ROCKWELL MEDICAL TECHNOLOGIES INC Form 10-Q November 04, 2010

# **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 þ **EXCHANGE ACT OF 1934** 

For the quarterly period ended September 30, 2010

or	
o TRANSITION REPORT PURSUANT TO SEC EXCHANGE ACT OF 1934 For the transition period fromto	CTION 13 OR 15(D) OF THE SECURITIES
Commission File Number ROCKWELL MEDICAL TECT	
(Exact name of registrant as sp	pecified in its charter)
Michigan	38-3317208
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
30142 Wixom Road, Wixom, Michigan	48393
(Address of principal executive offices)	(Zip Code)
(248) 960-90	
(Registrant s telephone number (Former name, former address and former fise	
Indicate by check mark whether the registrant: (1) has filed all r	· ·
the Securities Exchange Act of 1934 during the preceding 12 mg	
required to file such reports), and (2) has been subject to such fi	
	b Yes o No
Indicate by check mark whether the registrant has submitted ele	*

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).

o Yes o 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.

Non-accelerated filer o Smaller reporting Large accelerated filer o Accelerated filer b (Do not check if a smaller company o reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

o Yes b 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 29, 2010

Common Stock, no par value

17,463,108 shares

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# PART I FINANCIAL INFORMATION

## **Item 1. Financial Statements**

# ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

As of September 30, 2010 and December 31, 2009

ASSETS		eptember 30, 2010 (unaudited)	D	ecember 31, 2009
Cash and Cash Equivalents Accounts Receivable, net of a reserve of \$25,700 in 2010 and \$31,000 in	\$	23,657,128	\$	23,038,095
2009		4,636,534		3,492,622
Inventory		2,534,644		3,088,352
Other Current Assets		844,141		329,876
Total Current Assets		31,672,447		29,948,945
Property and Equipment, net		3,272,869		3,631,549
Intangible Assets		190,613		214,337
Goodwill		920,745		920,745
Other Non-current Assets		163,624		163,645
Total Assets	\$	36,220,298	\$	34,879,221
LIABILITIES AND SHAREHOLDERS EQUITY				
Capitalized Lease Obligations	\$	23,220	\$	42,938
Accounts Payable		2,843,219		3,388,757
Accrued Liabilities		1,900,016		1,854,347
Customer Deposits		103,184		250,915
Total Current Liabilities		4,869,639		5,536,957
Capitalized Lease Obligations		11,740		19,062
Shareholders Equity:				
Common Shares, no par value, 17,463,108 and 17,200,442 shares issued				
and outstanding		55,993,030		53,545,394
Common Share Purchase Warrants, 3,338,569 and 3,318,569 warrants issued and outstanding		8,223,795		7,635,594
Accumulated Deficit		(32,877,906)		(31,857,786)
Accumulated Deficit		(32,677,700)		(31,037,700)
Total Shareholders Equity		31,338,919		29,323,202
Treat I in the control of the contro	Φ	26 220 200	ф	24.070.221
Total Liabilities and Shareholders Equity	\$	36,220,298	\$	34,879,221

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

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# ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY CONSOLIDATED INCOME STATEMENTS

For the three and nine months ended September 30, 2010 and September 30, 2009 (Unaudited)

	Three Months Ended Sept. 30, 2010		Three Months Ended Sept. 30, 2009		Nine Months Ended Sept. 30, 2010		Nine Months Ended Sept. 30, 2009	
Sales Cost of Sales	\$	<b>14,745,414</b> 12,345,221	\$	<b>14,158,234</b> 11,751,499	\$	<b>45,232,078</b> 37,746,691	\$	<b>39,968,018</b> 34,508,410
<b>Gross Profit</b> Selling, General and		2,400,193		2,406,735		7,485,387		5,459,608
Administrative Research and Product		2,431,367		1,946,570		6,847,606		5,078,073
Development		727,978		1,977,618		1,686,666		5,312,499
<b>Operating Income (Loss)</b>		(759,152)		(1,517,453)		(1,048,885)		(4,930,964)
Interest Expense (Income), Net		(15,795)		3,990		(28,765)		20,493
Net Income (Loss)	\$	(743,357)	\$	(1,521,443)	\$	(1,020,120)	\$	(4,951,457)
Basic Earnings (Loss) per Share		(\$0.04)		(\$0.11)		(\$0.06)		(\$0.35)
Diluted Earnings (Loss) per		(40.04)		(40.44)		(40.00)		(40.00)
Share		(\$0.04)		(\$0.11)		(\$0.06)		(\$0.35)
The accompanying	notes	are an integral	part 4	of the consolida	ted fi	nancial stateme	nts.	

# ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2010 and September 30, 2009 (Unaudited)

	For the nine months ended September 30,				
		2010		2009	
Cash Flows From Operating Activities:					
Net (Loss)	\$	(1,020,120)	\$	(4,951,457)	
Adjustments To Reconcile Net Loss To Net Cash Used In					
Operating Activities: Depreciation and Amortization		1,047,077		836,020	
Loss (Gain) on Disposal of Assets		16,822		20,403	
Share Based Compensation Non-employee Warrants		588,201		348,360	
Share Based Compensation Employees	2,392,688 1,3				
Changes in Assets and Liabilities:					
(Increase) Decrease in Accounts Receivable		(1,143,912)		143,449	
Decrease in Inventory		553,708		487,056	
(Increase) in Other Assets		(514,244)		(106,751)	
(Decrease) in Accounts Payable		(545,538)		(991,877)	
Increase (Decrease) in Other Liabilities		(102,062)		1,017,940	
Changes in Assets and Liabilities		(1,752,048)		549,817	
Cash Provided by (Used) In Operating Activities		1,272,620		(1,802,447)	
Cash Flows From Investing Activities:					
Purchase of Equipment		(682,295)		(1,080,495)	
Proceeds on Sale of Assets		800		5,120	
Purchase of Intangible Assets				(12,875)	
Cash (Used ) In Investing Activities		(681,495)		(1,088,250)	
Cash Flows From Financing Activities:					
Issuance of Common Shares and Purchase Warrants		54,948		184,997	
Payments on Notes Payable		(27,040)		(122,995)	
Cash Provided By Financing Activities		27,908		62,002	
Increase (Decrease) In Cash and Cash Equivalents		619,033		(2,828,695)	
Cash and Cash Equivalents at Beginning of Period		23,038,095		5,596,645	
Cash and Cash Equivalents at End of Period	\$	23,657,128	\$	2,767,950	

Supplemental Cash Flow disclosure

2010 2009
Interest Paid \$ 8,876 \$ 20,493

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

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### Rockwell Medical Technologies, Inc. and Subsidiary Notes to Consolidated Financial Statements

# 1. Description of Business

Rockwell Medical Technologies, Inc. and Subsidiary (collectively, we, our, us, or the Company) manufacture, s 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, clinical 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, 2009 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, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2009 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 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, 2010 and December 31, 2009 we had customer deposits of \$103,184 and \$250,915, respectively.

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# **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.

## **Research and Product Development**

We recognize research and product development costs as expenses are incurred. We incurred research and product development costs related to the commercial development, patent approval and regulatory approval of new products, including iron supplemented dialysate (SFP), aggregating approximately \$1.7 million and \$5.3 million in the first nine months of 2010 and 2009, 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. We completed a Phase 2 study of SFP in 2009 and intend to start our Phase 3 program in late 2010.

### **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 mon Septem		Nine months ended September 30,		
	2010	2009	2010	2009	
Basic Weighted Average Shares Outstanding Effect of Dilutive Securities	17,136,119	14,060,533	17,091,733	14,010,366	
Diluted Weighted Average Shares					
Outstanding	17,136,119	14,060,533	17,091,733	14,010,366	

#### 3. Inventory

Components of inventory as of September 30, 2010 and December 31, 2009 are as follows:

		S	eptember 30, 2010	I	December 31, 2009
Raw Materials Work in Process Finished Goods		\$	1,010,369 134,910 1,389,365	\$	1,051,781 196,603 1,839,968
Total	7	\$	2,534,644	\$	3,088,352

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#### 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, 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 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, 2009 as modified by our Quarterly Report on Form 10-Q for the period ended March 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.

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

We depend on government funding of healthcare.

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

We depend on key personnel.

Our business is highly regulated.

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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.

Health care reform could adversely affect our business.

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.

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.

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.

Our strategy is to develop high potential drug candidates while also expanding our dialysis products business, which had sales of \$45.2 million for the nine months ending September 30, 2010. We invested \$1.7 million in research and development expenses in the first nine months of 2010 compared to \$5.3 million in the first nine months of 2009, primarily related to SFP, our lead developmental drug.

We believe our SFP product has unique and substantive benefits compared to current treatment options and 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 can take several years. We believe that our current and prospective cash resources are sufficient to operate our business at current levels and to complete the regulatory approval process for SFP. However, expansion of our business and acquisition of new product lines would likely require additional capital.

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 customer and product mix may cause our gross profit and our gross profit margins to vary period to period. We also anticipate increases in fuel and other costs over the next year along with competitive pricing pressures in the renal market.

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The majority of our business is with domestic clinics who order routinely. Certain major distributors of our products internationally have not ordered consistently, however, 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 that the size and frequency of these orders will fluctuate from period to period. These orders may increase in future periods or may not recur at all.

# Results of Operations for the Three and Nine Months Ended September 30, 2010 and September 30, 2009 Sales

Sales in the third quarter of 2010 were \$14.7 million an increase of \$0.6 million or 4.1% over the third quarter of 2009. Sales for the first nine months of 2010 were \$45.2 million, an increase of \$5.3 million or 13.2% over the first nine months of 2009. The increases were due to increased sales with a single international distributor whose orders are dependent upon its success at winning national tenders. Sales to this single distributor increased \$1.4 million and \$6.7 million for the three and nine month periods ended September 30, 2010 compared to the same periods in 2009.

Our year to date sales to international distributors were up \$7.1 million and our domestic sales were down by \$1.8 million. Lower domestic sales were largely the result of a change in product mix reflecting a migration by customers to lower cost formulations and conversion to our Dri-Sate Dry Acid concentrate product line, both of which result in lowering providers—cost per treatment while improving our gross profit margins. We realized a significant shift to our Dri-Sate Dry Acid concentrate product line, with unit volumes increasing by 31% in the first nine months of 2010 compared to the first nine months of 2009, which reflects a continuing trend by our customers to convert from liquid to dry acid concentrate.

#### **Gross Profit**

Gross profit in the third quarter of 2010 was \$2.4 million unchanged from the third quarter of 2009. Gross profit margins were 16.3% compared to 17.0% in the third quarter of 2009 as revenues increased in the third quarter of 2010. Gross profit in the first nine months of 2010 was \$7.5 million compared to \$5.5 million in the first nine months of 2009. Gross profit margins increased to 16.5% in the first nine months of 2010 compared to 13.7% in the first nine months of 2009.

Substantial changes in product and customer mix coupled with increases in overall sales volumes improved our gross profit margins compared to the first nine months of last year. Domestic sales migrated toward our Dri-Sate Dry Acid concentrate product line, which provides a cost effective alternative to higher cost per treatment liquid products and which cost us less to deliver than liquid products. Customers also migrated toward lower cost formulations, which improved margins while not increasing costs to our customers. Over the last year, we incurred moderate increases in material, fuel and other operating costs while continuing to moderately increase our selling prices on maturing contracts. Average diesel fuel costs increased approximately 24% per gallon in the first nine months of 2010 compared to the first nine months of 2009.

## Selling, General and Administrative Expense

Selling, general and administrative (SG&A) expense during the third quarter of 2010 was \$2.4 million, an increase of \$0.5 million over the third quarter of 2009. The increase was primarily due to higher non-cash equity compensation of \$0.4 million.

SG&A was \$6.8 million in the first nine months of 2010 compared to \$5.1 million in the first nine months of 2009. The increase was primarily due to higher non-cash equity compensation expense of \$1.2 million and increased personnel costs of \$0.5 million. Personnel costs were higher due to a combination of compensation for new positions, increased performance bonuses, wage inflation and higher benefit costs.

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#### **Research and Development**

Research and development (R&D) costs were \$0.7 million and \$2.0 million in the third quarter of 2010 and 2009, respectively. R&D costs were \$1.7 million in the first nine months of 2010 compared to \$5.3 million in the first nine months of 2009. Spending in both years was primarily for development and approval of SFP. During 2009, we conducted a Phase 2b study which was completed in late 2009. We plan to commence our SFP Phase 3 clinical trials in late 2010 as well as other related studies. Research and development spending will increase significantly when the Phase 3 program commences.

# **Interest Income, Net**

Our net interest income was \$15,795 in the third quarter of 2010 compared to a net interest expense of \$3,990 in the third quarter of 2009. Net interest income in the first nine months of 2010 was \$28,765 compared to a net interest expense of \$20,493 in the first nine months of 2009. The increase in interest income was the result of investing the proceeds from the October 2009 equity offering in short term investments. However, we do not expect that this investment will continue to materially increase interest income due to the current low short term interest rate environment.

#### **Liquidity and Capital Resources**

We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions. Although these initiatives will require the expenditure of substantial cash resources, we believe our cash resources will be sufficient to fund our Phase 3 clinical program. Our cash resources include cash generated from our business operations and the \$20.4 million in net proceeds from our equity offering in October 2009. Our current assets exceeded our current liabilities by over \$26.8 million as of September 30, 2010 and included \$23.7 million in cash and cash equivalents.

In the first nine months of 2010, our cash increased by \$0.6 million as a result of cash flow generated from operations of \$1.3 million offset by \$0.7 million in capital expenditures. Cash provided by operations totaled \$1.3 million for the first nine months of 2010 and was primarily the result of \$3.0 million in cash generated from business operations partially offset by a \$1.7 million increase in working capital. Accounts receivable as of September 30, 2010 increased \$1.1 million compared to December 31, 2009 as a result of a large early payment made prior to year end which temporarily decreased accounts receivable at December 31, 2009. We also realized a \$0.5 million reduction in inventory due to normal fluctuations coupled with reduced inventory requirements for certain product lines.

We believe our cash resources are sufficient to fund our anticipated research and development activities as well as our ordinary operating cash requirements in the next twelve months. We expect to continue to generate positive cash flow from operations in 2011, excluding the effect of our research and development expenses, assuming stable operating results and relative stability in the markets for our key raw materials. However, if we use more cash than anticipated for SFP development, or are required to do more testing than expected or if the assumptions underlying our cash flow projections for 2011 prove to be incorrect 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 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.

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# 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, 2010, we had \$20.5 million in short term investments in a money market fund.

A hypothetical 100 basis point increase in market interest rates for short term liquid investments would increase our annualized interest income by approximately \$0.2 million, assuming we invested \$20.5 million in cash and that level remained constant for the year. We did not perform an analysis of a 100 basis point decrease in market interest rates as such an analysis would be meaningless given the current market rates.

### 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, 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, 2010 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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#### 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 2009 Annual Report on Form 10-K. Other than as previously updated in our Form 10-Q for the quarter ended March 31, 2010, there have been no material changes to the risk factors set forth in Item 1A of our Form 10-K for the year ended December 31, 2009.

#### Item 6. Exhibits

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

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#### **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, 2010 /s/ ROBERT L. CHIOINI

Robert L. Chioini

President and Chief Executive Officer (principal executive officer) (duly

authorized officer)

Date: November 4, 2010 /s/ THOMAS E. KLEMA

Thomas E. Klema

Vice President and Chief Financial Officer (principal financial officer and principal

accounting officer)

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# **10-Q EXHIBIT INDEX**

The following exhibits are filed as part of this report (unless otherwise noted to be previously filed, and therefore incorporated herein by reference). Our SEC file number is 000-23661.

Exhibit No. 4.11	<b>Description</b> Warrant issued to Capitol Securities Management, Inc. as of September 1, 2010 (Company s Form 8-K filed September 2, 2010).
4.12	Form of Amended and Restated Warrant issued to Messrs. Rick, Pizzirusso, Ries, Meyers, Pace and Bailey as of September 1, 2010 (Company s Form 8-K filed September 2, 2010).
10.35	Third Amendment to Industrial Lease Agreement between Rockwell Medical Technologies, Inc. and DCT DFW, LP dated July 7, 2010 (Company s Form 8-K filed on July 13, 2010).
10.37	Lease Renewal Agreement dated August 27, 2010, by and between Rockwell Medical Technologies, Inc. and International-Wixom, LLC (Company s Form 8-K filed September 2, 2010).
10.38	Advisory Agreement dated September 1, 2010 between the Company and Capitol Securities Management, Inc. (Company s Form 8-K filed September 2, 2010).
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
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