

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

May 07, 2010

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**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 March 31, 2010**  
**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 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.

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.

| Class                      | Outstanding as of April 30, 2010 |
|----------------------------|----------------------------------|
| Common Stock, no par value | 17,202,108 shares                |

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

**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEETS**  
**As of March 31, 2010 and December 31, 2009**

|   | <b>March 31,<br/>2010<br/>(unaudited)</b> | <b>December 31,<br/>2009</b> |
|---|---|------------------------------|
| <b>ASSETS</b>   |   |                              |
| Cash and Cash Equivalents   | \$ 24,634,222                             | \$ 23,038,095                |
| Accounts Receivable, net of a reserve of \$30,000 in 2010 and \$31,000 in 2009          | 2,971,123                                 | 3,492,622                    |
| Inventory   | 2,546,318                                 | 3,088,352                    |
| Other Current Assets  | 447,582                                   | 329,876                      |
| <br>Total Current Assets  | <br>30,599,245                            | <br>29,948,945               |
| <br>Property and Equipment, net   | <br>3,589,074                             | <br>3,631,549                |
| Intangible Assets   | 206,429                                   | 214,337                      |
| Goodwill  | 920,745                                   | 920,745                      |
| Other Non-current Assets  | 164,831                                   | 163,645                      |
| <br>Total Assets  | <br>\$ 35,480,324                         | <br>\$ 34,879,221            |
| <br><b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |   |                              |
| Capitalized Lease Obligations   | \$ 34,344                                 | \$ 42,938                    |
| Accounts Payable  | 3,769,327                                 | 3,388,757                    |
| Accrued Liabilities   | 1,349,186                                 | 1,854,347                    |
| Customer Deposits   | 477,044                                   | 250,915                      |
| <br>Total Current Liabilities   | <br>5,629,901                             | <br>5,536,957                |
| <br>Capitalized Lease Obligations   | <br>13,593                                | <br>19,062                   |
| Shareholders' Equity:   |   |                              |
| Common Shares, no par value, 17,202,108 and 17,200,442 shares issued and outstanding    | 54,290,988                                | 53,545,394                   |
| Common Share Purchase Warrants, 3,323,569 and 3,318,569 warrants issued and outstanding | 7,797,309                                 | 7,635,594                    |
| Accumulated Deficit   | (32,251,467)                              | (31,857,786)                 |
| <br>Total Shareholders' Equity  | <br>29,836,830                            | <br>29,323,202               |
| <br>Total Liabilities and Shareholders' Equity  | <br>\$ 35,480,324                         | <br>\$ 34,879,221            |



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

**For the three months ended March 31, 2010 and March 31, 2009**

(Unaudited)

|  | Three Months<br>Ended<br>March 31, 2010 | Three Months<br>Ended<br>March 31, 2009 |
|--|---|---|
| <b>Sales</b>                               | <b>\$ 14,979,952</b>                    | <b>\$ 12,796,772</b>                    |
| Cost of Sales                              | 12,666,423                              | 11,603,825                              |
| <b>Gross Profit</b>                        | <b>2,313,529</b>                        | <b>1,192,947</b>                        |
| Selling, General and Administrative        | 2,194,903                               | 1,560,815                               |
| Research and Product Development           | 517,415                                 | 1,338,310                               |
| <b>Operating (Loss)</b>                    | <b>(398,789)</b>                        | <b>(1,706,178)</b>                      |
| Interest Expense (Income), Net             | (5,109)                                 | 9,265                                   |
| <b>Net (Loss)</b>                          | <b>\$ (393,680)</b>                     | <b>\$ (1,715,443)</b>                   |
| <br><b>Basic Earnings (Loss) per Share</b> | <br><b>\$ (.02)</b>                     | <br><b>\$ (.12)</b>                     |
| <b>Diluted Earnings (Loss) per Share</b>   | <b>\$ (.02)</b>                         | <b>\$ (.12)</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 three months ended March 31, 2010 and March 31, 2009****(Unaudited)**

|   | <b>2010</b>          | <b>2009</b>           |
|---|----------------------|-----------------------|
| Cash Flows From Operating Activities:                                       |                      |                       |
| Net (Loss)  | <b>\$ (393,680)</b>  | <b>\$ (1,715,443)</b> |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: |                      |                       |
| Depreciation and Amortization   | 363,479              | 227,373               |
| Loss (Gain) on Disposal of Assets   | 7,539                | (5,121)               |
| Share Based Compensation Non-employee Warrants                              | 161,714              | 135,417               |
| Share Based Compensation Employees  | 740,446              | 373,823               |
| Changes in Assets and Liabilities:  |                      |                       |
| Decrease in Accounts Receivable   | 521,499              | 360,455               |
| Decrease in Inventory   | 542,034              | 345,796               |
| (Increase) in Other Assets  | (118,892)            | (46,633)              |
| Increase (Decrease) in Accounts Payable                                     | 380,570              | (1,376,481)           |
| (Decrease) in Other Liabilities   | (279,032)            | (260,684)             |
| Changes in Assets and Liabilities   | 1,046,179            | (977,547)             |
| Cash Provided by (Used) In Operating Activities                             | <b>1,925,677</b>     | <b>(1,961,498)</b>    |
| Cash Flows From Investing Activities:                                       |                      |                       |
| Purchase of Equipment   | (320,635)            | (234,563)             |
| Proceeds on Sale of Assets  |                      | 5,121                 |
| Purchase of Intangible Assets   |                      | (2,362)               |
| Cash (Used ) In Investing Activities  | <b>(320,635)</b>     | <b>(231,804)</b>      |
| Cash Flows From Financing Activities:                                       |                      |                       |
| Issuance of Common Shares and Purchase Warrants                             | 5,148                |                       |
| Payments on Notes Payable   | (14,063)             | (49,875)              |
| Cash (Used) By Financing Activities   | <b>(8,915)</b>       | <b>(49,875)</b>       |
| Increase (Decrease) In Cash and Cash Equivalents                            | 1,596,127            | (2,243,177)           |
| Cash and Cash Equivalents at Beginning of Period                            | 23,038,095           | 5,596,645             |
| Cash and Cash Equivalents at End of Period                                  | <b>\$ 24,634,222</b> | <b>\$ 3,353,468</b>   |
| Supplemental Cash Flow disclosure   |                      |                       |

|               | <b>2010</b>     | <b>2009</b>     |
|---------------|-----------------|-----------------|
| Interest Paid | <b>\$ 4,350</b> | <b>\$ 9,265</b> |

*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, 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, 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 month period ended March 31, 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 March 31, 2010 and December 31, 2009 we had customer deposits of \$477,044 and \$250,915, 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.

**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 \$0.5 million and \$1.3 million in the first quarter 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 plan to commence our SFP Phase 3 development program in 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:

|   | <b>Three months ended March 31,</b> |             |
|---|-------------------------------------|-------------|
|   | <b>2010</b>                         | <b>2009</b> |
| Basic Weighted Average Shares Outstanding   | 17,051,870                          | 13,979,325  |
| Effect of Dilutive Securities               |                                     |             |
| Diluted Weighted Average Shares Outstanding | 17,051,870                          | 13,979,325  |

**3. Inventory**

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

|                 | <b>March 31, 2010</b> | <b>December 31, 2009</b> |
|-----------------|-----------------------|--------------------------|
| Raw Materials   | \$ 904,266            | \$ 1,051,781             |
| Work in Process | 204,454               | 196,603                  |
| Finished Goods  | 1,437,598             | 1,839,968                |
| Total           | \$ 2,546,318          | \$ 3,088,352             |

**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

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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 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.

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.

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.

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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 \$54.7 million in 2009 and approximately \$15.0 million in the first quarter of 2010. Our research and development expenses were \$0.5 million in the first quarter of 2010 compared to \$1.3 million in the first quarter of 2009 when we were conducting a Phase 2b clinical trial of SFP, our lead drug candidate.

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 our cash resources will be sufficient to complete the SFP testing, FDA approval process and our other planned research and development activities.

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 may cause our gross profit and our gross profit margins to vary period to period. We anticipate a continued increase in fuel and other costs in 2010 along with competitive pricing pressures in the renal market.

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 we expect the size and frequency of these orders to fluctuate from period to period. These orders may increase in future periods or may not recur at all.

**Results of Operations for the Three Months Ended March 31, 2010 and March 31, 2009**

**Sales**

Sales in the first quarter of 2010 were \$15.0 million, an increase of \$2.2 million or 17.1% over the first quarter of 2009. This increase was almost entirely due to a \$2.2 million increase in sales to a single international distributor which increase is typical of certain distributors of our products internationally whose orders are dependent upon their success at winning local or national tenders. Our other international business increased by \$0.3 million or 31% while our domestic sales decreased by \$0.35 million or 3.1%. Lower domestic sales were largely the result of a change in

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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 35% compared to the first quarter of 2009 which reflects a continuing trend by our customers to convert from liquid to dry acid concentrate.

### **Gross Profit**

Gross profit in the first quarter of 2010 was \$2.3 million an increase of \$1.1 million or 94% over the first quarter of 2009. Gross profit margins were 15.4% compared to 9.3% in the first quarter of 2009. Substantial changes in product and customer mix impacted our gross profit margins compared to the first quarter last year and increases in overall sales volumes also contributed to improved margins. 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 only moderate increases in material, fuel and other operating costs while continuing to increase our selling prices on maturing contracts.

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

Selling, general and administrative expense during the first quarter of 2010 was \$2.2 million an increase of \$0.6 million over the first quarter of 2009. The increase was primarily due to a \$0.35 million increase in non-cash charges for equity compensation and \$0.25 million in higher compensation and personnel costs.

### **Research and Development**

Research and development costs were \$0.5 million and \$1.3 million in the first quarter of 2010 and 2009, respectively. Spending in both quarters 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 program in the second half of 2010 and expect to see research and development spending increase when the Phase 3 program commences.

### **Interest Income, Net**

Our net interest income was \$5,100 in the first quarter of 2010 compared to a net interest expense of \$9,300 in the first quarter of 2009. The increase in interest income was the result of the investment of the proceeds of the October 2009 equity offering in short term investments. However, we do not expect that this investment will continue to 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 adequate 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 \$24.9 million as of March 31, 2010 and included \$24.6 million in cash and cash equivalents.

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In the first quarter of 2010, our cash increased by \$1.6 million as a result of cash flow generated from operations of \$1.9 million offset by \$0.3 million in capital expenditures. Cash provided by operations totaled \$1.9 million for the quarter and was primarily the result of a \$1.0 million reduction in accounts receivable and inventory and \$0.9 million in cash generated from business operations. We realized a \$0.5 million reduction in accounts receivable which we anticipate to be temporary resulting from early payment of outstanding receivables by a certain customer. We also realized a \$0.5 million reduction in inventory due to normal inventory fluctuation in the first quarter compared to the fourth quarter of 2009. We anticipate inventory levels will increase in the second quarter and will fluctuate going forward.

We believe our cash resources are sufficient to fund our anticipated research and development activities as well as our ordinary operating cash requirements in 2010 and 2011. We expect to continue to generate positive cash flow from operations in 2010, 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 2010 and 2011 prove to be incorrect, 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. 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.

### **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 March 31, 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



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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 March 31, 2010 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 2009 Annual Report on Form 10-K. Due to the recent passage of health care reform legislation, the risk factors under the headings

Health care reform could adversely affect our business. and We depend on government funding of healthcare. are amended and restated as set forth below. Except as set forth below, there have been no material changes to the risk factors described in such Form 10-K.

**Health care reform could adversely affect our business.**

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. The federal Medicare and Medicaid programs are facing financial challenges and are looking at ways to reduce the costs of the Medicare and Medicaid programs. Similarly, many states have large deficits which may prove unsustainable, resulting in defaults on state debt obligations which may ultimately result in the reduction or curtailment of health care benefits or state Medicaid reimbursement.

In the United States, Congress recently enacted health reform legislation that will make significant changes to the health care payment and delivery system. The health reform legislation requires employers to provide employees with insurance coverage that meets minimum eligibility and coverage requirements or face penalties. The legislation also includes provisions that will impact the number of individuals with insurance coverage, the types of coverage and level of health benefits that will be required and the amount of payment providers performing health care services will receive. The legislation imposes implementation effective dates beginning in 2010 and extending through 2020. Many of the changes require additional guidance from government agencies or federal regulations. Therefore, it is difficult to determine at this time what impact the health reform legislation will have on the Company or its customers. The proposed changes in the Medicare and Medicaid programs, could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations. In addition, the health reform legislation imposes fees or excise taxes on pharmaceutical and device manufacturers based on their revenues, which could also have a material adverse effect on the Company.

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**We depend on government funding of healthcare.**

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare and Medicaid funding to be viable businesses. A variety of changes to health insurance and reimbursement are included in health reform legislation recently enacted by Congress. Some of these changes could have a negative impact on Medicare and Medicaid funding and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, our customers would be severely impacted, increasing our risk of not being paid in full by our customers. An increase in our exposure to uncollectible accounts could have a material adverse effect on our financial position, results of operations and cash flows.

In 2011, the government will implement a change to reimbursement practices by shifting to a fully bundled rate per dialysis session compared to the current practice of separately billed services and medications. This change increases the burden on dialysis treatment providers to effectively manage their cost of treatment and operations and may put more pressure on suppliers such as us to reduce costs. As a result, we may see increased pressure to reduce the cost of our products, which would have a negative impact on our revenue and gross profit margins.

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

On March 8, 2010, we entered into an advisory agreement with RJ Aubrey IR Services LLC, or RJ Aubrey, pursuant to which we issued warrants to acquire 20,000 shares of our common stock in a private placement exempt from registration under Section 4(2) of the Securities Act of 1933. The warrants were issued as compensation for investor relations consulting services rendered under the agreement. The advisory agreement with RJ Aubrey will terminate on December 31, 2010 and may be terminated by either party upon 30 days prior written notice. RJ Aubrey is a financially sophisticated accredited investor that 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 5,000 share increments on March 8, 2010, April 1, 2010, July 1, 2010, and October 1, 2010. The warrants will become exercisable on March 8, 2011 and will expire on March 8, 2013. Upon a termination of the advisory 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 \$6.14 per share. Once exercisable, the 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.

**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: May 7, 2010

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

Date: May 7, 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**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 4.10               | Warrant issued to RJ Aubrey IR Services LLC as of March 8, 2010.   |
| 10.34              | Advisory Agreement dated March 8, 2010 between the Company and RJ Aubrey IR Services 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 |