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 September 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 October 24, 2014**
Common Stock, no par value	43,603,407 shares

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of September 30, 2014 and December 31, 2013

(Unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Cash and Cash Equivalents	$ 3,016,837	$ 11,881,451
Investments Available for Sale	9,017,395	12,034,622
Accounts Receivable, net of a reserve of $52,000 in 2014 and $37,000 in 2013	4,189,666	4,578,319
Inventory	2,981,506	2,799,648
Other Current Assets	688,475	623,734
Total Current Assets	19,893,879	31,917,774
Property and Equipment, net	1,615,320	1,648,949
Intangible Assets	374,443	499,715
Goodwill	920,745	920,745
Other Non-current Assets	1,067,800	1,374,941
Total Assets	$ 23,872,187	$ 36,362,124
LIABILITIES AND SHAREHOLDERS' EQUITY		
Note Payable	$ 7,962,819	$ 2,308,145
Accounts Payable	5,171,391	8,686,153
Accrued Liabilities	3,816,884	6,647,828
Customer Deposits	329,117	207,545
Total Current Liabilities	17,280,211	17,849,671
Long Term Debt	12,051,824	17,916,914
Shareholders' Equity:		
Common Shares, no par value, 41,015,392 and 40,110,661 shares issued and outstanding	164,056,146	154,457,878
Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811
Accumulated Deficit	(173,734,079)	(158,790,569)
Accumulated Other Comprehensive Income	(7,584)	32,419

Total Shareholders' Equity (Deficit)	(5,459,848)	595,539
Total Liabilities And Shareholders' Equity	$ 23,872,187	$ 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 nine months ended September 30, 2014 and September 30, 2013

(Unaudited)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine months Ended September 30, 2014	Nine Months Ended September 30, 2013
Sales	**$ 13,743,778**	**$ 13,094,381**	**$ 39,740,791**	**$ 38,414,919**
Cost of Sales	11,473,961	11,461,100	33,772,125	33,815,593
Gross Profit	**2,269,817**	**1,633,281**	**5.968,666**	**4,599,326**
Selling, General and Administrative	4,098,835	3,386,367	12,403,240	10,541,124
Research and Product Development	1,301,824	10,611,219	6,103,716	33,588,458
Operating Income (Loss)	**(3,130,842)**	**(12,364,305)**	**(12,538,290)**	**(39,530,256)**
Interest and Investment Income, net	55,263	13,546	199,113	28,784
Interest Expense	892,027	857,505	2,604,333	949,735
Income (Loss) Before Income Taxes	(3,967,606)	(13,208,264)	(14,943,510)	(40,451,207)
Income Tax Expense	—	—	—	—
Net Income (Loss)	**$ (3,967,606)**	**$ (13,208,264)**	**$ (14,943,510)**	**$ (40,451,207)**
Basic Earnings (Loss) per Share	**$ (0.10)**	**$ (0.34)**	**$ (0.37)**	**$ (1.32)**
Diluted Earnings (Loss) per Share	**$ (0.10)**	**$ (0.34)**	**$ (0.37)**	**$ (1.32)**

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 nine months ended September 30, 2014 and September 30, 2013

(Unaudited)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine months Ended September 30, 2014	Nine Months Ended September 30, 2013
Net Income (Loss)	**$ (3,967,606)**	**$ (13,208,264)**	**$ (14,943,510)**	**$ (40,451,207)**
Unrealized Gain (Loss) on Available-for-Sale Investments	(58,848)	4,332	(40,003)	4,332
Comprehensive Income (Loss)	**$ (4,026,454)**	**$ (13,203,932)**	**$ (14,983,513)**	**$ (40,446,875)**

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 nine months ended September 30, 2014

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT	WARRANTS	AMOUNT			
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)	—	—	—	—	(14,943,510)	—	(14,943,510)
Unrealized (Loss) on Available-For-Sale Securities						(40,003)	(40,003)
Issuance of Common Shares	517,916	2,205,125	—	—	—	—	2,205,125
Restricted Stock Issuance	320,000						
Exercise of Purchase Warrants	66,815	1,099,892	(145,000)	(670,142)	—	—	429,750
Stock Option Based Expense	—	3,112,599	—	—	—	—	3,112,599
Restricted Stock Amortization	—	3,180,652	—	—	—	—	3,180,652
Balance as of September 30, 2014	41,015,392	$ 164,056,146	838,071	$ 4,225,669	$ (173,734,079)	$ (7,584)	$ (5,459,848)

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 nine months ended September 30, 2014 and September 30, 2013

(Unaudited)

	2014	2013
Cash Flows From Operating Activities:		
Net (Loss)	**$ (14,943,510)**	**$ (40,451,207)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	767,386	752,360
Share Based Compensation — Non-employee	—	1,435,344
Share Based Compensation- Employees	6,293,250	4,449,110
Amortization of Debt Issuance Costs	357,140	—
Non-Cash Interest Expense	353,994	426,938
Loss on Disposal of Assets	4,827	15,500
Loss on Sale of Investments, net	1,223	—
Changes in Assets and Liabilities:		
Decrease in Accounts Receivable	388,653	209,521
(Increase) in Inventory	(181,858)	(164,526)
Decrease (Increase) in Other Assets	(317,194)	606,263
(Decrease) in Accounts Payable	(3,514,762)	(7,722,004)
(Decrease) in Other Liabilities	(2,506,918)	(2,079,489)
Changes in Assets and Liabilities	(6,132,079)	(9,150,235)
Cash Used In Operating Activities	**(13,297,769)**	**(42,522,190)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	(10,000,611)
Sale of Investments Available for Sale	4,976,000	—
Purchase of Equipment	(613,311)	(496,302)
Proceeds on Sale of Assets	—	6,898
Cash Provided By (Used) In Investing Activities	**2,362,689**	**(10,490,015)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	2,634,876	50,625,357
Proceeds from the Issuance of Notes Payable	—	20,000,000
Debt Issuance Costs	—	(1,109,776)
Payments on Notes Payable and Capital Lease Obligations	(564,410)	(2,280)
Cash Provided By Financing Activities	**2,070,466**	**69,513,301**
Increase (Decrease) In Cash	**(8,864,614)**	**16,501,096**
Cash At Beginning Of Period	11,881,451	4,711,730
Cash At End Of Period	**$ 3,016,837**	**$ 21,212,826**

Supplemental Cash Flow disclosure

	2014	2013
Interest Paid	$ 1,906,022	$ 522,797

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.

Rockwell's lead investigational drug Triferic is currently under review by the U.S. Food and Drug Administration ("FDA") for the treatment of iron replacement and maintenance of hemoglobin in dialysis patients. Triferic's unique mode of action enables it to deliver iron to the bone marrow of dialysis patients in a physiological manner during their regular dialysis treatment, using dialysate as the delivery mechanism. Triferic has successfully completed the efficacy trials of its Phase 3 clinical study program.

Rockwell is preparing to launch its FDA approved generic drug Calcitriol to treat secondary hyperparathyroidism in dialysis patients. Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. Rockwell intends to market Calcitriol to hemodialysis patients in the U.S. dialysis market.

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. As one of the two major suppliers in the U.S., 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/distribution facilities located in the U.S.

We are regulated by the FDA under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We market products that have been approved for sale by the FDA.

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 nine months ended September 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

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December 31, 2013. Our 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 $9,017,395 as of September 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 $33,445 and gross unrealized losses were $41,029 as of September 30, 2014. We had net realized losses of $1,223 for the nine months ended September 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 September 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, primarily Triferic, aggregating approximately $1.3 million and $10.6 million for the three months ended September 30, 2014 and 2013, respectively, and $6.1 million and $33.6 million for the nine months ended September 30, 2014 and 2013, respectively. We completed Phase 3 efficacy trials related to Triferic in 2013. We submitted our NDA for Triferic to the FDA on March 24, 2014 and paid the new drug application fee of $2,169,100. Our initial fee waiver request as a small business was denied by the Small Business Administration but was later granted upon appeal. The New Drug Application ("NDA") fee was recognized as an expense in the first quarter of 2014, but that expense was reversed in the second quarter upon obtaining the waiver. We recorded a receivable as of June 30, 2014 for the amount of the refund, which was subsequently received in the third quarter of 2014.

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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 September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Basic Weighted Average Shares Outstanding	40,405,693	39,327,994	40,063,399	30,652,944
Effect of Dilutive Securities	—	—	—	—
Diluted Weighted Average Shares Outstanding	40,405,693	39,327,994	40,063,399	30,652,944

3. Inventory

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

	September 30, 2014	December 31, 2013
Raw Materials	$ 1,394,930	$ 1,142,776
Work in Process	207,434	254,714
Finished Goods	1,379,142	1,402,158
Total	$ 2,981,506	$ 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 that commenced 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 was 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 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 at September 30, 2014 was 14.5%. On October 2, 2014 the Company entered into an exclusive Distribution Agreement (the "Distribution Agreement") with Baxter Healthcare Corporation ("Baxter") as described below in Note 5 — Subsequent Events under which the Company is obligated to retire the Hercules debt within 180 days from the date of the Distribution Agreement.

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,

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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 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 September 30, 2014, the balance of the above debt matures as follows:

2014	(remainder of year)	$ 2,332,436
2015		7,624,034
2016		8,645,024
2017		834,095
Total Principal Payable		$ 19,435,589

In addition to the principal payable, there is an end of term fee of $1.1 million of which $579,054 has been accrued for as of September 30, 2014.

Interest accrued on the loan payable through September 30, 2014 was $202,454.

5. Subsequent Events

Warrant Exercise

We received $8.0 million in cash in October 2014 from the exercise of 838,071 warrants to purchase common stock at $9.55 per share just prior to their expiration. We issued 838,071 common shares upon exercise of the warrants.

Private Placement of Common Shares

On October 2, 2014, we entered into an Investment Agreement with Baxter under which we issued 1,316,944 common shares in conjunction with a private placement in exchange for $15.0 million at a per share price of $11.39, which was $2.21 above the share price at market close that day.

Under the terms of the Investment Agreement, Baxter agreed not to transfer any of the common shares until at least one year following the purchase of the shares, and is prohibited from engaging in any short sales with respect to the shares for three years following the purchase of the shares. In addition, until the earlier of (i) the end of the term of the Distribution Agreement or (ii) one year after the Company receives notice that Baxter and its affiliates no longer beneficially own the shares, Baxter will be bound by certain "standstill" provisions that prohibit Baxter from, among other things, beneficially owning more than 4.9% of the Company's common stock, participating in a solicitation of proxies, granting a proxy other than to Company management, acting or seeking to control the Company's management or board, or publicly proposing a business combination or extraordinary corporate transaction. The Investment Agreement also contains customary representations and warranties and standard indemnification provisions.

Distribution Agreement

On October 2, 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter has become the Company's exclusive agent for commercializing the Company's hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. The Company retains sales, marketing and distribution rights for its hemodialysis concentrate products for its current international customers and in those 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.

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Following the signing of the Distribution Agreement, Baxter paid the Company $20 million in cash (the "Upfront Fee). The Upfront Fee will be recognized as revenue in future periods over the term of the license based on sales projections over the term of the Distribution Agreement.

Under the Distribution Agreement, Baxter will purchase products from the Company at pre-determined gross margin-based prices per unit adjusted each year during the term and subject to an annual true up. Rockwell will continue to manage customer service, transportation and certain other functions for its current customers through at least December 31, 2017, for which Baxter will pay the Company an amount equal to the Company's related costs plus a slight mark-up.

During the initial transition period until Baxter assumes customer invoicing, which is expected to last until December 31, 2014, Rockwell will continue to recognize sales and invoice customers. We will provide Baxter with an equivalent economic value for the operating income related to those sales and will treat these payments as a reduction in revenue. Once Baxter assumes invoicing, Rockwell revenue will be based on our contractual distributor pricing to Baxter.

The Distribution Agreement requires Baxter to meet minimum annual purchase requirements (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. Purchases that exceed the minimum requirement in a given year may be carried forward and applied to future years' 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 any product in the United States 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.

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The Distribution Agreement also requires 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.

Baxter has also agreed to pay the Company during the term of the Distribution Agreement $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 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," "predict," "forecast," "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 iron-delivery drug Triferic, or 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 in Part II Item 1A of 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.

Risks Related To Our Drug Business

- Before it can be marketed, an investigational drug requires FDA approval, which is a long, 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 vitamin D injection may be delayed or it may not be widely adopted when launched.
- 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.
- We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products once they are approved. 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.

- 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 consequence of noncompliance.

Risks Related To Our Business As A Whole

- 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.

- We may not have sufficient product liability insurance.

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

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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-value 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 have been primarily related to our investigational iron-delivery drug Triferic, for which we submitted a NDA to the FDA in the first quarter of 2014. We expect our R&D spending for Triferic to decrease significantly going forward compared to 2013. Based upon clinical data, we believe Triferic has unique and substantive benefits compared to current treatment options. The Oncologic Drugs Advisory Committee of the FDA has recommended that the Phase 3 Triferic clinical efficacy and safety results support a positive benefit/risk to treat iron loss to maintain hemoglobin in hemodialysis patients. Triferic has a Prescription Drug User Fee Act date of January 24, 2015. Upon FDA approval, we intend to market Triferic.

We own the rights to manufacture and sell Calcitriol, our generic vitamin D injection, indicated for the treatment of secondary hyperparathyroidism. We received FDA approval to manufacture Calcitriol and we are currently working to have product manufactured and to secure sufficient inventory to launch Calcitriol, which we estimate may occur in the first half of 2015.

We continue to 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 that order routinely. International sales are typically more unpredictable.

As of September 30, 2014, we had $12.0 million in cash and investments. In early October 2014, we received $8.0 million in cash from the exercise of warrants, $20.0 million in cash from Baxter following the execution of the Distribution Agreement and a $15.0 million cash investment by Baxter in our

common stock in conjunction with the execution of the Distribution Agreement.

Distribution Agreement

As discussed in Note 5 to the Consolidated Financial Statements, on October 2, 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter has become the Company's exclusive agent for commercializing the Company's hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. The Company retains sales, marketing and distribution rights for its hemodialysis concentrate products for its current international customers and in those 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.

Under the Distribution Agreement, Baxter will purchase products from the Company at pre-determined gross margin-based prices per unit, adjusted each year during the term and subject to an annual true up. Rockwell will continue to manage customer service, transportation and certain other functions for its current customers through at least December 31, 2017, for which Baxter will pay the Company an amount equal to the Company's related costs plus a slight mark-up. The Distribution Agreement requires Baxter to meet minimum annual purchase requirements (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. Purchases that exceed the minimum requirement in a given year may be carried forward and applied to future years' requirements.

We expect the distribution relationship with Baxter under the Distribution Agreement to have a positive impact on our operating profit. Our operating costs will decrease and operating income will improve. Initially, our current sales level will decrease, but going forward we expect our overall domestic and global concentrate sales to increase as a result of the expanded marketing reach by Baxter, coupled with the anticipated expansion of our manufacturing operations in the Western United States.

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Results of Operations for the Three and Nine Months Ended September 30, 2014 and September 30, 2013

Sales

Sales in the third quarter of 2014 were $13.7 million, an increase of 5.0% compared to the third quarter of last year. International sales were $0.5 million or 39.4% higher than the third quarter of last year. Domestic sales increased 1.3%, net of a 0.9% decrease attributable to accounts acquired by a competitor. Product mix continues to move to higher margin CitraPure product lines. CitraPure products accounted for 65% of acid concentrate gallons sold in the third quarter compared to 39.7% in the third quarter of 2013. Liquid product continued to convert to more cost effective dry product, contributing to lower sales dollars and higher gross profit margins.

Sales for the first nine months of 2014 were $39.7 million, an increase of 3.5% compared to the first nine months of 2013. International sales were up $1.0 million or 24.5% and domestic sales were up $0.3 million or 1.0%. Product mix improved in the first nine months of 2014 largely due to conversions to our CitraPure product lines. CitraPure products accounted for 63.5% of acid concentrate gallons sold in the first nine months of 2014 compared to 23.7% in the first nine months of 2013. Our product mix continued to shift to dry product from liquid product resulting in higher gross profit while moderating the sales increase.

Gross Profit

Gross profit margin in the third quarter of 2014 increased 4.0 percentage points to 16.5% compared to 12.5% in the third quarter of 2013. Gross profit in the third quarter of 2014 was $2.3 million, an increase of 39.0% or $0.6 million compared to the third quarter last year. A more favorable mix of higher margin products, particularly CitraPure and dry product, was the primary driver behind higher gross profit margins.

Gross profit was $6.0 million in the first nine months of 2014 compared to $4.6 million in the first nine months of 2013, an increase of 29.8%. Gross profit margin for the first nine months of 2014 was 15.0%

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compared to 12.0% in the first nine months of 2013. The increase in gross profit was primarily due to the favorable impact of higher sales of our CitraPure and dry product.

Selling, General and Administrative Expense

Selling, general and administrative expense during the third quarter of 2014 was $4.1 million compared to $3.4 million in the third quarter of 2013. Non-cash equity compensation was $1.9 million in both the third quarter of 2014 and in the third quarter of 2013. Increased costs for personnel, marketing and intellectual property expenses related to preparation of our anticipated drug product launches accounted for the increase.

Selling, general and administrative expense for the first nine months of 2014 was $12.4 million compared to $10.5 million in the first nine months of 2013. Non-cash equity compensation expense was $6.3 million compared to $5.9 million in the first nine months of 2013. Increased costs for personnel, marketing and intellectual property expenses related to preparation of our anticipated drug product launches accounted for the increase.

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 nine months ended September 30, 2014 which aggregated $1.3 million and $6.1 million, respectively, compared to $10.6 million and $33.6 million in the three and nine months ended September 30, 2013, respectively. Spending in 2013

was primarily for conducting the Phase 3 clinical trial program for Triferic. Future research and product development spending on Triferic is expected to continue to diminish significantly compared to 2013.

Interest and Investment Income, Net

Our net interest and investment expense was $0.8 million in the third quarter of 2014, unchanged from the third quarter of 2013. Our net interest and investment expense was $2.4 million in the first nine months of 2014 compared to net interest and investment expense of $0.9 million in the first nine 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

As described in Note 5 to the Consolidated Financial Statements, we received $43.0 million in cash in early October 2014. Coupled with our cash and liquid investment resources of $12.0 million as of September 30, 2014, we believe we have sufficient cash resources to meet our cash requirements.

Our future cash requirements for our operations are anticipated to be primarily related to working capital for the launch of Triferic and Calcitriol. We expect our drug launches to require only modest amounts of incremental resources beyond those already in place. As noted, research and development spending for the remainder of 2014 is expected to be significantly lower than in 2013. Our 2015 research and development spending is expected to be at or below 2014 levels. Repayment of our note payable to Hercules, which is required to occur by March 31, 2015 pursuant to our Distribution Agreement with Baxter, will require approximately $20.5 million.

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Although the Distribution Agreement with Baxter is expected to improve our reported results of operations, we expect it to have a slightly negative impact on the cash flow from our concentrate operation initially. However, based on Baxter's required unit volume growth in our existing business footprint and the expected geographic expansion of our concentrate operations, we expect the cash flow from our concentrate operation to improve over time to eventually offset the initial reduction in cash flow.

We may elect to expand the geographic reach of our concentrate business in the United States to include expansion in the Western United States where we have only a limited presence today. Baxter has agreed to pay us $10 million (the "Facility Fee") to build a new manufacturing facility located in the Pacific time zone, payable in installments. The Facility Fee will be reduced to the extent that the facility is not operational within 12 months after the start of construction.

If we believe additional capital will give us greater opportunity to pursue our business strategy or if we otherwise determine it is prudent to raise additional capital, then we may seek additional funding through business development arrangements, joint ventures, additional debt or equity financings or other business arrangements.

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 except as described above.

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 September 30, 2014 we had an outstanding principal balance of $19.4 million related to a long-term secured loan we entered into in June 2013. The loan bears interest at (a) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (b) 12.50%, whichever is greater. 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 $194,000 per year.

We have invested $9.0 million in available for sale securities which are invested in short term bond funds which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short term duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical

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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.

PART II — OTHER INFORMATION

Item 1A. Risk Factors

On October 2, 2014, we entered into the Distribution Agreement with Baxter. As discussed in Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Quarterly Report on Form 10-Q, pursuant to the terms of the Distribution Agreement, Baxter will become our exclusive agent for commercialization activities for our hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. In light of the material effects the Distribution Agreement is expected to have on the Company's dialysate concentrate business, the Company has amended and restated in their entirety the risk factors included in "Risk Factors" in Item 1A of Part I of the Company's 2013 Annual Report on Form 10-K as set forth below.

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RISKS RELATED TO OUR DRUG BUSINESS

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

Performing clinical trials and obtaining FDA approval for any drug can take a long time. Clinical trials typically take months or years to complete. Once trials are completed and the New Drug Application, or NDA, is submitted to the FDA, the FDA may find deficiencies in our NDA, may raise safety or efficacy concerns or may otherwise require additional clinical testing or impose other requirements before granting approval, which could significantly delay approval or result in us not receiving approval at all.

Clinical trials and the NDA approval process are also expensive. Any such delays, additional testing or other requirements may require us to raise additional capital, which may not be available when needed or may be available only on terms that are not in the best interests of the Company and its shareholders, or which result in substantial dilution of shareholders' voting power and ownership. If approval is not granted, our entire investment in the related products may be worthless, any licensing rights could be forfeited and the price of our common stock could substantially decline.

Even if Triferic is approved by the FDA, we may not be able to market it successfully.

Even if approval is granted by the FDA, the commercial success of Triferic will depend on a number of factors, including the following:

- one drug currently dominates treatment for iron deficiency and Triferic will have to compete against it and possibly other existing and future products;
- it may be difficult to gain market acceptance from dialysis chains, anemia managers and nephrologists or such acceptance may be slower than expected. Market acceptance will depend on a number of factors, such as demonstration of safety and efficacy, cost-effectiveness, advantages over existing products, and the reimbursement policies of government and third party payers, including Medicare;
- maintaining compliance with ongoing regulatory requirements applicable to Triferic which may be imposed by the FDA as part of the approval or which apply generally to the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping applicable to the product;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization, and our ability to execute our marketing strategy without significant additional expenditures;
- our ability to avoid third party patent interference or patent infringement claims; and
- a continued acceptable safety profile of Triferic following approval. Later discovery of previously unknown problems with Triferic or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in regulatory action that could have a material adverse effect on our ability to manufacture and market Triferic.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be able to generate revenues through the sale of Triferic. If we are not successful in commercializing Triferic, or are significantly delayed in doing so, our entire investment in Triferic may be worthless, our licensing rights

could be forfeited and the price of our common stock could substantially decline.

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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The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides that patent holders may apply for an extension of patent term for drugs for a period of up to five years to compensate for time spent in development and regulatory approval. There can be no assurance that we will receive the extension of the patent term provided under the Hatch-Waxman Act for either of the licensed Triferic patents expiring in 2016. If we fail to receive such extension, our ability to prevent competitors from manufacturing, marketing and selling generic versions of Triferic could be impaired and we would have to rely on the protection afforded us by the U.S. patent we hold on the synthesis and formulation of our pharmaceutical grade formulation of Triferic which expires in 2029 or on other patents related to Triferic that may be issued to us in the future.

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

We recently received FDA approval to manufacture a generic version of Calcitriol. Although we have received approval to manufacture Calcitriol, 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, if we are unable to find one or more approved suppliers that can make the product in sufficient quantities or if we experience operational issues with our supplier, we may not be able to market Calcitriol or the launch may be delayed.

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 in 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.

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.

The approval procedures for marketing our new drug products, such as Triferic, outside the U.S. vary from country to country, can be difficult to obtain and carry the same risks as FDA approval. In particular, regulatory approval in foreign countries may require additional testing and may otherwise be expensive and time consuming to undertake. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional government approval for price reimbursement under national health insurance systems.

Even if we obtain the necessary foreign approval in a particular market, we do not have substantial expertise selling and marketing on an international level and therefore may not be successful in realizing commercial value from our products. Our strategy for addressing the need for expertise in obtaining foreign approvals and marketing in foreign markets is to out-license rights to our drugs in markets outside the United States. However, we may not be successful in finding a partner or partners who will be willing to invest in our drugs outside the United States. If we are not successful in out-licensing our drugs outside of the United States or entering into some other business development arrangement to obtain the necessary approvals to commercialize them, we may be forced to seek regulatory approval and market these products ourselves. If we elect to seek approval ourselves, it may take longer than expected to obtain regulatory approval and to market and manufacture our drugs, and we may decide to delay or abandon development efforts in certain markets.

Any such delay or abandonment, or any failure to receive one or more foreign approvals, may have a material adverse effect on the benefits otherwise expected from marketing in foreign countries.

We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products once they are approved. 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.

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We may not be able to obtain needed raw materials, packaging components and manufacturing capacity for a variety of reasons, including among others:

- we may be required to purchase certain raw materials and packaging components from unaffiliated third-party suppliers who may not be able to supply us consistently or at all;
- regulatory requirements or action by regulatory agencies or others;
- adverse financial or other strategic developments at or affecting the supplier or contract manufacturer;
- unexpected demand for or shortage of raw materials or packaging components;
- failure to comply with cGMP standards which results in quality or product failures, adulteration, contamination and/or recall;
- limitations in capacity of contract manufacturers; and
- changes in product demand.

If we are unable to obtain the raw materials, components and manufacturing capacity we require, or if we are charged more than expected for these items, we may not be able to produce our drug products or our gross profit margins may be materially adversely affected.

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.

Many dialysis providers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. These providers depend on Medicare and Medicaid funding to be viable businesses. A variety of changes to health insurance and reimbursement are included in health reform legislation enacted by Congress in recent years. Some of these changes could have a negative impact on Medicare and Medicaid funding, which fund the majority of dialysis costs in the United States, and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, these providers would be severely impacted, increasing our risk of not being paid in full. An increase in our exposure to uncollectible accounts could have a material adverse effect on our financial position, results of operations and cash flows.

In the United States, the Medicare Improvements for Patients and Providers Act of 2008 or "MIPPA" changed the dialysis reimbursement method from the prior practice of separately billed services and medications to a single bundled prospective rate for Medicare outpatient ESRD facilities beginning January 1, 2011, with full implementation by January 1, 2012. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to this change in reimbursement practice which could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations.

As a result of these changes to Medicare reimbursement, the dialysis provider industry may continue to consolidate. This may result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry.

Health care reform could adversely affect our business.

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The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. The federal Medicare and Medicaid programs are facing financial challenges and are looking at ways to reduce the costs of the Medicare and Medicaid programs. Similarly, many states have large deficits which may prove unsustainable, resulting in defaults on state debt obligations which may ultimately result in the reduction or curtailment of health care benefits or state Medicaid reimbursement.

In the United States, Congress enacted the Patient Protection and Affordable Care Act in 2010, as amended by the Health Care and Education Affordability Reconciliation Act, referred to collectively as PPACA, which has resulted in significant changes to the health care payment and delivery system. The PPACA requires employers to provide employees with insurance coverage that meets minimum eligibility and coverage requirements or face penalties. The PPACA also includes provisions that impact the number of individuals with insurance coverage, including expansion of those eligible for Medicaid in some states, the types of coverage and level of health benefits that are required and the amount of payment providers performing health care services receive. The PPACA imposes implementation through 2020. The U.S. government faces structural deficits that may require changes to government funded healthcare programs such as Medicare and Medicaid which may negatively impact customers of our products. On March 1, 2013, the President issued a sequestration order that imposed a 2% "across the board" reduction in Medicare reimbursement. Our financial position, results of operations, and cash flows and ability to commercialize our drug products could be materially impacted by the PPACA, future health care reform or reduced Medicare and Medicaid spending by the federal government.

Beginning in early 2014 and annually thereafter, device and pharmaceutical manufacturers are required to report to the FDA regarding certain financial relationships they have with physicians and teaching hospitals. This reporting requirement will increase governmental scrutiny on our contractual relationships with physicians and teaching hospitals and will increase the risk that inadvertent violations result in liability under the federal fraud and abuse laws, which could have a material adverse effect on our results of operations, financial position and cash flows.

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.

Baxter may terminate the Distribution Agreement at any time at its discretion upon 270 days' written notice to us. In addition, Baxter may terminate the Distribution Agreement if:

- We are in bankruptcy or insolvent;
- We are in breach of the agreement and have failed to cure the breach within the applicable cure period;
- 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;
- We have a change of control; or
- Baxter gives us written notice that it 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.

In addition, if Baxter were to fail to purchase its minimum purchase requirement, its distribution rights would become non-exclusive. If, after December 31, 2017, the Distribution Agreement is terminated or Baxter's rights become non-exclusive, we would be required to reassume distribution of hemodialysis concentrate and ancillary products in the United States and various foreign countries and re-establish commercial arrangements with our current customers. Further, our concentrate products are distribution-intensive, resulting in a high cost to deliver relative to the selling prices of our products and we may have to re-establish, or may be unable to maintain,

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competitive pricing for our products in order to be profitable. If the Distribution Agreement is terminated or Baxter's distribution rights become non-exclusive, such events could have a material and 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.

Pursuant to the terms of the Distribution Agreement, we may be required to repay a portion of the upfront fee and facility fee to Baxter upon the occurrence of a "Refund Trigger Event." A "Refund Trigger Event" means any of the following:

- A change of control of the Company involving any of certain specified companies;
- A termination by Baxter due to our bankruptcy, insolvency or uncured breach, or due to price increases that exceed the stated thresholds;
- A termination by either party due to a force majeure;
- The 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
- Any regulatory action or ruling relating to a covered product that materially and adversely affects Baxter's commercialization of the product.

Any of these events would obligate us to repay 50% of the upfront fee and facility fee 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. Any such repayment could result in a material negative impact on our financial condition and cash reserves.

In addition, if Baxter terminates the Distribution Agreement because it 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.

If we are required to make any such refund payment, we may need to reallocate funds from other parts of our business, which could force us to change or delay plans for use of that capital. We may be forced to obtain financing or raise capital on terms that are unfavorable to us, or financing or additional capital may not be available at all. In any such event, our financial condition, results of operations and cash flows could be materially and adversely affected.

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

In October 2014, we entered into our Distribution Agreement with Baxter pursuant to which Baxter will become our exclusive agent for commercializing our hemodialysis concentrate and ancillary products in the United States and various foreign countries. If Baxter were to commit insufficient financial and other resources to the marketing and distribution of our products, or if our products were to lose focus within Baxter or are otherwise not being marketed as effectively as we have marketed them in the past, unit sales of our products may fall, resulting in lower revenues and gross margin for us, which could have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we may not be able to transition the sales and marketing activities of these products to Baxter successfully or Baxter could fail to price the product adequately to allow its sales of our products to be profitable to it, either of which could cause Baxter to exercise its right to terminate the Distribution Agreement or to fail to purchase the minimum requirements and allow its distribution rights to become nonexclusive. Any such termination or failure could have a material and adverse effect on our financial condition, results of operations and cash flows.

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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.

Beginning in October 2014, our concentrate and ancillary products are primarily sold to or through Baxter. Its sales of our products are highly concentrated in a few customers and Baxter's loss of any of those customers could adversely affect our results of operations. One customer in particular accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. If Baxter were to lose this customer or the relationship with any other major dialysis chain customers, it could have a substantial negative impact on our cash flow and operating results.

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

There is intense competition in the hemodialysis products market. The primary competitor in the market for our concentrate products is a large diversified company which has substantial financial, technical, manufacturing, marketing and research and management resources. Our distributor, Baxter, may not be able to successfully compete with them or other companies. The primary competitor has historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell. Baxter may be at a disadvantage in competing against their marketing strategies to sell our products. Furthermore, the primary competitor is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 37% of all U.S. patients through its clinics. This competitor has routinely acquired smaller clinic chain operations that we service and may acquire more of the customers we service in the future. In addition, if the Distribution Agreement were to terminate or if the distribution rights were to become non-exclusive, Baxter may be able to compete with us, which could materially and adversely affect our business.

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

A significant portion of our costs relates to chemicals and other raw materials, which are subject to price volatility based on demand and are highly influenced by the overall level of economic activity in the U.S. and abroad. These costs have tended to rise from year to year and are likely to continue to rise in the future. Under our Distribution Agreement with Baxter, such cost inflation may result in increases in the prices we charge Baxter. If these increases exceed specified levels in the Distribution Agreement, Baxter is permitted to terminate the Distribution Agreement and obtain a refund of a portion of the fees we received from Baxter. Any such termination or refund would have a material adverse effect on our business, results of operations, financial position and cash flows.

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

The testing, manufacture and sale of the concentrate products we manufacture are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before medical devices can be commercially marketed in the United States, the FDA must give either 510(k) clearance or pre-market

approval for the devices. If we do not comply with these requirements, we may be subject to a variety of sanctions, including fines, injunctions, seizure of products, suspension of production, denial of future regulatory approvals, withdrawal of existing regulatory approvals and criminal prosecution. Our concentrate business could be adversely affected by any of these actions.

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding manufacturing quality. Our failure to comply with these regulations could result in FDA

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action or product liability litigation adverse to us. Any of these events could constitute a breach by us of the Distribution Agreement, providing Baxter with various remedies that would be material and adverse to us, including without limitation, termination of the Distribution Agreement. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations and, if such higher costs result in price increases that exceed the thresholds specified in the Distribution Agreement, could give Baxter the right to terminate the Distribution Agreement and obtain a partial refund of certain fees paid to us pursuant to that agreement.

RISKS RELATED TO OUR BUSINESS AS A WHOLE

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

Our success depends heavily on the efforts of Robert L. Chioini, our founder and Chief Executive Officer, Dr. Ajay Gupta MD, our Chief Scientific Officer, Dr. Raymond D. Pratt, our Chief Medical Officer, and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for the strategic direction of the Company and for managing our sales and marketing efforts. Dr. Gupta is primarily responsible for discovery and development of new technologies. Dr. Pratt is primarily responsible for the clinical development, testing and regulatory approval of our products. None of our executive management have current employment agreements with the Company. If we lose the services of Mr. Chioini, Dr. Gupta, Dr. Pratt or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

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 success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We could incur substantial costs in seeking enforcement of our patent rights against infringement, and we cannot guarantee that such patents will successfully preclude others from using technology that we rely upon. We have no knowledge of any infringement or patent litigation, threatened or filed at this time. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our products infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from selling products, forced to pay damages and compelled to defend against litigation. Moreover, if Baxter is prevented from selling from any of our concentrate or ancillary products due to a patent infringement or if its ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, Baxter may be entitled to terminate our Distribution Agreement and obtain a refund of a portion of the upfront fee and facility fee.

We may not have sufficient product liability insurance.

As a supplier of medical products, we may face potential liability from a person who claims that he or she suffered harm as a result of using our products. We maintain products liability insurance in the amount of $5 million per occurrence and $5 million in the aggregate. We cannot be sure that it will remain economical to retain our current level of insurance, that our current insurance will remain available or that such insurance would be sufficient to protect us against liabilities associated with our business, particularly if it expands substantially in the wake of the potential FDA approval of Triferic. We may be sued, and we may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by product liability litigation and that could harm our marketing ability. Any litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. Our business, financial condition and

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results of operations could be adversely affected by an uninsured or inadequately insured product liability claim in the future.

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

The Distribution Agreement prohibits us from entering into a subsequent contract encumbering the assets used in our concentrate business without the prior written consent of Baxter, and Baxter would be under no obligation to provide us with consent. The assets used in our concentrate business currently constitute a substantial portion of the assets we own. As a result, unless our cash flows improve enough to support financing through unsecured indebtedness, we may not be able to obtain debt financing and our capital financing options may become limited. If we are unable to obtain adequate capital, our business and our expansion strategy may be materially and adversely affected.

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: November 10, 2014

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

Date: November 10, 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
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

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Robert L. Chioini, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Robert L. Chioini
Robert L. Chioini
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)

I, Thomas E. Klema, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Thomas E. Klema
Thomas E. Klema

Vice President and Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Rockwell Medical, Inc. (the "Company") on Form 10-Q for the quarter ending September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I, Robert L. Chioini, Chief Executive Officer of the Company and I, Thomas E. Klema, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

1. the Periodic Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 10, 2014

/s/ Robert L. Chioini
Robert L. Chioini
President and Chief Executive Officer

Dated: November 10, 2014

/s/ Thomas E. Klema
Thomas E. Klema
Vice President and Chief Financial Officer