of December 31, 2003. The allowance for doubtful accounts has decreased from \$470,000 at December 31, 2003 to \$424,000 at September 30, 2004. The downturn in the economy worldwide has resulted in increased difficulty in collecting certain accounts. Certain international dealers have some aged unpaid invoices that have not been resolved. The Company has addressed its credit procedures and collection efforts and have instituted changes that require more payments at the time of sale via letters of credit and not on a credit term basis.

The Company intends to continue its efforts to reduce the allowance for doubtful accounts as a percentage of accounts receivable. The Company has ongoing efforts to collect a significant portion of the sales price in advance of the sale or in a timely manner after delivery. The majority of the receivables included in the allowance for doubtful accounts are a result of sales before the Company implemented the various changes to improve the collectibility of our receivables. During the nine months ended September 30, 2004, the Company had a net recovery of receivables previously allowed for of \$46,000 and during the twelve months ended December 31, 2003, the Company added a net of \$123,000 to the allowance for doubtful accounts. The Company believes that by requiring a large portion of payment prior to shipment, it has greatly improved the collectibility of its receivables.

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The Company carried an allowance for obsolete or estimated non-recoverable inventory of \$1,416,000 at September 30, 2004, or approximately 65% of total inventory, respectively. This inventory reserve was decreased by \$226,000 during the nine months ended September 30, 2004 due to management's evaluation of the recoverability of certain inventory items. The Company's means of expansion and development of product has been largely from acquisition of businesses, product lines, existing inventory, and the rights to specific products. Through such acquisitions, the Company has acquired substantial inventory, some of which the eventual use and recoverability was uncertain. In addition, the Company has a significant amount of inventory relating to the Photon(TM) laser system, which does not yet have FDA approval in order to sell the product domestically. Therefore, the allowance for inventory was established to reserve for these potential eventualities.

On a quarterly basis, the Company attempts to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if the Company identifies products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products. The Company intends to make efforts to sell these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced. During the fourth quarter of 2003, the Company sold all inventory and rights associated with the Phaco SIsTem(TM) and Odyssey(TM) for \$125,000. Because the full amount of inventory related to the SIsTem(TM) and Odyssey(TM) had been fully reserved, no cost of sales were recorded in connection with this sale, thus resulting in gross profit

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equal to the sales price of \$125,000. The Company does not expect the sales of these items, if any, to be significant in the future.

At this time, the Company's Photon(TM) Laser Ocular Surgery Workstation requires regulatory FDA approval in order to be sold in the United States. Any possible future efforts to complete the clinical trials on the Photon(TM) in order to file for FDA approval would depend on the Company obtaining adequate funding. The Company estimates that the liquidity needed to complete the clinical trials in order to obtain the necessary regulatory approval on the Photon(TM) to be approximately \$225,000.

Effect of Inflation and Foreign Currency Exchange

The Company has not realized a reduction in the selling price of its products as a result of domestic inflation. Nor has the Company experienced unfavorable profit reductions due to currency exchange fluctuations or inflation with its foreign customers. All sales transactions to date have been denominated in U.S. Dollars.

Impact of New Accounting Pronouncements

In November 2003, the EITF reached a consensus on Issue No.00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for certain arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on the Company's operating results or financial condition.

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In December 2003, the FASB issued Interpretation No. 46 ("FIN 46R") (revised December 2003), Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 ("ARB 51"), which addresses how a business enterprise should evaluate whether it has a controlling interest in an entity though means other than voting rights and accordingly should consolidate the entity. FIN 46R replaces FASB Interpretation No. 46 (FIN 46), which was issued in January 2003. Before concluding that it is appropriate to apply ARB 51 voting interest consolidation model to an entity, an enterprise must first determine that the entity is not a variable interest entity (VIE). As of the effective date of FIN 46R, an enterprise must evaluate its involvement with all entities or legal structures created before February 1, 2003, to determine whether consolidation requirements of FIN 46R apply to those entities. There is no grandfathering of existing entities. Public companies must apply either FIN 46 or FIN 46R immediately to entities created after January 31, 2003 and no later than the end of the first reporting period that ends after March 15, 2005. The adoption of FIN 46 had no effect on the Company's consolidated financial position, results of operations or cash flows.

In April 2003, FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133, Accounting for Derivatives and Hedging Activities. SFAS 149 is generally effective for derivative instruments, including derivative instruments embedded in certain contracts, entered into or modified after June 30, 2003. The adoption of SFAS 149 did not have a material impact on the Company's operating results or financial condition.

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In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 clarifies the accounting for certain financial instruments with characteristics of both liabilities and equity and requires that those instruments be classified as liabilities in statements of financial position. Previously, many of those financial instruments were classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. On November 7, 2003, FASB Staff Position 150-3 was issued, which indefinitely deferred the effective date of SFAS 150 for certain mandatory redeemable non-controlling interests. As the Company does not have any of these financial instruments, the adoption of SFAS 150 did not have any impact on its financial statements.

In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. SAB 104 revises or rescinds portions of the interpretive guidance included in Topic 13 of the codification of staff accounting bulletins in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The adoption of SAB 104 did not have a material effect on the Company's results of operations or financial position.

Item 3 Controls and Procedures

a) Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of September 30, 2004. Based on this evaluation, our principal executive officer and our principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective and adequately designed to ensure that the information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms.

(b) Changes in internal controls over financial reporting.

During the quarter ended September 30, 2004, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II Other Information

Item 1. Legal Proceedings

An action was brought against the Company in March 2000 by George Wiseman, a former employee, in the Third District Court of Salt Lake County, State of Utah. The complaint alleges that the Company owes Mr. Wiseman 6,370 shares of its common stock plus costs, attorney's fees and a wage penalty (equal to 1,960 additional shares of its common stock) pursuant to Utah law. The action is based upon an extension of a written employment agreement. The Company disputes the amount allegedly owed and intends to vigorously defend against the action.

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An action was brought against the Company on September 11, 2000 by PhotoMed International, Inc. and Daniel M. Eichenbaum, M.D. in the Third District Court of Salt Lake County, State of Utah. The action involves an amount of royalties that are allegedly due and owing to PhotoMed International, Inc. and Dr. Eichenbaum under a license agreement dated July 7, 1993, with respect to the sale of certain equipment, plus costs and attorney's fees. Discovery has taken place and the Company has paid royalties of \$14,736 to bring all payments up to date through June 30, 2001. The Company has been working with PhotoMed and Dr. Eichenbaum to ensure that the calculations have been correctly made on the royalties paid as well as the proper method of calculation for the future.

It is anticipated that once the parties can agree on the correct calculations on the royalties, the legal action will be dismissed. The issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon(TM) laser system has been sold and no systems returned. Thus, the amount of royalties due, according to the Company's calculations, is \$600. The Company intends to make payment of this amount to PhotoMed and Dr. Eichenbaum and, as a result, to have the legal action dismissed. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend their complaint to request termination of the license agreement and, if successful, the Company would lose its right to manufacture and sell the Photon(TM) laser system.

On May 14, 2003, a complaint was filed in the United States District Court, District of Utah, captioned Richard Meyer, individually and on behalf of all others similarly suited v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00448TC. The complaint also indicates that it is a "Class Action Complaint for Violations of Federal Securities Law and Plaintiffs Demand a Trial by Jury." The Company has retained legal counsel to review the complaint, which appears to be focused on alleged false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation.

More specifically, the complaint alleges that the Company falsely stated in its Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association for reimbursement to doctors in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for use of the Blood Flow Analyzer(TM). According to the complaint, the CPT code was critical. Without a reimbursement code, physicians would not purchase the Blood Flow Analyzer(TM) because they could not receive compensation for performance of medical procedures using the medical device. The complaint further contends that the Company never received the CPT code from the American Medical Association at any time. Nevertheless, it is alleged that the Company continued to misrepresent in its SEC filings and press releases that it had received the CPT code. It is also alleged that the Company have never made a full, corrective disclosure with respect to this alleged misstatement.

The complaint also alleges that on July 11, 2002, the Company issued a press release falsely announcing that it had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of its entire portfolio of products, with \$70 million in systems to be delivered over a two-year period, then another \$35 million of orders to be completed in the third year. The complaint further alleges that the Company had never received a true purchase order for its products. As a result of these

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alleged misstatements, the complaint contends that the price of the Company's shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased or retained the Company's common shares during that period suffered substantial damages. The complaint requests judgment for unspecified damages, together with interest and attorney's fees.

The Company disputes having issued false and misleading statements concerning the Blood Flow Analyzer(TM) and a purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. On April 25, 2001, the Company issued a press release that stated it had received authorization to use common procedure terminology or CPT code number 92120 for the Blood Flow Analyzer(TM). This press release was based on a letter the Company received from the CPT Editorial Research and Development Department of the American Medical Association stating that CPT code number 92120 was the appropriate common procedure terminology or CPT code number for doctors to use when reporting certain procedures performed with the Blood Flow Analyzer(TM).

Currently, there is reimbursement by insurance payors to doctors using the Blood Flow Analyzer(TM) in 22 states and partial reimbursement in four other states. The amount of reimbursement to doctors using the Blood Flow Analyzer(TM) generally ranges from \$56.00 to \$76.00 per patient, depending upon the insurance payor. Insurance payors providing reimbursement for the Blood Flow Analyzer(TM) have the discretion to increase or reduce the amount of reimbursement. The Company is endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. The Company believes it has continued to correctly represent in its Securities and Exchange Commission filings that the CPT Editorial Research and Development Department of the American Medical Association has advised it that CPT code number 92120 is the appropriate CPT code for the Company's Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

On July 11, 2002, the Company issued a press release that stated it received a purchase order from Westland Financial Corporation and Valdespino Associates Enterprises for 200 complete sets of its entire product portfolio of diagnostic and surgical equipment for Mexican ophthalmic practitioners, to be followed by a second order of 100 sets of equipment. The press release was based on a purchase order dated July 10, 2002 that the Company entered into with Westland Financial Corporation for the sale of 200 complete sets of its surgical and diagnostic equipment to Mexican ophthalmic practitioners. The press release also stated that the initial order was for \$70 million of the Company's equipment to be filled over a two-year period followed by the second order of \$35 million in equipment to be completed in the third year. The press release further stated that delivery would be made in tranches of 25 complete sets of the Company's equipment, beginning in 30 days from the date of the purchase order.

On September 13, 2002, the board of directors issued a press release regarding the status of the Company's product sales to the Mexican ophthalmic practitioners. In that press release the board stated that the Company had been in discussions for the prior nine months with Westland Financial Corporation, aimed at supplying the Company's medical device products to the Mexican market. Upon investigation, the board of directors had determined that the purchase order referenced in the July 11, 2002 press release was not of such a nature as to be enforceable for the purpose of sales or revenue recognition. In addition, the Company had not sent any shipment of medical products to Mexican ophthalmic practitioners nor received payment for those products pursuant to those discussions. The September 13, 2002 press release also stated that discussions were continuing with Westland Financial Corporation regarding sales and marketing activities for the Company's medical device products in Mexico, but the Company could not, at the time, predict or provide any assurance that any transactions would result.

On June 2, 2003, a complaint was filed in the United States District Court, captioned Michael Marrone v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00513 PGC. On July 11, 2003, a complaint was filed in the same United States District Court, captioned Lidia Milian v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00617PGC. Both complaints seek class action status. These cases are substantially similar in nature to the Meyer case, including the contention that as a result of allegedly false statements regarding the Blood Flow Analyzer(TM) and the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises, the price of the Company's common stock was artificially inflated and the persons who purchased the Company's common shares during the class period suffered substantial damages. In a press release dated July 11, 2003, captioned "Milberg Weiss announces the filing of a class action suit against Paradigm Medical Industries, Inc. on behalf of investors," the law firm of Milberg Weiss Bershad Hynen & Levach LLP, which represents purchasers of the Company's securities in the class action suit filed on July 11, 2003, stated that the Company's alleged misrepresentations caused the market price of the stock to be artificially inflated during the class period. As a result, it is alleged that investors suffered millions of dollars in damages from the Company's alleged misstatements.

The cases request judgment for unspecified damages, together with interest and attorney's fees. These cases have now been consolidated with the Meyer case into a single action, captioned In re: Paradigm Medical Industries Securities Litigation, Case No. 03-CV-448TC. The law firm of Milberg Weiss Bershad & Schulman LLP is representing purchasers of the Company's securities in the consolidated class action. On June 28, 2004, a consolidated amended class action complaint was filed on behalf of purchasers of the Company's securities. The consolidated complaint is similar to the three class action complaints and alleges that the Company made false representations regarding the CPT code for the Blood Flow Analyzer(TM), but it includes additional allegations that the Company failed to disclose in a timely manner that doctors were being denied reimbursement for procedures performed with the Blood Flow Analyzer(TM). The consolidated complaint also alleges that the Company made false statements regarding the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. The Company believes the consolidated complaint is without merit and intends to vigorously defend and protect its interests in the case.

The Company was issued a Directors and Officers Liability and Company Reimbursement Policy by United States Fire Insurance Company for the period from July 10, 2002 to July 10, 2003 that contains a \$5,000,000 limit of liability, which is excess of a \$250,000 retention. The officers and directors named in the consolidated cases have requested coverage under the policy. U.S. Fire is currently investigating whether it may have a right to deny coverage for the consolidated cases based upon policy terms, conditions and exclusions or to rescind the policy based upon misrepresentations contained in the Company's application for insurance.

The Company has paid \$30,000 to U.S. Fire toward satisfaction of the \$250,000 retention that is applicable to the consolidated cases. The Company has advised U.S. Fire that it cannot pay the \$250,000 retention due to its current financial circumstances. As a consequence, on January 8, 2004, the Company entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance the Company's retention obligation in consideration for which the Company has agreed to reimburse U.S. Fire the sum of \$5,000 a month, for a period of six months, with the first of such payments due on February 15, 2004.

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Thereafter, commencing on August 15, 2004, the Company is currently required to reimburse U.S. Fire the sum of \$10,000 per month until the entire amount of \$250,000 has been reimbursed to U.S. Fire. The Company has made the \$5,000 payments due to U.S. Fire on February 15, March 15, April 15, May 15, June 15, and July 15, 2004, leaving a remaining retention obligation to U.S. Fire of \$220,000.

In the event U.S. Fire determines that the Company or its former officers and directors named in the consolidated cases are not entitled to coverage under the policy, or that it is entitled to rescind the policy, or should the Company be declared in default under the non-waiver agreement, for not making the monthly payments in a timely manner that are owed to U.S. Fire, then the Company agrees to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that it may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement. Moreover, if U.S. Fire denies coverage for the consolidated cases under the policy, the Company would owe its litigation counsel in the class action lawsuits, for any legal fees not paid by U.S. Fire. However, U.S. Fire has currently agreed to pay the legal fees relating to the class action lawsuits.

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The Company will be in default under the non-waiver agreement if it fails to make any payment due to U.S. Fire thereunder when such payment is due, or institute proceedings to be adjudicated as bankrupt or insolvent. U.S. Fire's obligation to advance defense costs under the agreement will terminate in the event that the \$5,000,000 policy limit of liability is exhausted. If U.S. Fire denies coverage for the consolidated cases under the policy and the Company is not successful in defending and protecting its interests in the cases, resulting in a judgment against the Company for substantial damages, it would be unable to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On July 10, 2003, a complaint was filed in the United States District Court, District of Utah captioned Innovative Optics, Inc. and Barton Dietrich Investments, L.P. v. Paradigm Medical Industries, Inc., Mackey Price & Thompson, Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV 00582DB. The complaint claims that Innovative and Barton entered into an asset purchase agreement with the Company on January 31, 2002, in which the Company agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint claims the Company breached the asset purchase agreement. The complaint also claims that the Company allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to induce Innovative to sell its assets and purchase the shares of the Company's common stock at artificially inflated prices while simultaneously deceiving Innovative and Barton into believing that the Company's shares were worth more than they actually were. The complaint contends that had Innovative and Barton known the truth they would not have sold Innovative to the Company, would not have purchased the Company's stock for the assets of Innovative, or would not have purchased the stock at the inflated prices that they allegedly paid. The complaint further contends that as a result of the allegedly false statements, Innovative and Barton suffered substantial damages in an amount to be proven at trial.

The complaint also claims that 491,250 of the shares to be issued to Innovative in the asset purchase transaction were not issued on a timely basis and the Company did not file a registration statement with the Securities and

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Exchange Commission within five months of the closing date of the asset purchase transaction. As a result, the complaint alleges that the value of the shares of the Company's common stock issued to Innovative in the transaction declined, and Innovative and Barton suffered damages in an unspecified amount to be proven at trial. The Company filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. The Company believes the complaint is without merit and intends to vigorously defend and protect its interests in the action. If the Company is not successful in defending and protecting its interests in this action, and a judgment for substantial damages is entered against it, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would be unable to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On October 14, 2003, an action was filed in the Third Judicial District Court, Salt Lake County, State of Utah, captioned Albert Kinzinger, Jr., individually and on behalf of all others similarly situated vs. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle, Randall A. Mackey, and John Hemmer, Case No. 030922608. The complaint also indicates that it is a "Class Action Complaint for Violations of Utah Securities Laws and Plaintiffs Demand a Trial by Jury." The Company has retained legal counsel to review the complaint, which appears to be focused on alleged false or misleading statements pertaining to the Blood Flow Analyzer(TM). More specifically, the complaint alleges that the Company falsely stated in Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for the Blood Flow Analyzer(TM).

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The purpose of these statements, according to the complaint, was to induce investors to purchase shares of the Company's Series E preferred stock in a private placement transaction at artificially inflated prices. The complaint contends that as a result of these statements, the investors that purchased shares of the Company's Series E preferred stock in the private offering suffered substantial damages to be proven at trial. The complaint also alleges that the Company sold Series E preferred shares without registering the sale of such shares or obtaining an exemption from registration. The complaint requests rescission, compensatory damages and treble damages, including interest and attorney's fees. The Company filed an answer to the complaint. The Company believes the complaint is without merit and intends to vigorously defend its interests in the action. If the Company is not successful in defending and protecting its interests in the action, resulting in a judgment against it for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would be unable to pay such liability and, as a result, would be forced to seek bankruptcy protection.

An action was filed on June 20, 2003 in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030914195) by CitiCorp Vendor Finance, Inc., formerly known as Copelco Capital, Inc. The complaint claims that \$49,626 plus interest is due for the leasing of two copy machines that were delivered to the Company's Salt Lake City facilities on or about April of 2000. The action also seeks an award of attorney's fees and costs incurred in the collection. The Company disputes the amounts allegedly owed, asserting that the equipment it returned to the leasing company did not work properly. A responsive pleading has been filed. The Company is currently engaged in settlement

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discussions with CitiCorp.

The Company received demand letters dated July 18, 2003, September 26, 2003 and November 10, 2003 from counsel for Douglas A. MacLeod, M.D., a shareholder of the Company. In the July 18, 2003 letter, Dr. MacLeod demands that he and certain entities with which he is involved or controls, namely the Douglas A. MacLeod, M.D. Profit Sharing Trust, St. Marks' Eye Institute and Milan Holdings, Ltd., be issued a total of 2,296,667 shares of the Company's common stock and warrants to purchase 1,192,500 shares of its common stock at an exercise price of \$.25 per share. Dr. MacLeod claims that these common shares and warrants are owing to him and the related entities under the terms of a mutual release dated January 16, 2003, which he and the related entities entered into with the Company. Dr. MacLeod renewed his request for these additional common shares and warrants in the September 26, 2003 and November 10, 2003 demand letters. The Company believes that Dr. MacLeod's claims and assertions are without merit and that neither he nor the related entities are entitled to any additional shares of its common stock or any additional warrants under the terms of the mutual release. The Company intends to vigorously defend against any legal action that Dr. MacLeod may bring.

On August 3, 2003, a complaint was filed against the Company by Corinne Powell, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030918364). Defendants consist of the Company and Randall A. Mackey, Dr. David M. Silver and Keith D. Ignatz, directors of the Company. The complaint alleges that at the time the Company laid off Ms. Powell on March 25, 2003, she was owed \$2,030 for business expenses, \$11,063 for accrued vacation days, \$12,818 for unpaid commissions, the fair market value of 50,000 stock options exercisable at \$5.00 per share that she claims she was prevented from exercising, attorney's fees and a continuing wage penalty under Utah law. The Company disputes the amounts allegedly owed and intends to vigorously defend and protect its interests in the action.

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On September 10, 2003, an action was filed against the Company by Larry Hicks in the Third Judicial District Court, Salt Lake County, State of Utah, (Civil No. 030922220), for payments due under a consulting agreement with the Company. The complaint claims that monthly payments of \$3,083 are due for the months of October 2002 to October 2003 under a consulting agreement and, if the agreement is terminated, for the sum of \$110,000 minus whatever the Company has paid Mr. Hicks prior to such termination, plus costs, attorney's fees and a wage penalty pursuant to Utah law. The Company disputes the amount allegedly owed and intends to vigorously defend against such action.

On May 25, 2004, an action was brought against the Company by Jeffrey F. Poore, former President and Chief Executive Officer of the company, in the Third Judicial District Court of Salt Lake County, State of Utah (Civil No. 040910875). The complaint alleges that the Company unlawfully terminated the written employment agreement between Mr. Poore and the Company. As a result, Mr. Poore demands judgment against the Company for \$350,000, representing his annual salary for the two remaining years under the employment agreement, for money judgment based on the value of his benefits for the two remaining years under the employment agreement, including profit sharing plans, 401(k) and cafeteria plans, health, hospitalization, dental, disability and other insurance plans canceled by the Company, and for money judgment equal to the value of the stock options granted to him under the employment agreement. The Company disputes the amounts allegedly owed in the complaint and believes that there was a sufficient basis to terminate Mr. Poore's employment for cause under the terms of the employment agreement. Accordingly, the Company intends to vigorously defend against the action.

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On August 9, 2004, a third party complaint was brought against the Company by Wakefield Eye Center. The original action was brought by American Express Business Corporation against Westfield Eye Center on May 27, 2004 in the District Court, Clark County, State of Nevada (Civil No. A486307, Dept. No. XXI) concerning the financing of the purchase of a Blood Flow Analyzer(TM) involving Westfield Eye Center. The transaction took place during the latter half of 2001. Westfield Eye Center takes the position that if there is liability of Westfield to American Express this liability is ultimately the Company and the other third-party defendants. The amount being sought against Westfield Eye Center by American Express in the original action includes the sum of \$29,765.83, together with interest and attorney's fees. Westfield's alleged claims against the Company include fraud, breach of contract, promissory estoppel, declaratory relief, negligence, negligent supervision, damages for injuries resulting from actions of employee/contractor, wilful and wanton misconduct, conspiracy, and breach of fiduciary duty as well as costs and attorney's fees. Westfield also seeks punitive damages. The Company has filed an answer to the third party complaint in which we deny liability. Formal discovery in the matter involving us has not commenced. The Company intends to vigorously defend the action.

The Company is not a party to any other material legal proceedings outside the ordinary course of its business or to any other legal proceedings which, if adversely determined, would have a material adverse effect on its financial condition or results of operations.

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Item 2. Changes in Securities

None.

Item 3. Defaults Upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

On September 28, 2004, the Company entered into an Investment Banking Agreement with Alpha Advisory Services, Inc. Under the terms of the Agreement, Alpha Advisory Services is to use its best efforts to provide the following services to the Company: (i) review of and make recommendations regarding the Company's business plan and promotional materials; (ii) identify and contact potential investors in the United States and Europe for potential investment in the Company's securities; (iii) organize meetings with potential investors and participate in such meetings; and (iv) assist the Company in future financings, mergers, acquisitions and potential buyouts.

The term of the Agreement is for a period of three months, which is to be automatically renewed for successive one-year terms. Following the initial three month period, either party may terminate the agreement upon 15 days written notice to the other party. In consideration for the services to be performed under the agreement, Alpha Advisory Services is to receive a fee of \$3,000 per month, plus reasonable travel and other expenses, plus warrants to purchase 25,000 shares of the Company's common stock at \$.15 per share. The warrants are exercisable, on a cashless basis, over a two year period from the date of issuance.

On October 25, 2004, the Company entered into a Manufacturing and

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Distribution Agreement with E-Technologies, Inc., a Iowa based developer of software and related technology for technical applications. Under the terms of the agreement, E-Technologies granted to the Company the exclusive right to manufacture, market, sell and distribute an ultrasonic biomicroscope. Upon execution of the agreement, the Company paid \$30,000 to E-Technologies for engineering costs associated with the development of the biomicroscope. Once the biomicroscope receives FDA approval, the Company agrees to pay E-Technologies an additional fee of \$45,000.

In consideration for the exclusive right to manufacture and distribute the biomicroscope, the Company agrees to pay E-Technologies the sum of \$5,000 for each of the first 25 biomicroscopes sold by the Company. Thereafter, the Company agrees to pay E-Technologies the sum of \$4,000 for each biomicroscope sold. As an additional condition, the Company agrees to sell 25 biomicroscopes during the first 12 months after the biomicroscope receives FDA approval. The agreement is effective for a term of two years. After the expiration of the two year period, the agreement is to automatically renew for additional one year periods, unless either party elects to terminate the agreement upon at least 30 days prior written notice to the other party before the end of any term of the agreement.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

The following Exhibits are filed herewith pursuant to Rule 601 of Regulation S-B or are incorporated by reference to previous filings.

| Exhibit No. | Document Description |
|----------------|---|
| 2.1 | Amended Agreement and Plan of Merger between Paradigm Medical Industries, Inc., a California corporation and Paradigm Medical Industries, Inc., a Delaware corporation(1) |
| 3.1 | Certificate of Incorporation(1) |
| 3.2 | Amended Certificate of Incorporation(10) |
| 3.3 | Bylaws(1) |
| 4.1 | Warrant Agency Agreement with Continental Stock Transfer & Trust Company(3) |
| 4.2 | Specimen Common Stock Certificate (2) |
| 4.3 | Specimen Class A Warrant Certificate(2) |
| 4.4 | Form of Class A Warrant Agreement(2) |
| 4.5 | Underwriter's Warrant with Kenneth Jerome & Co., Inc.(3) |
| 4.6 | Warrant to Purchase Common Stock with Note Holders re bridge financing (1) |
| 4.7 | Specimen Series C Convertible Preferred Stock Certificate(4) |
| 4.8 | Certificate of the Designations, Powers, Preferences and Rights of the Series C Convertible Preferred Stock(4) |
| 4.9 | Specimen Series D Convertible Preferred Stock Certificate (6) |
| 4.1 | Certificate of the Designations, Powers, Preferences and Rights of the Series D Convertible Preferred Stock (7) |
| 4.11 | Warrant to Purchase Common Stock with Cyndel & Co. (6) |
| 4.12 | Warrant to Purchase Common Stock with R.F. Lafferty & Co., Inc. (6) |
| 4.13 | Warrant to Purchase Common Stock with Dr. Michael B. Limberg (7) |
| 4.14 | Warrant to Purchase Common Stock with John W. Hemmer (7) |
| 4.15 | Stock Purchase Warrant with Triton West Group, Inc.(9) |
| 4.16 | Warrant to Purchase Common Stock with KSH Investment Group, Inc.(9) |

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| 4.17 | Warrant to Purchase Common Stock with Consulting for Strategic Growth, Ltd.(9) |
| 4.18 | Certificate of Designations, Powers, Preferences and Rights of the Series G Convertible Preferred Stock (14) |
| 10.1 | Exclusive Patent License Agreement with PhotoMed(1) |
| 10.2 | Consulting Agreement with Dr. Daniel M. Eichenbaum(1) |
| 10.3 | 1995 Stock Option Plan (1) |
| 10.4 | Employment Agreement with Thomas F. Motter (5) |
| 10.5 | Stock Purchase Agreement with Ocular Blood Flow, Ltd. and Malcolm Redman (7) |
| 10.6 | Consulting Agreement with Malcolm Redman (7) |
| 10.7 | Royalty Agreement with Malcolm Redman (7) |
| 10.8 | Registration Rights with Malcolm Redman (7) |
| 10.9 | Employment Agreement with Mark R. Miehle (8) |
| 10.10 | Agreements with Steven J. Bayern and Patrick M. Kolenik (8) |
| 10.11 | Private Equity Line of Credit Agreement with Triton West Group, Inc. (9) |
| 10.12 | Asset Purchase Agreement with Innovative Optics, Inc. and Barton Dietrich Investments, L.P.(10) |
| 10.13 | Escrow Agreement with Innovative Optics, Inc., Barton Dietrich Investments, L.P. (10) |
| 10.14 | Assignment and Assumption Agreement with Innovative Optics, Inc.(10) |

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| 10.15 | General Assignment and Bill of Sale with Innovative Optics, Inc.(10) |
| 10.16 | Non-Competition and Confidentiality Agreement with Mario F. Barton(10) |
| 10.17 | Termination of Employment Agreement with Mark R. Miehle(12) |
| 10.18 | Consulting Agreement with Mark R. Miehle(12) |
| 10.19 | Employment Agreement with Jeffrey F. Poore (13) |
| 10.20 | License Agreement with Sunnybrook Health Science Center(15) |
| 10.21 | Major Account Facilitator Contract(15) |
| 10.22 | Mutual Release with Douglas A. MacLeod, M.D. and Others(15) |
| 10.23 | Purchase Agreement with American Optisurgical, Inc.(15) |
| 10.24 | Purchase Order with Westland Financial Corporation(16) |
| 10.25 | Non-Waiver Agreement with United States Fire Insurance Company(16) |
| 10.26 | Employment Agreement with John Y. Yoon(17) |
| 10.27 | Consulting Agreement with Dr. John Charles Casebeer(18) |
| 10.28 | Consulting Agreement with Kinexsys Corporation(18) |
| 10.29 | Stock Purchase and Sale Agreement with William Ungar(19) |
| 10.30 | Employment Agreement with Aziz A. Mohabbat (20) |
| 10.31 | Investment Banking Agreement with Alpha Advisory Services, Inc. |
| 10.32 | Manufacturing and Distribution Agreement with E-Technologies, Inc. |
| 31.1 | Certification pursuant to 18 U.S.C. Section 1350, as enacted by Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2 | Certification pursuant to 18 U.S.C. Section 1350, as enacted by Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1 | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

(1) Incorporated by reference from Registration Statement on Form

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- SB-2, as filed on March 19, 1996.
- (2) Incorporated by reference from Amendment No. 1 to Registration Statement on Form SB-2, as filed on May 14, 1996.
 - (3) Incorporated by reference from Amendment No. 2 to Registration Statement on Form SB-2, as filed on June 13, 1996.
 - (4) Incorporated by reference from Annual Report on Form 10-KSB, as filed on April 16, 1998.
 - (5) Incorporated by reference from Report on Form 10-QSB, as filed on November 12, 1998.
 - (6) Incorporated by reference from Registration Statement on Form SB-2, as filed on April 29, 1999.
 - (7) Incorporated by reference from Report on Form 10-QSB, as filed on August 16, 2000.
 - (8) Incorporated by reference from Report on Form 10-QSB, as filed on November 1, 2000.
 - (9) Incorporated by reference from Report on Form 10-KSB, as filed on April 16, 2001.
 - (10) Incorporated by reference from Current Report on Form 8-K, as filed on March 5, 2002.
 - (11) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-3, as filed on March 20, 2002.
 - (12) Incorporated by reference from Report on Form 10-QSB, as filed on November 18, 2002.

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- (13) Incorporated by reference from Registration Statement on Form SB-2, as filed on July 7, 2003.
- (14) Incorporated by reference from Report on Form 10-QSB, as filed on November 14, 2003.
- (15) Incorporated by reference from Amendment No. 2 to Registration Statement on Form SB-2, as filed on December 15, 2003.
- (16) Incorporated by reference from Amendment No. 3 to Registration Statement on Form SB-2, as filed on February 27, 2004.
- (17) Incorporated by reference from Current Report on Form 8-K, as filed on March 23, 2004.
- (18) Incorporated by reference from Annual Report on Form 10-KSB, as filed on April 14, 2004.
- (19) Incorporated by reference from Report on Form 10-QSB, as filed on August 16, 2004.
- (20) Incorporated by reference from Amendment No. 6 to Registration Statement on Form SB-2, as filed on October 20, 2004.

(b) Reports on Form 8-K

No reports were filed by the Company during the quarter ended September 30, 2004.

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PARADIGM MEDICAL INDUSTRIES, INC.

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November 15, 2004

/s/John Y. Yoon

John Y. Yoon
President and Chief Executive Officer

November 15, 2004

/s/ Luis A. Mostacero

Luis A. Mostacero, Controller