

ROCKWELL MEDICAL, INC.  
Form 10-Q  
May 12, 2014  
[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, 2014**

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

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

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.

<b>Class</b>	<b>Outstanding as of April 30, 2014</b>
Common Stock, no par value	40,759,976 shares

---

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>	11
<u>Item 3 - Quantitative and Qualitative Disclosures about Market Risk</u>	15
<u>Item 4 - Controls and Procedures</u>	15
<u>Part II - Other Information</u>	
<u>Item 1A - Risk Factors</u>	16
<u>Item 2 - Unregistered Sales of Equity Securities and Use of Proceeds</u>	16
<u>Item 6 - Exhibits</u>	16
<u>Signatures</u>	17
<u>Exhibit Index</u>	18

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

As of March 31, 2014 and December 31, 2013

(Unaudited)

	March 31, 2014	December 31, 2013
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 661,117	\$ 11,881,451
Investments Available for Sale	14,068,482	12,034,622
Accounts Receivable, net of a reserve of \$41,000 in 2014 and \$37,000 in 2013	4,100,453	4,578,319
Inventory	2,909,828	2,799,648
Other Current Assets	602,393	623,734
Total Current Assets	22,342,273	31,917,774
Property and Equipment, net	1,761,165	1,648,949
Intangible Assets	457,958	499,715
Goodwill	920,745	920,745
Other Non-current Assets	1,311,411	1,374,941
Total Assets	\$ 26,793,552	\$ 36,362,124
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Note Payable Capitalized Lease Obligations	\$ 4,113,013	\$ 2,308,145
Accounts Payable	5,133,267	8,686,153
Accrued Liabilities	4,605,573	6,647,828
Customer Deposits	244,314	207,545
Total Current Liabilities	14,096,167	17,849,671
Long Term Debt	16,224,575	17,916,914
Shareholders' Equity:		
Common Shares, no par value, 40,759,976 and 40,110,661 shares issued and outstanding	158,776,957	154,457,878
Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811
Accumulated Deficit	(166,596,095)	(158,790,569)
Accumulated Other Comprehensive Income	66,279	32,419

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

Total Shareholders Equity (Deficit)	(3,527,190)	595,539
Total Liabilities And Shareholders Equity	\$ 26,793,552	\$ 36,362,124

*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, 2014 and March 31, 2013**

(Unaudited)

	<b>Three Months Ended March 31, 2014</b>	<b>Three Months Ended March 31, 2013</b>
<b>Sales</b>	<b>\$ 12,963,652</b>	<b>\$ 12,336,374</b>
Cost of Sales	11,283,694	11,055,394
<b>Gross Profit</b>	<b>1,679,958</b>	<b>1,280,980</b>
Selling, General and Administrative	4,090,199	3,916,783
Research and Product Development	4,615,197	12,754,518
<b>Operating Income (Loss)</b>	<b>(7,025,438)</b>	<b>(15,390,321)</b>
Interest and Investment Income, net	74,215	10,672
Interest Expense	854,303	75
Income (Loss) Before Income Taxes	(7,805,526)	(15,379,724)
Income Tax Expense		
<b>Net Income (Loss)</b>	<b>\$ (7,805,526)</b>	<b>\$ (15,379,724)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ (0.20)</b>	<b>\$ (0.72)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ (0.20)</b>	<b>\$ (0.72)</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, 2014 and March 31, 2013**

(Unaudited)

	<b>Three Months Ended March 31, 2014</b>	<b>Three Months Ended March 31, 2013</b>
<b>Net Income (Loss)</b>	<b>\$ (7,805,526)</b>	<b>\$ (15,379,724)</b>
Unrealized Gain on Available-for-Sale Investments	33,860	
<b>Comprehensive Income (Loss)</b>	<b>\$ (7,771,666)</b>	<b>\$ (15,379,724)</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, 2014**

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED	ACCUMULATED	TOTAL
	SHARES	AMOUNT	WARRANTS	AMOUNT	DEFICIT	OTHER COMPREHENSIVE INCOME (LOSS)	SHAREHOLDERS' EQUITY
Balance as of December 31, 2013	40,110,661	\$ 154,457,878	983,071	\$ 4,895,811	\$ (158,790,569)	\$ 32,419	\$ 595,539
Net Loss					(7,805,526)		(7,805,526)
Unrealized Gain on Available-For-Sale Securities						33,860	33,860
Issuance of Common Shares	262,500	1,044,975					1,044,975
Restricted Stock Issuance	320,000						
Exercise of Purchase Warrants	66,815	1,099,892	(145,000)	(670,142)			429,750
Stock Option Based Expense		1,036,371					1,036,371
Restricted Stock Amortization		1,137,841					1,137,841
Balance as of March 31, 2014	40,759,976	\$ 158,776,957	838,071	\$ 4,225,669	\$ (166,596,095)	\$ 66,279	\$ (3,527,190)

*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, 2014 and March 31, 2013

(Unaudited)

	2014	2013
Cash Flows From Operating Activities:		
<b>Net (Loss)</b>	<b>\$ (7,805,526)</b>	<b>\$ (15,379,724)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	257,761	250,530
Share Based Compensation - Non-employee		966,227
Share Based Compensation- Employees	2,174,212	1,350,959
Amortization of Debt Issuance Costs	113,529	
Non-Cash Interest Expense	112,529	
Loss on Disposal of Assets	1,662	5,109
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	477,866	(30,367)
Increase in Inventory	(110,180)	(215,871)
Decrease (Increase) in Other Assets	(243,936)	257,464
Increase (Decrease) in Accounts Payable	(3,552,886)	1,266,909
Increase (Decrease) in Other Liabilities	(1,790,208)	220,809
Changes in Assets and Liabilities	(5,219,344)	1,498,944
<b>Cash Used In Operating Activities</b>	<b>(10,365,177)</b>	<b>(11,307,955)</b>
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	
Purchase of Equipment	(329,882)	(153,380)
Proceeds on Sale of Assets		5,998
<b>Cash Used In Investing Activities</b>	<b>(2,329,882)</b>	<b>(147,382)</b>
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	1,474,725	12,518,733
Payments on Notes Payable and Capital Lease Obligations		(829)
<b>Cash Provided By Financing Activities</b>	<b>1,474,725</b>	<b>12,517,904</b>
<b>Increase (Decrease) In Cash</b>	<b>(11,220,334)</b>	<b>1,062,567</b>
Cash At Beginning Of Period	11,881,451	4,711,730
<b>Cash At End Of Period</b>	<b>\$ 661,117</b>	<b>\$ 5,774,297</b>

Supplemental Cash Flow disclosure

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

	2014	2013
Interest Paid	\$ 628,244	\$ 75

*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. We have obtained global licenses for certain dialysis related drugs which we are developing and are seeking FDA approval to market.

Rockwell has submitted a New Drug Application ( NDA ) to the Federal Food and Drug Administration ( FDA ) for its lead drug candidate, Triferic . The application is under review by the FDA.

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 Triferic upon FDA market approval.

We are regulated by the 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 related equipment.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

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, 2013 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, 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2013 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. Our

Table of Contents

Annual Report on Form 10-K for the fiscal year ended December 31, 2013 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.

**Investments Available for Sale**

Investments Available for Sale are short-term investments, consisting 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). These funds generally hold high credit quality short term debt instruments. These instruments are subject to changes in fair market value due primarily to changes in interest rates. The fair value of these investments was \$14,068,482 as of March 31, 2014. 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. Gross unrealized gains were \$77,932 and gross unrealized losses were \$11,653 as of March 31, 2014. There were no realized gains or losses in the first quarter of 2014.

The Company evaluated the near term interest rate environment, the expected holding period of the investments along with the duration of the fund portfolios in assessing the severity and duration of the potential impairment. Based on that evaluation the Company does not consider those investments to be other-than-temporarily impaired at March 31, 2014.

**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, Triferic , aggregating approximately \$4.6 million and \$12.8 million for the three months ended March 31, 2014 and 2013, respectively. We have completed the human clinical trials related to Triferic and submitted an NDA to the FDA in the first quarter of 2014. First quarter costs included a \$2.2 million NDA review fee paid to the FDA for the review of Triferic .

#### **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

Table of Contents

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,	
	2014	2013
Basic Weighted Average Shares Outstanding	39,812,820	21,241,000
Effect of Dilutive Securities		
Diluted Weighted Average Shares Outstanding	39,812,820	21,241,000

**3. Inventory**

Components of inventory as of March 31, 2014 and December 31, 2013 are as follows:

	March 31,		December 31,	
	2014		2013	
Raw Materials	\$	1,243,020	\$	1,142,776
Work in Process		231,936		254,714
Finished Goods		1,434,872		1,402,158
Total	\$	2,909,828	\$	2,799,648

**4. Loans Payable**

As of June 14, 2013, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Technology III, L.P. ("Hercules") pursuant to which the Company received a loan in the aggregate principal amount of \$20.0 million. The Company is required to repay the aggregate principal balance under the Loan Agreement in 30 equal monthly installments of principal and interest commencing on September 1, 2014.

The loan will mature and become due on March 1, 2017, subject to adjustment as provided below, and will bear interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%. The Company will be required to make monthly interest only payments through August 31, 2014. Monthly principal and interest payments will be due on the loan following the interest only period through the maturity date. The loan may be prepaid at any time after June 14, 2014 without penalty and will mature and become due upon any change in control of the Company. The Company paid debt issuance costs of \$1.1 million including a fee of \$0.2 million at closing to Hercules, which are recorded as a noncurrent asset, and is required to pay a fee of \$1.1 million upon any prepayment or at maturity. The \$1.1 million fee due upon any prepayment or at maturity is accrued using the effective interest rate method over the life of the loan. The effective interest rate of the loan is 14.5%.

In connection with the loan, the Company granted Hercules a security interest in substantially all of the Company's assets other than motor vehicles, real property and certain intellectual property and other interests. The Loan Agreement provides for standard indemnification of Hercules and contains representations, warranties and non-financial covenants of the Company. The Loan Agreement contains covenants that,



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

among other things, limit the Company's ability to incur additional indebtedness, transfer assets, acquire assets of or merge with another entity and pay dividends to the Company's shareholders. The Loan Agreement defines event of default, to include, among other events, the occurrence of an event that results in a material adverse effect upon the Company's business operations, properties, assets or condition (financial or otherwise), the collateral or the perfection of the security interest, or the Company's ability to perform its obligations under the Loan Agreement.

Table of Contents

The balance of the above debt matures at March 31, 2014 as follows:

2014 (remainder of year)	\$	2,308,145
2015		7,544,935
2016		8,555,035
2017		1,591,885
Total Principal Payable	\$	20,000,000

Interest accrued on the loan payable through March 31, 2014 was \$215,278.

**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 drug Triferic also known as Soluble Ferric Pyrophosphate 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 SEC, including, without limitation, in Item 1A Risk Factors in our Form 10-K for the year ended December 31, 2013.

- Before it can be marketed, our lead drug candidate requires FDA approval, a long, expensive process with no guarantee of success.

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

- Even if Triferic is approved by the FDA, we may not be able to market it successfully.
- If we do not obtain protection under the Hatch-Waxman Act to extend patent protection for Triferic, our business may be harmed.
- FDA approval to manufacture Calcitriol may take longer than we anticipate and commercial launch may be delayed or may not be widely adopted when launched.

Table of Contents

- We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.
- We may not be successful in obtaining foreign regulatory approvals or in arranging a business development, out-licensing or other venture to realize commercialization of our drug products outside of the United States.
- Our dialysis concentrate business is substantially dependent on a few customers that account for a substantial portion of our sales. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our dialysis business and on our ability to market our new drug products.
- We operate in a very competitive market against a substantially larger competitor with greater resources.
- We may not be successful in maintaining our gross profit margins.
- We depend on government funding of health care, changes in which could impact our ability to be paid in full for our products, increase pricing pressures or cause consolidation in the dialysis provider market.
- We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products for our commercially marketed drug products once they are approved. We may not be able to obtain the raw materials, components and manufacturing capacity we need, or the cost of the materials, components and manufacturing capacity may be higher than expected, any of which could have a material adverse effect on our expected results of operations, financial position and cash flows.
- Health care reform could adversely affect our business.
- We depend on key personnel, the loss of which could harm our ability to operate.
- Our business is highly regulated, which increases our costs and results in risks relating to potential noncompliance.
- We may not have sufficient products liability insurance.

- Shares eligible for future sale may negatively affect the market price of our common shares.
- Our stock price could be volatile.
- 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.
- Structural 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

Table of Contents

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, 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 Triferic for which we submitted a New Drug Application with the U.S. Food and Drug Administration in the first quarter of 2014. We expect our spending for Triferic to decrease significantly going forward. Based upon clinical data, we believe Triferic has unique and substantive benefits compared to current treatment options.

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. We plan to market Calcitriol once we obtain approval to manufacture it.

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.

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

As of March 31, 2014, we had \$14.7 million in cash and investments. We believe our current cash resources are adequate to meet our expected needs as we do not anticipate substantial cash requirements to fund our operations going forward. We may seek additional funding through business development, joint ventures and other business arrangements, or through additional debt or equity financings if we believe market conditions are advantageous or if we believe raising additional capital would be appropriate to give us further flexibility to pursue our business strategy.

### **Results of Operations for the Three Months Ended March 31, 2014 and March 31, 2013**

#### **Sales**

Sales in the first quarter of 2014 increased 5.1% to \$13.0 million from \$12.4 million in the first quarter of 2013. The majority of the sales increase was due to higher international sales while most of our domestic sales growth was offset by several factors including conversion to dry product from liquid product and reduced sales to clinics acquired by a competitor.

Table of Contents

**Gross Profit**

Gross profit margin in the first quarter of 2014 increased 2.6 percentage points to 13.0% from 10.4% in the first quarter of 2013. Gross profit dollars in the first quarter were \$1.7 million, an increase of 31% or \$0.4 million compared to the first quarter last year. The increase in gross profit was primarily due to the favorable impact of higher sales of our CitraPure product lines. Higher operating and delivery costs have been largely offset by higher prices in the aggregate.

**Selling, General and Administrative Expense**

Selling, general and administrative expense during the first quarter of 2014 was \$4.1 million compared to \$3.9 million in the first quarter of 2013. Non-cash equity compensation was \$2.2 million in the first quarter of 2014 compared to \$1.3 million in the first quarter of 2013. In the first quarter of 2013, we recognized a non-cash expense of \$0.9 million related to the extension of certain warrants.

**Research and Product Development**

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, Triferic<sup>®</sup>, aggregating approximately \$4.6 million and \$12.8 million for the three months ended March 31, 2014 and 2013, respectively. We submitted an NDA for Triferic<sup>®</sup> to the FDA in the first quarter of 2014. Development costs in the first quarter of 2014 were primarily related to NDA preparation and filing as well as completion of the Triferic<sup>®</sup> Phase 3 longer term safety study work and related documentation. First quarter 2014 expense included a \$2.2 million fee paid to the FDA in connection with the NDA filing for the review of Triferic<sup>®</sup>. Spending in 2013 was primarily for conducting the Phase 3 clinical trial program for Triferic<sup>®</sup>. We have completed the human clinical trials related to Triferic<sup>®</sup> and future spending on Triferic<sup>®</sup> is expected to diminish significantly in each of the remaining quarters of 2014 compared to the corresponding periods in 2013.

**Interest and Investment Income, Net**

Our net interest and investment expense was \$0.8 million in the first quarter of 2014 compared to net interest and investment income of \$11,000 in the first quarter of 2013. The increase in net interest expense was due to borrowings under the June 2013 \$20 million secured loan.

**Liquidity and Capital Resources**

Our strategy is centered on obtaining regulatory approval to market Triferic<sup>®</sup> and developing other high potential drug candidates, while also expanding our dialysis products business. Now that the planned clinical trials for Triferic<sup>®</sup> are complete and the related NDA has been filed, we expect our cash usage to decrease substantially compared to recent periods. Product development expense will aggregate approximately \$4.0 -



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

\$4.5 million for the remaining three quarters of 2014 in total. We believe we have adequate cash resources to launch Triferic once approved by the FDA.

Our cash resources include cash generated from our business operations, the \$50.4 million in net proceeds generated from equity offerings during 2013 and the \$20.0 million borrowed under the secured loan agreement executed in June 2013. The repayment and other terms of the loan are described in Note 4 to our Consolidated Financial Statements. We were in compliance with the terms of the loan agreement and there was no event of default as of March 31, 2014. As of March 31, 2014, our cash and investments were \$14.7 million and our current assets exceeded our current liabilities by \$8.2 million.

Table of Contents

We expect to generate positive cash flow from operations in 2014, excluding research and development related expenditures. The Company intends to expand its customer relationships and to introduce Calcitriol. We anticipate our business development efforts will result in increased cash availability and higher future cash flows if successful. We believe that cash flow from operations will increase substantially once we achieve commercial launch of our new products.

The Company is in discussions with potential business development partners to license rights to its products outside the United States and to partner its dialysis business with interested parties including joint ventures, partnerships and or other marketing arrangements, any of which could provide additional liquidity, if completed. We do not expect to require additional cash resources to execute our business plan. However, if we believe market conditions are advantageous or that raising additional capital would otherwise be appropriate to give us further flexibility to pursue our business strategy, we may seek to raise additional debt or equity capital.

Our contractual obligations are described in our Form 10-K for the year ended December 31, 2013. There have been no material changes to that information since December 31, 2013.

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

**Interest Rate Risk**

Our current exposure to interest rate risk is primarily on our long term debt. As of March 31, 2014 we owed \$20,000,000 in current and long term debt related to a loan we entered into in June 2013. The loan bears interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%. We are exposed to interest rate risk on this loan to the extent the prime rate rises above 3.25%. If the prime rate were to increase to 3.25%, a hypothetical 100 basis point increase above that rate would increase interest expense by \$200,000 per year.

We have invested \$14.1 million in available for sale securities which are 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 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

Table of Contents

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**

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 1A. Risk Factors**

There have been no material changes to the risk factors described in our 2013 Form 10-K.

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

On March 28, 2014, DaVita Healthcare Partners, Inc. exercised its warrant to purchase 100,000 shares of the Company's common stock using a cashless exercise method pursuant to which no cash was exchanged and the exercise price consideration was satisfied entirely by cancellation of a portion of the warrant. A total of 21,815 shares were issued and the warrant is no longer outstanding. The deemed exchange of the warrant for shares of common stock for no additional consideration and without paying remuneration for soliciting such exchange was exempt under Section 3(a)(9) of the Securities Act of 1933, as amended.

**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 12, 2014

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

Date: May 12, 2014

/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>
10.54	Form of Restricted Stock Award Agreement June 2013 (Executive Version)
10.56	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 22, 2014 (appendix to Company's Proxy Statement for the 2014 Annual Meeting of Shareholders filed April 14, 2014)
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.