ROCKWELL MEDICAL, INC.
Form 10-Q
May 07, 2015
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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 March 31, 2015

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 No o

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 No o

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 April 30, 2015**
Common Stock, no par value	50,269,383 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 March 31, 2015 and December 31, 2014

(Unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
Cash and Cash Equivalents	$ 63,332,646	$ 65,800,451
Investments Available for Sale	19,997,509	19,927,310
Accounts Receivable, net of a reserve of $53,000 in 2015 and $52,000 in 2014	4,665,831	4,472,002
Inventory	5,196,006	3,920,185
Other Current Assets	813,503	587,201
Total Current Assets	94,005,495	94,707,149
Property and Equipment, net	1,401,292	1,496,912
Intangible Assets	290,929	332,686
Goodwill	920,745	920,745
Other Non-current Assets	542,223	542,224
Total Assets	**$ 97,160,684**	**$ 97,999,716**
LIABILITIES AND SHAREHOLDERS EQUITY		
Accounts Payable	$ 5,137,855	$ 5,294,515
Accrued Liabilities	4,863,079	4,325,997
Customer Deposits	338,792	183,890
Total Current Liabilities	10,339,726	9,804,402
Deferred License Revenue	18,999,293	19,492,520
Shareholders Equity:		
Common Shares, no par value, 50,269,383 and 50,284,007 shares issued and outstanding	251,766,056	249,018,189
Accumulated Deficit	(183,816,920)	(180,117,726)
Accumulated Other Comprehensive Income (Loss)	(127,471)	(197,669)
Total Shareholders Equity	67,821,665	68,702,794

Total Liabilities And Shareholders Equity	**$ 97,160,684**	**$ 97,999,716**

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 months ended March 31, 2015 and March 31, 2014

(Unaudited)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Sales	**$ 13,883,961**	**$ 12,963,652**
Cost of Sales	11,571,618	11,283,694
Gross Profit	**2,312,343**	**1,679,958**
Selling, General and Administrative	5,325,761	4,090,199
Research and Product Development	799,591	4,615,197
Operating Income (Loss)	**(3,813,009)**	**(7,025,438)**
Interest and Investment Income, net	113,815	74,215
Interest Expense		854,303
Income (Loss) Before Income Taxes	**(3,699,194)**	**(7,805,526)**
Income Tax Expense		
Net Income (Loss)	**$ (3,699,194)**	**$ (7,805,526)**
Basic Earnings (Loss) per Share	**$ (0.07)**	**$ (0.20)**
Diluted Earnings (Loss) per Share	**$ (0.07)**	**$ (0.20)**

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 months ended March 31, 2015 and March 31, 2014

(Unaudited)

	Three Months Ended March 31, 2015	Three Months Ended March 31, 2014
Net Income (Loss)	**$ (3,699,194)**	**$ (7,805,526)**
Unrealized Gain on Available-for-Sale Investments	70,198	33,860
Comprehensive Income (Loss)	**$ (3,628,996)**	**$ (7,771,666)**

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 Three Months Ended March 31, 2015

(Unaudited)

	COMMON SHARES		ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER S
	SHARES	AMOUNT	DEFICIT	INCOME (LOSS)	EQUITY
Balance as of December 31, 2014	50,284,007	$ 249,018,189	$ (180,117,726)	$ (197,669)	$ 68,702,794
Net (Loss)			(3,699,194)		(3,699,194)
Unrealized (Loss) on Available-For-Sale Securities				70,198	70,198
Issuance of Common Shares	125,166	918,884			918,884
Stock Option Based Expense		1,215,369			1,215,369
Restricted Stock Amortization		2,077,215			2,077,215
Restricted Stock Tendered in Satisfaction of Tax Liabilities	(139,790)	(1,463,601)			(1,463,601)
Balance as of March 31, 2015	**50,269,383**	**$ 251,766,056**	**$ (183,816,920)**	**$ (127,471)**	**$ 67,821,665**

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 three months ended March 31, 2015 and March 31, 2014

(Unaudited)

	2015	2014
Cash Flows From Operating Activities:		
Net (Loss)	**$ (3,699,194)**	**$ (7,805,526)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	207,858	257,761
Share Based Compensation- Employees	3,292,584	2,174,212
Restricted Stock Tendered in Satisfaction of Tax Liabilities	(1,463,601)	
Amortization of Debt Issuance Costs		113,529
Non-Cash Interest Expense		112,529
Loss on Disposal of Assets	2,424	1,662
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(193,829)	477,866
(Increase) in Inventory	(1,275,821)	(110,180)
(Increase) in Other Assets	(226,301)	(243,936)
(Decrease) in Accounts Payable	(156,661)	(3,552,886)
Increase (Decrease) in Other Liabilities	691,984	(1,790,208)
Deferred License Revenue	(493,227)	
Changes in Assets and Liabilities	(1,653,855)	(5,219,344)
Cash (Used In) Operating Activities	**(3,313,784)**	**(10,365,177)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale		(2,000,000)
Purchase of Equipment	(77,705)	(329,882)
Proceeds from Sale of Assets	4,800	
Cash (Used In) Investing Activities	**(72,905)**	**(2,329,882)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	918,884	1,474,725
Cash Provided By Financing Activities	**918,884**	**1,474,725**
Increase (Decrease) In Cash	**(2,467,805)**	**(11,220,334)**
Cash At Beginning Of Period	65,800,451	11,881,451
Cash At End Of Period	**$ 63,332,646**	**$ 661,117**

	2015	2014

Interest Paid	$	$ 628,244

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 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 United States and abroad.

We are currently 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. We have obtained global licenses for certain dialysis related drugs which we are developing and planning to market.

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or ESRD . We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States.

We are regulated by the Federal Food and Drug Administration (FDA) under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We obtained FDA approval of TrifericTM our branded dialysis iron maintenance therapy drug, in January 2015. We have also received 510(k) approval from the FDA to market hemodialysis solutions and powders and, to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

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, 2014 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 months ended March 31, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2014 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 includes a description of our significant accounting policies.

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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.

The initial payment received from our long-term Distribution Agreement has been deferred and classified as deferred license revenue. Deferred license revenue is being recognized based on the proportion of product shipments to Baxter Healthcare Corporation (Baxter) in each period to total expected sales volume for the term of the agreement.

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 $19,997,509 as of March 31, 2015. 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 $23,839 and gross unrealized losses were $151,310 as of March 31, 2015. There were no realized gains or losses in the first quarter of 2015.

The Company has evaluated the near term interest rate environment and 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, 2015.

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 recently FDA approved iron delivery maintenance drug, Triferic , aggregating approximately $0.8 million and $4.6 million for the three months ended March 31, 2015 and 2014, respectively.

We submitted our NDA for TrifericTM 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 of 2014, and that expense was reversed in the second quarter of 2014 upon notification of the successful appeal.

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Share Based Compensation

We measure the cost of employee services received in exchange for equity awards, including stock options, based on the grant date fair value of the awards in accordance with ASC 718-10, *Compensation Stock Compensation.* The cost of equity based compensation is recognized as compensation expense over the vesting period of the awards.

We estimate the fair value of compensation involving stock options utilizing the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, and an expected forfeiture rate, and is subject to various assumptions. We believe the valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to ASC 718-10 requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants.

The Company s Long Term Incentive Plan permits grantees to tender shares to the Company in satisfaction of liabilities related to the exercise of equity awards, including the exercise price of options and tax liabilities related to equity awards. During the first quarter of 2015, 139,790 shares were tendered to the Company in satisfaction of $1,463,601 of such liabilities.

Net Earnings Per Share

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

	Three Months Ended March 31,	
	2015	**2014**
Basic Weighted Average Shares Outstanding	49,667,434	39,812,820
Effect of Dilutive Securities		
Diluted Weighted Average Shares Outstanding	49,667,434	39,812,820

3. Inventory

Components of inventory as of March 31, 2015 and December 31, 2014 are as follows:

	March 31,	**December 31,**

	2015	2014
Raw Materials	$ 3,460,108	$ 2,197,143
Work in Process	212,496	197,106
Finished Goods	1,523,402	1,525,936
Total	$ 5,196,006	$ 3,920,185

4. Distribution Agreement

As of October 2, 2014, we entered into a Distribution Agreement with Baxter, pursuant to which Baxter became the Company s exclusive agent for sales, marketing and distribution activities for the Company s hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial

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term of 10 years. The Distribution Agreement does not include any of the Company s drug products. The Company will retain sales, marketing and distribution rights for its hemodialysis concentrate products in specified foreign countries in which the Company has an established commercial presence. During the term of the Distribution Agreement, Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products.

Pursuant to the Distribution Agreement, Baxter paid the Company $20 million in cash in early October (the Upfront Fee). The Upfront Fee has been deferred and will be recognized as revenue based on the proportion of product shipments to Baxter in each period to total expected sales volume over the term of the Distribution Agreement. The Company recognized revenue associated with the Upfront Fee totaling $493,227 for the quarter ended March 31, 2015.

Under the Distribution Agreement, Baxter will purchase products from the Company at established gross margin-based prices per unit, adjusted each year during the term. The Company will continue to manage customer service, transportation and certain other functions for its current customers on Baxter s behalf through at least December 31, 2017, in exchange for which Baxter will pay the Company an amount equal to the Company s related costs to provide such functions plus a slight mark-up.

The Distribution Agreement also requires Baxter to meet minimum annual gallon-equivalent purchase levels, subject to a cure period and certain other relief, in order to maintain its exclusive distribution rights. The minimum purchase levels increase each year over the term of the Distribution Agreement. Orders in any contract year that exceed the minimum will be carried forward and applied to future years minimum requirements. The Distribution Agreement also contains provisions governing the operating relationship between the parties, the Company s obligations to maintain specified manufacturing capacity and quality levels, remedies, as well as representations, warranties and indemnification obligations of the parties.

Either party may terminate the Distribution Agreement upon the insolvency or material breach of the other party or in the event of a force majeure. In addition, Baxter may also terminate the Distribution Agreement at any time upon 270 days prior written notice to the Company or if (1) prices increase beyond certain thresholds and notice is provided within 45 days after the true up payment is due for the year in which the price threshold is exceeded, (2) a change of control of the Company occurs and 270 days notice is provided, or (3) upon written notice that Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product. If Baxter terminates the Distribution Agreement under the discretionary termination or the price increase provisions, it would be subject to a limited non-compete obligation in the United States with respect to certain products for a period of two years.

If a Refund Trigger Event occurs, the Company would be obligated to repay a portion of the Upfront Fee and Facility Fee (described below) as follows: 50% if the event occurs prior to December 31, 2016, 33% if the event occurs in 2017 or 2018, and 25% if the event occurs in 2019, 2020 or 2021. A Refund Trigger Event means any of the following: (1) a change of control of the Company involving any of certain specified companies; (2) a termination by Baxter due to the Company s bankruptcy or breach, or due to price increases that exceed the stated thresholds; (3) a termination by either party due to a force majeure; (4) settlement or adjudication of any claim, action or litigation relating to a covered product that materially and adversely affects Baxter s commercialization of the product; and (5) any regulatory action or ruling relating to a covered product that materially and adversely affects Baxter s commercialization of the product. In addition, if Baxter terminates the Distribution Agreement because Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product prior to the end of 2018, Baxter would be entitled to a refund of up to $10 million, or $6.6 million if the termination occurs in 2019. In no event would Baxter be entitled to more than one refund payment.

The Distribution Agreement also required the Company to prepay its outstanding secured long-term indebtedness within 180 days and prohibits the Company from entering into a subsequent contract encumbering the assets used in the Company s concentrate business without the prior written consent of Baxter.

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Baxter has also agreed to pay the Company $10 million (the Facility Fee) to build and operate a new manufacturing facility located in the Pacific time zone to service customers in the Western United States. The Facility Fee will be reduced to the extent that the facility is not operational within 12 months after the start of construction. Except for any leased components, the Company will own the facility when completed.

The Distribution Agreement may be extended an additional five years by Baxter if Baxter achieves a specified sales target and pays an extension fee of $7.5 million. If the first extension occurs, the Distribution Agreement term may later be extended an additional five years at Baxter s option at no additional cost.

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 TrifericTM also known as Ferric Pyrophosphate Citrate or SFP and Calcitriol 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 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, 2014.

Risks Related To Our Drug Business

- Although TrifericTM has recently been approved by the FDA, we may not be able to commercialize it successfully.

- TrifericTM is currently limited to use in patients receiving hemodialysis treatments and has not been approved for other indications. Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, which may limit our ability to market our drug products.

- If we do not obtain protection under the Hatch-Waxman Act to extend patent protection for TrifericTM, our business may be harmed.

- Although Calcitriol has been approved by the FDA, we may not be able to commercialize it successfully.

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- We may not be successful in obtaining foreign regulatory approvals or in arranging an out-licensing or other venture to realize commercialization of our drug products outside of the United States. If we are successful in out-licensing our drug products, the licensee or partner may not be effective at marketing our products in certain markets or at all.

- We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products. We may not be able to obtain the raw materials, proper components or manufacturing capacity we need, or the cost of the materials, components or 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.

- Before it can be marketed, an investigational drug requires FDA approval, which is a long, expensive process with no guarantee of success.

- Our drug business will depend on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market.

- Health care reform could adversely affect our business.

Risks Related To Our Concentrate Business

- The Distribution Agreement with Baxter may be terminated or Baxter may lose exclusivity, requiring us to resume commercialization, which could have a material adverse effect on our financial condition, results of operations and cash flows.

- We may be required to repay a portion of the fees received from Baxter, which could materially and adversely affect our financial position and cash reserves.

- The transition to Baxter of commercialization of our concentrate and ancillary products may not be successful.

- A few customers account for a substantial portion of the end user sales of our concentrate products. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our concentrate business.

- The concentrate market is very competitive and has a large competitor with substantial resources.

- We may be affected materially and adversely by increases in raw material costs.

- Our concentrate business is highly regulated, which increases our costs and the risk and consequences of noncompliance.

Risks Related To Our Business As A Whole

- We may not be successful in expanding our product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.

- Our drug and concentrate businesses are highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, financial condition and results of operations.

- We depend on key personnel, the loss of which could harm our ability to operate.

- 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.

- Our products may have undesirable side effects and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.

- We may be unable to obtain certain debt financing in the future as a result of our arrangement with Baxter.

Risks Related To Our Common Stock

- Shares eligible for future sale may affect the market price of our common shares.

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- The market price for our common stock is 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 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 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 United States and abroad.

We are currently 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. In January 2015, we received FDA approval to market Triferic our lead branded drug. Based on our clinical trial results, we believe Triferic has the potential to capture significant market share due to its unique attributes and clinical benefits, including savings on nursing administration time, potential to reduce expensive ESA treatments and excellent safety profile. We also received FDA approval to manufacture Calcitriol an injectable generic vitamin D analogue. We plan to launch both of these drugs in 2015.

In the fourth quarter of 2014, we strengthened our balance sheet to position the Company for future growth and development. We raised net proceeds of approximately $55 million in a public offering of our common shares and sold $15 million of common shares to Baxter in a private offering. We also received $20 million in cash from Baxter related to the Distribution Agreement related to our concentrate products. We fully paid off our high interest rate long term debt and we have no debt on our balance sheet. Overall, we had cash and investments of $83.3 million as of March 31, 2015 and $85.7 million as of December 31, 2014.

We expect to achieve profitability following the launch of our drug products and to generate positive cash flow from our business operations as a result.

Distribution Agreement

As discussed in Note 4 to the Consolidated Financial Statements, on October 2, 2014, we entered into an exclusive Distribution Agreement with Baxter, a leading global dialysis products company, pursuant to which Baxter will become our exclusive agent for sales, marketing and distribution activities for our concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. We will retain sales, marketing and distribution rights for our hemodialysis concentrate products in specified foreign countries in which we have an established commercial presence. During the term of the Distribution Agreement,

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Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products. The Distribution Agreement relates solely to our concentrate business and excludes any future drug related business.

Under the Distribution Agreement, Baxter will purchase products from us at gross margin-based prices per unit, adjusted each year during the term and subject to an annual true up. We will continue to manage customer service, transportation and certain other functions for our current customers through at least December 31, 2017, for which Baxter will pay us an amount equal to our related costs to provide such functions plus a slight mark-up. The Distribution Agreement also requires Baxter to meet minimum annual gallon-equivalent purchase levels, subject to a cure period and certain other relief, in order to maintain its exclusive distribution rights. The minimum purchase levels increase each year over the term of the Distribution Agreement. Orders in any contract year that exceed the minimum will be carried forward and applied to future years minimum requirements.

In light of the gross margin-based pricing terms, the arrangement for Baxter to reimburse us the cost of customer service, transportation and other functions performed for it through at least 2017, and Baxter s requirement to meet increasing minimum concentrate purchase levels, we expect the distribution relationship with Baxter under the Distribution Agreement to have a positive impact on our operating profit. Following a transition period expected to be completed in the second quarter of 2015, our revenue from dialysis concentrates and ancillary products will reflect the wholesale prices paid by Baxter and will be reduced accordingly pursuant to our Distribution Agreement. Similarly, our distribution costs included in costs of sales and administration costs included in selling, general and administrative expense will be passed through to Baxter and will be reduced accordingly. We expect the net effect of these changes to result in an improvement in gross profit of approximately $1.2 million per annum compared to operating results for our domestic concentrate business prior to the Distribution Agreement. Included in the higher expected operating income is recognition of deferred licensing revenue.

We expect our overall domestic and global concentrate sales to increase in the long term as a result of the expanded marketing channel provided by Baxter as well as the anticipated expansion of our manufacturing operations to the Western United States as a result of funding provided through the Distribution Agreement.

Results of Operations for the Three Months Ended March 31, 2015 and March 31, 2014

Sales

Our sales in the first quarter of 2015 were $13.9 million, an increase of $0.9 million or 7.1% compared to the first quarter of 2014 and consisted of dialysis concentrates and other dialysis related ancillary products sold domestically and internationally. Our domestic sales, which represented 85.2% of our sales in the first quarter, increased $0.8 million or 6.6% compared to the first quarter of 2014. Our international sales, which represented 14.8% of our net sales or $2.1 million in the first quarter, increased 7.2% over the first quarter of 2014 due to increased sales volumes.

Our overall domestic revenue on the business distributed under the Baxter Distribution Agreement increased $0.65 million or 6.1% compared to the first quarter of 2014 and included amortization of deferred license revenue of $0.5 million. Volume increases in sales of our CitraPure product lines was the primary reason behind increased sales in the first quarter of 2015 compared to the first quarter of 2014.

Gross Profit

Gross profit in the first quarter of 2015 was $2.3 million, an increase of $0.6 million or 37.6% over the first quarter of 2014. Gross profit margins increased by 3.7 percentage points to 16.7%. Gross profit increased largely due to the effects of the Distribution Agreement and higher sales compared to the first quarter of 2014. Gross profit was favorably impacted by the

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recognition of deferred license revenue under the Baxter Distribution Agreement of $0.5 million in the first quarter of 2015.

Selling, General and Administrative Expense

Selling, general and administrative expense during the first quarter of 2015 was $5.3 million compared to $4.1 million in the first quarter of 2014. Non-cash equity compensation was $3.3 million in the first quarter of 2015 compared to $2.2 million in the first quarter of 2014 accounting for the majority of the increase in SG&A costs. Increased costs for personnel, marketing and intellectual property expenses related to preparation of our anticipated drug product launches also increased approximately $0.2 million compared to the first quarter of 2014.

Research and Product Development

We incurred research and product development costs related to the commercial development, patent approval and regulatory approval of new products, including our TrifericTM which was approved by the FDA in the first quarter of 2015. R&D spending was $0.8 million in the first quarter of 2015 compared to $4.6 million in the first quarter of 2014. Future R&D spending in 2015 is expected to be primarily related to other TrifericTM indications.

Interest and Investment Income, Net

Our net interest and investment income was $0.1 million compared to a net expense of $0.8 million in the first quarter of 2014. We incurred no interest expense in the first quarter of 2015 as a result of paying off our long term debt in the fourth quarter of 2014. Interest expense was $854,000 in the first quarter of 2014.

Liquidity and Capital Resources

We have adequate capital resources and substantial liquidity to pursue our business strategy. Our strategy is centered on developing and licensing high potential drug candidates including TrifericTM, for which we received FDA approval to market in late January 2015. We intend to commercialize TrifericTM using Rockwell s sales and marketing infrastructure with minor additional resources added to support commercialization.

As of March 31, 2015, we had $94.0 million in current assets and net working capital of $83.7 million. We had $83.3 million in cash and investments with $63.3 million in cash as of March 31, 2015. We have no debt.

In the first quarter of 2015, we incurred $0.8 million in research and product development costs and we increased our inventory $1.3 million. Other cash used in operations included approximately $1.5 million related to the satisfaction of tax obligations related to restricted stock tendered to the Company by restricted stock grantees. We intend to source our drug products from contract manufacturing organizations. Capital expenditures on our current facilities are not expected to materially exceed depreciation expense.

We expect cash flow from operations to be positive following the launch of our drug products in 2015.

Future research and product development spending on the TrifericTM platform is expected to include clinical testing in connection with pediatric testing, peritoneal dialysis and certain other indications and is expected to be minor in relation to the Company s cash resources. Our expected future cash investment for anticipated product launches is expected to be primarily related to working capital for inventory and accounts receivable in the near term.

The Company is in discussions with multiple potential business development partners to out-license rights to Rockwell s products outside the United States. We are considering other business development arrangements

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including joint ventures, partnerships and other transactions related to our products or other future products that we may develop or license.

Our contractual obligations are described in our Form 10-K for the year ended December 31, 2014. There have been no material changes to that information since December 31, 2014 except as described above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have invested $20.0 million in available for sale securities that 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 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.

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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

For information regarding risk factors affecting us, see Risk Factors in Item 1A of Part I of our 2014 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K.

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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs
January 2015			n/a	n/a
February 2015			n/a	n/a
March 2015	139,790	$ 10.47	n/a	n/a
Total	139,790	$ 10.47	n/a	n/a

Under the provisions of the Company s Long Term Incentive Plan, 139,790 shares were tendered to the Company in satisfaction of tax liabilities associated with the vesting of restricted stock awards. The Company has no publicly announced share repurchase program.

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: May 7, 2015

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

Date: May 7, 2015

/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
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