ROCKWELL MEDICAL, INC.
Form 10-Q
July 31, 2014
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United States

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2014

or

o 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	**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. x Yes o 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). x Yes o 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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). o Yes x 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 July 25, 2014**
Common Stock, no par value	40,895,726 shares

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of June 30, 2014 and December 31, 2013

(Unaudited)

	June 30, 2014	December 31, 2013
ASSETS		
Cash and Cash Equivalents	$ 2,858,724	$ 11,881,451
Investments Available for Sale	9,076,243	12,034,622
Accounts Receivable, net of a reserve of $45,000 in 2014 and $37,000 in 2013	4,218,917	4,578,319
Other Receivable	2,169,883	
Inventory	2,784,142	2,799,648
Other Current Assets	589,074	623,734
Total Current Assets	21,696,983	31,917,774
Property and Equipment, net	1,650,003	1,648,949
Intangible Assets	416,200	499,715
Goodwill	920,745	920,745
Other Non-current Assets	1,197,882	1,374,941
Total Assets	$ 25,881,813	$ 36,362,124
LIABILITIES AND SHAREHOLDERS EQUITY		
Note Payable	$ 5,969,511	$ 2,308,145
Accounts Payable	6,276,561	8,686,153
Accrued Liabilities	2,784,711	6,647,828
Customer Deposits	284,105	207,545
Total Current Liabilities	15,314,888	17,849,671
Long Term Debt	14,480,606	17,916,914
Shareholders Equity:		
Common Shares, no par value, 40,895,726 and 40,110,661 shares issued and outstanding	161,575,859	154,457,878
Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811

Accumulated Deficit	(169,766,473)	(158,790,569)
Accumulated Other Comprehensive Income	51,264	32,419
Total Shareholders Equity (Deficit)	(3,913,681)	595,539
Total Liabilities And Shareholders Equity	$ 25,881,813	$ 36,362,124

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2014 and June 30, 2013

(Unaudited)

	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Sales	**$ 13,033,361**	**$ 12,984,164**	**$ 25,997,013**	**$ 25,320,538**
Cost of Sales	11,014,469	11,299,099	22,298,163	22,354,493
Gross Profit	**2,018,892**	**1,685,065**	**3,698,850**	**2,966,045**
Selling, General and Administrative	4,214,205	3,237,974	8,304,404	7,154,757
Research and Product Development	186,695	10,222,721	4,801,892	22,977,239
Operating Income (Loss)	**(2,382,008)**	**(11,775,630)**	**(9,407,446)**	**(27,165,951)**
Interest and Investment Income, net	69,633	4,566	143,848	15,238
Interest Expense	858,003	92,155	1,712,306	92,230
Income (Loss) Before Income Taxes	(3,170,378)	(11,863,219)	(10,975,904)	(27,242,943)
Income Tax Expense				
Net Income (Loss)	**$ (3,170,378)**	**$ (11,863,219)**	**$ (10,975,904)**	**$ (27,242,943)**
Basic Earnings (Loss) per Share	**$ (0.08)**	**$ (0.38)**	**$ (0.28)**	**$ (1.04)**
Diluted Earnings (Loss) per Share	**$ (0.08)**	**$ (0.38)**	**$ (0.28)**	**$ (1.04)**

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three and six months ended June 30, 2014 and June 30, 2013

(Unaudited)

	Three Months Ended June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Net Income (Loss)	**$ (3,170,378)**	**$ (11,863,219)**	**$ (10,975,904)**	**$ (27,242,943)**
Unrealized Gain (Loss) on Available-for-Sale Investments	(15,015)		18,845	
Comprehensive Income (Loss)	**$ (3,185,393)**	**$ (11,863,219)**	**$ (10,957,059)**	**$ (27,242,943)**

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

For The Six Months Ended June 30, 2014

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS			ACCUMULATED OTHER	
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER S 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					(10,975,904)		(10,975,904)
Unrealized Gain on Available-For-Sale Securities						18,845	18,845
Issuance of Common Shares	398,250	1,612,077					1,612,077
Restricted Stock Issuance	320,000						
Exercise of Purchase Warrants	66,815	1,099,892	(145,000)	(670,142)			429,750
Stock Option Based Expense		2,072,194					2,072,194
Restricted Stock Amortization		2,333,818					2,333,818
Balance as of June 30, 2014	40,895,726	$ 161,575,859	838,071	$ 4,225,669	$ (169,766,473)	$ 51,264	$ (3,913,681)

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2014 and June 30, 2013

(Unaudited)

	2014	2013
Cash Flows From Operating Activities:		
Net (Loss)	**$ (10,975,904)**	**$ (27,242,943)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	506,465	502,178
Share Based Compensation Non-employee		1,200,785
Share Based Compensation- Employees	4,406,012	2,779,121
Amortization of Debt Issuance Costs	227,058	
Non-Cash Interest Expense	225,058	
Loss on Disposal of Assets	4,827	5,516
Loss on Sale of Investments, net	1,223	
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	359,402	(144,560)
Decrease (Increase) in Inventory	15,506	(266,960)
Decrease (Increase) in Other Assets	(2,393,555)	528,866
(Decrease) in Accounts Payable	(2,409,592)	(6,529,600)
(Decrease) in Other Liabilities	(3,578,224)	(3,666,596)
Changes in Assets and Liabilities	(8,006,463)	(10,078,850)
Cash Used In Operating Activities	**(13,611,724)**	**(32,834,193)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	
Sale of Investments Available for Sale	4,976,000	
Purchase of Equipment	(428,831)	(313,014)
Proceeds on Sale of Assets		6,898
Cash Provided By (Used) In Investing Activities	**2,547,169**	**(306,116)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	2,041,828	50,463,613
Proceeds from the Issuance of Notes Payable		20,000,000
Debt Issuance Costs		(1,081,279)
Payments on Notes Payable and Capital Lease Obligations		(1,688)
Cash Provided By Financing Activities	**2,041,828**	**69,380,646**
Increase (Decrease) In Cash	**(9,022,727)**	**36,240,337**
Cash At Beginning Of Period	11,881,451	4,711,730
Cash At End Of Period	**$ 2,858,724**	**$ 40,952,067**

Supplemental Cash Flow disclosure

	2014	2013
Interest Paid	$ 1,267,133	$ 1,952

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

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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 received FDA approval to manufacture Calcitriol during the second quarter of 2014 and is targeting late 2014 to launch Calcitriol.

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, sales and distribution infrastructure has enabled the Company to build strong customer relationships that it intends to leverage 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

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 that 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 and six months ended June 30, 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

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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 $9,076,243 as of June 30, 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 $63,736 and gross unrealized losses were $12,472 as of June 30, 2014. We had net realized losses of $1,223 for the six months ended June 30, 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 June 30, 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 investigational iron delivery maintenance drug, Triferic , aggregating approximately $0.2 million and $10.2 million for the three months ended June 30, 2014 and 2013, respectively and $4.8 million and $23.0 million for the six months ended June 30, 2014 and 2013, respectively. We substantially completed the human clinical trials related to Triferic in 2013. We submitted our NDA for Triferic to the FDA on March 24, 2014 and paid the standard new drug application fee under the Prescription Drug User Fee Act of $2,169,100. The Company sought qualification as a small business in order to waive the fee. However, the application to obtain the waiver was denied by the Small Business Administration. The Company subsequently appealed that determination and on June 9, 2014, the waiver was granted. The NDA fee was recognized as an expense in the first quarter, and that expense was reversed in the second quarter upon notification of the successful appeal, which was announced in June 2014. We recorded an other receivable as of June 30, 2014 for the amount of the refund, which was subsequently received in the third quarter.

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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 June 30, 2014	Three Months Ended June 30, 2013	Six Months Ended June 30, 2014	Six Months Ended June 30, 2013
Basic Weighted Average Shares Outstanding	39,965,169	31,191,079	39,889,416	26,243,526
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	39,965,169	31,191,079	39,889,416	26,243,526

3. Inventory

Components of inventory as of June 30, 2014 and December 31, 2013 are as follows:

	June 30, 2014	December 31, 2013
Raw Materials	$ 1,228,385	$ 1,142,776
Work in Process	199,313	254,714
Finished Goods	1,356,444	1,402,158
Total	$ 2,784,142	$ 2,799,648

4. Loans Payable

On 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, 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

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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.

As of June 30, 2014, the balance of the above debt matures 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 June 30, 2014 was $208,333.

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 the Company, 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, Triferic requires FDA approval, a long and expensive process with no guarantee of success.

- 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.

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- Commercial launch of Calcitriol may be delayed or it may not be widely adopted when launched.

- 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.

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Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow and financial position. There can be no assurance that future results will meet expectations. We do not undertake and expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Overview and Recent Developments

Rockwell Medical, 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.

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 compared to prior periods. Based upon clinical data, we believe Triferic has unique and substantive benefits compared to current treatment options.

We own the rights to manufacture and sell an FDA-approved generic vitamin D injection, Calcitriol, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We recently received FDA approval to manufacture Calcitriol and are targeting the end of 2014 to launch Calcitriol.

We sell a wide range of products with varying profit margins and pricing arrangements. Changes in our customer order patterns or product mix in future quarters could impact gross profit.

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

As of June 30, 2014, we had $11.9 million in cash and investments. In addition, following our successful appeal to obtain a waiver of our previously paid NDA application fee, we received a refund of the $2.2 million fee in early July 2014, which is not included in the June 30, 2014

total of 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. If we believe additional capital will give us greater opportunity to pursue our business strategy, then we may seek additional funding through business development, joint ventures, other business arrangements, and additional debt or equity financings.

Results of Operations for the Three and Six Months Ended June 30, 2014 and June 30, 2013

Sales

Sales in the second quarter of 2014 were $13.0 million, an increase of 0.4% compared to the second quarter of last year. Domestic sales increased 1%, partially offset by reductions in sales to accounts acquired by a competitor aggregating 1.2% of domestic sales for the period. International orders were 3% less than the second quarter of last year due to order timing differences between quarters.

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Sales for the first six months of 2014 were $26.0 million, an increase of 2.7% compared to the first half of 2013. International sales were up $0.5 million or 18.1% and domestic sales were up $0.2 million or 1%. Product mix improved in the first half of 2014 largely due to CitraPure product conversions. CitraPure products accounted for 63% of acid concentrate gallons sold in the first half of 2014 compared to 15% in the first half of 2013.

Gross Profit

Gross profit margin in the second quarter of 2014 increased 2.5 percentage points to 15.5% from 13.0% in the second quarter of 2013. Gross profit in the second quarter was $2.0 million, an increase of 19.8% or $0.3 million compared to the second quarter of last year.

Gross profit was $3.7 million in the first half of 2014 compared to $3.0 million in the first half of 2013, an increase of 24.7%. Gross profit margin for the first six months of 2014 was 14.2% compared to 11.7% in the first half of 2013. The increases in gross profit in both periods were primarily due to the favorable impact of higher sales of our CitraPure product lines coupled with efforts to reduce operating and distribution costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the second quarter of 2014 was $4.2 million compared to $3.2 million in the second quarter of 2013. Non-cash equity compensation was $2.2 million in the second quarter of 2014 compared to $1.7 million in the second quarter of 2013. Increased costs for personnel and marketing accounted for the remainder of the increase.

Selling, general and administrative expense for the first six months of 2014 was $8.3 million compared to $7.2 million in the first half of 2013. Non-cash equity compensation expense was $4.4 million compared to $3.0 million in the first six months of 2013. In 2013, there was a non-recurring expense aggregating $0.9 million related to equity warrants. We also incurred higher costs in support of current and prospective changes in business activity.

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 investigational iron delivery drug Triferic in the three and six months ended June 30, 2014 which aggregated $0.2 million and $4.8 million, respectively, compared to $10.2 and $ 23.0 million in the three and six months ended June 30, 2013, respectively. We submitted an NDA for Triferic to the FDA in the first quarter of 2014. Spending in 2013 was primarily for conducting the Phase 3 clinical trial program for Triferic . Future spending on Triferic is expected to diminish significantly in each of the remaining quarters of 2014 compared to the corresponding periods in 2013.

In the first quarter of 2014 we paid a $2.2 million NDA review fee to the FDA after being denied a small business waiver of the fee by the Small Business Administration (SBA). We appealed that determination and won. The SBA reversed its position during the second quarter and the US Treasury refunded the $2.2 million fee to us in the third quarter of 2014. We recognized the initial fee payment as an expense in the first quarter of 2014 and we reversed that expense in the second quarter. As a result, our R&D expense in the second quarter of 2014 was $0.2 million.

Interest and Investment Income, Net

Our net interest and investment expense was $0.8 million in the second quarter of 2014 compared to net interest and investment expense of $0.1 million in the second quarter of 2013. Our net interest and investment

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expense was $1.6 million in the first six months of 2014 compared to net interest and investment expense of $0.1 million in the first six months of 2013. The increase in net interest expense was due to borrowings under a $20 million secured loan in June 2013.

Liquidity and Capital Resources

We believe our cash resources are adequate to fund our projected cash requirements to launch our drug products. We anticipate significantly lower spending on research and development in the second half of 2014 compared to the $4.8 million incurred in the first half of 2014. We expect to use cash to build up inventory of Calcitriol in preparation for our launch of marketing efforts for that product before the end of 2014. We believe our existing cash and investment resources are adequate for the projected working capital requirements to launch Calcitriol.

Our cash and investment 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 June 30, 2014. As of June 30, 2014, our cash and investments were $11.9 million and our current assets exceeded our current liabilities by $6.4 million. The $2.2 million NDA filing fee refund received in the third quarter will also supplement our cash resources.

We expect to continue 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 regarding its products, including joint ventures, partnerships and other marketing arrangements, any of which is expected to provide additional liquidity, if completed. If we believe additional capital will give us greater opportunity to pursue our business strategy then we may seek additional funding through business development, joint ventures, other business arrangements, and additional debt or equity financings.

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 June 30, 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 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or 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 above 3.25%, a hypothetical 100 basis point increase above that rate would increase interest expense by $200,000 per year.

We have invested $9.1 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.

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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 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.

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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 2013 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K, except as described below.

On June 23, 2014, we announced that the FDA had approved our Supplemental Abbreviated New Drug Application to manufacture Calcitriol, our low-cost generic active vitamin D drug. As a result, failure to receive such approval is no longer a material risk. To reflect this change, the risk factor in our 2013 Annual Report on Form 10-K entitled 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. has been amended and restated in its entirety as follows.

Commercial launch of Calcitriol may be delayed or it may not be widely adopted when launched.

We recently received FDA approval to manufacture Calcitriol, the ANDA for which we acquired from a third party. Although we have received approval to manufacture, we still must meet certain ongoing regulatory requirements for product testing and stability of our commercially marketed products. If our testing does not meet approvable standards or if we experience operational issues with our CMO we may not be able to market Calcitriol.

The market for generic drugs such as Calcitriol is generally very competitive, which may make it difficult for us to capture significant market share. If we have success capturing market share with Calcitriol, it may attract other entrants to market their own Calcitriol product which could have a material adverse effect on our future revenues and results of operations. Branded competitors may aggressively lower their prices to maintain market share.

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, INC.
(Registrant)

Date: July 31, 2014

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

Date: July 31, 2014

/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

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.

Exhibit No.	Description
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