

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

November 13, 2008

**Table of Contents**

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

(Mark One)

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the quarterly period ended September 30, 2008**

**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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

(Do not check if a smaller  
reporting company)

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.

Edgar Filing: ROCKWELL MEDICAL TECHNOLOGIES INC - Form 10-Q

Class	Outstanding as of October 31, 2008
Common Stock, no par value	13,834,953 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>	14
<u>Item 4 - Controls and Procedures</u>	14
<u>Part II - Other Information</u>	
<u>Item 1 - Legal Proceedings</u>	14
<u>Item 1A - Risk Factors</u>	14
<u>Item 2 - Unregistered Sales of Equity Securities and Use of Proceeds</u>	14
<u>Item 6 - Exhibits</u>	15
<u>Signatures</u>	16
<u>Exhibit Index</u>	17
<u>EX-10.25</u>	
<u>EX-10.26</u>	
<u>EX-10.27</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</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, 2008 and December 31, 2007**

	<b>September 30, 2008 (Unaudited)</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 7,481,792	\$ 11,097,092
Accounts Receivable, net of a reserve of \$96,000 in 2008 and \$69,000 in 2007	5,356,536	4,687,229
Inventory	3,166,566	2,559,051
Other Current Assets	535,437	302,573
<b>Total Current Assets</b>	<b>16,540,331</b>	<b>18,645,945</b>
Property and Equipment, net	3,332,569	2,840,331
Intangible Assets	248,338	270,446
Goodwill	920,745	920,745
Other Non-current Assets	116,850	125,667
<b>Total Assets</b>	<b>\$ 21,158,833</b>	<b>\$ 22,803,134</b>
 <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Notes Payable & Capitalized Lease Obligations	\$ 187,682	\$ 194,239
Accounts Payable	3,977,321	2,982,899
Accrued Liabilities	2,252,257	1,122,737
Customer Deposits	331,043	337,396
<b>Total Current Liabilities</b>	<b>6,748,303</b>	<b>4,637,271</b>
Long Term Notes Payable & Capitalized Lease Obligations	58,190	204,837
Shareholders Equity:		
Common Shares, no par value, 13,834,953 and 13,815,186 shares issued and outstanding	34,262,611	33,415,106
Common Share Purchase Warrants, 1,414,169 and 1,204,169 warrants issued and outstanding	3,413,443	3,038,411
Accumulated Deficit	(23,323,714)	(18,492,491)
<b>Total Shareholders Equity</b>	<b>14,352,340</b>	<b>17,961,026</b>
<b>Total Liabilities And Shareholders Equity</b>	<b>\$ 21,158,833</b>	<b>\$ 22,803,134</b>

*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, 2008 and September 30, 2007**  
(Unaudited)

	<b>Three Months Ended Sept. 30, 2008</b>	<b>Three Months Ended Sept. 30, 2007</b>	<b>Nine Months Ended Sept. 30, 2008</b>	<b>Nine Months Ended Sept. 30, 2007</b>
<b>Sales</b>	<b>\$ 13,533,986</b>	<b>\$ 11,073,774</b>	<b>\$ 38,128,359</b>	<b>\$ 31,096,399</b>
Cost of Sales	12,755,377	9,953,863	35,400,671	28,942,171
<b>Gross Profit</b>	<b>778,609</b>	<b>1,119,911</b>	<b>2,727,688</b>	<b>2,154,228</b>
Selling, General and Administrative	2,314,188	765,457	5,183,675	2,288,903
Research and Product Development	993,262	735,393	2,557,718	2,319,452
<b>Operating (Loss)</b>	<b>(2,528,841)</b>	<b>(380,939)</b>	<b>(5,013,705)</b>	<b>(2,454,127)</b>
Interest Expense (Income), net	(17,795)	51,973	(182,482)	101,924
<b>Net (Loss)</b>	<b>\$ (2,511,046)</b>	<b>\$ (432,912)</b>	<b>\$ (4,831,223)</b>	<b>\$ (2,556,051)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ (.18)</b>	<b>\$ (.04)</b>	<b>\$ (.35)</b>	<b>\$ (.22)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ (.18)</b>	<b>\$ (.04)</b>	<b>\$ (.35)</b>	<b>\$ (.22)</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, 2008 and September 30, 2007**

(Unaudited)

	<b>2008</b>	<b>2007</b>
Cash Flows From Operating Activities:		
Net (Loss)	<b>\$ (4,831,223)</b>	<b>\$ (2,556,051)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	651,710	601,362
(Gain) on Disposal of Assets	(7,534)	
Warrants issued for Services	375,032	
Stock Option Compensation	740,783	
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	(669,307)	(1,444,062)
(Increase) in Inventory	(607,515)	(133,895)
(Increase) in Other Assets	(224,047)	(54,285)
Increase in Accounts Payable	994,422	51,394
Increase (Decrease) in Other Liabilities	1,123,167	(265,281)
Changes in Assets and Liabilities	616,720	(1,846,129)
Cash (Used) In Operating Activities	<b>(2,454,512)</b>	<b>(3,800,818)</b>
Cash Flows From Investing Activities:		
Purchase of Equipment	(1,122,958)	(766,314)
Proceeds on Sale of Assets	9,555	
Purchase of Intangible Assets	(903)	(6,286)
Cash (Used ) In Investing Activities	<b>(1,114,306)</b>	<b>(772,600)</b>
Cash Flows From Financing Activities:		
Proceeds From Borrowings on Line of Credit		1,800,000
Issuance of Common Shares and Purchase Warrants	106,722	386,099
Payments on Notes Payable	(153,204)	(275,554)
Cash Provided (Used) By Financing Activities	<b>(46,482)</b>	<b>1,910,545</b>
(Decrease) In Cash	(3,615,300)	(2,662,873)
Cash At Beginning Of Period	11,097,092	2,662,873
Cash At End Of Period	<b>\$ 7,481,792</b>	<b>\$ -0-</b>
Supplemental Cash Flow disclosure		
	2008	2007
Interest Paid	\$41,523	\$108,159
	-0-	\$ 53,676



Non-Cash Investing and Financing Activity    Equipment Acquired Under  
Capital Lease Obligations

*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. References in these Notes to the Company, we, our and us are references to Rockwell Medical Technologies, Inc. and its subsidiaries.

We are regulated by the Federal Food and Drug Administration, or 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 and to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer. We have also obtained global licenses for certain dialysis related drugs which we are developing and for which we are seeking FDA approval to market.

**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 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, 2007 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 month and nine month periods ended September 30, 2008 are not necessarily indicative of the results to be expected for the year ending December 31, 2008. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2007 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 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 GAAP. 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 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 September 30, 2008 and December 31, 2007, we had customer deposits of \$331,043 and \$337,396, respectively.

**Table of Contents****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 (SFP), aggregating approximately \$2.5 million and \$2.3 million in the first nine months of 2008 and 2007, respectively. We are conducting human clinical trials on SFP and we recognize the costs of these clinical trials as the costs are incurred and services are performed over the duration of the trials.

**Net 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 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,	
	2008	2007	2008	2007
Basic Weighted Average Shares Outstanding	13,834,953	11,619,117	13,826,208	11,545,725
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	13,834,953	11,619,117	13,826,208	11,545,725

**3. Inventory**

Components of inventory as of September 30, 2008 and December 31, 2007 are as follows:

	September 30,		December 31,	
	2008		2007	
Raw Materials	\$ 1,205,527		\$ 1,096,191	
Finished Goods	1,961,039		1,462,860	
Total Inventory	\$ 3,166,566		\$ 2,559,051	

**4. Fair Value Measurements**

On January 1, 2008, the Company adopted the methods of fair value as described in Statement of Financial Accounting Standards, or SFAS, No. 157, Fair Value Measurements (SFAS 157) to value its financial assets and liabilities. The adoption of the provisions of this pronouncement related to financial assets and liabilities did not have a material impact on our financial condition or consolidated results of operation. As defined in SFAS 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

## **Table of Contents**

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value. The Company's cash and cash equivalents are valued using Level 1 inputs in the fair value hierarchy as these short term investments are immediately available at the Company's direction and without market risk to principal. The Company does not have other financial assets that would be characterized as Level 2 or Level 3 assets.

SFAS 157 is effective for non-financial assets and liabilities for the year beginning January 1, 2009. We are currently assessing the impact of this pronouncement as it relates to non-financial assets and liabilities.

The Company chose not to elect the fair value option as prescribed by SFAS No. 159, *The Fair Value Option for Financial Assets and Liabilities Including an Amendment of Financial Accounting Standards Board, or FASB, Statement No. 115 (SFAS 159)* for its financial assets and liabilities that had not been previously carried at fair value. Therefore, material financial assets and liabilities not carried at fair value, such as the Company's trade accounts receivable and payable are still reported at their face values.

Although the Company has not elected the fair value option for financial assets and liabilities existing at January 1, 2008 or transacted in the nine months ended September 30, 2008, any future transacted financial asset or liability will be evaluated for the fair value election as prescribed by SFAS 159 and valued under the provisions of SFAS 157.

### **5. Litigation Settlement**

In the third quarter of 2008, the Company reached a settlement with respect to certain litigation related to property and equipment the Company had leased from the plaintiffs. The Company recorded an expense of \$750,000 in the third quarter of 2008 pursuant to this settlement agreement.

### **6. Common Share Purchase Warrants**

The Company has entered into several consulting agreements for which consideration for some or all of the services rendered include Common Share Purchase Warrants. During 2008, three such agreements were entered into, including one entered into subsequent to the end of the third quarter of 2008 on November 5, 2008, which provide for the right to purchase in the aggregate up to 460,000 Common Shares at prices ranging from \$1.99 to \$9.00. The warrants were valued using the Black-Scholes method with an aggregate estimated fair market value of \$445,000 to be amortized over the period that services are rendered under the agreements ranging from 12 to 18 months. The warrants have terms of three to four years and expire between November 5, 2011 and September 30, 2012. However, warrants issued under two of the agreements may be canceled if the agreement is terminated under conditions specified in the agreements.

### **7. Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations (SFAS 141R)*. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for fiscal years beginning after December 15, 2008, and will be adopted by the Company in the first quarter of 2009. We do not expect the adoption of SFAS 141R to have a material effect on our consolidated results of operations and financial condition.

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

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. References in this report to *we*, *our* and *us* are references to Rockwell Medical Technologies, Inc. and its subsidiaries.

### **Forward-Looking Statements**

The discussion that follows contains certain forward-looking statements, including without limitation statements relating to our anticipated future financial condition, operating results, cash flows and our business plans, as well as the timing and cost of obtaining FDA approval of our new SFP product. Also, when we use words such as *may*, *might*, *will*, *should*, *believe*, *expect*, *anticipate*, *estimate*, *continue*, *predict*, *forecast*,



**Table of Contents**

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, without limitation, in Item 1A Risk Factors in our Form 10-K for the year ended December 31, 2007 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. Our business is substantially dependent on several customers that account for the majority of our sales. The loss of any of these customers would have a material adverse effect on our results of operations and cash flows.

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

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.

We depend on government funding of healthcare.

We may not be successful in improving our gross profit margins and our business may remain unprofitable.

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

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 cash to fund clinical trials and drug approval efforts in future years.

We may not have sufficient product liability insurance.

Our Board of Directors is subject to potential deadlock.

Shares eligible for future sale may affect the market price of our common shares.

The market price of our securities may be volatile.

Voting control and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.

We do not anticipate paying dividends in the foreseeable future.

## **Table of Contents**

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. 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 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 Healthcare, Inc., or 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 dialysis provider in the United States. As a result, the number of clinics we service increased by over 50% during 2007 and to a lesser extent in 2008. Largely as a result of the increase in serviced clinics, our sales increased by over 50% in 2007 compared to 2006 and by 22.6% in the first nine months of 2008 compared to the first nine months of 2007.

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 us for an adequate and sustainable return on investment. We anticipate that we will continue to gain domestic market share, though not as dramatically as in 2007.

As a result of the 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. We expanded and relocated 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 continue to raise our average selling prices in 2008 to offset the higher costs of diesel fuel and raw materials. While we raised prices on maturing contracts in 2007 and in the first nine months of 2008, we have not fully recovered the significant ongoing increases in fuel and key raw materials, which have reduced our gross profit margins. If we are successful in implementing price increases in the remainder of 2008 and beyond, our gross profit margins may improve and increase the profitability of our core business operations. However, commodity markets, particularly diesel fuel and feedstock materials that are key raw materials and packaging components, continued to increase during the first nine months of 2008 at higher than anticipated rates and may require higher than anticipated price increases. 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 gross profit, 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 as feasible and we generally enter into customer contracts of similar or lesser duration to mitigate our exposure to raw material and other cost increases. In October 2008, we began to realize a decline in diesel fuel costs compared to the third quarter of 2008 following a global softening in oil prices.



**Table of Contents**

We could also experience changes in our customer and product mix in future quarters that could impact gross profit, since we sell a wide range of products with varying profit margins and to customers with varying order patterns. These changes in mix may cause our gross profit and our gross profit margins to 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.

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 that order routinely, certain major distributors of our products internationally have not ordered consistently, resulting in variation in our 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 realized substantial growth from new international customers in the third quarter of 2008 and anticipate that we may realize an increased portion of our business from international markets in the future due to higher demand and penetration into new markets.

We are seeking to gain FDA approval for SFP, our iron supplemented dialysate product. We believe our SFP product, which has a unique method of action and other substantive benefits compared to current IV iron treatment options, has the potential to compete in the iron maintenance therapy market. The cost to obtain regulatory approval for a drug in the United States is expensive and the approval process can take several years. Due to the significant expenditures expected over the next several years, we expect to incur losses during the approval process.

**Results of Operations for the Three and Nine Months Ended September 30, 2008 and September 30, 2007**  
**Sales**

Sales in the third quarter of 2008 were \$13.5 million, an increase of \$2.5 million or 22.2% over the third quarter of 2007. We increased our domestic market share and realized a significant increase in international orders in the third quarter of 2008. In 2007, we substantially increased our domestic market share following the exit of Gambro from our market. In both 2007 and 2008, we increased prices on maturing contractual arrangements due to rising fuel and material cost increases. Sales of our dialysis concentrate product lines, which represented over 95% of our sales in the third quarter of 2008, increased approximately 24% in the third quarter of 2008 compared to the third quarter of 2007. Our international sales increased by \$1.1 million in the third quarter of 2008 to \$1.6 million from \$0.5 million in the third quarter of 2007 due to our penetration into new markets and increased orders from our international distributors.

Sales in the first nine months of 2008 were \$38.1 million, which represented a \$7 million or 22.6% increase over the first nine months of 2007. We increased our domestic market share with domestic sales 16.7% higher than the first nine months of 2007. Overall, approximately 75% of our sales increase in the first nine months of 2008 compared to 2007 was due to unit volume growth with the remainder attributable to higher prices. International sales increased by 147% to \$3.5 million during the first nine months of 2008 over the comparable period of 2007.

**Gross Profit**

Gross profit in the third quarter of 2008 was \$0.78 million compared to \$1.1 million in the third quarter of 2007. Gross profit margins decreased to 5.8% in the third quarter of 2008 compared to 10.1% in the third quarter of 2007.

**Table of Contents**

The decrease in gross profit was primarily the result of significantly higher costs for fuel, transportation operations, key raw material ingredients in our products and other operating costs that more than offset the effect of our price increases. Record diesel fuel prices in the third quarter of 2008 caused the fuel cost per mile driven to increase by over 51% compared to the third quarter of 2007 with the aggregate increase in fuel costs accounting for the overall decrease in gross profit. If fuel and other operating costs remain at October 2008 levels, we anticipate that fourth quarter fuel, transportation and other operating expenses may be \$0.2-\$0.3 million lower than the in third quarter of 2008.

Gross profit for the first nine months of 2008 was \$2.7 million, an increase of \$0.6 million compared to the first nine months of 2007. Gross profit margins increased to 7.2% in the first nine months of 2008 compared to 6.9% in the first nine months of 2007. Improvement in gross profit was due to a combination of higher prices, increased volume of products sold in 2008 and the effect of \$500,000 in facility relocation costs incurred in the first quarter of 2007. Our price increases have only partially offset the cost increases in our key cost drivers material and fuel. In order to improve our gross profit margins, we expect to continue to raise prices and to encourage the migration of our product mix to more cost effective powder products from liquid products, which are more expensive to deliver.

**Selling, General and Administrative Expense**

Selling, general and administrative expense, or SG&A, during the third quarter of 2008 increased by \$1.5 million compared to the third quarter of 2007. Half of the increase was attributable to the settlement of certain litigation in the third quarter of 2008 for \$0.75 million. See Part II Item 1 Litigation of this report. Other operating costs increased by \$0.75 million compared to the third quarter of 2007, including non-cash expenses for employee and director stock options and common share purchase warrants paid to consultants, which aggregated \$0.3 million in the third quarter of 2008. Other increases in operating expenses included increased personnel costs of approximately \$0.3 million, higher information technology costs and higher legal services costs primarily pertaining to litigation and intellectual property matters.

SG&A costs increased by \$2.9 million in the first nine months of 2008 compared to the first nine months of 2007, including non-cash expenses for employee and director stock options and common share purchase warrants paid to consultants which aggregated \$1.1 million. The aforementioned legal settlement represented \$0.75 million of the increase while increased personnel costs were \$0.8 million. We incurred higher costs to support information technology improvements of \$0.1 million and incurred higher costs for legal services for litigation and intellectual property matters aggregating \$0.2 million.

**Research and Development**

Research and development costs were \$1.0 million in the third quarter of 2008 compared to \$0.7 million in the third quarter of 2007. In the first nine months of 2008, total research and development spending was \$2.6 million compared to \$2.3 million in the first nine months of 2007. Spending in all periods was primarily devoted to development and approval of SFP, our proprietary anemia drug used to treat iron deficiency in dialysis patients. Spending in 2007 was primarily related to completion of our pre-clinical testing plan and preparation for clinical trials while spending in 2008 was primarily for human clinical testing and other development expenses. We anticipate total SFP related development and regulatory approval spending to be approximately \$4-5 million in the next twelve months.

**Interest Income, Net**

Net interest income increased by \$0.1 million and \$0.3 million in the third quarter and nine months ended September 30, 2008, respectively, compared to the comparable periods of 2007 primarily due to investment income from our cash investments following our equity offering in late 2007 and, to a lesser extent, to a decrease in interest expense because of lower overall borrowings.

## **Table of Contents**

### **Liquidity and Capital Resources**

We have two major areas of strategic focus in our business. First, we plan to develop our dialysis products business and to expand our product offering to include drugs and vitamins administered to dialysis patients. Second, we expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions. All of these initiatives require investments of substantial amounts of capital.

In 2007, we raised approximately \$12.75 million in equity capital (net of related expenses) primarily for the purpose of funding the clinical development and FDA approval of SFP. We expect to spend approximately \$4-5 million on SFP development and testing in the next twelve months. We believe our cash resources are sufficient to fund our foreseeable requirements for SFP and ordinary course operating requirements in the year ahead. Should our testing and clinical trial expenses exceed our capital resources in the future, we may need to seek additional sources of financing or an international development partner to facilitate the domestic and global approval of SFP.

Our cash resources include cash generated from our business operations and the remaining proceeds from our November 2007 equity offering. As of September 30, 2008, we had \$7.5 million in cash. Through the first nine months of 2008, we used \$3.6 million in cash which included \$1.1 million in capital expenditures. During the first nine months of 2008, we used \$2.5 million in cash in our operations, compared to \$3.8 million in the first nine months of 2007. The use of cash in 2008 was primarily due to our net loss of \$4.8 million, partially offset by non-cash charges for stock option expense and warrant expense totaling \$1.1 million and depreciation and amortization of \$0.6 million. Other liabilities increased by \$1.1 million from December 31, 2007 due to accrued expenses associated with the aforementioned legal settlement that will be funded over the next two quarters.

We expect to add additional manufacturing equipment and one or more facilities to continue expanding our production and distribution network 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. As we had no foreseeable borrowing requirements under our line of credit, we allowed our prior working capital line of credit to expire on April 1, 2008. We expect to negotiate a new working capital and equipment financing arrangement in the future as needed.

We believe our current and expected sources of liquidity and capital resources discussed above will be adequate to fund our cash requirements through 2009. However, we may need to raise additional capital or enter into development arrangements with an international partner in order to fully execute our strategic plan. 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.

### **Interest Rate Risk**

Our current exposure to interest rate risk is limited to changes in interest rates on short term investments of cash. As of September 30, 2008, we had invested \$7.25 million in commercial paper with a financial institution.

A hypothetical 100 basis point increase or decrease in market interest rates for commercial paper would increase or reduce, respectively, our annualized interest income by approximately \$0.1 million, assuming our cash 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.

**Table of Contents**

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

Not applicable.

**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, that are designed to ensure that material information required to be disclosed in our 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, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we 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, within a company have been detected.

As of the end of the period covered by this report, 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 the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our 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 1. Legal Proceedings**

On September 24, 2008, the Company executed a Mutual Release and Settlement Agreement with FWLL, LLC and ST Holdings, Inc. ( Plaintiffs ), which had previously leased to the Company a facility and related equipment, to settle the outstanding litigation it had brought against the Company in South Carolina on June 6, 2007. Pursuant to the Mutual Release and Settlement Agreement, the Company will make two payments to Plaintiffs: an initial payment of \$375,000 to be made by October 24, 2008 and a second payment of \$375,000 to be made on or before January 1, 2009. The parties also agreed to dismiss with prejudice all claims in the above litigation, to a mutual non-disparagement covenant and to a mutual release and waiver of all claims each may have against the other.

**Item 1A. Risk Factors**

For information regarding risk factors affecting us, see Risk Factors in Item 1A of Part I of our 2007 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

**Table of Contents**

On September 30, 2008, we entered into an advisory agreement with RJ Aubrey IR Services LLC, or RJ Aubrey, pursuant to which we issued warrants to acquire 60,000 shares of our common stock in a private placement exempt from registration under Section 4(2) of the Securities Act. The warrants were issued as compensation for the investor relations consulting services to be rendered under the agreement. RJ Aubrey is a financially sophisticated accredited investor who had access to information relating to the investment, the warrants were sold in a manner not involving general solicitation or advertising and the warrants and underlying shares are subject to customary restrictions on transfer.

The warrants are earned in 20,000 share increments on September 30, 2008, January 1, 2009 and July 1, 2009. The warrants will expire on September 30, 2012. Upon a termination of the agreement (A) by us due to a material breach of the agreement by RJ Aubrey or (B) by RJ Aubrey, any unearned warrants at the time of such termination will expire. The warrants have an exercise price of \$6.50 per share. Warrants may be exercised in whole or in part at any time until their expiration by the submission of an exercise notice accompanied by payment of the exercise price in cash or certified check or by cashless exercise. To the extent the shares issuable upon exercise of the warrants are not registered prior to issuance, they will bear a legend restricting transfer. The agreement with RJ Aubrey will terminate on December 31, 2009 and may be terminated by either party upon 30 days prior written notice.

The terms and conditions of the warrants will be set forth in a separate agreement containing terms and conditions set forth above and such other terms and conditions as are mutually acceptable to us and RJ Aubrey.

Additionally, on November 5, 2008, we entered into an advisory agreement with Emerald Asset Advisors, LLC, or Emerald, pursuant to which we issued warrants to acquire 300,000 shares of our common stock in a private placement exempt from registration under Section 4(2) of the Securities Act. The warrants were issued as compensation for services to be rendered over a 12 month period under the agreement, including introducing the Company to potential licensing partners and acquisition candidates and acting as a liaison to the equity investment community. Emerald is a financially sophisticated accredited investor who had access to information relating to the investment, the warrants were sold in a manner not involving general solicitation or advertising and the warrants and underlying shares are subject to customary restrictions on transfer.

The warrants were immediately earned and will become exercisable on November 5, 2009. The warrants will expire on the earlier of (i) November 5, 2011, or (ii) the termination of the agreement prior to November 5, 2009 (A) by us due to a material breach of the agreement by Emerald or (B) by Emerald. The warrants have an exercise price of \$1.99 per share. Warrants may be exercised in whole or in part at any time until their expiration by the submission of an exercise notice accompanied by payment of the exercise price in cash or certified check. We have agreed to use reasonable commercial efforts to register, under the Securities Act of 1933, the shares to be issued upon exercise of the warrants. To the extent the shares issuable upon exercise of the warrants are not registered prior to issuance, they will bear a legend restricting transfer.

The terms and conditions of the warrants will be set forth in a separate agreement containing terms and conditions set forth above and such other terms and conditions as are mutually acceptable to us and Emerald.

**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 13, 2008

/s/ ROBERT L. CHIOINI  
Robert L. Chioini  
President and Chief Executive Officer  
(principal executive officer) (duly authorized  
officer)

Date: November 13, 2008

/s/ THOMAS E. KLEMA  
Thomas E. Klema  
Vice President and Chief Financial Officer  
(principal financial officer and principal accounting  
officer)

**Table of Contents**

**10-Q EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.25	Mutual Release and Settlement Agreement dated September 24, 2008 by and among the Company, FWLL, LLC and ST Holdings, Inc.
10.26	Advisory Agreement dated September 30, 2008 between the Company and RJ Aubrey IR Services LLC
10.27	Advisory Agreement dated November 5, 2008 between the Company and Emerald Asset Advisors, LLC
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