

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

May 06, 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 March 31, 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)

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
(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).

o Yes p 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, 2011 |
|----------------------------|----------------------------------|
| Common Stock, no par value | 17,843,608 shares |

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

| | Page |
|---|------|
| <u>Part I Financial Information (unaudited)</u> | |
| <u>Item 1 Financial Statements (unaudited)</u> | |
| <u>Consolidated Balance Sheets</u> | 3 |
| <u>Consolidated Statements of Income</u> | 4 |
| <u>Consolidated Statements of 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> | 12 |
| <u>Item 4 Controls and Procedures</u> | 13 |
| <u>Part II Other Information</u> | |
| <u>Item 1A Risk Factors</u> | 13 |
| <u>Item 6 Exhibits</u> | 13 |
| <u>Signatures</u> | 14 |
| <u>Exhibit Index</u> | 15 |
| <u>EX-31.1</u> | |
| <u>EX-31.2</u> | |
| <u>EX-32.1</u> | |

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

**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS
As of March 31, 2011 and December 31, 2010**

| | March 31, 2011 (unaudited) | December 31, 2010 |
|---|---|------------------------------|
| ASSETS | | |
| Cash and Cash Equivalents | \$ 7,952,402 | \$ 12,263,449 |
| Investments Available for Sale | 12,035,087 | 11,938,098 |
| Accounts Receivable, net of a reserve of \$29,000 in 2011 and \$23,000 in 2010 | 4,687,658 | 4,507,296 |
| Inventory | 2,782,396 | 2,936,878 |
| Other Current Assets | 678,378 | 1,020,647 |
| Total Current Assets | 28,135,921 | 32,666,368 |
| Property and Equipment, net | 2,841,571 | 3,049,513 |
| Intangible Assets | 159,656 | 166,657 |
| Goodwill | 920,745 | 920,745 |
| Other Non-current Assets | 2,831,881 | 163,624 |
| Total Assets | \$ 34,889,774 | \$ 36,966,907 |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| Capitalized Lease Obligations | \$ 15,199 | \$ 18,215 |
| Accounts Payable | 2,701,365 | 3,659,507 |
| Accrued Liabilities | 2,807,411 | 2,577,022 |
| Customer Deposits | 201,912 | 165,476 |
| Total Current Liabilities | 5,725,887 | 6,420,220 |
| Capitalized Lease Obligations | 5,683 | 8,750 |
| Shareholders Equity: | | |
| Common Shares, no par value, 17,743,608 and 17,513,608 shares issued and outstanding | 58,679,444 | 57,017,236 |
| Common Share Purchase Warrants, 3,138,569 and 3,338,569 warrants issued and outstanding | 8,130,502 | 8,275,509 |
| Accumulated Deficit | (37,453,422) | (34,541,185) |
| Accumulated Other Comprehensive Loss | (198,320) | (213,623) |
| Total Shareholders Equity | 29,158,204 | 30,537,937 |

| | | |
|--|----------------------|----------------------|
| Total Liabilities And Shareholders Equity | \$ 34,889,774 | \$ 36,966,907 |
|--|----------------------|----------------------|

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

3

Table of Contents

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

For the three months ended March 31, 2011 and March 31, 2010

(Unaudited)

| | Three Months Ended March 31, 2011 | Three Months Ended March 31, 2010 |
|--|--|--|
| Sales | \$ 13,290,787 | \$ 14,979,952 |
| Cost of Sales | 11,639,242 | 12,666,423 |
| Gross Profit | 1,651,545 | 2,313,529 |
| Selling, General and Administrative | 2,246,553 | 2,194,903 |
| Research and Product Development | 2,402,596 | 517,415 |
| Operating Income (Loss) | (2,997,604) | (398,789) |
| Interest and Dividend Income | 85,968 | 9,458 |
| Interest Expense | 601 | 4,349 |
| Income (Loss) Before Income Taxes | (2,912,237) | 393,680 |
| Income Tax Expense | | |
| Net Income (Loss) | \$ (2,912,237) | \$ (393,680) |
| Basic Earnings (Loss) per Share | (\$.17) | (\$.02) |
| Diluted Earnings (Loss) per Share | (\$.17) | (\$.02) |

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 Quarter Ended March 31, 2011
(Unaudited)**

| | COMMON SHARES | | PURCHASE WARRANTS | | ACCUMULATED OTHER COMPREHENSIVE INCOME | | TOTAL SHAREHOLDERS' EQUITY |
|---|---------------|---------------|----------------------|--------------|---|--------------|----------------------------------|
| | SHARES | AMOUNT | WARRANTS | AMOUNT | DEFICIT | (LOSS) | |
| 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 | | | | | (2,912,237) | | (2,912,237) |
| Unrealized Gains on Available-for-Sale Investments | | | | | | 15,303 | 15,303 |
| Comprehensive Loss | | | | | | | (2,896,934) |
| Issuance of Common Shares | 30,000 | 61,370 | | | | | 61,370 |
| Issuance of Purchase Warrants | | | | 2,993 | | | 2,993 |
| Exercise of Purchase Warrants | 200,000 | 546,000 | (20,000) | (148,000) | | | 398,000 |
| Stock Option Based Expense | | 901,435 | | | | | 901,435 |
| Restricted Stock Amortization | | 153,403 | | | | | 153,403 |
| Balance as of March 31, 2011 | 17,743,608 | \$ 58,679,444 | 3,318,569 | \$ 8,130,502 | \$ (37,453,422) | \$ (198,320) | \$ 29,158,204 |

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, 2011 and March 31, 2010**

(Unaudited)

| | 2011 | 2010 |
|---|-----------------------|----------------------|
| Cash Flows From Operating Activities: | | |
| Net (Loss) | \$ (2,912,237) | \$ (393,680) |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: | | |
| Depreciation and Amortization | 329,955 | 363,479 |
| Loss (Gain) on Disposal of Assets | 6,070 | 7,539 |
| Share Based Compensation Non-employee Warrants | 2,993 | 161,714 |
| Share Based Compensation Employees | 1,054,838 | 740,446 |
| Changes in Assets and Liabilities: | | |
| Decrease (Increase) in Accounts Receivable | (180,362) | 521,499 |
| Decrease in Inventory | 154,482 | 542,034 |
| Decrease (Increase) in Other Assets | (2,325,988) | (118,892) |
| Increase (Decrease) in Accounts Payable | (958,142) | 380,570 |
| Increase (Decrease) in Other Liabilities | 266,825 | (279,032) |
| Changes in Assets and Liabilities | (3,043,185) | 1,046,179 |
| Cash Provided By (Used) In Operating Activities | (4,561,566) | 1,925,677 |
| Cash Flows From Investing Activities: | | |
| Purchase of Equipment | (121,082) | (320,635) |
| Purchase of Investments Available for Sale | (81,686) | |
| Cash Used In Investing Activities | (202,768) | (320,635) |
| Cash Flows From Financing Activities: | | |
| Issuance of Common Shares and Purchase Warrants | 459,370 | 5,148 |
| Payments on Notes Payable | (6,083) | (14,063) |
| Cash Provided By (Used) In Financing Activities | 453,287 | (8,915) |
| Increase (Decrease) In Cash and Cash Equivalents | (4,311,047) | 1,596,127 |
| Cash and Cash Equivalents at Beginning of Period | 12,263,449 | 23,038,095 |
| Cash and Cash Equivalents at End of Period | \$ 7,952,402 | \$ 24,634,222 |
| Supplemental Cash Flow disclosure | | |
| Interest Paid | 2011 \$ 601 | 2010 \$ 4,350 |

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 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 month period ended March 31, 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 March 31, 2011 and December 31, 2010 we had customer deposits of \$201,912 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 months ended March 31, 2011 and March 31, 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 \$2.4 million and \$0.5 million for the three months ended March 31, 2011 and March 31, 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 March 31, | |
|---|---|-------------|
| | 2011 | 2010 |
| Basic Weighted Average Shares Outstanding | 17,307,179 | 17,051,870 |
| Effect of Dilutive Securities | | |
| Diluted Weighted Average Shares Outstanding | 17,307,179 | 17,051,870 |

3. Inventory

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

| | March 31, 2011 | December 31, 2010 |
|-----------------|---------------------------|------------------------------|
| Raw Materials | \$ 949,118 | \$ 1,082,807 |
| Work in Process | 193,132 | 148,712 |
| Finished Goods | 1,640,146 | 1,705,359 |
| Total | \$ 2,782,396 | \$ 2,936,878 |

4. Other Assets

We have included advances to a contract service provider in other assets. These advances will offset future liabilities incurred with this service provider for services and travel over the duration of the clinical trials conducted on our behalf by the service provider. As of March 31, 2011, \$2.7 million has been advanced to this service provider.

Table of Contents

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, predict, 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, 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.

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.

Table of Contents

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.

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. Our lead developmental drug, Soluble Ferric Pyrophosphate or SFP, is indicated for the treatment of iron deficiency anemia in hemodialysis patients. We believe SFP has unique and substantive benefits compared to current treatment options and has the potential to compete in the iron maintenance 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 may cause our gross profit and our gross profit margins to vary period to period. We anticipate continued increases in fuel and other costs in 2011 along with competitive pricing pressures in the renal market. 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 quarter in comparison with the first quarter of 2010.

The majority of our business is with domestic clinics who order routinely. Certain major distributors of our products internationally have not ordered consistently resulting in fluctuation in our international sales from period to period. These international orders may increase in future periods or may not recur at all.

Table of Contents

Results of Operations for the Three Months Ended March 31, 2011 and March 31, 2010

Sales

Sales in the first quarter of 2011 were \$13.3 million compared to \$15.0 million in the first quarter of 2010. Sales decreased \$1.7 million or 11.3% with international sales decreasing \$1.25 million and domestic sales decreasing \$0.45 million compared to the first quarter of 2010. International sales were \$2.45 million in the first quarter of 2011 compared to \$3.7 million in the first quarter of 2010, a decrease of 33%. Reduced purchase volume from one large international distributor accounted for \$0.9 million of the change while higher than normal purchase orders were realized in the first quarter of 2010 for other international accounts. 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. Our Dri-Sate dry acid concentrate gallons increased to 55% of acid concentrate equivalent gallons from 46% in the first quarter of 2010.

Gross Profit

Gross profit in the first quarter of 2011 was \$1.7 million compared to \$2.3 million in the first quarter of 2010. Approximately \$0.4 million of the decrease in gross profit was due to the impact of lower sales volumes while increased costs for fuel and inflationary increases in material costs, net of pricing changes accounted for the remainder. Gross profit margins were 12.4% in the first quarter of 2011 compared to 15.4% in the first quarter of 2010.

Selling, General and Administrative Expense

Selling, general and administrative expense (SG&A) during the first quarter of 2011 was \$2.2 million an increase of 2.4% over the first quarter of 2010. A slight increase in non-cash charges for equity compensation was mostly offset by a reduction in other SG&A costs compared to the first quarter of 2010. Total non-cash charges for equity compensation aggregated \$1.06 million compared to \$0.9 million in the first quarter of 2010.

Research and Development

Research and development costs were \$2.4 million and \$0.5 million in the first quarter of 2011 and 2010, respectively. Spending in both quarters was primarily for development and approval of SFP. In the first quarter of 2011, our Phase III testing began with the initiation of three clinical trials related to SFP.

Interest Income, Net

Our net interest income was \$85,000 in the first quarter of 2011 compared to a net interest income of \$5,000 in the first quarter of 2010. The increase in net interest income was the result of higher yields on our cash investments.

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 spending to increase substantially in 2011 over 2010 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 trials. We will invest in our Phase III clinical development program as well as other development initiatives over the next several years.

Table of Contents

Our cash resources include cash generated from our business operations and the proceeds from our equity offering in 2009. Our current assets exceeded our current liabilities by over \$22.4 million as of March 31, 2011 and included \$20.0 million in cash and short term investments. In the first quarter of 2011, we advanced \$2.7 million in cash to fund future vendor activities for our clinical development program, which represented the majority of the \$4.6 million in cash we used in our operations during the first quarter of 2011 compared to the \$1.9 million in cash generated by our operations in the first quarter of 2010. The \$2.5 million increase in our net loss, resulting from the increase in research and development expense and the decrease in gross profit coupled with a \$1.0 million decrease in accounts payable also contributed to the use of cash during the first quarter 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 2011 and 2012. We expect to generate positive cash flow from operations in 2011, excluding the effect of our research and development expenses, assuming relative stability in the markets for fuel and our key raw materials and relatively stable revenues. In addition, we may realize substantial cash proceeds from warrants that expire in each of the next two years. We realized cash from warrant exercises of \$400,000 in the first quarter of 2011.

The cost to obtain regulatory approval for a drug in the United States is expensive and can take several years. 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 the next two years 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 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 March 31, 2011, we had \$12 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

Table of Contents

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 March 31, 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: May 6, 2011

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

Date: May 6, 2011

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

14

Table of Contents

10-Q EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|---|
| 4.13 | Warrant dated February 16, 2011 (Company's Form 8-K filed February 23, 2011). |
| 10.39 | Products Purchase Agreement dated February 16, 2011, by and between Rockwell Medical Technologies, Inc. and DaVita Inc. (with certain portions deleted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934) (Company's Form 10-K filed March 7, 2011). |
| 10.40 | Agreement to Extend the Lease Agreement, Options to Purchase and Option to Lease dated February 17, 2011, by and between Rockwell Medical Technologies, Inc. and EZE Management Properties Limited Partnership (Company's Form 8-K filed February 24, 2011). |
| 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 |