

ROCKWELL MEDICAL, INC.  
Form 10-Q  
May 08, 2013  
[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, 2013**

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, INC.

(Exact name of registrant as specified in its charter)

**Michigan**  
(State or other jurisdiction of  
incorporation or organization)

**38-3317208**  
(I.R.S. Employer  
Identification No.)

**30142 Wixom Road, Wixom, Michigan**  
(Address of principal executive offices)

**48393**  
(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).  Yes  No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Edgar Filing: ROCKWELL MEDICAL, INC. - Form 10-Q

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 May 1, 2013**

Table of Contents

**Rockwell Medical, Inc.**

**Index to Form 10-Q**

	<b>Page</b>
<u>Part I - Financial Information (unaudited)</u>	
<u>Item 1 - Financial Statements (unaudited)</u>	
<u>Consolidated Balance Sheets</u>	3
<u>Consolidated Income Statements</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss)</u>	5
<u>Consolidated Statements of Changes in Shareholders' Equity</u>	6
<u>Consolidated Statements of Cash Flows</u>	7
<u>Notes to Consolidated Financial Statements</u>	8
<u>Item 2 - Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	14
<u>Item 4 - Controls and Procedures</u>	14
<u>Part II - Other Information</u>	
<u>Item 6 - Exhibits</u>	15
<u>Signatures</u>	16
<u>Exhibit Index</u>	17

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

As of March 31, 2013 and December 31, 2012

	March 31, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 5,774,297	\$ 4,711,730
Accounts Receivable, net of a reserve of \$34,600 in 2013 and \$26,000 in 2012	4,462,299	4,431,932
Inventory	2,865,510	2,649,639
Other Current Assets	1,086,167	1,356,131
Total Current Assets	14,188,273	13,149,432
Property and Equipment, net	1,791,942	1,858,442
Intangible Assets	624,987	666,744
Goodwill	920,745	920,745
Other Non-current Assets	442,223	429,723
Total Assets	\$ 17,968,170	\$ 17,025,086
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Capitalized Lease Obligations	\$ 1,451	\$ 2,280
Accounts Payable	16,100,474	14,833,565
Accrued Liabilities	12,288,923	12,015,978
Customer Deposits	82,997	135,133
Total Current Liabilities	28,473,845	26,986,956
Capitalized Lease Obligations		
Shareholders' Equity:		
Common Shares, no par value, 25,859,138 and 21,494,696 shares issued and outstanding	106,884,342	92,866,458
Common Share Purchase Warrants, 2,175,407 and 2,233,240 warrants issued and outstanding	7,996,964	7,178,929
Accumulated Deficit	(125,386,981)	(110,007,257)
Accumulated Other Comprehensive Loss		
Total Shareholders' Equity (Deficit)	(10,505,675)	(9,961,870)
Total Liabilities And Shareholders' Equity	\$ 17,968,170	\$ 17,025,086

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

Table of Contents**ROCKWELL MEDICAL, INC. AND SUBSIDIARY****CONSOLIDATED INCOME STATEMENTS****For the three months ended March 31, 2013 and March 31, 2012**

(Unaudited)

	<b>Three Months Ended March 31, 2013</b>	<b>Three Months Ended March 31, 2012</b>
<b>Sales</b>	<b>\$ 12,336,374</b>	<b>\$ 12,028,417</b>
Cost of Sales	11,055,394	10,401,941
<b>Gross Profit</b>	<b>1,280,980</b>	<b>1,626,476</b>
Selling, General and Administrative	3,916,783	2,898,684
Research and Product Development	12,754,518	9,405,547
<b>Operating Income (Loss)</b>	<b>(15,390,321)</b>	<b>(10,677,755)</b>
Interest and Investment Income, net	10,672	111,097
Interest Expense	75	253
Income (Loss) Before Income Taxes	(15,379,724)	(10,566,911)
Income Tax Expense		
<b>Net Income (Loss)</b>	<b>\$ (15,379,724)</b>	<b>\$ (10,566,911)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ (0.72)</b>	<b>\$ (0.54)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ (0.72)</b>	<b>\$ (0.54)</b>

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

Table of Contents

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

**For the three months ended March 31, 2013 and March 31, 2012**

(Unaudited)

	<b>Three Months Ended March 31, 2013</b>	<b>Three Months Ended March 31, 2012</b>
<b>Net Income (Loss)</b>	\$ (15,379,724)	\$ (10,566,911)
Unrealized Gain on Available-for-Sale Investments		100,709
<b>Comprehensive Income (Loss)</b>	<b>\$ (15,379,724)</b>	<b>\$ (10,466,202)</b>

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



Table of Contents**ROCKWELL MEDICAL, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY****For The Three Months Ended March 31, 2013**

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED	OTHER	TOTAL
	SHARES	AMOUNT	WARRANTS	AMOUNT	DEFICIT	INCOME (LOSS)	SHAREHOLDER S EQUITY
Balance as of December 31, 2012	21,494,696	\$ 92,866,458	2,233,240	\$ 7,178,929	\$ (110,007,257)	\$	(9,961,870)
Net Loss					(15,379,724)		(15,379,724)
Issuance of Common Shares	4,313,609	12,153,752					12,153,752
Purchase Warrant Expense				966,227			966,227
Exercise of Purchase Warrants	50,833	513,173	(57,833)	(148,192)			364,981
Stock Option Based Expense		960,144					960,144
Restricted Stock Amortization		390,815					390,815
Balance as of March 31, 2013	25,859,138	\$ 106,884,342	2,175,407	\$ 7,996,964	\$ (125,386,981)	\$	(10,505,675)

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

Table of Contents

## ROCKWELL MEDICAL, INC. AND SUBSIDIARY

## CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended March 31, 2013 and March 31, 2012

(Unaudited)

	2013	2012
Cash Flows From Operating Activities:		
<b>Net (Loss)</b>	<b>\$ (15,379,724)</b>	<b>\$ (10,566,911)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In		
Operating Activities:		
Depreciation and Amortization	250,530	277,200
Share Based Compensation - Non-employee	966,227	285,568
Share Based Compensation- Employees	1,350,959	1,203,821
Loss (Gain) on Disposal of Assets	5,109	10,395
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	(30,367)	7,741
Decrease (Increase) in Inventory	(215,871)	93,892
Decrease in Other Assets	257,464	240,838
Increase (Decrease) in Accounts Payable	1,266,909	(702,612)
Increase in Other Liabilities	220,809	848,199
Changes in Assets and Liabilities	1,498,944	488,058
<b>Cash Provided By (Used) In Operating Activities</b>	<b>(11,307,955)</b>	<b>(8,301,869)</b>
Cash Flows From Investing Activities:		
Purchase of Equipment	(153,380)	(88,543)
Proceeds on Sale of Assets	5,998	350
<b>Cash (Used) In Investing Activities</b>	<b>(147,382)</b>	<b>(88,193)</b>
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	12,518,733	16,317,287
Payments on Notes Payable and Capital Lease Obligations	(829)	(3,067)
<b>Cash Provided By Financing Activities</b>	<b>12,517,904</b>	<b>16,314,220</b>
<b>Increase (Decrease) In Cash</b>	<b>1,062,567</b>	<b>7,924,158</b>
Cash At Beginning Of Period	4,711,730	5,715,246
<b>Cash At End Of Period</b>	<b>\$ 5,774,297</b>	<b>\$ 13,639,404</b>

2013

2012

Interest Paid	\$	75	\$	253
---------------	----	----	----	-----

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

Table of Contents

**Rockwell Medical, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements**

**1. Description of Business**

Rockwell Medical, Inc. and Subsidiary (collectively, we, our, us, or the Company) is a fully-integrated pharmaceutical company targeting end-stage renal disease ( ESRD ) and chronic kidney disease ( CKD ) with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis.

Rockwell's lead drug candidate, Soluble Ferric Pyrophosphate ( SFP ), is in late-stage clinical development and is for the treatment of iron deficiency in dialysis patients. SFP is nearing completion of its Phase 3 clinical studies (CRUISE-1 and CRUISE-2).

Rockwell is preparing to launch its FDA approved generic drug called Calcitriol to treat secondary hyperparathyroidism in dialysis patients. Calcitriol active vitamin D injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. Rockwell intends to launch Calcitriol as soon as it receives FDA manufacturing approval.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. Rockwell's products are used to maintain human life, by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. Rockwell has three manufacturing and distribution facilities located in the U.S. and its operating infrastructure is a ready-made sales and distribution channel that is able to provide seamless integration into the commercial market for its drug products, Calcitriol and SFP upon FDA market approval.

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 and related equipment.

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

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or GAAP, and with the instructions to Form 10-Q and Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2012 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 months ended March 31, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013. You should read our unaudited interim

Table of Contents

financial statements together with the financial statements and related footnotes for the year ended December 31, 2012 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 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.

**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 expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including our anemia related iron maintenance drug candidate, Soluble Ferric Pyrophosphate, or SFP, aggregating approximately \$12.8 million and \$9.4 million for the three months ended March 31, 2013 and 2012, respectively. We are conducting human clinical trials on SFP. 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. The calculation of basic weighted average shares outstanding excludes unvested restricted stock. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	Three months ended March 31,	
	2013	2012
Basic Weighted Average Shares Outstanding	21,241,000	19,441,971
Effect of Dilutive Securities		
Diluted Weighted Average Shares Outstanding	21,241,000	19,441,971

Table of Contents**3. Inventory**

Components of inventory as of March 31, 2013 and December 31, 2012 are as follows:

	March 31, 2013		December 31, 2012
Raw Materials	\$ 1,131,476	\$	1,018,648
Work in Process	170,464		179,922
Finished Goods	1,563,570		1,451,069
Total	\$ 2,865,510	\$	2,649,639

**4. Other Current Assets**

Other current assets includes amounts advanced to contract services providers. These advances will offset future liabilities incurred with contract services providers for services and travel related to our clinical trials. As of March 31, 2013, the amount included in other current assets was \$0.5 million.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. References in this report to we, our and us are references to Rockwell Medical, Inc. and its subsidiary.

**Forward-Looking Statements**

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

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere,



## Edgar Filing: ROCKWELL MEDICAL, INC. - Form 10-Q

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 SEC, including, without limitation, in Item 1A Risk Factors in our Form 10-K for the year ended December 31, 2012.

- 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 a few customers that account for a substantial portion of our sales. The loss of any of these customers would have a material adverse effect on our results of operations and cash flow.
- We operate in a very competitive market against a substantially larger competitor with greater resources.
- Our lead drug candidate requires FDA approval and expensive clinical trials before it can be marketed.

Table of Contents

- Even if we receive FDA approval to manufacture and market our new drug products, we may not be able to market them successfully.
  
- There is substantial doubt about our ability to continue as a going concern.
  
- We require substantial additional financing to achieve our goals, and such financing may result in substantial dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
  
- We may not be successful in maintaining our gross profit margins.
  
- We depend on government funding of health care.
  
- Health care reform could adversely affect our business.
  
- We depend on key personnel.
  
- Our business is highly regulated.
  
- We depend on contract research organizations and independent clinicians 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 delaying our development plans or causing us 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.

## Edgar Filing: ROCKWELL MEDICAL, INC. - Form 10-Q

- Our Board of Directors is subject to potential deadlock.
- Shares eligible for future sale may affect the market price of our common shares.
- We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.
- 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.

Table of Contents

**Overview and Recent Developments**

Rockwell Medical, Inc. is a fully-integrated pharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

We are developing unique, proprietary renal drug therapies. These novel 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 drugs while expanding our dialysis products business. Our dialysis products business has been cash flow positive, excluding research and development expenses, and provides a ready-made sales and distribution infrastructure to market our drugs and other related products used in dialysis.

Our product development costs were primarily related to SFP, our lead drug which is nearing completion of its Phase 3 clinical studies. Based upon clinical data, we believe SFP has unique and substantive benefits compared to current treatment options. Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We expect to incur substantial costs relating to product testing and development over the next two years and we expect to incur losses from operations in 2013. In addition to our SFP testing and approval process, we plan to spend additional amounts in the future on testing and development of SFP technology for other medical indications.

In 2011, we acquired an FDA approved generic vitamin D injection, Calcitriol, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We have submitted the necessary manufacturing data to the FDA to obtain commercial marketing approval and intend to begin marketing Calcitriol following regulatory approval from the FDA which we expect later this year.

As of March 31, 2013 we had \$5.8 million in cash. In March 2013, we completed a common stock offering for \$12.9 million in gross proceeds and approximately \$12.1 million in net proceeds. We expect to raise additional capital in order to fund our planned development.

In the first quarter of 2013, our sales increased 2.6% or \$0.3 million compared to the first quarter of 2012. The increase in sales was a result of new domestic business which increased 5.5% over the first quarter of 2012.

We anticipate that our gross profit margins will be favorably impacted by revenue from Calcitriol once we obtain FDA approval for manufacturing changes.

We may 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.

The majority of our business is with domestic clinics who order routinely. From time to time, we have experienced volatility in international orders.

**Going Concern**

Due to our recurring losses and need for additional working capital, there is substantial doubt about our ability to continue as a going concern. Management is taking steps to improve our financial condition. The financial statements and the accompanying footnotes have been prepared on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business for the foreseeable future,

Table of Contents

and do not include any adjustment to reflect the possible future effects of our inability to raise the additional capital needed to continue as a going concern.

**Results of Operations for the Three Months Ended March 31, 2013 and March 31, 2012**

**Sales**

Sales in the first quarter of 2013 were \$12.3 million compared to \$12.0 million in the first quarter of 2012. Sales increased \$0.3 million or 2.6% due to increased domestic sales of \$0.6 million compared to the first quarter of 2012. Domestic sales were 5.5% or \$0.6 million higher than the first quarter last year primarily due to increased sales volumes. International sales were \$0.3 million lower than the first quarter of 2012 due to timing of orders.

**Gross Profit**

Gross profit margins in the first quarter of 2013 were 10.4% compared to 13.5% in the first quarter of 2012, a decrease of 3.1 percentage points. Gross profit dollars in the first quarter were \$1.3 million a decrease of \$0.3 million compared to the first quarter last year. This decrease in gross profit was primarily due to higher material costs coupled with increased operating costs compared to the first quarter of 2012. Operating costs increased due to inflation and increased costs due to government regulations.

**Selling, General and Administrative Expense**

Selling, general and administrative expense during the first quarter of 2013 was \$3.9 million compared to \$2.9 million in the first quarter of 2012. We incurred a non-cash charge of \$0.9 million related to the extension of certain expiring common stock purchase warrants in 2013. Non-cash equity compensation was \$1.7 million in the first quarter of 2013 compared to \$1.5 million in the first quarter of 2012. We recognized an increase in cost related to the recently mandated medical device tax of \$0.2 million in the first quarter of 2013.

**Research and Development**

Research and development cost was \$12.8 million compared to \$9.4 million in the first quarter of 2012. Spending in both years was primarily for clinical testing and development of SFP with the increase in 2013 due to increased testing associated with the SFP Phase 3 clinical program.

**Interest and Investment Income, Net**

Our net interest and investment income was \$10,700 in the first quarter of 2013 compared to net interest and investment income of \$111,100 in the first quarter of 2012. The decrease in net interest and investment income was due to lower levels of invested funds in 2013 compared to 2012.

### **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 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 be significant as we execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States. We used \$11.3 million in cash for operations in the first quarter of 2013. Costs for research and development were \$12.8 million in the first quarter of 2013.

Table of Contents

Our cash resources also include cash generated from the proceeds of equity offerings, including the receipt of \$12.1 million in net proceeds from an equity offering completed in March 2013. We had \$5.8 million in cash as of March 31, 2013. Our current liabilities were \$28.5 million while our current assets were \$14.2 million as of March 31, 2013. We are evaluating various business development and strategic partnering options as well as sources of equity and debt financing alternatives in order to meet our current and future cash requirements. We expect to complete one or more financing or partnering transactions.

Our ability to continue as a going concern is dependent upon raising additional capital through debt, equity, licensing or other business development or partnering transactions. If we do not complete one or more transactions and raise a substantial amount of additional capital in the near term, we would not have sufficient cash resources to complete our business development plans and we may be forced to delay, reduce, curtail, or cease our research and development efforts or our business operations as a whole.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

**Foreign Currency Exchange Rate Risk**

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

**Item 4. Controls and Procedures**

**Disclosure Controls and Procedures**

Management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that are designed to ensure that material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our



disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

Table of Contents

**Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act) during the most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**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, INC.  
(Registrant)

Date: May 8, 2013

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

Date: May 8, 2013

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

Table of Contents

**10-Q EXHIBIT INDEX**

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated. Exhibits not required for this report have been omitted. Our Commission file number is 000-23661.

<b>Exhibit No.</b>	<b>Description</b>
3.1	Restated Articles of Incorporation, as amended as of May 1, 2013.
10.50	Common Stock Purchase Agreement, dated March 20, 2013, between the Company and the investors party thereto (Company's Form 8-K filed March 20, 2013).
10.51	Placement Agency Agreement, dated March 20, 2013, among the Company, Chardan Capital Markets, LLC and Newbridge Securities Corporation (Company's Form 8-K filed March 20, 2013).
10.52	Form of Subscription Agreement, dated March 20, 2013 (Company's Form 8-K filed March 20, 2013).
10.53	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective April 30, 2013 (appendix to Company's Proxy Statement for the 2013 Annual Meeting of Shareholders filed March 29, 2013)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS	* XBRL Instance Document
101.SCH	* XBRL Taxonomy Extension Schema
101.CAL	* XBRL Taxonomy Extension Calculation Linkbase
101.DEF	* XBRL Taxonomy Extension Definition Database
101.LAB	* XBRL Taxonomy Extension Label Linkbase
101.PRE	* XBRL Taxonomy Extension Presentation Linkbase

---

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

