

ROCKWELL MEDICAL TECHNOLOGIES INC  
Form 10-Q  
November 04, 2011  
[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, 2011

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)

<b>Michigan</b> (State or other jurisdiction of incorporation or organization)	<b>38-3317208</b> (I.R.S. Employer Identification No.)
<b>30142 Wixom Road, Wixom, Michigan</b> (Address of principal executive offices)	<b>48393</b> (Zip Code)
<b>(248) 960-9009</b>  (Registrant's telephone number, including area code)	
<b>(Former name, former address and former fiscal year, if changed since last report)</b>	

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  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.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

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.

Class	Outstanding as of October 31, 2011
Common Stock, no par value	18,666,668 shares

**Table of Contents**

**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 Changes in Shareholders' Equity and Comprehensive Income (Loss)</u>	5
<u>Consolidated Statements of Cash Flows</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	9
<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 1A - Risk Factors</u>	14
<u>Item 6 - Exhibits</u>	14
<u>Signatures</u>	15
<u>Exhibit Index</u>	16

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

As of September 30, 2011 and December 31, 2010

	September 30,	
	2011 (unaudited)	December 31, 2010
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 8,421,915	\$ 12,263,449
Investments Available for Sale	11,813,813	11,938,098
Accounts Receivable, net of a reserve of \$27,000 in 2011 and \$23,000 in 2010	4,258,403	4,507,296
Inventory	2,234,685	2,936,878
Other Current Assets	1,373,083	1,020,647
<b>Total Current Assets</b>	<b>28,101,899</b>	<b>32,666,368</b>
Property and Equipment, net	2,458,987	3,049,513
Intangible Assets	839,676	166,657
Goodwill	920,745	920,745
Other Non-current Assets	2,269,158	163,624
<b>Total Assets</b>	<b>\$ 34,590,465</b>	<b>\$ 36,966,907</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Capitalized Lease Obligations	\$ 8,662	\$ 18,215
Accounts Payable	3,609,235	3,659,507
Accrued Liabilities	5,892,021	2,577,022
Customer Deposits	114,778	165,476
<b>Total Current Liabilities</b>	<b>9,624,696</b>	<b>6,420,220</b>
Capitalized Lease Obligations	3,078	8,750
Shareholders' Equity:		
Common Shares, no par value, 18,502,901 and 17,513,608 shares issued and outstanding	65,290,668	57,017,236
Common Share Purchase Warrants, 2,707,440 and 3,338,569 warrants issued and outstanding	7,067,924	8,275,509
Accumulated Deficit	(47,033,236)	(34,541,185)
Accumulated Other Comprehensive Loss	(362,665)	(213,623)
<b>Total Shareholders' Equity</b>	<b>24,962,691</b>	<b>30,537,937</b>
<b>Total Liabilities And Shareholders' Equity</b>	<b>\$ 34,590,465</b>	<b>\$ 36,966,907</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, 2011 and September 30, 2010

(Unaudited)

	Three Months Ended Sept. 30, 2011	Three Months Ended Sept. 30, 2010	Nine Months Ended Sept. 30, 2011	Nine Months Ended Sept. 30, 2010
<b>Sales</b>	<b>\$ 11,976,329</b>	<b>\$ 14,745,414</b>	<b>\$ 37,069,423</b>	<b>\$ 45,232,078</b>
Cost of Sales	10,600,144	12,345,221	32,970,644	37,746,691
<b>Gross Profit</b>	<b>1,376,185</b>	<b>2,400,193</b>	<b>4,098,779</b>	<b>7,485,387</b>
Selling, General and Administrative	2,271,350	2,431,367	6,890,500	6,847,606
Research and Product Development	4,221,118	727,978	9,937,476	1,686,666
<b>Operating Income (Loss)</b>	<b>(5,116,283)</b>	<b>(759,152)</b>	<b>(12,729,197)</b>	<b>(1,048,885)</b>
Interest and Dividend Income	77,107	17,257	240,617	37,641
Interest Expense	408	1,462	1,513	8,876
Income (Loss) Before Income Taxes	(5,039,584)	(743,357)	(12,490,093)	(1,020,120)
Income Tax Expense	1,958		1,958	
<b>Net Income (Loss)</b>	<b>\$ (5,041,542)</b>	<b>\$ (743,357)</b>	<b>\$ (12,492,051)</b>	<b>\$ (1,020,120)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>(\$ .28)</b>	<b>(\$ .04)</b>	<b>(\$ .71)</b>	<b>(\$ .06)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>(\$ .28)</b>	<b>(\$ .04)</b>	<b>(\$ .71)</b>	<b>(\$ .06)</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 CHANGES IN SHAREHOLDERS EQUITY &**  
**COMPREHENSIVE INCOME (LOSS)**

**For The Nine Months Ended September 30, 2011**

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDERS EQUITY
	SHARES	AMOUNT	WARRANTS	AMOUNT			
Balance as of December 31, 2010	17,513,608	\$ 57,017,236	3,338,569	\$ 8,275,509	\$ (34,541,185)	\$ (213,623)	\$ 30,537,937
Net Loss					(12,492,051)		(12,492,051)
Unrealized Loss on Available-for-Sale Investments						(149,042)	(149,042)
Comprehensive Loss							(12,641,093)
Issuance of Common Shares	289,953	268,361					268,361
Issuance of Purchase Warrants			100,000	105,274			105,274
Exercise of Purchase Warrants	699,340	4,736,135	(731,129)	(1,312,859)			3,423,276
Stock Option Based Expense		2,564,437					2,564,437
Restricted Stock Amortization		460,210					460,210
Additional Paid in Capital		244,289					244,289
Balance as of September 30, 2011	18,502,901	\$ 65,290,668	2,707,440	\$ 7,067,924	\$ (47,033,236)	\$ (362,665)	\$ 24,962,691

*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, 2011 and September 30, 2010**

(Unaudited)

	2011	2010
Cash Flows From Operating Activities:		
Net (Loss)	\$ (12,492,051)	\$ (1,020,120)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	928,208	1,047,077
Loss on Disposal of Assets	27,572	16,822
Share Based Compensation Non-employee Warrants	105,274	588,201
Share Based Compensation Employees	3,024,647	2,392,688
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	248,893	(1,143,912)
Decrease in Inventory	702,193	553,708
(Increase) in Other Assets	(2,457,970)	(514,244)
Decrease in Accounts Payable	(50,272)	(545,538)
Increase (Decrease) in Other Liabilities	2,714,301	(102,062)
Changes in Assets and Liabilities	1,157,145	(1,752,048)
Cash Provided By (Used) In Operating Activities	<b>(7,249,205)</b>	<b>1,272,620</b>
Cash Flows From Investing Activities:		
Purchase of Equipment	(344,250)	(682,295)
Proceeds on Sale of Assets		800
Purchase of Intangible Assets	(144,023)	
Purchase of Investments Available for Sale	(24,757)	
Cash Used In Investing Activities	<b>(513,030)</b>	<b>(681,495)</b>
Cash Flows From Financing Activities:		
Issuance of Common Shares and Exercise of Purchase Warrants	3,935,926	54,948
Payments on Notes Payable	(15,225)	(27,040)
Cash Provided By (Used) In Financing Activities	<b>3,920,701</b>	<b>27,908</b>
Increase (Decrease) In Cash and Cash Equivalents	(3,841,534)	619,033
Cash and Cash Equivalents at Beginning of Period	12,263,449	23,038,095
Cash and Cash Equivalents at End of Period	<b>\$ 8,421,915</b>	<b>\$ 23,657,128</b>
Supplemental Cash Flow disclosure		
Interest Paid	2011 \$ 1,513	2010 \$ 8,876

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



## **Table of Contents**

### **Rockwell Medical Technologies, Inc. and Subsidiary**

#### **Notes to Consolidated Financial Statements**

##### **1. Description of Business**

Rockwell Medical Technologies, Inc. and Subsidiary (collectively, we, our, us, or the Company) 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 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.

We have obtained global licenses for certain dialysis related drugs which we are developing and for which we are seeking FDA approval to market. We plan to devote substantial resources to the development, testing and FDA approval of our lead drug candidate.

##### **2. Summary of Significant Accounting Policies**

###### **Basis of Presentation**

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated in consolidation. 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, 2010 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, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2010 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 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 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, 2011 and December 31, 2010 we had customer deposits of \$114,778 and \$165,476, respectively.

**Table of Contents****Cash and Cash Equivalents**

We consider cash on hand, money market funds, unrestricted certificates of deposit and short term marketable securities with an original maturity of 90 days or less as cash and cash equivalents.

**Investments Available for Sale**

Investments Available for Sale are short-term investments, consisting principally of investments in short term duration bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense. There were no such realized gains or losses during the three and nine months ended September 30, 2011 and September 30, 2010.

**Research and Product Development**

We recognize research and product development expenses as 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 \$4.2 million and \$9.9 million for the three and nine months ended September 30, 2011, respectively, and approximately \$0.7 million and \$1.7 million for the three and nine months ended September 30, 2010, respectively.

We are conducting human clinical trials on iron supplemented dialysate and we recognize the costs of the human clinical trials as the costs are incurred and services 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 September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Basic Weighted Average Shares Outstanding	17,862,573	17,136,119	17,582,833	17,091,733
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	17,862,573	17,136,119	17,582,833	17,091,733

**3. Inventory**

Components of inventory as of September 30, 2011 and December 31, 2010 are as follows:

	September 30, 2011	December 31, 2010
Raw Materials	\$ 877,410	\$ 1,082,807
Work in Process	159,756	148,712
Finished Goods	1,197,519	1,705,359
Total	\$ 2,234,685	\$ 2,936,878



## **Table of Contents**

### **4. Other Current Assets**

Other current assets includes amounts advanced to a contract services provider. These advances will offset future liabilities incurred with this service provider for services and travel related to our clinical trials. As of September 30, 2011, the amount included in other current assets was \$0.6 million.

### **5. Other Non-Current Assets**

Other Non-current assets includes amounts advanced to a contract services provider. These advances will offset future liabilities incurred with this service provider for services and travel related to our clinical trials. As of September 30, 2011, the amount included in other non-current assets was \$1.9 million.

## **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**

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, projected, intend, or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the timing and costs of obtaining FDA approval of our new Soluble Ferric Pyrophosphate or SFP product and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

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 or, if made elsewhere, as of the date made. 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 below and elsewhere 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, 2010.

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 one of our customers that accounts for a significant portion of our sales. The loss of this customer would have a material adverse effect on our results of operations and cash flow.

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 we may not be able to market it successfully.

**Table of Contents**

We may not be successful in maintaining our gross profit margins.

We depend on government funding of healthcare.

Health care reform could adversely affect our business.

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

We depend on key personnel.

Our business is highly regulated.

We depend on contract research organizations and consultants to manage and conduct our clinical trials and if they fail to follow our protocol or meet FDA regulatory requirements our clinical trial data and results could be compromised causing us to delay our development plans or have to do more testing than planned.

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

We may not have sufficient products 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.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow 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**

Rockwell Medical operates in a single business segment as a specialty pharmaceutical company offering innovative products targeting end-stage renal disease, chronic kidney disease, and iron deficiency anemia. As an established manufacturer delivering high-quality hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad, we provide products used to maintain human life, remove toxins and replace critical nutrients in the dialysis patient's bloodstream.

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

We are currently developing unique, proprietary renal drug therapies. These exclusive renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome. In July 2011, we acquired the right to manufacture and market in the United States a generic version of an injectable form of Vitamin -D (Calcitriol) for cash. We anticipate obtaining regulatory approval to begin marketing this drug later in 2012. Our initial focus will be on marketing this drug to our current customers. We are not yet able to assess the potential impact on sales of this drug on our results of operations. Regulatory approval and payment of the remaining cash purchase price is not expected to have a material impact on our liquidity or capital resources.



## **Table of Contents**

Our principal strategy is to develop high potential drug candidates while also expanding our dialysis products business. Our lead drug candidate SFP is a late-stage investigational drug designed to treat hemodialysis patients suffering from iron loss. SFP appears to provide clinical benefits compared to current treatment options and if approved for marketing has the potential to compete in the iron therapy market.

We could 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 have caused our gross profit and our gross profit margins to vary period to period. During 2011, we have experienced higher prices in certain key commodities used in the production and distribution of our products including the cost of diesel fuel. These higher prices, along with competitive pricing pressures in the renal market have resulted in lower margins in 2011 compared to last year.

The majority of our business is with domestic clinics who order routinely. The renewal of our supply arrangement with our largest customer in the first quarter of 2011 had no material impact on our results for the nine months ended September 30, 2011 in comparison with the same period of the prior year.

Certain major distributors of our products internationally have not ordered consistently resulting in significant fluctuation in our international sales from period to period. These international orders may increase in future periods or may not recur at all. Orders for our largest international market that occurred in 2010 have not recurred since the first quarter of 2011 and are not expected to recur in 2011. As a result our international sales have decreased in 2011 compared to 2010.

## **Results of Operations for the Three and Nine Months Ended September 30, 2011 and September 30, 2010**

### **Sales**

Sales in the third quarter of 2011 were \$12.0 million compared to \$14.7 million in the third quarter of 2010. Sales decreased \$2.7 million or 18.8% largely due to reduced purchase volumes from one international distributor of \$1.8 million with lower domestic sales accounting for the remainder. Domestic sales were down \$1.0 million due to changes in product mix as well as due to the loss of certain smaller chain accounts that were acquired by other customers for whom we do not supply products. Over the last year, customers have continued to convert to our Dri-Sate Dry Acid concentrate product line, which lowers providers' cost per treatment and reduces our sales, but improves our gross profit margins due to a reduction in shipping costs.

Sales for the first nine months of 2011 decreased \$8.2 million or 18.0% to \$37.1 million compared to \$45.3 million in the first nine months of 2010. International sales during the period decreased \$6.0 million or 55.1% to \$4.9 million, with reduced purchase volumes from a single distributor accounting for \$5.7 million of the decrease.

Domestic sales decreased \$2.2 million or 6.3% in the first nine months of 2011, primarily due to the change in product mix. Our Dri-Sate dry acid concentrate gallons increased to 57% of acid concentrate equivalent gallons from 46% in the first nine months of 2010. To a lesser extent, we also experienced some downward pricing pressure with the implementation of the bundled reimbursement program by Medicare in 2011. Domestic sales also declined by \$1.0 million due to the loss of certain smaller chain accounts that were acquired by other customers for whom we do not supply products.

### **Gross Profit**

Gross profit in the third quarter of 2011 decreased \$1.0 million to \$1.4 million compared to \$2.4 million in the third quarter of 2010. About \$0.6 million of the decrease was due to reduced sales volumes generally and another \$0.2 million was due to reduced sales volumes as a result of incentives and changes to product mix. Cost increases for fuel, materials and labor, net of a reduction in operating costs accounted for the remainder of the decrease. Gross profit margin decreased to 11.5% compared to 16.3% in the third quarter of 2010.

## **Table of Contents**

Gross profit in the first nine months of 2011 decreased \$3.4 million to \$4.1 million compared to \$7.5 million in the first nine months of 2010. Approximately \$2.1 million of the decrease was due to the lower sales volumes generally and another \$0.6 million was due to reduced sales volumes as a result of incentives and changes to product mix. Cost increases for fuel, material and labor net of operating expense decreases accounted for the remainder. Gross profit margins in the first nine months of 2011 were 11.1% compared to 16.5% for the first nine months of 2010.

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

Selling, general and administrative expense ( SG&A ) during the third quarter of 2011 was \$2.3 million, a decrease of \$0.1 million or 6.6% compared to the third quarter of 2010. The decrease was due to lower charges for non-cash equity compensation.

SG&A expense was relatively unchanged in the first nine months of 2011 compared to the first nine months of 2010.

### **Research and Development**

Research and development costs were \$4.2 million and \$0.7 million in the third quarter of 2011 and 2010, respectively. Research and development spending in the first nine months of 2011 was \$9.9 million compared to \$1.7 million in the first nine months of 2010. Spending in both years was primarily for development and approval of SFP, with the increase in 2011 due to the commencement of our Phase III clinical trials related to SFP.

### **Interest Income, Net**

Our net interest income was \$77,000 in the third quarter of 2011 compared to net interest income of \$16,000 in the third quarter of 2010. For the nine months ending September 30, 2011, our net interest income was \$239,000 compared to \$29,000 in the first nine months of 2011. These increases in net interest income were the result of higher yields on our investments due to the shift from money market investments to short term bond funds.

### **Liquidity and Capital Resources**

Our strategy is centered on obtaining regulatory approval to market SFP and developing other high potential drug candidates, while also expanding our dialysis products business. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions and other product development opportunities. These initiatives will require the expenditure of substantial cash resources. We expect our cash needs for research and development to continue to increase as clinical development and patient testing activities increase for our Phase III clinical testing program for SFP. The timing and magnitude of such spending is largely dependent upon the initiation and pace of execution of the Phase III clinical program. We will invest in our Phase III clinical development program as well as other development initiatives over the next several years.

Our cash resources include cash generated from our business operations and the proceeds from our equity offering in 2009. Our cash position as of September 30, 2011 was \$20.2 million including cash and short term investments. In the first nine months of 2011, our cash position decreased \$4.0 million from December 31, 2010. We used \$7.2 million in cash to fund operations in the first nine months of 2011, which was largely to fund our research and development expenditures. Our current business operation excluding research and development activities continues to generate positive cash flow to mitigate these expenditures. Our inventory levels and accounts receivable decreased, providing approximately \$1.0 million in cash. We advanced funds to research and development service providers for future clinical testing related expenses and as of September 30, 2011, such advances aggregated \$2.5 million.

In the first nine months of 2011, we used approximately \$0.5 million in cash for investing activities including the addition of fixed assets totaling \$0.3 million and in-licensing intellectual property \$0.1 million. We realized \$3.9

## **Table of Contents**

million from the issuance of common shares that were primarily from the exercise of warrants in the first nine months of 2011.

We believe our current and prospective sources of cash resources will be sufficient to complete the SFP testing and FDA approval process and to fund our other anticipated research and development activities and ordinary course operating cash requirements in 2012. We expect to continue generating positive cash flow from operations in 2011, excluding the effect of our research and development expenses. In addition, we may continue to realize substantial cash proceeds from warrants over the next year.

The cost to obtain regulatory approval for a drug in the United States is expensive and such approval can take several years to obtain. Under a variety of circumstances, such as if we do more testing than currently expected, or if the assumptions underlying our cash flow projections prove to be incorrect and our core business does not generate cash flow as we anticipate, or if we pursue opportunities to expand our business, we may need to obtain additional cash, such as through equity financing, debt financing of capital expenditures or a line of credit, to supplement our working capital. We explore opportunities from time to time to increase our cash resources, to reduce our liquidity risk and to have resources available to permit us to pursue expansion opportunities. Alternatively, we may seek to enter into product development arrangements with an international partner in order to fully execute our strategic plan. We may also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets and other potential funding sources.

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

#### **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, 2011, we had \$11.8 million invested in short term bond funds which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short term duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

#### **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, 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,

## **Table of Contents**

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. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 fiscal quarter ended September 30, 2011 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **Item 1A. Risk Factors**

For information regarding risk factors affecting us, see **Risk Factors** in Item 1A of Part I of our 2010 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K.

### **Item 6. Exhibits**

See Exhibit Index following the 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 4, 2011

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

Date: November 4, 2011

/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</b>	
<b>No.</b>	<b>Description</b>
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
101.INS *	XBRL Instance Document
101.SCH *	XBRL Taxonomy Extension Schema
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase
101.DEF *	XBRL Taxonomy Extension Definition Database
101.LAB *	XBRL Taxonomy Extension Label Linkbase
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase

\* XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.