

ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10QSB
May 13, 2005

U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-QSB

(MARK ONE)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2005

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 000-23-661 _____

ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Exact name of small business issuer as specified in its charter)

MICHIGAN

(State or other jurisdiction of
incorporation or organization)

38-3317208

(I.R.S. Employer Identification No.)

30142 WIXOM ROAD
WIXOM, MICHIGAN 48393

(Address of principal executive offices)

(248) 960-9009

(Issuer's telephone number)

(Former name, former address and former fiscal year, if changed since last report)

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

State the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date: 8,608,530 Common Shares outstanding as of April 30, 2005.

Transitional Small Business Disclosure Format (Check one):

Yes No

=====

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of March 31, 2005 and December 31, 2004

(Whole Dollars)

ASSETS

Cash and Cash Equivalents.....	\$
Restricted Cash Equivalents.....	
Accounts Receivable, net of a reserve of \$44,500 in 2005 and \$44,500 in 2004.....	
Inventory.....	
Other Current Assets.....	
Total Current Assets.....	
Property and Equipment, net.....	
Intangible Assets.....	
Goodwill.....	
Other Non-current Assets.....	
Total Assets.....	\$

LIABILITIES AND SHAREHOLDERS' EQUITY

Short Term Borrowings.....	\$
Notes Payable & Capitalized Lease Obligations.....	
Accounts Payable.....	
Customer Deposits.....	
Accrued Liabilities.....	
Total Current Liabilities	
Long Term Notes Payable & Capitalized Lease Obligations.....	
Shareholders' Equity:	
Common Share, no par value, 8,596,531 and 8,556,531 shares issued and outstanding.....	
Common Share Purchase Warrants, 3,761,071 and 3,761,071 shares issued and outstanding.....	
Accumulated Deficit.....	
Total Shareholders' Equity.....	
Total Liabilities And Shareholders' Equity.....	\$

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

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND MARCH 31, 2004

(WHOLE DOLLARS)
(Unaudited)

	THREE MONTHS ENDED MARCH 31, 2005 -----	THREE MONTHS ENDED MARCH 31, 2004 -----
SALES	\$5,619,508	\$4,307,844
Cost of Sales	4,950,092	3,612,884
	-----	-----
GROSS PROFIT	669,416	694,960
Selling, General and Administrative.....	647,659	570,411
	-----	-----
OPERATING INCOME	21,757	124,549
Other Income	137,468	-
Interest Expense, net	50,010	44,332
	-----	-----
NET INCOME	\$ 109,215	\$ 80,217
	=====	=====
BASIC EARNINGS PER SHARE	\$.01	\$.01
DILUTED EARNINGS PER SHARE	\$.01	\$.01

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

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED MARCH 31, 2005 AND MARCH 31, 2004

(WHOLE DOLLARS)
(Unaudited)

2005

CASH FLOWS FROM OPERATING ACTIVITIES:

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NET INCOME.....	\$ 109,215	\$
Adjustments To Reconcile Net Income To Net Cash Used For		
Operating Activities:		
Depreciation and Amortization.....	167,156	
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable.....	(194,528)	
(Increase) in Inventory.....	(997,503)	
(Increase) in Other Assets.....	(81,902)	
Increase in Accounts Payable.....	499,188	
Increase in Customer Deposits.....	1,214,328	
Increase (Decrease) in Other Liabilities.....	(53,903)	

Changes in Assets and Liabilities.....	385,680	

CASH PROVIDED BY OPERATING ACTIVITIES.....	662,051	
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of Equipment.....	(60,281)	

CASH (USED IN) INVESTING ACTIVITIES.....	(60,281)	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Borrowing on Line of Credit.....	4,648,395	
Payments on Line of Credit.....	(4,590,077)	
Payments on Notes Payable and Capital Lease Obligations.....	(63,553)	
Issuance of Common Shares.....	103,750	

CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES.....	98,515	
INCREASE IN CASH.....	700,285	
CASH AT BEGINNING OF PERIOD.....	166,195	

CASH AT END OF PERIOD.....	\$ 866,480	\$
	=====	==
Supplemental Cash Flow Disclosure:		
Interest Paid.....	\$ 50,057	\$
	=====	==
Non-Cash Investing and Financing Activity -		
Equipment Acquired Under Capital Lease Obligations.....	\$ 17,009	\$
	=====	==

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

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with kidneys that do not function properly. We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients' blood and replace nutrients during the kidney dialysis process. We primarily sell our products in the United States.

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We are regulated by the United States Food and Drug Administration (the "FDA") under the Federal Drug and Cosmetics Act, as well as by other Federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders. We also have 510(k) approval to sell our Dri-Sate (R) Dry Acid Concentrate product line and Dri-Sate(R) Dry Acid Mixing System.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

Our consolidated financial statements include our accounts and the accounts of our wholly owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated.

In the opinion of our management, all adjustments have been included which are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three month period ended March 31, 2005 are not necessarily indicative of the results to be expected for the year ending December 31, 2005. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2004 included in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004 includes a description of our significant accounting policies.

Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. In most instances title for goods shipped internationally transfers to the buyer once it leaves our facility and therefore, we recognize revenue upon shipment to foreign customers.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale. At March 31, 2005, we had customer deposits of \$1,225,333.

EARNINGS PER SHARE

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an

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antidilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

Three months ended

March 31,

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	----- 2005 -----	2004 -----
Basic Weighted Average Shares Outstanding	8,580,267	8,535,524
Effect of Dilutive Securities	749,785	801,956
	-----	-----
Diluted Weighted Average Shares Outstanding	9,330,052	9,337,480
	=====	=====

3. LINE OF CREDIT

On March 29, 2005, we entered into a new line of credit with a financial institution. The loan agreement provides for revolving borrowings by us of up to \$2,750,000. We are permitted to borrow up to 80% of eligible accounts receivable and 40% of eligible inventory up to \$600,000. Borrowings under the loan agreement are secured by accounts receivable, inventory and certain other assets. The annual interest rate payable on revolving borrowings under the loan agreement is the lender's prime rate plus 75 basis points. The lender's commitment to make revolving borrowings under the loan agreement expires on March 31, 2006. As of March 31, 2005 we had borrowed \$511,000 under this line of credit.

4. OTHER INCOME

We were the plaintiff in certain litigation that was settled in the first quarter of 2005. Since we have realized the full proceeds of the settlement, which totaled approximately \$241,000, we have recognized \$137,468 of other income from this settlement in the first quarter of 2005. A portion of the cash received was from the exercise of stock options by the defendant which totaled \$103,750.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the statements in this report are forward-looking statements. These forward-looking statements include statements relating to our performance in this Management's Discussion and Analysis of Financial Condition and Results of Operations. In addition, we may make forward-looking statements in future filings with the Securities and Exchange Commission and in written material, press releases and oral statements. Forward-looking statements include statements regarding the intent, belief or current expectations of us or our officers, including statements preceded by, followed by or including forward-looking terminology such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "projected," or similar expressions, with respect to various matters.

Our actual results might differ materially from those projected in the forward-looking statements depending on various important factors. These important factors include the cost of obtaining FDA approval to market our new iron supplemented dialysate product, the challenges associated with developing new products, the uncertainty of acceptance of our products by the hemodialysis community, competition in our market, and the other factors discussed under the caption "Risk Factors" in our Registration Statement on Form SB-2 (file no. 333-31991) effective January 26, 1998 and elsewhere in our public filings and in this report, all of which constitute cautionary statements identifying important factors with respect to the forward-looking statements, including risks and uncertainties, that could cause actual results to differ materially from those in the forward-looking statements.

All forward-looking statements in this report are based on

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information available to us on the date of this report. We do not undertake to update any forward-looking statements that may be made by us or on our behalf in this report or otherwise.

OVERVIEW

We operate in a single business segment: the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process. Our business has gained market share each year and our sales have grown each year since our inception in 1996. In 2004, our revenue grew 20% to \$17.9 million and we earned \$211,000. We increased our sales by over 30% for the first three months of 2005 compared to last year's first quarter. Our net earnings were \$109,215 in the first quarter of 2005 and we expanded our operations in the Southeastern United States by adding a third manufacturing facility in March of 2005.

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We believe that our core concentrate and supply business can continue to be profitable; however, the dialysis supply market is very competitive and we compete against companies with substantially greater resources than us. We expect to continue growing our business while executing our strategic plan to expand our product lines, expand our geographic reach and to develop our proprietary technology.

We are seeking to gain FDA approval for our iron supplemented dialysate product (which we also refer to as dialysate iron). We believe our iron supplemented dialysate product has the potential to compete in the iron maintenance therapy market. If we are successful in introducing our dialysate iron product, we believe it is possible that we may also increase our market share for the other products we sell. The cost to obtain regulatory approval for a drug in the United States is substantial and we expect that the development costs of our iron supplemented dialysate product will require us to raise additional funds or collaborate with a strategic partner. These substantial costs include those expected to be incurred in order to conduct required clinical trials and to obtain marketing approval which costs may offset some or all of any profits generated from sales of our existing products during the approval process, and we may incur losses. We expect the approval process to take between two and three years and there is no assurance we will be successful.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2005

Our sales in the first quarter of 2005 were \$5,619,508 and increased by 30.4% over the first quarter of 2004. Sales of our dialysis concentrates represented 85% of our sales in the first quarter of 2005 and increased 40% over the first quarter of 2004. Sales of our ancillary products decreased by a net \$68,000 largely as a result of a reduction of blood tubing sales to a single customer which was partially offset by an increase in dialysis kit sales as a result of the purchase order described below.

We have continued to realize sales growth with national and regional dialysis chains throughout the eastern half of the United States over the last year. In February of 2005, we announced that we had signed multiple supply agreements with several dialysis chains and regional units of national chains in the Southeastern United States. The aggregate annual revenue from these dialysis chains is anticipated to be approximately \$2,500,000. We began to fulfill these supply agreements beginning in March of 2005 and expect to realize the full quarterly revenue impact during the second quarter of 2005. We also opened a third manufacturing facility in the month of March 2005 to support the business under these supply agreements in addition to our existing portfolio of business

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in the Southeastern United States.

We achieved accelerated growth in the Southeastern United States through the sale of our liquid acid concentrate product lines over the last six months. Overall, we experienced substantial unit growth in our liquid product lines with the aggregate gallons of liquid acid sold increasing by 70% from the first quarter of 2004. We achieved a faster and more profitable operational start-up by gaining a critical mass of customers in a short time frame by penetrating this region with our liquid products. We will attempt to convert many of these new liquid concentrate customers to our Dri-Sate Dry Acid Concentrate products.

We received a significant purchase order from a single distributor for dialysis products totaling \$6,500,000 and fulfilled approximately \$625,000 of this purchase order in the first quarter which is included in our sales results. We anticipate filling the majority of this purchase order during the second quarter of 2005. Similar purchase orders may or may not recur in the future.

Gross profit was \$669,416 in the first quarter of 2005 which represented a decrease of \$25,544 from the first quarter of 2004. Our overall gross profit margins in the first quarter of 2005 were 11.9% as compared to 16.1% in the first quarter of 2004. Most of the gross profit margin decrease resulted from higher distribution costs to develop business in the Southeastern United States. While we experienced a significant sales increase of 30.4% we made an investment in the geographic expansion of our business and added a third manufacturing facility that increased our costs of operation.

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We also increased our production staffing in our other facilities to prepare for anticipated growth in our production output. These costs combined with higher distribution costs reduced our gross profit in the first quarter.

Despite our higher sales volumes, our gross profit margins decreased largely due to high distribution and delivery costs for our products which more than offset productivity improvements from higher production volumes. Our total distribution and delivery costs have increased by approximately 3 percent of sales from the first quarter of 2004. This increase was attributable to two major factors. First, and most substantially, a majority of the new business we added in the last year was in geographic areas that were beyond the normal distribution range for our plants in Texas and Michigan with strong growth in the Southeast and along the eastern seaboard. We anticipate that having a facility in the Southeastern United States will enable us to realize improvements in distribution efficiencies and will mitigate the negative impact from supplying the Southeastern United States from our other facilities. Second, delivery cost to all of our customers has risen significantly due to increased fuel costs. Fuel cost increases since the first quarter of 2004 have reduced our gross profit margins by 1.2 percent of sales as compared to the first quarter of 2004.

Selling, general and administrative expense as a percent of sales in the first quarter of 2005 decreased to 11.5% of sales from 13.2% of sales in the first quarter of 2004 or an improvement of 1.7% of sales. Our selling, general and administrative expenses increased \$77,000, or 13.5%, compared to the first quarter of 2004. The majority of the cost increase was due to additional resources and internal infrastructure added to handle increased transaction activity associated with our 40% increase in concentrate sales. Dialysate iron development expenses represented about 25% of the increase in selling, general and administrative costs. Overall, dialysate iron expenses totaled \$50,000 in the first quarter of 2005 compared to \$32,000 in the first quarter of 2004.

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Operating Income in the first quarter of 2005 was \$21,757 which was a reduction in profitability of \$102,792 compared to the first quarter of 2004. Operating income to sales decreased by 2.5 percentage points which is roughly equivalent to the increase in distribution costs as a percent of sales. We anticipate that as a result of our addition of a facility in the Southeast in March, that our second quarter distribution costs for our concentrate business should decrease by 1 to 2 percent to sales.

We were the plaintiff in certain litigation that was settled in the first quarter of 2005. Since we have realized the full proceeds of the settlement, which totaled approximately \$241,000, we have recognized \$137,468 of other income from this settlement in the first quarter of 2005. A portion of the cash received was from the exercise of stock options by the defendant which totaled \$103,750.

Interest expense for the first quarter of 2005 was \$50,010 and increased \$5,678 over the first quarter of last year.

Earnings after tax for the first quarter of 2005 was \$109,215 or 1.9 % of sales, which was \$ 29,000 or 36% higher than the first quarter of 2004. Earnings per share of \$.01 was the same as the first quarter of 2004. Fully diluted earnings per share was \$.01 in both periods.

LIQUIDITY AND CAPITAL RESOURCES

Our strategy is to expand our operations to serve dialysis providers throughout the United States. We anticipate that, as a result of our existing supply agreements, our customer relationships and our changing market dynamics, we have the opportunity to capture substantial market share that will lead to sustaining and increasing our profitable operations. We expect that we will continue to realize substantial growth during 2005 and that we will require additional working capital and capital expenditures to fund this growth. In addition, over the next several years, we expect to make substantial investments in our dialysate iron product in order to gain FDA approval to market dialysate iron.

In 2004, we generated cash from our business operations and reinvested those funds into the development and expansion of our business. Cash flow generated from our business operations aggregated \$840,000 in 2004 after adjusting our earnings for non-cash charges against earnings for depreciation and amortization. We realized substantial growth of over 40% in our core concentrate business in the first quarter of 2005. Based on current and prospective developments that we anticipate in our business in 2005, we will require additional working capital and capital

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expenditures to support our development plans. Positive cash flow from operations is anticipated to provide a portion of the funding that we anticipate we may need to support future growth.

In addition to funding provided by operations, we intend to raise additional capital. We continue to engage in discussions with various potential financing sources including potential lenders, strategic partners and investors.

In addressing our need for additional working capital, we obtained a new line of credit with a financial institution which expands our borrowing capacity. This credit line has a \$2.75 million credit limit. We are permitted to borrow up to 80% of our eligible accounts receivable and 40% of eligible inventory up to \$600,000. As of March 31, 2005 we had borrowed \$511,000 under

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this credit line.

We reached a financial settlement in a legal action we brought against the defendant. As a result, we realized gross cash proceeds in the first half of 2005 of approximately \$241,000.

We are seeking FDA approval for our dialysate iron drug product. The development and approval of drugs can be expensive and take a long time. The development and approval costs may offset some or all of our earnings during the approval process. We estimate the cash required to fund approval of our new iron supplemented dialysate product will be between \$5,000,000 - \$7,000,000 over the next several years. We may raise these funds ourselves or if we do not raise the capital to fund this project ourselves, we may decide to seek a partner with greater technical and financial resources to facilitate FDA approval of this product.

We plan to raise the capital required to expand our operations and fund our new product development strategy through a combination of cash flow from operations, debt or equity financing arrangements and/or licensing arrangements; however we may not be successful.

If we are not successful in raising additional funds, we may be required to alter our growth strategy, defer spending on business development, curtail production expansion plans or take other measures to conserve our cash resources.

In addition, the dialysis provider market that we serve is becoming increasingly concentrated. As a result, our business is predominantly with national and regional dialysis chains. If we were to lose a significant portion of our business with major national and regional dialysis chains, it could have a substantial negative impact on our cash flow and operating results. If we were to lose a substantial portion of our business, it may have a detrimental impact on our ability to continue our operations in their current form or to continue to execute our business strategy. If we lost a substantial portion of our business, we would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

ITEM 3. CONTROLS AND PROCEDURES

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of March 31, 2005. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of March 31, 2005 in ensuring that information required to be disclosed by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the Exchange Act rules and forms. There was no change in our internal control over financial reporting

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identified in connection with such evaluation that occurred during our fiscal quarter ended March 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and

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procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We were the plaintiff in certain litigation that was settled in the first quarter of 2005. We received gross proceeds from this settlement of approximately \$241,000. We received cash of \$130,000 during the first quarter of 2005 and \$111,000 in the second quarter of 2005. A portion of the cash received was from the exercise of stock options by the defendant during the first quarter of 2005 which totaled \$103,750. The balance of the settlement was paid May 4, 2005. As we have realized the full proceeds of the settlement, the Company has recognized \$137,000 of income from this settlement in the first quarter of 2005.

ITEM 6. EXHIBITS

- 31.1 Certifications of Chief Executive Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certifications of the Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications of the Chief Executive Officer and Chief Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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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.

ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Registrant)

Date: May 12, 2005

/s/ ROBERT L. CHIOINI

Robert L. Chioini
President, Chief Executive
Officer and Director (Principal
Executive Officer)

Date: May 12, 2005

/s/ THOMAS E. KLEMA

Thomas E. Klema
Vice President of Finance, Chief
Financial Officer, Treasurer and
Secretary (Principal Financial

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Officer and Principal Accounting
Officer)

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10-QSB EXHIBIT INDEX

EXHIBIT NO. -----	DESCRIPTION -----
EX-31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EX-31.2	Certification of the Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
EX-32.1	Certifications of the Chief Executive Officer and Chief Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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