

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

November 08, 2007

**Table of Contents**

**United States  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-Q**

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
**For the quarterly period ended September 30, 2007**

or

**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 000-23661  
ROCKWELL MEDICAL TECHNOLOGIES, INC.**

(Exact name of registrant 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)

(Zip Code)

(248) 960-9009

(Registrant's telephone number, including area code)  
(Former name, former address and former fiscal year,  
if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

**APPLICABLE ONLY TO CORPORATE ISSUERS:**

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class

Outstanding as of October 31, 2007

Common Stock, no par value

11,634,749 shares



**Rockwell Medical Technologies, Inc.**  
**Index to Form 10-Q**

	Page
<u>Part I - Financial Information (unaudited)</u>	
<u>Item 1 - Financial Statements (unaudited)</u>	
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Statements of Income</u>	4
<u>Consolidated Statements of Cash Flows</u>	5
<u>Notes to Consolidated Financial Statements</u>	6
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	13
<u>Item 4 - Controls and Procedures</u>	13
<u>Part II - Other Information</u>	
<u>Item 6 - Exhibits</u>	14
<u>Signatures</u>	15
<u>Exhibit Index</u>	16
<u>Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)</u>	
<u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)</u>	
<u>Certification pursuant to Section 1350</u>	

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements**

**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS  
As of September 30, 2007 and December 31, 2006**

	<b>SEPTEMBER 30, 2007 (Unaudited)</b>	<b>DECEMBER 31, 2006</b>
<b>ASSETS</b>		
Cash and Cash Equivalents	\$	\$ 2,662,873
Accounts Receivable, net of a reserve of \$105,930 in 2007 and \$72,500 in 2006	4,918,464	3,474,402
Inventory	2,793,993	2,660,098
Other Current Assets	317,716	261,473
Total Current Assets	8,030,173	9,058,846
Property and Equipment, net	2,841,601	2,587,771
Intangible Assets	428,930	457,846
Goodwill	920,745	920,745
Other Non-current Assets	125,667	127,625
Total Assets	\$ 12,347,116	\$ 13,152,833
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Short Term Borrowings	\$ 1,800,000	\$
Notes Payable & Capitalized Lease Obligations	232,984	369,551
Accounts Payable	2,971,652	2,920,258
Accrued Liabilities	851,856	1,114,592
Customer Deposits	45,729	48,274
Total Current Liabilities	5,902,221	4,452,675
Long Term Notes Payable & Capitalized Lease Obligations	240,734	326,045
Shareholders Equity:		
Common Shares, no par value, 11,634,749 and 11,500,349 shares issued and outstanding	23,533,808	23,147,709
Accumulated Deficit	(17,329,647)	(14,773,596)
Total Shareholders Equity	6,204,161	8,374,113
Total Liabilities And Shareholders Equity	\$ 12,347,116	\$ 13,152,833

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

Table of Contents

**Rockwell Medical Technologies, Inc. and Subsidiary**  
**Consolidated Income Statements**  
**For the three and nine months ended September 30, 2007 and September 30, 2006**  
**(Whole dollars)**  
**(Unaudited)**

	<b>Three Months Ended Sept. 30, 2007</b>	<b>Three Months Ended Sept. 30, 2006</b>	<b>Nine Months Ended Sept. 30, 2007</b>	<b>Nine Months Ended Sept. 30, 2006</b>
<b>Sales</b>	<b>\$ 11,073,774</b>	<b>\$ 7,379,201</b>	<b>\$ 31,096,399</b>	<b>\$ 19,410,357</b>
Cost of Sales	9,953,863	6,785,796	28,942,171	17,568,497
<b>Gross Profit</b>	<b>1,119,911</b>	<b>593,405</b>	<b>2,154,228</b>	<b>1,841,860</b>
Selling, General and Administrative	765,457	592,767	2,288,903	1,912,544
Research and Product Development	735,393	1,621,821	2,319,452	3,381,643
<b>Operating (Loss)</b>	<b>(380,939)</b>	<b>(1,621,183)</b>	<b>(2,454,127)</b>	<b>(3,452,327)</b>
Interest Expense (Income), net	51,973	486	101,924	(32,383)
<b>Net (Loss)</b>	<b>(\$432,912)</b>	<b>(\$1,621,669)</b>	<b>(\$2,556,051)</b>	<b>(\$3,419,944)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>(\$.04)</b>	<b>(\$.14)</b>	<b>(\$.22)</b>	<b>(\$.31)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>(\$.04)</b>	<b>(\$.14)</b>	<b>(\$.22)</b>	<b>(\$.31)</b>

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

**Table of Contents**

**Rockwell Medical Technologies, Inc. and Subsidiary**  
**Consolidated Statements of Cash Flows**  
**For the nine months ended September 30, 2007 and September 30, 2006**  
(Unaudited)

	<b>2007</b>	<b>2006</b>
<b>Cash Flows From Operating Activities:</b>		
<b>Net (Loss)</b>	<b>(\$2,556,051)</b>	<b>(\$3,419,944)</b>
Adjustments to Reconcile Net (Loss) to Net Cash Used for Operating Activities:		
Depreciation and Amortization	601,362	542,480
Loss on Disposal of Equipment		653
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(1,444,062)	87,245
(Increase) in Inventory	(133,895)	(495,316)
(Increase) in Other Assets	(54,285)	(59,408)
Increase in Accounts Payable	51,394	629,688
Increase (Decrease) in Customer Deposits	(2,545)	353,124
(Decrease) in Accrued Liabilities	(262,736)	(42,008)
Changes in Assets and Liabilities	(1,846,129)	473,325
<b>Cash (Used In) Operating Activities</b>	<b>(3,800,818)</b>	<b>(2,403,486)</b>
<b>Cash Flows from Investing Activities:</b>		
Purchase of Equipment	(766,314)	(522,937)
Purchase of Intangible Assets	(6,286)	(104,115)
<b>Cash (Used In) Investing Activities</b>	<b>(772,600)</b>	<b>(627,052)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from Borrowing on Line of Credit	1,800,000	
Payments on Line of Credit		(1,800,000)
Payments on Notes Payable and Capital Lease Obligations	(275,554)	(442,836)
Issuance of Common Shares	386,099	9,008,859
<b>Cash Provided By Financing Activities</b>	<b>1,910,545</b>	<b>6,766,023</b>
<b>Increase (Decrease) In Cash</b>	<b>(2,662,873)</b>	<b>3,735,485</b>
<b>Cash At Beginning Of Period</b>	<b>2,662,873</b>	<b>299,031</b>
<b>Cash At End Of Period</b>	<b>\$ -0-</b>	<b>\$ 4,034,516</b>
Supplemental Cash Flow Disclosure:		
Interest Paid	\$ 108,159	\$ 102,304



Non-Cash Investing and Financing Activity	Equipment Acquired Under			
Capital Lease Obligations		\$	53,676	\$ 45,940

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

5

---

**Table of Contents**

**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 End Stage Renal Disease, or ESRD. 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.

We are regulated by the Federal Food and Drug Administration, 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 our 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. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or GAAP, and with the instructions to Form 10-Q and Rule 10-01 of Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2006 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

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 and nine month periods ended September 30, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2006 included in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006. Our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2006 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. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We require certain customers, mostly international customers, to pay for our products 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 September 30, 2007 and December 31, 2006 we had customer deposits of \$45,729 and \$48,274, respectively.

**Table of Contents**

In the quarter ended March 31, 2006, we reached a settlement with a customer related to its breach of several purchase contracts. Under the terms of the settlement, we were paid \$755,000 in exchange for release of the customer's future obligations under these contracts. All of this settlement was recognized as a component of revenue in 2006.

**Research and Product Development**

We recognize research and product development costs as expenses are incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including iron supplemented dialysate, aggregating approximately \$2,319,452 and \$3,381,643 in the first nine months of 2007 and 2006, respectively.

During 2006, we entered into a number of research and development related contracts for safety, pharmacology and toxicology testing of our iron dialysate drug product under which we made commitments to spend \$3.4 million. Services under the contracts were to be performed over periods ranging from 3 to 15 months. We recognized the cost of these contracts as research and development expense over the periods in which the testing was performed and on a basis reflective of the level of activity under those contracts in each period. During 2006, we expensed approximately \$2.9 million under these contracts. In the first nine months of 2007, we expensed \$.5 million, which constituted the remainder of the costs under these contracts.

**Earnings Per Share**

We computed our basic earnings 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 anti-dilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	Three months ended Sept. 30,		Nine months ended Sept. 30,	
	2007	2006	2007	2006
Basic Weighted Average Shares Outstanding	11,619,117	11,463,210	11,545,725	11,090,338
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	11,619,117	11,463,210	11,545,725	11,090,338

**3. Inventories**

Components of inventory as of September 30, 2007 and December 31, 2006 are as follows:

	September 30, 2007	December 31, 2006
Raw Materials	\$ 913,595	\$ 717,876
Finished Goods	1,880,398	1,942,222
Total Inventory	\$ 2,793,993	\$ 2,660,098

**4. Line of Credit**

On March 23, 2007, we renewed our 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 our eligible accounts receivable and up to 40% of our 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 credit agreement contains a covenant which limits our ability to incur other indebtedness and a financial covenant requiring a minimum level of tangible net worth.



**Table of Contents**

The lender's commitment to make revolving borrowings under the loan agreement expires on April 1, 2008. As of September 30, 2007, we had outstanding borrowings of \$1,800,000 under this line of credit.

**5. Long-Term Incentive Plan**

On May 24, 2007, the shareholders approved the adoption of a long term incentive plan (LTIP). The Company has reserved an aggregate of 1,000,000 Common Shares that can be awarded under the LTIP. The Compensation Committee may grant stock options, restricted stock, restricted stock units and performance based cash or stock based awards under the LTIP. No equity grants had been issued under the plan as of September 30, 2007.

The Company's 1997 Stock Option Plan terminated as to future grants on May 24, 2007. Immediately prior to termination of future grants, 489,856 shares were available for grant. No stock options were granted under the 1997 Stock Option Plan during 2007.

**6. Recent Accounting Pronouncements**

In June 2006, the Financial Accounting Standards Board issued Financial Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48, which is an interpretation of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes, provides guidance on the manner in which tax positions taken or to be taken on tax returns should be reflected in an entity's financial statements prior to their resolution with taxing authorities. The adoption of the provisions of this pronouncement did not have a material impact on our financial position or results of operations.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Forward Looking Statements**

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. The discussion that follows contains certain forward-looking statements relating to our anticipated future financial condition, operating results, cash flows and our current business plans. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, forecast, projected, intend or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements.

These forward-looking statements represent our outlook only as of the date of this report. We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report and from time to time in our other reports filed with the Securities and Exchange Commission, including under Item 1 Description of Business Risk Factors and Forward Looking Statements in our Form 10-KSB for the year ended December 31, 2006 and the following:

The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue.

We operate in a very competitive market against substantially larger competitors with greater resources.

**Table of Contents**

Orders from our international distributors may not result in recurring revenue.

Our new drug product requires FDA approval and expensive clinical trials before it can be marketed.

Even if our new drug product is approved by the FDA it may not be successfully marketed, and may not be eligible for Medicare reimbursement.

We depend on government funding of healthcare.

We may not have sufficient cash to operate the business.

The market price of our securities may be volatile.

We may not be successful in improving our gross profit margins and our business may not achieve an acceptable level of profitability.

Our suppliers may increase their prices faster than we are able to raise our prices to offset such increases. We may have limited ability to gain a raw material pricing advantage by changing vendors for certain raw materials.

We depend on key personnel.

Our business is highly regulated.

Foreign approvals to market our new drug products may be difficult to obtain.

Health care reform could adversely affect our business.

We may not have sufficient products liability insurance.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows and financial position. There can be no assurance that future results will meet expectations. While we believe that the forward-looking statements in this report are reasonable, the reader should not place undue reliance on any forward-looking statement. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as may be required by applicable law.

**Overview and Recent Developments**

We operate in a single business segment, the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the kidney dialysis process. We have gained domestic market share each year since our inception in 1996. Our aggregate sales in the first nine months of 2007 increased 60% compared to the nine months ended September 30, 2006. Our strategy is to continue to develop and expand our dialysis products business while at the same time developing new products including pharmaceutical products for this market.

Our strategy is also to expand the geographic footprint of our business in North America. We realized a unique business opportunity to do so in the last quarter of 2006 and the first quarter of 2007 due to the exit of one of our competitors, Gambro, from the market. Concurrent with Gambro's withdrawal from the concentrate business, we began to service many of the chain and independent clinics serviced by Gambro, including many clinics owned by DaVita, Inc., the second largest U.S. dialysis provider. During the first nine months of 2007, the number of clinics we service increased by over 50%.

**Table of Contents**

We intend to continue to increase the size of our customer portfolio in order to expand our production and distribution operations into regions where we previously had business but no production facility. We believe this strategic initiative will ultimately lead to efficiencies and economies of scale, and will position the Company for an adequate and sustainable return on investment. We anticipate that we will continue to gain domestic market share.

As a result of the dramatic increase in sales volume and the increased geographic diversity of the clinics we serve, we took actions during the first quarter of 2007 to ensure adequacy of product supply and uninterrupted order fulfillment for the new business we added. Our main initiative in this regard was to relocate one of our production facilities in a region where the additional business we acquired had outstripped our ability to properly supply, distribute and service the business. As a result of this relocation, we incurred costs aggregating approximately \$500,000 for physical relocation, extra labor, plant start-up expenses, distribution start-up expenses, inventory write-offs and dual facility operating costs during the start-up period. Although these costs are not expected to recur at this location, we expect to incur similar types of costs in other regions as we continue to adjust our production and distribution facilities to meet new or changing demand.

We are in the process of raising our average selling prices in 2007 in part to offset these additional costs and the higher costs of raw materials and fuel. In the second quarter of 2007, we implemented price increases with an overall weighted average annual impact on gross profit margins of approximately 6%. Price increases on other maturing contracts have been and are expected to be renewed at higher-than-current rates throughout the remainder of 2007 and in 2008. If we are successful in implementing these increases, our gross profit margins may continue to improve and increase the profitability of our core business operations with our gross profit exceeding our selling, general and administrative expenses in those quarters. However, we could experience changes in our customer and product mix in future quarters that could negatively impact gross profit. Since we sell a wide range of products with varying profit margins and to customers with varying order patterns, our gross profit and our gross profit margins could vary period to period. As we add business in certain markets and regions in order to increase the scale of our business operations, we may incur additional costs that are greater than the additional revenue generated from these initiatives until we have achieved a scale of operations that is profitable.

Increased operating costs that are subject to inflation, such as fuel and material costs, may not be recoverable through price increases to our customers if our competitors do not also raise prices. If we are not able to recover cost increases, it could materially adversely affect our business, financial condition and results of operations. We generally enter into short and medium term contracts of one to two years for our major raw materials and we generally enter into customer contracts of similar duration to mitigate our exposure to raw material and other cost increases.

The dialysis supply market is very competitive and is characterized by having a few dialysis providers treating the majority of patients in the United States. We compete against companies which have substantially greater resources than we have. Our revenue is highly concentrated in a few customers and the loss of any of those customers would adversely affect our results. However, 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, which may include adding facilities and personnel to support our growth.

While the majority of our business is with domestic clinics who order routinely, certain major distributors of our products internationally have not ordered consistently, resulting in variation in our international sales from period to period. We anticipate that we will realize substantial orders from time to time from our largest international distributors but we expect the size and frequency of these orders to fluctuate from period to period. These orders may increase in future quarters or may not recur at all.

We are seeking to gain FDA approval for our iron supplemented dialysate product, soluble ferric pyrophosphate (SFP). We believe our SFP product, which has a unique method of action and other substantive benefits compared to current treatment options, has the potential to compete in the iron maintenance therapy market. The cost to obtain

## **Table of Contents**

regulatory approval for a drug in the United States is expensive and can take several years. We expect to devote substantial resources to this drug approval effort until it is completed.

### **Results of Operations for the Three and Nine Months Ended September 30, 2007 and September 30, 2006**

#### **Sales**

Sales in the third quarter of 2007 were \$11.1 million and were \$3.7 million or 50% higher than the third quarter of 2006. Our substantial revenue growth over the third quarter of 2006 was almost entirely due to domestic sales growth. Growth in our domestic business over the last year has been mainly due to the exit of Gambro from our market and the contraction of another competitor. Concurrent with Gambro's exit from the concentrate market, we began to service a significant portion of the DaVita clinics formerly serviced by Gambro and have gained a substantial amount of new business from other dialysis providers over the last year.

We realized substantial sales growth in our domestic business in 2007 primarily due to growth in national and regional chain accounts. Our domestic sales increased by 80.8% in the third quarter of 2007 compared to the third quarter of 2006. Approximately 75% of the domestic sales increase was due to increased unit volumes across our dialysis concentrate product lines, with the remainder attributable to higher prices.

Our sales to both foreign and domestic based international distributors of our products was approximately \$470,000 in the third quarter of 2007 or 4.3% of our total sales. These international sales decreased \$1.1 million in the third quarter of 2007 compared to the third quarter last year primarily due to approximately \$1.25 million in orders from major distributors for certain business in Latin America in the third quarter of 2006 that were not renewed in 2007. International orders to Latin America, which did not recur in the third quarter of 2007, represented approximately 16% of sales in the third quarter of 2006. Our other international business increased approximately 60% over the third quarter of 2006.

Sales of our dialysis concentrate product lines, which represented over 93% of our sales in the third quarter of 2007, increased approximately 47% in the third quarter of 2007 compared to the third quarter of 2006. The primary increase in sales was in our liquid and powder acid concentrate products, sales of which increased approximately 87% predominantly due to a 107% increase in liquid acid gallons sold.

Our sales in the first nine months of 2007 were \$31.1 million, an increase of \$11.7 million or 60.2% over the sales in the first nine months of 2006. This increase was largely due to the market share gains and domestic sales growth resulting from the exit of Gambro and the contraction of another competitor as discussed above, partially offset by the effect of a breach of contract settlement that increased sales by \$755,000 in the first quarter of 2006. Domestic sales in the first nine months of 2007 increased by 72% over the first nine months of 2006. Unit volume increases in our business accounted for the majority of the domestic sales increase in the first nine months of 2007 compared to the first nine months of 2006.

Sales to DaVita clinics represented approximately 74% of the total increase in domestic sales while growth in sales to other national chains, regional chains and other independent clinics increased by over 32% and represented slightly over 26% of the growth in domestic business in the first nine months of 2007 compared to the first nine months of 2006. Our international sales were approximately 5% of total sales in the first nine months of 2007 compared to 12.1% of total sales in the first nine months of 2006. The decrease in international sales was attributable to the above mentioned orders from Latin America in 2006.

#### **Gross Profit**

Gross profit in the third quarter of 2007 increased by \$527,000 or 89% to \$1.1 million compared to \$.6 million in the third quarter of 2006. Gross profit margins increased to 10.1% from 8.0% in the third quarter of 2006. This increase in gross profit and margins was due to a combination of higher prices and higher volume of products sold. We have increased prices on maturing contractual arrangements resulting from rising raw material, fuel and other operating costs incurred over the last year.

Gross profit in the first nine months of 2007 increased by \$312,000 to \$2.2 million compared to \$1.8 million in the first nine months of 2006. Gross profit margins decreased to 6.9% from 9.5% primarily due to the impact of the aforementioned \$755,000 breach of contract settlement received in 2006 and the \$500,000 of facility relocation costs incurred in the first quarter of 2007. Some of the new business we added was in geographic areas that were distant from our facilities. In order to improve the margins on our new business we have and continue to expect to raise prices



and to better position our supply chain to service

## **Table of Contents**

this business. We anticipate that gross profit and gross profit margins may fluctuate in future interim periods depending upon the timing of price increases compared to material cost increases and the cost of additional facility relocation or expansion.

### **Selling, General and Administrative Expense**

Selling, general and administrative expense, or SG&A during the third quarter of 2007 decreased as a percent of sales to 6.9% from 8.0% in the third quarter of 2006 due to our increased sales. However, overall SG&A expense increased by \$172,690 or 29% during the third quarter of 2007 compared to the third quarter of 2006. The increase in costs was primarily due to increased resources to support our overall growth over the last year, including additional personnel and information technology resources.

Similarly, in the first nine months of 2007, SG&A expense decreased to 7.4% of sales from 9.9% of sales in the first nine months of 2006. However, SG&A expense increased \$376,359 or 19.7% compared to the first nine months of 2006, mostly due to increased costs to support our growth, including additional personnel, increased marketing expenditures and investments in information technology resources.

### **Research and Development**

Research and development costs were \$735,393 or 6.6% of sales compared to \$1,621,821 or 22% of sales in the third quarter of 2006. Spending in both periods was primarily devoted to development and approval of SFP, our proprietary anemia drug used to treat iron deficiency in dialysis patients. Spending in the third quarter of 2007 was primarily related to preparation to commence human clinical trials which began in the fourth quarter of 2007. Fourth quarter 2007 R&D spending can be expected to increase substantially above the third quarter spending level as a result of the human clinical trials.

In the first nine months of 2007, research and product development expense was \$2,319,452 or 7.5% of sales compared to \$3,381,643 or 17.4% of sales in the first nine months of 2006. Costs incurred in 2006 were primarily for non-clinical testing of SFP. Expenditures in 2007 included expenditures for non-clinical testing and costs related to preparation for human clinical testing.

### **Interest Expense, Net**

Net interest expense increased by \$51,487 in the third quarter of 2007 compared to the third quarter of 2006. Interest expense increased by \$26,671 due to increased borrowings under our line of credit while interest income was \$24,816 lower due to short term investment income realized in the third quarter of 2006.

Net interest expense in the first nine months of 2007 increased \$134,307 compared to the first nine months of 2006 largely due to a decrease in interest income on short term investments of \$128,452. Interest income in 2006 was the result of the investment of the net proceeds of the stock offering that occurred in the first quarter of 2006. Those funds have been largely used for the development and approval of SFP.

### **Liquidity and Capital Resources**

We have two major areas of strategic focus in our business. First, we plan to develop our dialysis products business. Second, we expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP. Both of these initiatives require investments of substantial amounts of capital.

During the first nine months of 2007, we used approximately \$4.8 million in cash to fund operating and investing activities and repayment of long term debt. To fund these costs we used our available cash and borrowed \$1.8 million on our line of credit. Much of the borrowing on our credit line was used to fund the increase in our accounts receivable which increased by \$1.4 million resulting from the overall growth in our business. We do not anticipate our accounts receivable to increase in the fourth quarter. Similarly, we do not anticipate any significant increases in cash requirements for operating activities other than research and development. We reduced our long term debt and capital lease obligations by \$222,000 in the first nine months of 2007, which included \$122,000 related to the final payments on a note payable that was repaid in the second quarter of 2007.

**Table of Contents**

We also incurred certain large cash expenditures to support our 60% sales growth in the first three quarters of 2007. We used approximately \$500,000 in cash in the first quarter of 2007 to fund the relocation and start-up of a new facility. We also incurred approximately \$500,000 in start-up costs for new business and increases in material costs in the first quarter of 2007. However, we have subsequently increased prices for customers representing over half of our gross sales, thereby raising our overall margins and improving operating cash flow. Our dialysis products business showed substantial improvement in operating results in the last two quarters compared to the first quarter with both sales and gross margins increasing. If we continue to add new business and realize price increases in excess of material cost increases as anticipated, we expect to continue to generate increased cash flow from our dialysis products business in the fourth quarter of 2007, before research and development expenses. Similar to the third quarter, we expect fourth quarter 2007 results to achieve positive cash flow from operations before research and development expenditures and thereby mitigate a portion of the cash impact of funding increased research and development expenditures. As a result, we believe our cash resources and other sources of liquidity will be adequate to fund our cash requirements for 2007.

We expect to continue to expand our production and distribution network in 2008, which will require additional capital. We anticipate that we will enter into equipment leasing arrangements and other lending arrangements to fund the majority of capital expenditures associated with facility expansions or additions. If we require additional working capital to support facility or business growth, we believe our current working capital line will be sufficient to meet our short term working capital needs.

In the first nine months of 2007, our research and development costs were \$2.3 million. Over the next year we anticipate spending approximately \$5 - \$6 million on SFP testing and approval. In addition, our longer term pharmaceutical product development initiatives and regulatory approval work will also require sources of funding in addition to cash flows from our operations. We expect that we will need to borrow additional funds and to raise additional capital in order to execute our strategic plan. The maximum amount of borrowing permitted under our working capital line is \$2.75 million. As of September 30, 2007, we had borrowed \$1.8 million under our working capital line. The terms of our working capital line are discussed in Note 4 to the consolidated financial statements. In our efforts to obtain additional capital resources, we will evaluate both debt and equity financing as potential sources of funds. We will also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets as well as other potential funding sources. Should we not be able to obtain additional financing, we may be forced to alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk****Interest Rate Risk**

Our exposure to interest rate risk is limited to borrowings under our line of credit. Our borrowings under our line of credit were \$1.8 million as of September 30, 2007. A 100 basis point increase in the prime rate of our lending institution would increase annual interest expense by \$18,000, assuming our borrowing level remained constant for the year.

**Foreign Currency Exchange Rate Risk**

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

**Item 4. Controls and Procedures****Disclosure Controls and Procedures**

Management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rule 13a-15 of the Securities Exchange Act of 1934, as amended (the Exchange Act) that are designed to cause the material information required to be disclosed by us in the reports we file or submit under the Exchange Act to be recorded, processed, summarized, and reported to the extent applicable within the time periods required by the Securities and Exchange Commission's rules and forms, and for such information to be accumulated



**Table of Contents**

and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with a company have been detected.

As of the end of the period covered by this report, we performed an evaluation under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures pursuant to Rule 13a-15 of the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

**Changes in Internal Control over Financial Reporting**

No changes were made to our internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act) during the last fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 6. Exhibits**

See Exhibit Index following signature page, which is incorporated herein by reference.

**Table of Contents**

**SIGNATURES**

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

ROCKWELL MEDICAL TECHNOLOGIES, INC.

(Registrant)

Date: November 8, 2007

/s/ ROBERT L. CHIOINI

Robert L. Chioini  
President, Chief Executive Officer and  
Director  
(principal executive officer) (duly authorized  
officer)

Date: November 8, 2007

/s/ THOMAS E. KLEMA

Thomas E. Klema  
Vice President of Finance, Chief Financial  
Officer, Treasurer and Secretary (principal  
financial officer and principal accounting  
officer)

**Table of Contents**

**10-Q EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.19	Consulting Agreement, dated as of October 3, 2007 (filed as an exhibit to the Company's Current Report on Form 8-K on October 9, 2007 and incorporated herein by reference)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934