ROCKWELL MEDICAL, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/07/16 for the Period Ending 09/30/16

Address	30142 S WIXOM RD
	WIXOM, MI 48393
Telephone	2489609009
CIK	0001041024
Symbol	RMTI
SIC Code	3845 - Electromedical and Electrotherapeutic Apparatus
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Michigan	**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. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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 28, 2016**
Common Stock, no par value	51,527,711 shares

Rockwell Medical, Inc.
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PART I – FINANCIAL INFORMATIO N

Item 1. Financial Statement s

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEET S

As of September 30, 2016 and December 31, 2015

(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Cash and Cash Equivalents	$ 19,293,454	$ 31,198,182
Investments Available for Sale	38,434,312	39,482,732
Accounts Receivable, net of a reserve of $39,000 in 2016 and $75,000 in 2015	8,031,196	5,046,733
Inventory	11,760,269	7,871,780
Other Current Assets	2,264,583	1,026,889
Total Current Assets	79,783,814	84,626,316
Property and Equipment, net	1,506,155	1,646,568
Intangible Assets	42,555	165,657
Goodwill	920,745	920,745
Other Non-current Assets	601,187	462,839
Total Assets	$ 82,854,456	$ 87,822,125
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 3,396,789	$ 3,995,216
Accrued Liabilities	3,825,374	3,831,356
Customer Deposits	91,005	264,879
Total Current Liabilities	7,313,168	8,091,451
Deferred License Revenue	19,783,978	17,410,852
Shareholders' Equity:		
Common Shares, no par value, 51,527,711 and 51,501,877 shares issued and outstanding	265,648,345	257,773,494
Accumulated Deficit	(209,286,794)	(194,538,176)
Accumulated Other Comprehensive Income	(604,241)	(915,496)
Total Shareholders' Equity	55,757,310	62,319,822
Total Liabilities And Shareholders' Equity	$ 82,854,456	$ 87,822,125

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENT S

For the three and nine months ended September 30, 2016 and September 30, 2015

(Unaudited)

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Sales	$ 12,814,815	$ 14,378,528	$ 39,894,380	$ 41,218,065
Rebates	—	—	—	
Cost of Sales	11,234,934	11,875,122	35,130,045	34,336,359
Gross Profit	1,579,881	2,503,406	4,764,335	6,881,706
Selling, General and Administrative	5,070,127	3,827,904	15,071,238	12,989,261
Research and Product Development	1,261,863	1,246,727	4,639,617	2,931,577
Operating Income (Loss)	(4,752,109)	(2,571,225)	(14,946,520)	(9,039,132)
Interest and Investment Income	188,847	156,672	602,429	388,638
Interest (Expense)	—	—	—	—
Income (Loss) Before Income Taxes	(4,563,262)	(2,414,553)	(14,344,091)	(8,650,494)
Income Tax Expense	—	—	(404,527)	—
Net Income (Loss)	$ (4,563,262)	$ (2,414,553)	$ (14,748,618)	$ (8,650,494)
Basic Earnings (Loss) per Share	$ (0.09)	$ (0.05)	$ (0.29)	$ (0.17)
Diluted Earnings (Loss) per Share	$ (0.09)	$ (0.05)	$ (0.29)	$ (0.17)

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three and nine months ended September 30, 2016 and September 30, 2015

(Unaudited)

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Net Income (Loss)	**$ (4,563,262)**	**$ (2,414,553)**	**$ (14,748,618)**	**$ (8,650,494)**
Unrealized Gain (Loss) on Available-for-Sale Investments	115,541	(270,017)	311,273	(382,441)
Foreign Currency Translation Adjustments	(18)		(18)	
Comprehensive Income (Loss)	**$ (4,447,739)**	**$ (2,684,570)**	**$ (14,437,363)**	**$ (9,032,935)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUIT Y

For the nine months ended September 30, 2016

(Unaudited)

	COMMON SHARES		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT			
Balance as of December 31, 2015	51,501,877	257,773,494	(194,538,176)	(915,496)	62,319,822
Net Loss	—	—	(14,748,618)	—	(14,748,618)
Unrealized Gain on Available-for-Sale Investments	—	—	—	311,273	311,273
Foreign Currency Rate Changes	—	—	—	(18)	(18)
Issuance of Common Shares	25,834	80,161	—	—	80,161
Stock Option Based Expense	—	4,523,370	—	—	4,523,370
Restricted Stock Amortization	—	3,271,320	—	—	3,271,320
Balance as of September 30, 2016	51,527,711	$ 265,648,345	$ (209,286,794)	$ (604,241)	$ 55,757,310

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOW S

For the nine months ended September 30, 2016 and September 30, 2015

(Unaudited)

	2016	2015
Cash Flows From Operating Activities:		
Net (Loss)	**$ (14,748,618)**	**$ (8,650,494)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	583,501	608,152
Share Based Compensation—Employees	7,794,690	6,097,122
Restricted Stock Retained in Satisfaction of Tax Liabilities	—	(2,912,859)
Loss on Disposal of Assets	7,340	4,292
Loss on Sale of Investments Available for Sale	26,820	58,095
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(2,984,463)	(1,424,485)
(Increase) in Inventory	(3,888,489)	(3,495,096)
(Increase) in Other Assets	(1,376,042)	(1,014,009)
(Decrease) in Accounts Payable	(598,427)	(71,121)
(Decrease) in Other Liabilities	(179,856)	(1,259,560)
Increase (decrease) in Deferred License Revenue	2,373,126	(1,479,681)
Changes in Assets and Liabilities	(6,654,151)	(8,743,952)
Cash (Used) In Provided By Operating Activities	**(12,990,418)**	**(13,539,644)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(23,158,809)	(21,800,000)
Sale of Investments Available for Sale	24,491,678	1,468,656
Purchase of Equipment	(328,322)	(336,856)
Proceeds on Sale of Assets	1,000	4,800
Cash (Used In) Investing Activities	**1,005,547**	**(20,663,400)**
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares and Purchase Warrants	80,161	1,575,333
Cash Provided By Financing Activities	**80,161**	**1,575,333**
Effects of exchange rate changes	(18)	—
(Decrease) Increase In Cash	(11,904,728)	(32,627,711)
Cash At Beginning Of Period	31,198,182	65,800,451
Cash At End Of Period	**$ 19,293,454**	**$ 33,172,740**

Supplemental Cash Flow disclosure

	2016	2015
Interest Paid	$ —	$ —

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

Rockwell Medical, Inc. and Subsidiaries

Notes to Consolidated Financial Statement s

1. Description of Business

Rockwell Medical, Inc. and Subsidiaries (collectively, "we", "our", "us", or the "Company") is a fully-integrated pharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad.

We are currently developing unique, proprietary renal drug therapies. These novel renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome. We have obtained global licenses for certain dialysis related drugs which we are developing and planning to market.

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

We are regulated by the Federal Food and Drug Administration ("FDA") under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We hold several FDA product approvals including both drugs and medical devices.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited. 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, 2015 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, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2015 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 includes a description of our significant accounting policies.

Revenue Recognition

Our policy is to recognize revenue consistent with authoritative guidance for revenue recognition including the provisions of the Financial Accounting Standards Board Accounting Standards Codification. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

Consistent with these guidelines we recognize revenue at the time we transfer title to our products to our customers which generally occurs 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 apply judgment as we analyze each element of our contractual agreements to determine appropriate revenue recognition. The terms of our contractual agreements may include milestone payments if specified research and development objectives are achieved, non-refundable licensing fees, milestone payments on sales or royalties from product sales.

When entering into an arrangement, we first determine whether the arrangement includes multiple deliverables and is subject to the accounting guidance in ASC subtopic 605-25, Multiple-Element Arrangements. If we determine that an arrangement includes multiple elements, we determine whether the arrangement should be divided into separate units of accounting and how the arrangement consideration should be measured and allocated among the separate units of accounting. An element qualifies as a separate unit of accounting when the delivered element has standalone value to the customer. Our arrangements do not include a general right of return relative to delivered elements. Any delivered elements that do not qualify as separate units of accounting are combined with other undelivered elements within the arrangement as a single unit of accounting. If the arrangement constitutes a single combined unit of accounting, we determine the revenue recognition method for the combined unit of accounting and recognize the revenue either on a straight-line basis or on a modified proportional performance method over the period from inception through the date the last deliverable within the single unit of accounting is delivered.

Non-refundable upfront license fees are recorded as deferred revenue and recognized into revenue over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. In arrangements that include license rights and other non-contingent deliverables, such as participation in a steering committee, these deliverables do not have standalone value because the non-contingent deliverables are dependent on the license rights. That is, the non-contingent deliverables would not have value without the license rights, and only we can perform the related services. Upfront license rights and non-contingent deliverables, such as participation in a steering committee, do not have standalone value as they are not sold separately and they cannot be resold. In addition, when non-contingent deliverables are sold with upfront license rights, the license rights do not represent the culmination of a separate earnings process. As such, we account for the license and the non-contingent deliverables as a single combined unit of accounting. In such instances, the license revenue in the form of non-refundable upfront payments is deferred and recognized over the applicable relationship period.

For milestone payments based on sales and for royalties based on sales, we recognize revenue in the quarter that the information related to the sales becomes available and collectability is reasonably assured.

We received an upfront payment of $4 million pursuant to our License Agreement with Wanbang Biopharmaceutical Co., Ltd. ("Wanbang"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. in February 2016. Deferred license revenue is being recognized over the term of the license agreement.

The initial payment of $20 million received pursuant to our long-term Distribution Agreement (the "Distribution Agreement") with Baxter Healthcare Corporation ("Baxter") in October 2014 has been accounted for as deferred license revenue. Deferred license revenue is being recognized based on the proportion of product shipments to Baxter in each period to total expected sales volume for the term of the agreement. See Note 5 to condensed consolidated financial statements for information related to our ongoing arbitration with Baxter.

We recognize other revenues at the time the related fees and or payments are earned.

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 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 $38,434,312 as of September 30, 2016. 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 $857 and gross unrealized losses were $605,080 as of September 30, 2016. Realized gains in the third quarter of 2016 and year to date were $156,461 while realized losses were $183,281.

The Company has evaluated the near term interest rate environment and the expected holding period of the investments along with the duration of the fund portfolios in assessing the severity and duration of potential impairments. Based on that evaluation the Company does not consider those investments to be other-than-temporarily impaired at September 30, 2016.

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 aggregating approximately $1.3 million and $4.6 million for the three and nine months ended September 30, 2016, respectively.

Share Based Compensation

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

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

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, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Basic Weighted Average Shares Outstanding	50,677,076	50,222,787	50,675,667	49,988,684
Effect of Dilutive Securities	—	—	—	—
Diluted Weighted Average Shares Outstanding	50,677,076	50,222,787	50,675,667	49,988,684

3. Inventory

Components of inventory as of September 30, 2016 and December 31, 2015 are as follows:

	September 30, 2016	December 31, 2015
Raw Materials	$ 8,621,522	$ 5,504,915
Work in Process	145,089	165,910
Finished Goods	2,993,658	2,200,955
Total	$ 11,760,269	$ 7,871,780

4. Contractual Agreement Revenue

In February 2016, we entered into exclusive licensing and manufacturing supply agreements with Wanbang Biopharmaceutical Co., Ltd. ("Wanbang"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd., for the rights to commercialize the Company's Triferic ® and Calcitriol drugs for ESRD patients, that also includes new therapeutic indications for Triferic ®, in the People's Republic of China, (the "Wanbang Agreement").

Under the terms of the Wanbang Agreement, we received an upfront payment of $4 million which we are recognizing over the term of the agreement. Rockwell may also receive milestone payments upon achievement of certain regulatory milestones in the future.

Contingent upon and following regulatory approval of each drug in connection with the Wanbang Agreement, Rockwell would receive ongoing earnings from product sales which would be recognized in the period that the sales are reported. In addition, Rockwell could also receive sales milestone payments or additional regulatory milestone payments.

5. Baxter Distribution Agreement

Rockwell has asserted that Baxter is in material default for, among other things, non-payment of certain amounts owed under the Distribution Agreement. Baxter has asserted that Rockwell is in material default under the Distribution Agreement. Pursuant to the dispute resolution terms of the Distribution Agreement, we are engaged in an arbitration process to resolve our respective claims. Baxter made a partial payment of past due amounts owed to us in October 2016 of $3.6 million against approximately $4.1 million in past due receivables outstanding at September 30, 2016. Each party seeks damages and other relief from the other party. We do not believe that Baxter's claims or defenses are supported by facts. As a result, we have not reserved for the amounts owed to us by Baxter under the Distribution Agreement.

We also notified Baxter during the fourth quarter of 2016 that it was in breach of the minimum purchase requirement for concentrate products during the contract year ending October 2, 2016 and that Baxter's distribution rights would become non-exclusive unless it cured the deficiency. Baxter failed to cure the deficiency during the cure period prescribed in the Distribution Agreement and Baxter disputed its responsibility to cure the deficiency. We subsequently provided Baxter with notice of loss of exclusivity due to its failure to cure as provided in the Distribution Agreement. The determination of whether a breach occurred resulting in a loss of exclusivity and the outcome of the other pending disputes with Baxter will be determined through the arbitration process.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation s

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 subsidiaries.

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 Triferic ® also known as Ferric Pyrophosphate Citrate or SFP and Calcitriol, statements relating to our disputes with Baxter and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, and from time to time in our other reports filed with the SEC, including, without limitation, in "Item 1A — Risk Factors" in our Form 10-K for the year ended December 31, 2015 and the risks listed below.

Risks Related To Our Drug Business

- Although Triferic ® has been approved by the FDA and was recently made available for commercial use, we may not be able to commercialize it successfully.
- Triferic ® is currently limited to use in adult patients receiving hemodialysis treatments and has not been approved for other indications. Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, which may limit our ability to market our drug products.
- If we do not obtain protection under the Hatch-Waxman Act to extend patent protection for Triferic ® , our business may be harmed.
- Although Calcitriol has been approved by the FDA, we may not be able to commercialize it successfully.
- 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. Even if we are successful in out-licensing our drug products, the licensee or partner may not be effective at marketing our products in certain markets or at all.
- We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products. We may not be able to obtain the raw materials, proper components or manufacturing capacity we need, or the cost of the materials, components or manufacturing capacity may be higher than expected, any of which could have a material adverse effect on our expected results of operations, financial position and cash flows.
- Before it can be marketed, an investigational drug requires FDA approval, which is a long, expensive process with no guarantee of success.
- Our drug business will depend on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market.
- Health care reform could adversely affect our business.

Risks Related To Our Concentrate Business

- We are in arbitration to resolve disputes with Baxter regarding the Distribution Agreement, which could result in termination of the Distribution Agreement or have other material adverse consequences for us.
- The Distribution Agreement with Baxter may be terminated or Baxter may lose exclusivity, requiring us to commercialize our products direct to customers, 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 may not be successful in expanding our product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.
- Our drug and concentrate businesses are highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, financial condition and results of operations.
- We depend on key personnel, the loss of which could harm our ability to operate.
- We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.
- Our products may have undesirable side effects and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.
- We may be unable to obtain certain debt financing in the future as a result of our arrangement with Baxter.

Risks Related To Our Common Stock

- Shares eligible for future sale may affect the market price of our common shares.
- The market price for our common stock is volatile.
- We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.
- Structural and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.
- We do not anticipate paying dividends in the foreseeable future.

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

Overview

Rockwell is a fully-integrated pharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad.

Our business focus is on 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.

In January 2015, we received U.S. FDA approval for Triferic ®, our innovative iron replacement drug which is the only FDA-approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients.

Following FDA approval, we successfully completed the scale up of Triferic ®'s active pharmaceutical ingredient to commercial scale production which should enable us to meet expected demand and reduce our unit cost. We also established redundancy in our supply chain to help ensure an uninterrupted and adequate product supply of our Triferic ® active pharmaceutical ingredient to support future sales efforts.

Triferic ® received a Medicare reimbursement code from the Centers for Medicare & Medicaid Services ("CMS") effective July 2015. Following the completion of the public comment period in November 2015, we met with CMS to gain transitional add-on reimbursement for Triferic ®. Since then, we have been actively working to obtain transitional add-on reimbursement for Triferic ®, which will give Medicare beneficiaries a greater chance to gain access to Triferic ® and provide dialysis providers a separate reimbursement for Triferic ® that will cover their administration and conversion cost to move to a new innovative therapy. We believe Triferic ® meets the criteria for add-on reimbursement and that dialysis patients will greatly benefit from the use of Triferic ®. If add-on reimbursement is granted, it is expected to be available for two years and may give dialysis providers additional incentive to adopt Triferic ®.

We intend to develop Triferic ® to address other clinical needs. We are continuing our development work on peritoneal dialysis, total parenteral nutrition and other indications. In addition, we initiated a clinical study on an orphan indication. We intend to license our other Triferic ® indications to partners who can optimize the commercial opportunities. We also continue to evaluate opportunities to in-license other products that will complement our product portfolio.

In addition to marketing Triferic ®, we are working to produce sufficient inventory to begin marketing Calcitriol, our FDA approved generic Vitamin-D injection. We are dependent upon contract manufacturing organizations to manufacture Calcitriol for us. On May 4, 2016 we announced that our third party contract manufacturer found that one of the inactive ingredients used in completed Calcitriol product earmarked for commercial sale was out of specification for stability. The stability issue was not related to the active pharmaceutical ingredient in Calcitriol, which is supplied by a different manufacturer. We believe this issue has been resolved. The FDA has requested additional stability data demonstrating compliance and we expect to submit that data later this month. We are in the process of manufacturing additional batches to ensure that our products meet the specifications and stability requirements prior to commercial release.

Nearly all of our revenue in 2015 and in the first nine months of 2016 was from our dialysis concentrate business. We supply approximately 25% of the domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas as well as the Pacific Rim.

Under our October 2014 Distribution Agreement with Baxter, Baxter holds the exclusive distribution rights for of our dialysis concentrates in the United States and certain foreign markets. The Distribution Agreement does not include our drug products. Rockwell receives a pre-defined gross profit margin on its concentrate products sold pursuant to the Distribution Agreement, which adjusts each year over the term of the agreement and is subject to an annual true-up. The Distribution Agreement requires Baxter to achieve certain minimum purchase requirements to maintain its exclusivity under the agreement. In October 2016, we notified Baxter that they did not meet the minimum purchase requirements. Baxter disputed our assertion of a breach of the minimum purchase requirements and Baxter did not subsequently cure the deficiency in the prescribed period. The dispute regarding whether Baxter maintains exclusive distribution rights and the various other disputes with Baxter under the Distribution Agreement are the subject of a pending arbitration proceeding. See Part II - Item 1 – Legal Proceedings.

Recent Developments

We are making significant progress regarding our international business development efforts for Triferic ®, including securing a licensing agreement with Wanbang Biopharmaceutical for the rights to commercialize our Triferic ® and Calcitriol products for ESRD patients in the People's Republic of China. We believe that China will ultimately become

a significant market for the Company due to its large and growing dialysis population with a hemodialysis market projected by some industry participants to become the largest in the world over the next several years. It is a market that we also expect will provide an ideal opportunity for our other Triferic ® therapeutic indications. We have a strategy for each major market and region and we are actively pursuing other licensing and distribution arrangements.

In the third quarter of 2016, we entered into an exclusive license and manufacturing supply with ARAM Medical for the sale of Triferic ® and Calcitriol in the Kingdom of Saudi Arabia and a number of other countries in the Middle East for an initial term of 10 years. In consideration for the exclusive rights, ARAM Medical will pay us a licensing fee and a royalty on product sales, and has committed to annual minimum purchase quantities. ARAM Medical will also assume responsibility for all clinical and regulatory expenses for the countries covered by its agreement. Commercial sales activity will commence following regulatory approval. Rockwell retains manufacturing responsibilities for both Triferic ® and Calcitriol.

Results of Operations for the Three and Nine Months Ended September 30, 2016 and September 30, 2015

Sales

Our sales in the third quarter of 2016 were $12.8 million, a decrease of $1.6 million or 10.9% from the third quarter of 2015. Our domestic dialysis concentrate business revenue in the third quarter of 2016 decreased $0.3 million or 2.9% compared to the third quarter of 2015 due to lower unit volume. Our international dialysis concentrate revenue was $0.2 million lower than the third quarter of 2015. Third party contract manufacturing sales decreased $0.9 million compared to the third quarter of 2015 due to the completion of a manufacturing contract in the second quarter of 2015. Nearly all of our product sales were dialysis concentrate product sales and related ancillary items.

Our sales for the first nine months of 2016 were $39.9 million, a decrease of $1.3 million or 3.2% compared to the first nine months of 2015. Our domestic concentrate revenue increased $0.8 million or 2.5 % compared to the first nine months of 2015 due to increased concentrate product sales. Our international concentrate revenue for the first nine months of 2016 decreased $0.7 million or 12.7% compared to the first nine months of last year due to lower order volume. Third party contract manufacturing sales decreased $1.5 million compared to the first nine months of 2015 due to the completion of a manufacturing contract in the second quarter of 2015.

We continue to market to and educate our customers on Triferic ® while working to obtain transitional add on reimbursement for Triferic ® . Until we obtain transitional add on reimbursement, or until we cease trying to obtain it, we expect Triferic ® sales activity will not be significant. Sales of Triferic ® were not material in the first nine months of 2016. We recognized approximately $0.2 million in deferred license revenue related the Wanbang Agreement during the first nine months of 2016.

Gross Profit

Gross profit in the third quarter of 2016 was $1.6 million which was $0.9 million less than in the third quarter of 2015. Higher manufacturing and regulatory expenses related to manufacturing of our drug products reduced gross profit by $0.4 million in the third quarter of 2016 compared to the third quarter of last year. The remainder of the decrease was due to lower unit volumes on contract manufacturing sales and on domestic and international business compared to the third quarter of 2015.

Gross profit for the first nine months of 2016 was $4.8 million which was $2.1 million less than in the first nine months of 2015. Gross profit decreased by $1.5 million due to higher manufacturing and other direct costs related to our drug products which included $0.3 million in value added taxes paid on the $4 million in licensing payments received on our international licensing agreement for China. The remainder of the decrease was due to lower unit volumes on contract manufacturing sales and on domestic and international business.

Selling, General and Administrative Expense

Selling, general and administrative expense during the third quarter of 2016 was $5.1 million compared to $3.8 million in the third quarter of 2015. The $1.3 million increase in expense was primarily due to non-cash equity compensation costs increasing by $1.5 million in comparison to the third quarter last year.

Selling, general and administrative expense for the first nine months of 2016 were $15.1 million compared to $13.0 million in the first nine months of 2015. The $2.1 million increase was primarily due to higher non-cash equity compensation of $1.7 million and higher legal expenses of $0.4 million.

Research and Product Development Expense

We incur research and product development costs related to the commercial development, patent approval and regulatory approval of new products, including Triferic ® and other clinical indications for Triferic ® in various markets and jurisdictions. Research and development expense was $1.3 million and $4.6 million in the third quarter and first nine months of 2016, respectively, compared to $1.2 million and $2.9 million in the third quarter and first nine months of 2015, respectively, reflecting additional clinical research work for other Triferic ® indications.

Interest and Investment Income, Net

Our net interest and investment income was $0.2 million in the third quarter of 2016 compared to $0.2 million in the third quarter of 2015. For the first nine months of 2016, our net interest and investment income was $0.6 million compared to $0.4 million in the first nine months of 2015. The increases in net investment income were due to a higher level of invested funds.

Income Tax Expense

We recognized approximately $0.4 million in income tax expense in the first nine months of 2016 compared to no income tax expense in the first nine months of 2015. Our income tax expense pertained to foreign income taxes paid related to license payments received under the Wanbang Agreement. The amount of foreign income tax paid can be credited against future U.S. tax liabilities and carried forward to offset future US income tax liabilities.

Liquidity and Capital Resources

We believe our capital resources and substantial liquidity are adequate to pursue our business strategy.

As of September 30, 2016, we had current assets of $79.8 million and net working capital of $72.5 million. We have approximately $57.7 million in cash and investments as of September 30, 2016. Our uses of cash have primarily been for research and product development, investments in inventory to support our product launches and for operating expenses. Cash flow from operations used $13.0 million in the first nine months of 2016, which included research and development expenses of $4.6 million, and increases of $3.9 million in inventory and $3.0 million in accounts receivable. We also received $3.3 million net of taxes pursuant to the Wanbang Agreement. Our capital expenditures for the first nine months of 2016 were $0.3 million.

We anticipate that we will increase our inventory and accounts receivable as we increase our drug product sales. We also expect to invest in research and product development in the year ahead as we work to expand potential uses for Triferic ®, although spending on these indications is expected to be minor in relation to the Company's current cash resources. We believe that we have adequate capital resources to make these investments in accounts receivable, inventory and research and product development. We expect to generate positive cash flow from operations when sales of our drug products become significant.

We have no long term debt as of September 30, 2016 and do not expect to incur interest expense in 2016.

With respect to future capital equipment spending, we intend to source our drug products from contract manufacturing organizations. Other capital expenditures on our current facilities are not expected to materially exceed depreciation expense in the year ahead.

The Company is in discussions with multiple potential business development partners to out-license rights to Rockwell's products outside the United States. Such licensing arrangements often include upfront fees, research and development milestones, other developmental milestone payments and royalties. If such licensing arrangements are negotiated for certain markets, we may receive such consideration in the future in addition to those we are already entitled to receive under existing agreements including our recently completed licensing agreement for China. In

addition to the initial milestone payment under the Wanbang Agreement, we may receive up to an additional $35 million over the life of the agreement in regulatory and revenue milestone payments plus ongoing earnings. We are also considering other business development arrangements including joint ventures, partnerships and other transactions related to our products or other future products that we may develop or license.

Our contractual obligations are described in our Form 10-K for the year ended December 31, 2015. There have been no material changes to that information since December 31, 2015 except as described above.

Item 3. Quantitative and Qualitative Disclosures About Market Ris k

Interest Rate Risk

Pending their use in the operating business, we have invested $38.4 million in available for sale securities that are invested in short term bond funds, which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short 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 that exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

Foreign Currency Exchange Rate Risk

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

Item 4. Controls and Procedure s

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 1. Legal Proceedings.

On September 12, 2016, Baxter Healthcare Corporation ("Baxter") initiated an arbitration proceeding against Rockwell in accordance with the International Institute for Conflict Prevention and Resolution, Inc.'s Rules for Non-Administered Arbitration under the Exclusive Distribution Agreement with Baxter, dated October 2, 2014 (the "Distribution Agreement"). Baxter alleges that Rockwell has breached the Distribution Agreement in various respects associated with its dealings with customers, its allocation of expenses and its true-up notices, and by improperly threatening to build a West Coast facility. Baxter seeks declaratory relief giving Baxter the right to terminate the Distribution Agreement and recover a portion of the upfront fee, injunctive relief to prevent Rockwell from establishing a West Coast facility, and unspecified damages.

Rockwell filed a response denying all of Baxter's claims of breach and wrongdoing, and has counterclaimed that Baxter is itself in breach of the Distribution Agreement for failing to pay substantial accounts receivable and for repudiating its obligation to pay the West Coast facility fee. Rockwell is seeking damages, declaratory, injunctive and other equitable relief, as well as interest, costs and attorney fees.

In addition, in October 2016, we gave notice to Baxter that it breached the minimum purchase requirement for the contract year ending October 2, 2016 and that we intended to cause its distribution rights to become non-exclusive unless it cured the shortfall within the 30-day period specified in the Distribution Agreement. Baxter disputed the existence of a breach and failed to cure the deficiency. Rockwell subsequently provided Baxter with notice of loss of exclusivity due to its failure to cure as provided in the Distribution Agreement. The determination of whether a breach occurred resulting in a loss of exclusivity and the outcome of the other pending disputes with Baxter will be determined through the arbitration process.

Item 1A. Risk Factors.

As disclosed above under "Item 1. Legal Proceedings," Rockwell is a party to an arbitration with Baxter involving the Distribution Agreement, pursuant to which Baxter is Rockwell's exclusive distributor for sales of Rockwell's concentrate products in the United States. In light of the disputes with Baxter and the potential outcomes of the arbitration, Rockwell is modifying the risk factors contained in "Item 1A Risk Factors" of its Annual Report on Form 10-K for the year ended December 31, 2015 by amending and restating the risks formerly entitled "The transition to Baxter of commercialization of our concentrate and ancillary products may not be successful.", "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." and "The concentrate market is very competitive and has a large competitor with substantial resources.", in each case as set forth below.

We are in arbitration to resolve disputes with Baxter regarding the Distribution Agreement, which could result in termination of the Distribution Agreement or have other material adverse consequences for us.

In October 2014, we entered into the Distribution Agreement pursuant to which Baxter became our exclusive agent for commercializing our hemodialysis concentrate and ancillary products in the United States and various foreign countries. The Agreement does not involve Rockwell's drug products. In September 2016, Baxter initiated an arbitration proceeding against us, alleging that we have materially breached the Distribution Agreement in various respects. Baxter seeks declaratory relief giving Baxter the right to terminate the Distribution Agreement and recover a portion of the upfront fee, injunctive relief to prevent us from establishing a West Coast facility, and unspecified damages. We filed a response denying all of Baxter's claims of breach and wrongdoing, and have counterclaimed that Baxter is itself in material breach of the Distribution Agreement for failing to pay certain accounts receivable and for repudiating its obligation to pay the West Coast facility fee. We are seeking damages, declaratory, injunctive and other equitable relief, as well as interest, costs and attorney fees. In addition, in October 2016, we gave notice to Baxter that it breached the minimum purchase requirement for the contract year ending October 2, 2016 and that we intended to cause its distribution rights to become non-exclusive unless it cured the shortfall within the 30-day period specified in the Distribution Agreement. Baxter disputed the existence of a breach and failed to cure the shortfall. Rockwell

subsequently provided Baxter with notice of loss of exclusivity due to its failure to cure as provided in the Distribution Agreement. The determination of whether a breach occurred resulting in a loss of exclusivity and the outcome of the other pending disputes with Baxter will be determined through the arbitration process.

There can be no assurance that our disputes with Baxter will be resolved in the arbitration in our favor. If resolution of the dispute permits Baxter to not pay us the amounts owed to us, requires us to pay amounts to Baxter in excess of any reserve we may establish in connection with this matter or requires us to refund a portion of the upfront payment made by Baxter to us, it could have a material adverse effect on our results of operations, cash flows and financial condition. In addition, if we are not permitted to receive the up to $10 million facility fee from Baxter in connection with our potential establishment of a concentrate facility on the West Coast, it could adversely and materially impact business development in the future. Moreover, the arbitration process will be expensive and may divert management's attention away from operation of our business.

In addition, given the possibility that either the Distribution Agreement will be terminated by us or Baxter upon completion of the arbitration or that Baxter's distribution rights will become non-exclusive, we believe that Baxter is unlikely to commit material financial and other resources to the marketing and distribution of our products while the arbitration process continues. As a result, unit sales of our products may fall and we may lose customers to our competitors during the arbitration process, 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. Further, if the Distribution Agreement were to terminate or if Baxter's distribution rights were to become non-exclusive, we may have to compete with Baxter for our customers to the extent their contracts are not assigned by Baxter to us. Such competition could negatively impact our sales and margins. Any such impact, or our inability to otherwise reacquire customers, could have a material and adverse effect on our results of operations, cash flows and financial condition. Our competitors may also seek to disrupt our business relationship and utilize the Baxter dispute in their sales efforts to displace Baxter, which could have the effect of further reducing our sales and adversely affecting our results of operations, cash flows and financial condition.

The Distribution Agreement with Baxter may be terminated or Baxter may lose exclusivity, which may require us to commercialize our products direct to customers, 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 upon the occurrence of certain events including, without limitation, a material breach by us that we fail to cure within the applicable cure period.

We have the right to terminate the Distribution Agreement if Baxter is in material breach and fails to cure within the applicable cure period.

In September 2016, Baxter initiated an arbitration proceeding against us alleging material breaches of the Distribution Agreement and seeking various forms of relief, including the right to terminate the Distribution Agreement. We have filed a response denying all of Baxter's claims and a counterclaim alleging that Baxter is in material breach of the Distribution Agreement.

In addition, in October 2016, we gave notice to Baxter that it breached the minimum purchase requirement for the contract year ending October 2, 2016 and that we intended to cause its distribution rights to become non-exclusive unless it cured the shortfall within the 30-day period specified in the Distribution Agreement. Baxter failed to cure the shortfall and disputed the existence of a breach. Rockwell subsequently provided Baxter with notice of loss of exclusivity due to its failure to cure as provided in the Distribution Agreement. The dispute regarding whether Baxter maintains exclusive distribution rights and the various other disputes with Baxter under the Distribution Agreement are the subject of a pending arbitration proceeding.

If the Distribution Agreement is terminated by either party or Baxter's rights become non-exclusive, we may be required to commercialize our concentrate products in the United States and re-establish commercial arrangements with our former direct customers. We may be unable to recapture our former direct customers or to sell our products profitably. Any of these outcomes or 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 a portion of the facility fee to Baxter upon the occurrence of a "Refund Trigger Event." A "Refund Trigger Event" includes, among other events, an uncured material breach by us. Occurrence of a Refund Trigger Event would obligate us to refund 50% of the $20 million upfront fee (and any portion of the facility fee paid by Baxter) 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.

In September 2016, Baxter initiated an arbitration proceeding against us alleging material breaches of the Distribution Agreement and seeking various forms of relief, including the right to terminate the Distribution Agreement and receive a refund of a portion of the upfront fee. We have filed a response denying all of Baxter's claims and a counterclaim alleging that Baxter is in material breach of the Distribution Agreement.

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 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, research and management resources. We and 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 concentrate products we sell. We and 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 40% of all U.S. patients through its clinics. This competitor has routinely acquired smaller clinic chain operations which we supply through Baxter. This competitor may acquire more of the customers we service in the future.

Item 6. Exhibits

See Exhibit Index following the signature page, which is incorporated herein by reference.

SIGNATURE S

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 7, 2016

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

Date: November 7, 2016

/s/ THOMAS E. KLEMA
Thomas E. Klema
Vice President and Chief Financial Officer
(principal financial officer and principal accounting officer)

10-Q EXHIBIT INDE X

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 7, 2016

/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 7, 2016

/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, 2016 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 7, 2016

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

Dated: November 7, 2016

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