

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-Q

November 06, 2009

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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 September 30, 2009**

**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

Smaller reporting company

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reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
 Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

| Class                      | Outstanding as of October 30, 2009 |
|----------------------------|------------------------------------|
| Common Stock, no par value | 17,060,410 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 September 30, 2009 and December 31, 2008**

|   | <b>September 30,<br/>2009<br/>(Unaudited)</b> | <b>December 31,<br/>2008</b> |
|---|---|------------------------------|
| <b>ASSETS</b>   |   |                              |
| Cash and Cash Equivalents   | \$ 2,767,950                                  | \$ 5,596,645                 |
| Accounts Receivable, net of a reserve of \$55,000 in 2009 and \$97,000 in 2008          | 5,086,207                                     | 5,229,656                    |
| Inventory   | 2,674,569                                     | 3,161,625                    |
| Other Current Assets  | 520,583                                       | 440,765                      |
| <b>Total Current Assets</b>   | <b>11,049,309</b>                             | <b>14,428,691</b>            |
| Property and Equipment, net   | 3,491,495                                     | 3,249,003                    |
| Intangible Assets   | 229,991                                       | 240,656                      |
| Goodwill  | 920,745                                       | 920,745                      |
| Other Non-current Assets  | 147,820                                       | 120,887                      |
| <b>Total Assets</b>   | <b>\$ 15,839,360</b>                          | <b>\$ 18,959,982</b>         |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |   |                              |
| Notes Payable & Capitalized Lease Obligations   | \$ 68,594                                     | \$ 176,850                   |
| Accounts Payable  | 4,219,095                                     | 5,210,972                    |
| Accrued Liabilities   | 1,804,868                                     | 1,464,828                    |
| Customer Deposits   | 923,086                                       | 245,186                      |
| <b>Total Current Liabilities</b>  | <b>7,015,643</b>                              | <b>7,097,836</b>             |
| Long Term Notes Payable & Capitalized Lease Obligations                                 | 26,464  | 41,203                       |
| Shareholders Equity:  |   |                              |
| Common Shares, no par value, 14,220,410 and 14,104,690 shares issued and outstanding    | 36,378,500                                    | 34,799,093                   |
| Common Share Purchase Warrants, 2,154,169 and 2,114,169 warrants issued and outstanding | 3,726,758                                     | 3,378,398                    |
| Accumulated Deficit   | (31,308,005)                                  | (26,356,548)                 |
| <b>Total Shareholders Equity</b>  | <b>8,797,253</b>                              | <b>11,820,943</b>            |
| <b>Total Liabilities and Shareholders Equity</b>  | <b>\$ 15,839,360</b>                          | <b>\$ 18,959,982</b>         |

*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, 2009 and September 30, 2008**  
(Unaudited)

|  | <b>Three<br/>Months<br/>Ended<br/>Sept. 30,<br/>2009</b> | <b>Three<br/>Months<br/>Ended<br/>Sept. 30,<br/>2008</b> | <b>Nine Months<br/>Ended<br/>Sept. 30,<br/>2009</b> | <b>Nine Months<br/>Ended<br/>Sept. 30,<br/>2008</b> |
|--|--|--|---|---|
| <b>Sales</b>                             | <b>\$ 14,158,234</b>                                     | <b>\$ 13,533,986</b>                                     | <b>\$ 39,968,018</b>                                | <b>\$ 38,128,359</b>                                |
| Cost of Sales                            | 11,751,499   | 12,893,377   | 34,508,410  | 35,798,671  |
| <b>Gross Profit</b>                      | <b>2,406,735</b>   | <b>640,609</b>   | <b>5,459,608</b>                                    | <b>2,329,688</b>                                    |
| Selling, General and Administrative      | 1,946,570  | 2,176,188  | 5,078,073   | 4,785,675   |
| Research and Product Development         | 1,977,618  | 993,262  | 5,312,499   | 2,557,718   |
| <b>Operating (Loss)</b>                  | <b>(1,517,453)</b>                                       | <b>(2,528,841)</b>                                       | <b>(4,930,964)</b>                                  | <b>(5,013,705)</b>                                  |
| Interest Expense (Income), Net           | 3,990  | (17,795)   | 20,493  | (182,482)   |
| <b>Net (Loss)</b>                        | <b>\$ (1,521,443)</b>                                    | <b>\$ (2,511,046)</b>                                    | <b>\$ (4,951,457)</b>                               | <b>\$ (4,831,223)</b>                               |
| <br>                                     |  |  |   |   |
| <b>Basic Earnings (Loss) per Share</b>   | <b>\$ (0.11)</b>   | <b>\$ (0.18)</b>   | <b>\$ (0.35)</b>                                    | <b>\$ (0.35)</b>                                    |
| <b>Diluted Earnings (Loss) per Share</b> | <b>\$ (0.11)</b>   | <b>\$ (0.18)</b>   | <b>\$ (0.35)</b>                                    | <b>\$ (0.35)</b>                                    |

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

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CONSOLIDATED STATEMENTS OF CASH FLOWS****For the nine months ended September 30, 2009 and September 30, 2008**

(Unaudited)

|   | <b>2009</b>           | <b>2008</b>           |
|---|-----------------------|-----------------------|
| Cash Flows From Operating Activities:                                       |                       |                       |
| Net (Loss)  | <b>\$ (4,951,457)</b> | <b>\$ (4,831,223)</b> |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: |                       |                       |
| Depreciation and Amortization   | 836,020               | 651,710               |
| Loss (Gain) on Disposal of Assets   | 20,403                | (7,534)               |
| Share Based Compensation Non-employee Warrants                              | 348,360               | 375,032               |
| Share Based Compensation Employees  | 1,394,410             | 740,783               |
| Changes in Assets and Liabilities:  |                       |                       |
| Decrease (Increase) in Accounts Receivable                                  | 143,449               | (669,307)             |
| Decrease (Increase) in Inventory  | 487,056               | (607,515)             |
| (Increase) in Other Assets  | (106,751)             | (224,047)             |
| Increase (Decrease) in Accounts Payable                                     | (991,877)             | 994,422               |
| Increase in Other Liabilities   | 1,017,940             | 1,123,167             |
| Changes in Assets and Liabilities   | 549,817               | 616,720               |
| Cash (Used) In Operating Activities   | <b>(1,802,447)</b>    | <b>(2,454,512)</b>    |
| Cash Flows From Investing Activities:                                       |                       |                       |
| Purchase of Equipment   | (1,080,495)           | (1,122,958)           |
| Proceeds on Sale of Assets  | 5,120                 | 9,555                 |
| Purchase of Intangible Assets   | (12,875)              | (903)                 |
| Cash (Used ) In Investing Activities  | <b>(1,088,250)</b>    | <b>(1,114,306)</b>    |
| Cash Flows From Financing Activities:                                       |                       |                       |
| Issuance of Common Shares and Purchase Warrants                             | 184,997               | 106,722               |
| Payments on Notes Payable   | (122,995)             | (153,204)             |
| Cash Provided (Used) By Financing Activities                                | <b>62,002</b>         | <b>(46,482)</b>       |
| (Decrease) In Cash  | (2,828,695)           | (3,615,300)           |
| Cash At Beginning Of Period   | 5,596,645             | 11,097,092            |
| Cash At End Of Period   | <b>\$ 2,767,950</b>   | <b>\$ 7,481,792</b>   |
| Supplemental Cash Flow disclosure   |                       |                       |
|   | 2009                  | 2008                  |
| Interest Paid   | \$ 20,493             | \$ 41,523             |

*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**

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or ESRD. We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients' blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States. References in these Notes to the Company, we, our and us are references to Rockwell Medical Technologies, Inc. and its subsidiaries.

We are regulated by the Federal Food and Drug Administration, or FDA, under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders and to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer. We have also obtained global licenses for certain dialysis related drugs which we are developing and for which we are seeking FDA approval to market. 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 of our wholly-owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or GAAP, and with the instructions to Form 10-Q and Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2008 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 September 30, 2009 are not necessarily indicative of the results to be expected for the year ending December 31, 2009. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2008 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 includes a description of our significant accounting policies.

In May 2009, the Financial Accounting Standards Board ( FASB ) issued authoritative guidance regarding the disclosure of subsequent events. We have evaluated subsequent events through the date of this filing and we do not believe there are any material subsequent events which would require further disclosure other than those noted below.

**Revenue Recognition**

We recognize revenue at the time we transfer title to our products to our customers consistent with GAAP. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

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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, 2009 and December 31, 2008, we had customer deposits of \$923,086 and \$245,186, respectively.

**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 \$5.3 million and \$2.6 million in the first nine months of 2009 and 2008, respectively. We are conducting human clinical trials on SFP and we recognize the costs of these clinical trials as the costs are incurred and services are performed over the duration of the trials.

**Net Earnings Per Share**

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

|  | <b>Three months ended Sept.</b> |             | <b>Nine months ended Sept. 30,</b> |             |
|--|---------------------------------|-------------|------------------------------------|-------------|
|  | <b>2009</b>                     | <b>2008</b> | <b>2009</b>                        | <b>2008</b> |
| Basic Weighted Average Shares Outstanding<br>Effect of Dilutive Securities | 14,060,533                      | 13,834,953  | 14,010,366                         | 13,826,208  |
| Diluted Weighted Average Shares<br>Outstanding                             | 14,060,533                      | 13,834,953  | 14,010,366                         | 13,826,208  |

**Reclassifications**

The Company has reclassified certain expenses from Selling, General and Administrative Expense to Cost of Sales in the 2008 consolidated income statement to conform with the current year presentation. The impact of the change was not material.

**3. Inventory**

Components of inventory as of September 30, 2009 and December 31, 2008 are as follows:

|                 | <b>September<br/>30,<br/>2009</b> | <b>December<br/>31,<br/>2008</b> |
|-----------------|-----------------------------------|----------------------------------|
| Raw Materials   | \$ 1,042,322                      | \$ 1,316,875                     |
| Work in Process | 177,362                           | 291,937                          |
| Finished Goods  | 1,454,885                         | 1,552,813                        |
| Total           | \$ 2,674,569                      | \$ 3,161,625                     |

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**4. Recent Accounting Pronouncements**

In June 2009, the FASB issued authoritative guidance codifying generally accepted accounting principles in the United States ( GAAP ). While the guidance was not intended to change GAAP, it did change the way the Company references these accounting principles in the Notes to the Consolidated Financial Statements. This guidance was effective for interim and annual reporting periods ending after September 15, 2009. There have been no changes to the content of our financial statements or disclosures as a result of implementing the Codification during the quarter ended September 30, 2009. However, as a result of implementation of the Codification, previous references to new accounting standards and literature are no longer applicable.

**5. Subsequent Events**

On October 5, 2009, the Company realized \$20.5 million in net proceeds from a registered direct offering of its common shares and warrants. The Company issued 2,840,000 shares of Rockwell s common stock and warrants to purchase up to 1,079,200 shares of common stock. The purchase price per unit was \$7.75, consisting of one common share and a warrant to purchase 0.38 shares. The shares of common stock and warrants were immediately separable and were issued separately. The warrants have a five-year term from the date of issuance and are exercisable beginning six months after the date of issuance, and will be exercisable at a price of \$9.55 per share. The Company intends to use the net proceeds from the offering for general corporate purposes, which may include funding of clinical trials and regulatory activities for SFP and other research and development expenses, and general and administrative expenses.

**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, 2008.

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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 flows.

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

Our new drug product requires FDA approval and expensive clinical trials before it can be marketed.

Even if our new drug product is approved by the FDA it may not be successfully marketed.

If prices of the key commodities we purchase change significantly, we may not be able to continue improving or sustain our current gross profit margins and our business may remain unprofitable.

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 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 flows and financial position. There can be no assurance that future results will meet expectations. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as may be required by applicable law.

**Overview and Recent Developments**

We currently operate in a single business segment, the manufacture and distribution of hemodialysis concentrates and ancillary products used in the kidney dialysis process. We have gained domestic market share each year since our inception in 1996 and we believe we currently service a significant share of the dialysis market in the United



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States. Our strategy is to continue to develop and expand our dialysis products business while at the same time developing new products, including pharmaceutical products for the end stage renal disease market. We are primarily focused on the approval of the use of our lead drug candidate, Soluble Ferric Pyrophosphate, or SFP, in dialysate but are also seeking to increase our pipeline of products, including SFP extensions into other applications as well as other technologies. During 2009, in furtherance of this strategy, we added two key leadership positions to our specialty pharmaceutical development team, a Chief Scientific Officer in the second quarter of 2009 and a Vice President of Clinical Development and Medical Affairs in the first quarter of 2009.

We completed our Phase IIb human clinical trial of SFP in October 2009. We expect to spend approximately \$1.5-\$2.0 million in the fourth quarter of 2009 related to our SFP clinical trial and development efforts. We plan to seek FDA approval to commence a Phase III clinical trial after obtaining the results of the Phase IIb trial.

Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We anticipate that costs to complete clinical trials and to obtain FDA approval to market SFP from 2010 until such approval may total approximately \$15 million depending on the duration and size of the studies required.

In the first nine months of 2009, sales in our commercial business operations increased 4.8% and our gross profit margins improved significantly following a decrease in gross profit margins in 2008. While we experienced substantial sales growth over the last several years, we also experienced unprecedented increases in the costs for chemicals, packaging materials and fuel. Price increases we implemented in response did not keep pace with the cost increases. As a result, our gross profit and gross profit margins decreased significantly in 2008.

We took actions in the last quarter of 2008 that improved our margins during 2009, including raising prices, changing vendors, changing our product mix and reducing operating costs. Softening of commodity prices also contributed to the improvement of our gross profit margins during that period.

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 and Nine Months Ended September 30, 2009 and September 30, 2008**

**Sales**

Sales in the third quarter of 2009 were \$14.2 million, an increase of \$0.6 million or 4.6% over the third quarter of 2008. For the third quarter of 2009, our international sales increased by \$0.2 million and our domestic sales increased by \$0.4 million compared to the third quarter of 2008. Sales in the first nine months of 2009 increased \$1.8 million or 4.8% compared to the first nine months of 2008 with domestic sales increasing \$1.6 million and international sales accounting for the remainder of the increase. Price increases on maturing contracts accounted for most of the sales increases, with the remainder attributable to increased unit volumes primarily in our Dri-Sate dry acid concentrate.

**Gross Profit**

Gross profit in the third quarter and first nine months of 2009 was \$2.4 million and \$5.5 million, respectively, compared to \$0.6 million and \$2.3 million in the third quarter and first nine months of 2008, respectively. Gross profit margins increased to 17.0% in the third quarter of 2009 from 4.7% in 2008 and to 13.7% in the first nine months of 2009 compared to 6.1% in 2008. Substantial changes in product and customer mix in the third quarter and first nine months of 2009 compared to the comparable periods of 2008 were the primary contributors to improved gross profit margins. Domestic sales migrated toward our Dri-Sate dry acid concentrate products, which provide a cost effective alternative to higher cost per treatment liquid products and cost us less to deliver than liquid products. Our Dri-Sate unit volumes increased by 44.9% and 35.9% compared to the third quarter and first nine months of

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2008. Customers also migrated toward lower cost formulations, which improved margins while not increasing costs to our customers. The increase in gross profit was also due to reductions in material costs, fuel costs and operating expenses. In early 2009, we entered into new supply contracts and made certain vendor changes, and also benefitted from reductions in costs for certain chemicals and fuel as well as management actions to gain efficiencies and reduce operating costs.

We reclassified certain quality assurance and operations management expenses totaling \$138,000 to cost of sales from selling, general and administrative expense for the third quarter of 2008 and \$398,000 for the first nine months of 2008 to maintain comparability of prior year results with the current year presentation.

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

Selling, general and administrative expense, or SG&A, during the third quarter of 2009 was \$1.9 million compared to \$2.1 million in the third quarter of 2008, a decrease of \$0.2 million or 10.6%. The decrease in third quarter 2009 SG&A expenses was due to a third quarter 2008 litigation settlement of \$0.75 million which did not recur in 2009. The effect of the 2008 settlement was partially offset by an increase in non-cash charges for equity compensation to \$0.7 million in the third quarter of 2009 compared to \$0.4 million in the third quarter of 2008. In addition, personnel costs increased approximately \$0.1 million as a result of increased headcount in support of our business growth and routine wage increases.

SG&A during the first nine months of 2009 was \$5.1 million compared to \$4.8 million in the first nine months of 2008, an increase of \$0.3 million or 6%. The increase was primarily due to a \$0.6 million increase in non-cash charges for equity compensation, \$0.4 million in higher personnel costs, and \$0.1 million in information technology related expenses. The increases were partially offset by a \$0.15 million reduction in legal expenses and the effect of the aforementioned \$0.75 million legal settlement in the third quarter of 2008.

### **Research and Development**

Research and development costs were \$2.0 million and \$5.3 million in the third quarter and first nine months of 2009, respectively, compared to \$1.0 million and \$2.6 million in the comparable periods of 2008, respectively. While spending in both years was primarily devoted to development and approval of SFP, the increases in research and development costs in 2009 were primarily due to significantly increased activity relating to the conduct of the Phase IIb clinical trial, which was completed in the fourth quarter of 2009. We anticipate fourth quarter 2009 research and development costs to be approximately \$1.5 to \$2.0 million.

### **Interest Income, Net**

Our net interest expense was \$4,000 in the third quarter of 2009 compared to net interest income of \$18,000 in the third quarter of 2008. Interest expense in the first nine months of 2009 was \$20,500 compared to \$182,500 in net interest income in the first nine months of 2008. The changes were due to fewer funds available for investment and our decision to hold funds in the form of cash due to substantially lower market interest rates compared to 2008. The investment of the proceeds of the October 2009 equity offering in short term investments is not expected to cause interest income to increase significantly due to the very low short term interest rate environment.

### **Liquidity and Capital Resources**

We have two major areas of strategic focus in our business: development of our dialysis products business and expansion of our product offering to include drugs, vitamins and therapeutic products administered to dialysis patients. We expect to expend substantial amounts in support of our clinical development plan and regulatory



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approval of SFP and its extensions. Each of these initiatives will require investments of substantial amounts of capital.

Upon completion of our Phase IIb clinical trial, we will seek FDA approval to conduct Phase III clinical trials for SFP. We anticipate that the cost to fund our Phase III clinical trials and to obtain FDA approval to market SFP will cost as much as \$15 million from 2010 until approval.

We closed a financing transaction in early October 2009 raising approximately \$20.5 million net of offering expenses. We intend to fund the remaining clinical development plan for SFP from the funds we raised and from cash generated from operations. Our cash balance as of the end of September 2009 was approximately \$2.7 million before the inclusion of the net proceeds of the October 2009 equity offering.

In the first nine months of 2009, we used \$2.8 million in cash, compared to \$3.6 million in the first nine months of 2008 largely due to a reduction in cash used in operations to \$1.8 million in the first nine months of 2009 from \$2.5 million in the first nine months of 2008. The decrease in cash used in operations during 2009 was primarily the result of a decrease in the loss from business operations before research and development expenses of \$2.1 million offset by a \$2.75 million increase in research and development expenditures compared to 2008. Included in the improved business operations cash flow was a reduction in working capital of \$0.55 million. Non-cash charges against operating results were \$2.6 million in the first nine months of 2009.

We expect to generate positive cash flow from operations during the year ahead, excluding our research and development expenses, assuming our improved operating results and continued stability in the markets for our key commodity materials. We believe that our current sources of capital and continued positive cash flow generation from our business operations, excluding research and development expenses, should provide adequate sources of liquidity and capital resources to execute our business plan.

**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, 2009, we had no short term investments. However, following the completion of our equity offering on October 5, 2009 in which we raised \$20.5 million, we anticipate having short term liquid investments in the future.

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 million in cash and that level remained constant for the year. We did not perform an analysis of a 100 point decrease in market interest rates as such an analysis would be meaningless.

**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.

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**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, 2009 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 2008 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K except as set forth below.

Due to the completion of the equity offering in October 2009, we believe the risk that we will not have sufficient cash to fund future growth or SFP development is no longer material to investors. As a result, the risk factor in Item 1A of our Form 10-K for the year ended December 31, 2008 entitled **We may not have sufficient cash to fund future growth or SFP development.** should be disregarded.

**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 6, 2009

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

Date: November 6, 2009

/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>  |
|--------------------|---|
| 4.3                | Form of Investor Warrant to Purchase Common Stock issuable by the Company to the investor signatories to the Subscription Agreement, filed as exhibit F to the Placement Agency Agreement which was filed as an exhibit to the Current Report on Form 8-K filed September 30, 2009 and incorporated herein by reference |
| 4.4                | Form of Placement Agent Warrant issuable by the Company to JMP Securities LLC and Wedbush Securities Inc., filed as an exhibit to the Current Report on Form 8-K filed September 30, 2009 and incorporated herein by reference  |
| 4.5                | Warrant issued to RJ Aubrey IR Services LLC as of September 30, 2008, filed as an exhibit to the registration statement on Form S-3 (file no. 333-160710) and incorporated herein by reference  |
| 4.6                | Warrant issued to Lions Gate Capital as of October 3, 2007, filed as an exhibit to the registration statement on Form S-3 (file no. 333-160710) and incorporated herein by reference  |
| 4.7                | Warrant issued to Capitol Securities Management, Inc. as of May 28, 2008, filed as an exhibit to the registration statement on Form S-3 (file no. 333-160710) and incorporated herein by reference  |
| 4.8                | Warrant issued to Emerald Asset Advisors, LLC, filed as an exhibit to the registration statement on Form S-3 (file no. 333-160710) and incorporated herein by reference   |
| 4.9                | Form of Warrant issued to Messrs. Rick, Pizzirusso, Ries, Meyers and Pace as of July 17, 2009, filed as an exhibit to the registration statement on Form S-3 (file no. 333-160710) and incorporated herein by reference   |
| 10.33              | Placement Agency Agreement with JMP Securities LLC and Wedbush Securities Inc. dated September 29, 2009 (including the form of Subscription Agreement included as exhibit A thereto), filed as an exhibit to the Company's Current Report of Form 8-K dated September 30, 2009 and incorporated herein by reference.    |
| 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  |