

ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10QSB
May 17, 2004

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, 2004

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

38-3317208

(State or other jurisdiction of
incorporation or organization)

(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: 8,543,772 Common Shares outstanding and 3,761,071 Common Share Purchase Warrants outstanding as of May 1, 2004.

Transitional Small Business Disclosure Format (Check one):
Yes No

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

AS OF MARCH 31, 2004 AND DECEMBER 31, 2003

(Whole Dollars)

	MARCH 31, 2004

ASSETS	
Cash and Cash Equivalents	\$ 368,563
Restricted Cash and Cash Equivalents	8,662
Accounts Receivable, net of a reserve of \$34,500 in 2004 and \$34,500 in 2003 ..	2,133,905
Inventory	1,611,053
Other Current Assets	147,472

Total Current Assets	4,269,655
Property and Equipment, net	2,152,270
Intangible Assets	307,952
Goodwill	920,745
Other Non-current Assets	125,558

Total Assets	\$ 7,776,180
	=====
LIABILITIES AND SHAREHOLDERS' EQUITY	
Short Term Borrowings	\$ 482,114
Notes Payable & Capitalized Lease Obligations	327,854
Accounts Payable	2,236,559
Accrued Liabilities	441,222

Total Current Liabilities	3,487,749
Long Term Notes Payable & Capitalized Lease Obligations	1,013,949
Shareholders' Equity:	
Common Share, no par value, 8,543,772 and 8,519,405 shares issued and outstanding	11,854,377
Common Share Purchase Warrants, 3,761,071 and 3,766,071 shares issued and outstanding	320,150
Accumulated Deficit	(8,900,045)

Total Shareholders' Equity	3,274,482

Total Liabilities And Shareholders' Equity	\$ 7,776,180
	=====

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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, 2004 AND MARCH 31, 2003

(WHOLE DOLLARS)
(Unaudited)

	THREE MONTHS ENDED MARCH 31, 2004	THREE MONTHS ENDED MARCH 31, 2003
	-----	-----
SALES	\$ 4,307,844	\$ 3,434,737
Cost of Sales	3,612,884	2,961,937
	-----	-----
GROSS PROFIT	694,960	472,800
Selling, General and Administrative	570,411	520,235
	-----	-----
OPERATING INCOME (LOSS)	124,549	(47,435)
Interest Expense, net	44,332	39,358
	-----	-----
NET INCOME (LOSS)	\$ 80,217	\$ (86,793)
	=====	=====
BASIC & DILUTED EARNINGS (LOSS) 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, 2004 AND MARCH 31, 2003

(WHOLE DOLLARS)
(Unaudited)

	2004	2003
	-----	-----
CASH FLOWS FROM OPERATING ACTIVITIES:		
NET INCOME (LOSS)	\$ 80,217	\$ (86,793)
Adjustments To Reconcile Net Income (Loss) To Net Cash Used For Operating Activities:		

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Depreciation and Amortization	145,316	104,996
Compensation Recognized for Stock Options & Warrants	-0-	26,250
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	35,659	(100,302)
(Increase) in Inventory	(260,762)	(54,718)
Decrease (Increase) in Other Assets	(41,592)	13,955
Increase in Accounts Payable	569,607	15,906
Increase (Decrease) in Other Liabilities	111,703	(16,898)
	-----	-----
Changes in Assets and Liabilities	414,615	(142,057)
	-----	-----
CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	640,148	(97,604)
CASH FLOWS FROM INVESTING ACTIVITIES:		
(Increase) in Restricted Cash Equivalents	-	(1,140)
Purchase of Equipment	(162,443)	(31,312)
	-----	-----
CASH (USED IN) INVESTING ACTIVITIES	(162,443)	(32,452)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Borrowing on Line of Credit	4,038,968	3,482,907
Payments on Line of Credit	(4,198,872)	(3,234,415)
Payments on Notes Payable and Capital Lease Obligations.....	(78,034)	(68,105)
Issuance of Common Shares	22,157	---
	-----	-----
CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(215,781)	180,387
INCREASE IN CASH	261,924	50,331
CASH AT BEGINNING OF PERIOD	106,639	133
	-----	-----
CASH AT END OF PERIOD	\$ 368,563	\$ 50,464
	=====	=====
Supplemental Cash Flow Disclosure:		
Interest Paid	\$ 44,378	\$ 39,409
	=====	=====
Non-Cash Investing and Financing Activity -		
Equipment Acquired Under Capital Lease Obligations	\$ 185,648	\$- 0-
	=====	=====

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

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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 lost 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 Dry Acid Concentrate product line and Dri-Sate Mixer.

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, 2004 are not necessarily indicative of the results to be expected for the year ending December 31, 2004. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2003 included in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 includes a description of our significant accounting policies.

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

	Three months ended March 31,	
	2004	2003
Weighted Average Shares Outstanding	8,535,524	8,488,283
Effect of Dilutive Securities	801,956	-
Diluted Shares Outstanding	9,337,480	8,488,283

3. LINE OF CREDIT

As of March 28, 2003, we renewed and expanded our credit facility under a \$2,500,000 revolving line of credit facility with a financial institution. The two year loan facility is secured by our accounts receivable and other assets. We are obligated to pay interest at the rate of two percentage points over the prime rate, plus other fees aggregating .25% of the loan balance. As of March 31, 2004, our outstanding borrowings under this loan facility were \$482,114.

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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 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 since our inception in 1996. Our sales have grown each year since we started. We incurred losses each year since we started until 2003 when the volume of our sales exceeded the cost of operating our business. We increased our sales by over 30% in 2003, allowing us to more fully utilize our facilities, equipment and staff, and causing our gross profit margins to increase. Those trends continued in the first quarter of 2004.

We believe that our core concentrate and supply business can continue to be profitable. The dialysis supply market is very competitive and we compete against companies with substantially greater resources than us. We expect to continue to grow our business while executing our strategic plan to expand our product lines, to 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 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 expensive 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. We expect to incur substantial costs to

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conduct required clinical trials and to obtain marketing approval which may offset some or all of any profits generated from sales of our existing

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products during the approval process. We expect this process to take between one and three years and we might not be successful.

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2004

Our sales in the first quarter of 2004 were \$4,307,844. Sales increased \$873,107 or 25.4% over our sales in the first quarter of 2003. Sales of our dialysis concentrates, which make up the majority of our sales, increased by 30% over the first quarter last year. We also realized sales increases in our ancillary product lines which increased 13% in total.

Our dialysis concentrate sales increase was led by the development of new business primarily for our Dri-Sate Dry Acid concentrate product line which utilizes our patented Dri-Sate Dry Acid Mixing System. Dri-Sate Dry Acid unit volumes increased by 32% over the first quarter of 2003. Similarly, sales of our bicarbonate product lines grew by 33% over the first quarter of 2003 due to unit volume growth.

Gross profit increased to \$694,960 in the first quarter of 2004 with gross profit margins increasing to 16.1% which was 2.4 percentage points higher than our gross profit margins in the first quarter of 2003. Gross profit increased by 47% or \$222,160 as compared to the first quarter of 2003. Higher gross profit and improved gross profit margins were primarily due to increased sales volumes. Higher sales translated into higher plant production volumes which lowered manufacturing costs per unit. However, increases in the global cost of oil translated into higher delivery costs and increased material costs for our products. Improvement in our margins was reduced as a result of increased costs for oil. We expect higher oil prices to continue to have an impact on our gross profit margins.

Selling, general and administrative expense as a percent of sales in the first quarter of 2004 decreased by 1.9 percentage points to 13.2% of sales from 15.1% of sales in the first quarter of 2003. Our selling, general and administrative expenses increased \$50,176 or 9.6% compared to the first quarter of 2003. We realized increases in personnel costs to handle increased transaction activity coupled with higher operating expenses including higher legal costs for securities law compliance and higher insurance costs. Our expenditures for product development of our dialysate iron product were at the same level as last year.

We are developing a drug product, dialysate iron, to provide iron supplements for the treatment of anemic dialysis patients. This drug product will be delivered to patients via our regular dialysis concentrate products. The cost of developing this drug product is expected to be substantial. We may fund the cost of product development ourselves or we may collaborate with a strategic partner or other third party in the development of this product. Future expenditures on product development will increase substantially once we commence Phase III clinical trials for dialysate iron. If we fund and incur the cost of product development ourselves, these future expenditures are likely to offset all of our income and we may incur losses during the duration of the product development phase for dialysate iron which may take between one and three years.

Our interest expense was \$44,378 in the first quarter of 2004 and increased by \$4,969 over the first quarter of 2003. The increase in interest expense was due to interest expense on assets under new capital leases offset by lower credit line borrowing costs.

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Our net income of \$80,217 was \$167,010 higher than the first quarter 2003 loss of (\$86,793). Our earnings per share was \$.01 in the first quarter of 2004. Our earnings per share improved \$.02 over the first quarter of 2003 where we reported a loss of \$ (.01) per share. The improvement in earnings per share was due to improved operating results due to higher sales volumes.

LIQUIDITY AND CAPITAL RESOURCES

We have utilized cash since we started business, and expect that we will require additional cash to fund our business development and operating requirements. We have substantially grown our business and have reduced our operating cash requirements. Until 2003, we had incurred operating losses each year since inception. We had a net profit of \$4,853 for

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2003 as a whole and we reported a net profit of \$185,000 in the second half or 2003. We reported a net profit of \$80,217 in the first quarter of 2004. In the first quarter of 2004, our cash balance increased by \$261,924. In 2003, we required cash to fund our development and operating activities including capital expenditures and working capital which was primarily provided by increasing the borrowings under our line of credit and through capital lease arrangements for equipment. In 2004, we anticipate that we will increase the borrowings under our line of credit and utilize lease arrangements to fund certain capital expenditures for manufacturing equipment and transportation equipment.

Our long term strategy is to expand our product line and operations to serve dialysis providers. We anticipate that, as a result of our existing supply agreements and our customer relationships, we have the capability to capture substantial market share that will lead to sustaining profitable operations. We expect that we will continue to realize substantial growth during 2004 and that we will require additional working capital and capital expenditures to fund this growth.

We renewed our line of credit with GE Healthcare Finance as of March 28, 2003 under a two year agreement. Under the new loan agreement, there is a \$2.5 million credit limit. We are permitted to borrow up to 80% of our eligible accounts receivable, and we are required to maintain a net worth of at least \$750,000. We anticipate that this credit line will be sufficient to fund much of our working capital requirements for our concentrate business operations in 2004. Borrowings under this line were \$482,114 at March 31, 2004.

In order for us to fund our working capital and capital expenditure requirements and to continue to execute our new product development strategy, we will require additional financing. We estimate the cost to fund development of our new iron supplemented dialysate product will be between \$3,000,000 - \$4,000,000 over the next one to two years. We believe that we will be able to raise the capital required to expand our operations and fund our new product development strategy through either debt or equity financing arrangements. We have identified possible sources of financing, and we are currently in negotiations with potential strategic partners, investors and lenders; however, we might not be successful in raising additional funds. If we are not successful in raising additional funds, we may be required to alter our growth strategy, defer spending on product development, curtail production expansion plans or take other measures to conserve our cash resources.

While we have raised our sales level each year and have customer commitments for additional business we might not be able to continue to increase our sales levels and market share and to sustain profitable operations. There can be no assurance that we will have or be able to raise sufficient funds to carry out

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our business plans and continue a profitable level of operations. These factors, among others, raise doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount or classification of liabilities that might be necessary should we be unable to continue as a going concern.

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, 2004. 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, 2004 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 identified in connection with such evaluation that occurred during our fiscal quarter ended March 31, 2004 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 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 filed a civil action on September 20, 2000 in the Circuit Court of Wayne County Michigan against Mr. Gary D. Lewis, individually and Wall Street Partners, Inc., a Michigan corporation, jointly and severally. We filed a breach of contract suit against Wall Street Partners, Inc. for breach of contract pertaining to consulting services provided us by Wall Street Partners, Inc and breach of duty claim against Mr. Gary D. Lewis. Also named in the suit was Mr. Gary D. Lewis, the principal of the consulting firm. Mr. Lewis is our former Chairman, a former director and in 2001 was the beneficial owner of more than 5% of our common shares. We requested recovery of amounts paid to Wall Street Partners, Inc. and Mr. Lewis.

On November 21, 2001 a jury found in our favor and awarded us \$350,000 plus interest. On December 13, 2001, an official judgment in the amount of \$175,000 with interest was entered for us against Mr. Lewis personally and a judgment in the amount of \$175,000 with interest was entered for us against Wall Street Partners. A motion by Mr. Lewis for re-trial was denied February 15, 2002. Mr. Lewis subsequently filed an appeal to the judgment.

The Michigan Court of Appeals rendered a decision with respect to defendant's appeal and remanded for retrial. The Appeals court concluded that the trial court erred with regard to the breach of duty claim against the

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defendant by failing to give the jury any instruction on ratification in response to a request for such instruction. We expect to retry the suit against Mr. Lewis. The Appeals court affirmed the breach of contract claim against Wall Street Partners, Inc. and therefore, the judgment against Wall Street Partners, Inc. was affirmed. The Defendant has sought a rehearing in the Michigan Court of Appeals and the motion for rehearing is pending.

ITEM 2. CHANGES IN SECURITIES

During the first quarter of 2004, we issued 5,000 Common Shares pursuant to an election to exercise a Common Share Purchase Warrant which was acquired by an investor during 2002 as part of a private placement of our Common Shares and such Common Share Purchase Warrants. The offer and sale of the above Common Shares upon exercise of the Common Share Purchase Warrants were exempt from the registration requirements of the Securities Act of 1933 (the "Act") under Section 4(2) of the Act and under Regulation D under the Act. The issuance of such Common Shares was limited to a person qualifying as an "Accredited Investor" within the meaning of Regulation D under the Act and was an isolated transaction. We relied on representations made in writing by the investor to determine our exemption. We received \$3,700 in gross proceeds in a single transaction as a result of the exercise of the Common Share Purchase Warrants. The Investor exercising these warrants received unregistered Common Shares.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

- 10.21 Supply Agreement between the Company and DaVita, Inc. dated May 5, 2004 with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.
- 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.

(b) Reports on Form 8-K.

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No reports on Form 8-K were filed by us during the quarter for which this report is filed. We furnished a Current Report on Form 8-K on March 2, 2004, reporting under Item 9 and Item 12 the information required by Item 12 - Results of Operations and Financial Condition in connection with our press release regarding fourth quarter 2003 results. No financial statements were filed, although we furnished the financial information included in the press release furnished with the Form 8-K Current Report.

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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 17, 2004

/s/ ROBERT L. CHIOINI

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

Date: May 17, 2004

/s/ THOMAS E. KLEMA

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

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10-QSB EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
EX-10.21	Supply Agreement between the Company and DaVita, Inc. dated May 5, 2004 with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.
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.