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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Rockwell Medical, Inc.

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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.