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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 June 30, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 July 31, 2017**
Common Stock, no par value	51,740,040 shares

Rockwell Medical, Inc.
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Triferic® is a registered trademark of Rockwell Medical, Inc.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of June 30, 2017 and December 31, 2016

(Unaudited)

	June 30, 2017	December 31, 2016
ASSETS		
Cash and Cash Equivalents	$ 8,327,695	$ 17,180,594
Investments Available for Sale	34,914,331	40,759,703
Accounts Receivable, net of a reserve of $7,000 in 2017 and $5,000 in 2016	4,880,969	6,393,228
Inventory	13,774,065	12,141,072
Other Current Assets	1,907,270	2,034,598
Total Current Assets	63,804,330	78,509,195
Property and Equipment, net	1,529,639	1,391,575
Inventory, Non-Current	2,725,958	1,826,554
Intangible Assets	4,205	4,382
Goodwill	920,745	920,745
Other Non-current Assets	490,738	501,187
Total Assets	$ 69,475,615	$ 83,153,638
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 3,869,646	$ 5,858,234
Accrued Liabilities	3,585,198	4,210,151
Customer Deposits	212,320	77,217
Total Current Liabilities	7,667,164	10,145,602
Deferred License Revenue	17,962,468	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 51,740,040 and 51,527,711 shares issued and outstanding	270,302,780	268,199,939
Accumulated Deficit	(226,166,099)	(214,341,092)
Accumulated Other Comprehensive Income	(290,698)	(902,548)
Total Shareholders' Equity	43,845,983	52,956,299
Total Liabilities And Shareholders' Equity	$ 69,475,615	$ 83,153,638

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2017 and June 30, 2016

(Unaudited)

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Sales	$ 13,243,107	$ 13,452,517	$ 27,835,361	$ 27,079,565
Cost of Sales	11,744,819	11,962,989	23,979,601	23,895,111
Gross Profit	1,498,288	1,489,528	3,855,760	3,184,454
Selling, General and Administrative	6,541,179	5,014,370	12,641,894	10,001,111
Research and Product Development	1,675,494	2,063,324	2,890,345	3,377,754
Operating Income (Loss)	(6,718,385)	(5,588,166)	(11,676,479)	(10,194,411)
Interest and Investment Income	(364,599)	227,020	(148,528)	413,582
Income (Loss) Before Income Taxes	(7,082,984)	(5,361,146)	(11,825,007)	(9,780,829)
Income Tax Expense	—	—	—	(404,527)
Net Income (Loss)	$ (7,082,984)	$ (5,361,146)	$ (11,825,007)	$ (10,185,356)
Basic Earnings (Loss) per Share	$ (0.14)	$ (0.11)	$ (0.23)	$ (0.20)
Diluted Earnings (Loss) per Share	$ (0.14)	$ (0.11)	$ (0.23)	$ (0.20)

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 six months ended June 30, 2017 and June 30, 2016

(Unaudited)

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Net Income (Loss)	**$ (7,082,984)**	**$ (5,361,146)**	**$ (11,825,007)**	**$ (10,185,356)**
Unrealized Gain on Available-for-Sale Investments	500,122	242,965	612,124	195,732
Foreign Currency Translation Adjustments	(65)		(274)	—
Comprehensive Income (Loss)	**$ (6,582,927)**	**$ (5,118,181)**	**$ (11,213,157)**	**$ (9,989,624)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the six months ended June 30, 2017

(Unaudited)

	COMMON SHARES		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT			
Balance as of December 31, 2016	51,527,711	$ 268,199,939	$ (214,341,092)	$ (902,548)	$ 52,956,299
Net Loss	—	—	(11,825,007)	—	(11,825,007)
Unrealized Gain on Available-for-Sale Investments	—	—	—	612,124	612,124
Foreign Currency Rate Changes	—	—	—	(274)	(274)
Issuance of Common Shares	—	—	—	—	—
Shares Issued in Exchange for Services	50,000	88,487			88,487
Stock Option Based Expense	—	2,203,686	—	—	2,203,686
Stock Tendered in Satisfaction of Tax Liabilities	(317,671)	(2,287,231)	—	—	(2,287,231)
Restricted Stock Amortization	480,000	2,097,899	—	—	2,097,899
Balance as of June 30, 2017	51,740,040	$ 270,302,780	$ (226,166,099)	$ (290,698)	$ 43,845,983

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2017 and June 30, 2016

(Unaudited)

	2017	2016
Cash Flows From Operating Activities:		
Net (Loss)	**$ (11,825,007)**	**$ (10,185,356)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	259,084	395,990
Share Based Compensation—Non-employee	88,487	—
Share Based Compensation—Employees	4,301,585	5,222,723
Loss on Disposal of Assets	3,634	258
Loss (gain) on Sale of Investments Available for Sale	368,519	(3,302)
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	343,993	(2,543,404)
(Increase) in Inventory	(2,532,397)	(3,137,896)
Decrease (Increase) in Other Assets	349,378	(54,132)
Increase (Decrease) in Accounts Payable	(1,988,717)	980,981
Increase (Decrease) in Other Liabilities	(489,857)	106,441
(Decrease) in Deferred License Revenue	(996,240)	(963,372)
Increase (Decrease) in Deferred Drug License Revenue	(136,362)	3,886,365
Changes in Assets and Liabilities	(5,450,202)	(1,725,017)
Cash (Used In) Operating Activities	**(12,253,900)**	**(6,294,704)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(27,262,362)	(9,259,648)
Sale of Investments Available for Sale	33,351,339	8,328,987
Purchase of Equipment	(401,055)	(229,287)
Proceeds on Sale of Assets	450	1,000
Cash Provided by (Used In) Investing Activities	**5,688,372**	**(1,158,948)**
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares	—	77,250
Restricted Stock Retained in Satisfaction of Tax Liabilities	(2,287,231)	—
Cash Provided By (Used In) Financing Activities	**(2,287,231)**	**77,250**
Effects of exchange rate changes	(140)	—
(Decrease) Increase In Cash	(8,852,899)	(7,376,402)
Cash At Beginning Of Period	17,180,594	31,198,182
Cash At End Of Period	**$ 8,327,695**	**$ 23,821,780**

Supplemental Cash Flow disclosure

	2017	2016
Income Taxes Paid	$ —	$ 404,527

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

Rockwell Medical, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

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 currently marketing and 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 also obtained licenses for certain dialysis related drugs which we are developing and planning to market globally.

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 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 essential nutrients in the blood of dialysis patients during their hemodialysis treatment. The majority of our sales occur 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, 2016 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of our management, all adjustments have been included that are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2016 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 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.

For international license agreements that we have entered into, 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 Exclusive 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 4 to condensed consolidated financial statements for information related to the settlement of arbitration proceedings 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.

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede the current revenue recognition requirements

in Topic 605, *Revenue Recognition*. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new guidance is effective for the year beginning January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is in the process of evaluating how the new revenue recognition standard could impact the financial statements and disclosures. For the majority of our sales transactions, the new standard is not expected to significantly change the timing of revenue recognition; however, we are still analyzing our licensing arrangements to determine the impact of the new standard. The new standard will also require expanded disclosures surrounding revenue in the notes to the financial statements.

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 in short term bonds and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). The portfolio generally consists of 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 $34,914,331 as of June 30, 2017. 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 losses were $289,753 as of June 30, 2017. There were realized losses of $473,871 and no realized gains in the second quarter. For the six months ended June 30, 2017, there were realized losses of $504,994 and no realized gains.

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 June 30, 2017.

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 $2.9 million and $3.4 million for the six months ended June 30, 2017 and 2016, respectively.

Share Based Compensation

We measure the cost of employee and non-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 June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Basic Weighted Average Shares Outstanding	51,031,899	50,676,787	50,859,927	50,674,954
Effect of Dilutive Securities	—	—	—	—
Diluted Weighted Average Shares Outstanding	51,031,899	50,676,787	50,859,927	50,674,954

3. Inventory

Components of inventory as of June 30, 2017 and December 31, 2016 are as follows:

	June 30, 2017	December 31, 2016
Raw Materials	$ 12,943,575	$ 10,903,084
Work in Process	234,326	86,452
Finished Goods	3,322,122	2,978,090
Total	$ 16,500,023	$ 13,967,626

4. Baxter Distribution Agreement

As of October 2, 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter became the Company's exclusive agent for sales, marketing and distribution activities for the Company's hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. The Distribution Agreement does not include any of the Company's drug products. The Company retains sales, marketing and distribution rights for its hemodialysis concentrate products in specified foreign countries in which the Company has an established commercial presence.

On September 12, 2016, 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 Distribution Agreement. Baxter alleged that Rockwell had breached the Distribution Agreement in various respects associated with its dealings with customers, its allocation of expenses and its true-up notices. Baxter sought 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 counterclaimed that Baxter itself is 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 of up to $10 million. Rockwell sought damages, declaratory, injunctive and other equitable relief, as well as interest, costs and attorney fees. In addition, in October 2016, Rockwell gave notice to Baxter that it breached the minimum purchase requirement for the contract year ended October 2, 2016 and that Rockwell intended to cause its distribution rights to become non-exclusive unless it cured the shortfall within the applicable cure period. Baxter disputed the existence of a breach.

On June 23, 2017, the Company and Baxter settled the arbitration (the "Settlement") related to all of the foregoing claims. The Settlement included a mutual release with respect to all known claims existing on the date of the Settlement and the arbitration was dismissed with prejudice. No payments were made by either party in connection with the Settlement.

In connection with the Settlement, on June 23, 2017, the Company and Baxter entered into a First Amendment to Exclusive Distribution Agreement and a First Amendment to Investment Agreement. The terms of the settlement included, among other things, modified pricing that provides incentive to Baxter to pursue new customers and increase future sales. Our Settlement with Baxter is not expected to have a material impact on our liquidity or results of operations.

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 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 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 under "Part II - Item 1A — Risk Factors".

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 and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad. We supply approximately 25% of the United States domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Substantially all of our sales were concentrate products and related ancillary items.

Our business strategy is developing unique, proprietary renal drug therapies that we can commercialize or out-license, while also expanding our dialysis products business. 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.

Triferic is our lead branded drug. We believe it has the potential to capture significant market share due to its improved clinical and cost-saving benefits. Triferic received FDA approval in 2015, and is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. Triferic received a reimbursement J-code, effective January 1, 2016. At about that time, we received clarification from CMS that Triferic would be included in the ESRD bundled payment which initiated our pursuit of transitional add-on reimbursement, which is available for new, innovative therapies. Although we cannot be certain, we believe that Triferic will receive transitional add-on reimbursement, which offers greater incentive for dialysis providers to adopt new, innovative therapies.

Until add-on reimbursement is resolved for Triferic, we do not anticipate realizing significant revenues from Triferic sales. In the meantime, we continue to make significant progress in marketing to and educating our customers about Triferic and the valuable benefit it delivers by improving patient outcomes and lowering costs. We also continue to provide Triferic to dialysis providers via a drug sample program, receiving favorable response to the positive clinical and cost saving benefits. Our marketing and selling efforts to nephrologists and nurses, as well as to patients, are effective and being received favorably. We have built significant inventory of Triferic in anticipation of receiving transitional add-on reimbursement. If we are unable to successfully commercialize Triferic and achieve sufficient sales volumes over the next one to two years, we may have to write off a portion of our inventory investment in Triferic, which would have an adverse effect on our results of operations.

Our global strategy is to license Triferic to key partners to commercialize internationally. We are actively pursuing international licensing opportunities in a number of countries and regions. During the second quarter of 2017, we terminated our licensee's rights to the Middle East region due to their material default under the terms of our agreement. We are pursuing other business development opportunities in the region. The termination of this license is not expected to have a material impact on our results of operations and did not impact our liquidity. Additionally, we are continuing development work on other clinical indications related to iron deficiency that address unmet patient needs and we are evaluating opportunities to in-license other products that will complement our product portfolio.

We are also working to begin marketing Calcitriol, generic injectable vitamin-D through contract manufacturing organizations ("CMOs"). Assuming timely approval by the FDA, we currently expect Calcitriol to be available for marketing later in 2017.

Rockwell sells its dialysis concentrates in the United States and certain foreign markets under the Distribution Agreement with Baxter. Rockwell receives a pre-defined gross profit margin on its concentrate products sold pursuant to the Distribution Agreement, subject to an annual true-up of costs. Baxter and Rockwell have reached a settlement on their dispute as discussed in more detail under Note 4 to the condensed consolidated financial statements and "Part II Item 1 "Legal Proceedings". The terms of the settlement included, among other things, modified pricing that provides incentive to Baxter to pursue new customers and increase future sales. Our settlement with Baxter is not expected to have a material impact on our liquidity or results of operations.

Results of Operations for the Three Months and Six Months Ended June 30, 2017 and June 30, 2016

Sales

Our sales in the second quarter of 2017 were $13.2 million, $0.2 million or 1.6% less than the second quarter of 2016 due to lower sales volumes. Our international sales were $0.1 million higher than the second quarter of 2016. Revenue recognized from licensing fees was $0.1 million less than in the second quarter of 2016.

Our sales in the first six months of 2017 were $27.8 million, an increase of $0.8 million or 2.8% over the first six months of 2016. Our domestic business increased $0.8 million over the first six months of 2016 which was due mainly to one-time additional orders from Baxter. Our international sales were at the same level as the first half of 2016.

Our drug business revenue was not significant in the first half of 2017 or 2016.

Gross Profit

Gross profit in the second quarter of 2017 was $1.5 million, unchanged from the second quarter of 2016. Gross profit margins were 11.3% in the second quarter of 2017 compared to 11.1% in the second quarter of 2016.

Gross profit in the first six months of 2017 was $3.9 million, an increase of $0.7 million or 21.1% over the first six months of 2016. Gross profit margins were 13.9% compared to 11.8% in the first half of 2016. The gross profit increase was partially due to both higher sales of our concentrate products and lower costs resulting from recognizing $0.3 million related to the licensing payment received following execution of our 2016 license agreement with Wanbang Biopharmaceutical Co., Ltd.

Selling, General and Administrative Expense

Selling, general and administrative expense during the second quarter of 2017 was $6.5 million compared to $5.0 million in the second quarter of 2016. The $1.5 million expense increase was primarily due to higher legal costs relating to outstanding litigation expenses and the 2017 annual meeting. A reduction in equity compensation costs of $0.4 million was partially offset by higher compensation and benefit costs of $0.2 million.

Selling, general and administrative expense during the first half of 2017 was $12.6 million compared to $10.0 million in the first half of 2016. The $2.6 million increase was primarily due to higher legal and professional costs relating to outstanding litigation and the 2017 annual meeting. Equity compensation costs decreased by $0.8 million compared to the first half of 2016, partially offset by higher compensation and benefit costs of $0.3 million. Marketing costs for Triferic increased $0.2 million compared to the first half of 2016.

Research and Product Development Expense

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, primarily Triferic, aggregating approximately $1.7 million and $2.1 million in the second quarter of 2017 and 2016, respectively. Research and product development costs incurred in the first six months of 2017 and 2016 were $2.9 million and $3.4 million, respectively and were largely related to Triferic development costs for use in other clinical indications and delivery presentations.

Interest and Investment Income, Net

Our net interest and investment income in the second quarter of 2017 was a loss of $0.4 million resulting from the repositioning of holdings in our short term bond portfolio in response to market changes, compared to income of $0.2 million in the second quarter of 2016. For the first six months of 2017, we incurred a loss of $0.1 million compared to income of $0.4 million in the first six months of 2016.

Income Tax Expense

We recognized no income tax expense in the second quarter of 2017 or 2016. We recognized no income tax expense in the first six months of 2017 compared to approximately $0.4 million in income tax expense in the first six months of 2016, which pertained to foreign income taxes paid related to license payments received under the Wanbang license agreement.

Liquidity and Capital Resources

We believe we have adequate capital resources and substantial liquidity to pursue our business strategy. In addition to operating our concentrate business, our strategy is centered on developing, marketing and licensing high potential drug products including Triferic.

As of June 30, 2017, we had current assets of $63.8 million and net working capital of $56.1 million. We have approximately $43.2 million in cash and investments as of June 30, 2017. Our uses of cash have primarily been for research and product development, investments in inventory to support our drug product launches and for operating expenses. Cash used in operating activities was $12.3 million in the first half of 2017, which included research and development expenses of $2.9 million and an increase of $2.5 million in inventory levels. We increased our Triferic inventory over the last year in preparation for commercializing Triferic and believe we have adequate inventory to meet anticipated requirements. We have classified $2.7 million of Triferic's active pharmaceutical ingredient as non-current inventory as of June 30, 2017.

We anticipate that we will increase our accounts receivable as we increase our drug product sales and we may also increase inventories to a more modest degree as we commercialize Triferic and Calcitriol. We also expect to continue investing in research and product development, such as clinical testing in connection with peritoneal dialysis, an orphan drug indication, pediatric indications and certain other indications, as we work to expand potential uses for Triferic. Future spending on such indications is expected to be minor in relation to the Company's 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 our drug products generate substantial sales.

We have no long term debt as of June 30, 2017 and do not expect to incur interest expense in 2017. Capital expenditures on our current facilities are not expected to materially exceed depreciation expense. Our capital expenditures were $0.4 million in the first half of 2017 compared to $0.2 million in the first half of 2016. We paid $2.3 million in withholding taxes in connection with restricted stock vesting in the second quarter of 2017.

The Company is in discussions with multiple potential business development partners to out-license rights to Rockwell's drug products outside the United States. Such licensing arrangements often include upfront fees, 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 that which we are already entitled to receive under existing agreements. 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have invested $34.9 million in available for sale securities that are invested in short term bonds and short term bond funds which typically yield higher returns than the interest realized in money market funds. While these bonds and bond 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 and we may incur unrealized losses from the reduction in market value of the bonds. If we sell some or all of our positions, 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 our portfolio of holdings, 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 investments.

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 1. Legal Proceedings

Baxter Arbitration

On September 12, 2016, 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 Distribution Agreement. Baxter alleged that Rockwell had breached the Distribution Agreement in various respects associated with its dealings with customers, its allocation of expenses and its true-up notices. Baxter sought 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 counterclaimed that Baxter itself is 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 of up to $10 million. Rockwell sought damages, declaratory, injunctive and other equitable relief, as well as interest, costs and attorney fees. In addition, in October 2016, Rockwell gave notice to Baxter that it breached the minimum purchase requirement for the contract year ended October 2, 2016 and that Rockwell intended to cause its distribution rights to become non-exclusive unless it cured the shortfall within the applicable cure period. Baxter disputed the existence of a breach.

On June 23, 2017, the Company and Baxter settled the arbitration (the "Settlement") related to all of the foregoing claims. The Settlement included a mutual release with respect to all known claims existing on the date of the Settlement and the arbitration was dismissed with prejudice. No payments were made by either party in connection with the Settlement.

In connection with the Settlement, on June 23, 2017, the Company and Baxter entered into a First Amendment to Exclusive Distribution Agreement and a First Amendment to Investment Agreement. The material terms of these amendments are described in the Company's Form 8-K filed June 29, 2017.

Richmond/Ravich Litigation

On March 8, 2017, Rockwell filed suit in the United States District Court for the Eastern District of Michigan against Richmond Brothers, Inc. and certain related entities, David S. Richmond, Mark H. Ravich and certain related trusts, and Matthew J. Curfman ("Richmond/Ravich Defendants"), and three individual Rockwell shareholders: Jay F. Joliat, Chris Paxos, and David Hagelstein (together with the "Richmond/Ravich Defendants," the "Rockwell Shareholders"). Since then, Rockwell voluntarily dismissed its claims against two of the individual shareholders, Chris Paxos and David Hagelstein. Rockwell's complaint alleges that the Rockwell Shareholders failed to timely file a Schedule 13D and that a Schedule 13G and Schedules 13D filed by the Richmond/Ravich Defendants contained various material misstatements and omissions, in violation of Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and the rules promulgated thereunder by the Securities and Exchange Commission. The complaint seeks declaratory and injunctive relief relating to these alleged violations, including requiring the Rockwell Shareholders to file new or amended Schedules 13D disclosing the proper date of their shareholder group's formation and providing accurate information about the group's membership and activities, and issuing a declaratory judgment finding that the Rockwell Shareholders violated Section 13(d) of the Exchange Act. On June 28, 2017, the Court denied the Richmond/Ravich Defendants' motion to dismiss this case, in which Defendant Jay F. Joliat had joined. The Court has set a scheduling conference in this case for August 28, 2017. Defendant Jay Joliat had previously answered the complaint on April 13, 2017. The deadline for Richmond/Ravich Defendants to file their answer to the complaint is August 21, 2017.

Other Proceedings

We are involved in certain other legal proceedings from time to time before various courts and governmental agencies. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims that are considered probable of loss. The resolution of these pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved.

Item 1A. Risk Factors

In light of recent developments, we are replacing in their entirety the risk factors disclosed in Item 1A of our Form 10-K for the year ended December 31, 2016. Such risk factors are amended and restated as set forth below.

RISKS RELATED TO OUR DRUG BUSINESS

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

The commercial success of Triferic will depend on a number of factors, including the following:

- Triferic will have to compete against current iron therapies and possibly other 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 Triferic's safety and efficacy, cost-effectiveness, advantages over existing products, and the reimbursement policies of government and third party payers, including Medicare;
- We are seeking transitional add-on reimbursement (separate payment outside of the ESRD bundled payment) for Triferic. In the absence of that, dialysis service providers are likely to adopt Triferic at a much slower rate than if Triferic is granted such status due to the cost of conversion and lack of an immediate financial incentive to adopt Triferic;
- Maintaining compliance with ongoing regulatory requirements applicable to Triferic 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;
- Competitors may engage in anti-competitive practices and other tactics to retain their market share;
- Avoidance of third party patent interference or patent infringement claims;
- A continued acceptable safety profile of Triferic; and
- Discovery of previously unknown problems with Triferic or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements.

An adverse development with respect to any of the foregoing may have a material adverse effect on our ability to manufacture and market Triferic. These factors are largely beyond our control. Accordingly, we cannot assure you that we will be able to generate significant 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 affected and the price of our common stock could substantially decline. Even if we were successful in commercializing Triferic, due to the highly concentrated nature of the market, our continued success may depend on adoption of Triferic by a few dialysis providers.

If we are unable to use our Triferic inventory before its shelf life expires, we may have to take a reserve which could have a material adverse effect on our results of operations and financial condition.

We cannot predict when or if we will secure transitional add-on reimbursement for Triferic or future usage of Triferic. We have invested approximately $12.9 million in Triferic inventory, including approximately $11 million in Triferic's active pharmaceutical ingredient and $1.9 million in finished goods inventory. The inventory has a shelf life ranging from one to three years. If we are unable to utilize some or all of the Triferic inventory before its shelf life expires, some or all of our investment in Triferic inventory may not be saleable, reducing the inventory we have available for sale and requiring us to reserve for the reduction in value. We may also need to reserve for inventory that we estimate will not be sold before such inventory expires. Any such inventory reserve could have a material adverse effect on our results of operations and financial condition.

Our ability to market Triferic and other FDA-approved drugs 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 Triferic and our other drug products.

Any new indication for an approved product requires FDA approval. Triferic is approved by the FDA for use in adult patients receiving hemodialysis treatments and has not yet been approved for other indications. We are not able to promote the products or encourage our customers to use the products for purposes other than those indications of use that are specifically approved by the FDA as safe and effective. If we are not able to obtain FDA approval for additional indications for Triferic, our ability to take full advantage of Triferic's market opportunity may be reduced and our business may be adversely affected. Moreover, if our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA that may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, debarment, exclusion and criminal prosecution, any of which could materially harm our business.

If we do not obtain protection under the Hatch-Waxman Act to extend patent protection for Triferic, our drug business may not reach its full potential.

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 the patent term for drugs for a period of up to five years to compensate for time spent in development and regulatory approval. We have applied for an extension, and received an interim one year extension but there can be no assurance that we will receive the full extension of the patent term provided under the Hatch-Waxman Act for either of the licensed Triferic patents that were scheduled to expire at the end of 2016. If we fail to receive the full extension, we would have to rely on the protection afforded us by the United States 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.

We depend on contract manufacturing organizations to manufacture our drug products. If these organizations are unable or unwilling to manufacture our drug products, or if these organizations fail to comply with FDA or other applicable regulations or otherwise fail to meet our requirements, our drug business will be harmed.

We rely on contract manufacturing organizations (CMOs) to make Triferic and Calcitriol. If any are unable to make the product in sufficient quantities and on a consistent basis, or become unwilling to produce the product for us, we may not be able to supply our customers with product in a timely manner.

The facilities and processes used by these CMOs to manufacture our drug products must be approved by the FDA and, where applicable, foreign regulators before the commercial products can be sold that were produced at a particular facility using a particular process. Even if approved, certain ongoing regulatory requirements for product testing and stability of our commercially marketed products must be met. We do not control the manufacturing processes of, and are dependent upon, these CMOs for compliance with current good manufacturing practices, referred to as cGMPs, and obtaining and maintaining their regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards such that approval is withdrawn, the CMO's production would be delayed or suspended and we may be forced to find another capable CMO and/or shift production to another CMO that is already approved and under contract with us. Any such failure could significantly hamper our ability to supply our customers in a timely manner, which may have a material adverse effect on our results of operations, financial condition and cash flows.

We rely on third party suppliers for raw materials and packaging components of our drug products. We may not be able to obtain the raw materials and proper components we need, or the cost of the materials or components may be higher than expected, any of which could impair our production or commercialization of drug products and have a material adverse effect on our results of operations, financial position and cash flows.

We may not be able to obtain needed raw materials or packaging components, or the price of such materials or components may rise significantly, for a variety of reasons, including among others:

- Business interruption, such as due to a force majeure, cyber attack or labor strike at a supplier;
- Regulatory requirements or action by regulatory agencies or others against a supplier, including delays in receiving necessary approvals;
- A supplier's failure to comply with cGMP standards which results in quality or product failures, adulteration, contamination and/or recall;
- Adverse financial or other strategic developments at or affecting a supplier;
- Termination of the supply contract by a supplier;
- Unexpected demand for or shortage of raw materials or packaging components; and
- Unexpected increases in our product demand.

Some of the suppliers for the raw materials or packaging components we need may be single-source suppliers. Finding an alternative source can be expensive and take a substantial amount of time, especially when regulatory approval is required to qualify the supplier. If we are unable to obtain the raw materials and components we require and are not able to establish alternative supply sources, or if the prices for raw materials or packaging components increase substantially, our CMOs may not be able to produce the desired quantities of our drug products or our expected gross profit margins may be materially adversely affected, any of which could be costly to us and have a material adverse effect on our results of operations, financial position and cash flows.

We may not be successful in obtaining foreign regulatory approvals or in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize our drug products outside of the United States. Even if we are successful in out-licensing our drug products and obtaining the required regulatory approvals, the licensees or partners may not be effective at marketing our products in certain markets or at all.

The approval procedures for marketing our new drug products, such as Triferic, outside the United States 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, should we attempt to develop international markets ourselves 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 is to license the rights to our drugs in markets outside the United States to partners who have resources to obtain regulatory approval. However, we may not be successful in finding partners in addition to those currently under contract, who will be willing to invest in our drugs outside the United States or our partners may be unable to obtain the necessary regulatory approvals. If we are not successful in out-licensing our drugs outside of the United States or entering into other arrangements with partners capable of obtaining the necessary regulatory approvals to commercialize our drug products, 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 an adverse effect on the benefits otherwise expected from marketing in foreign countries.

If we are successful in obtaining partners to commercialize our products in foreign markets, we will be dependent upon their effectiveness in selling and marketing our products in those foreign markets. These partners may face stiff competition, government price regulations, generic versions of our drug products, violations of our intellectual property rights and other negative events or may otherwise be ineffective in commercializing our products, any of which could reduce the market potential for our products and our success in those markets.

We may not be successful in expanding our drug 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.

As part of our business strategy to expand our drug product portfolio, we are seeking to acquire or in-license other drug products that we believe are a complementary fit with our current product portfolio as well as other products that we believe have substantial development potential. The negotiation of such arrangements can be a lengthy and complex process and there can be no assurance that any such negotiations will be completed on a timely basis or result in an arrangement that will enable us to effectively integrate, develop and launch such products effectively.

In addition, the market potential for new drug products is highly uncertain and evaluation of such potential requires significant judgment and assumptions. There is a significant risk that any new drug product may not be able to be brought to market as profitably as expected or at all. If the results of any new drug product initiative were materially worse than expected, it could have a material adverse effect on our financial results and condition.

Expansion of our drug business in the United States may require FDA approval of new drug candidates or indications for use. The process of obtaining FDA approval is a long and expensive process with no guarantee of success.

Expansion of our drug business will be dependent, in part, on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize new drug candidates. The process of performing clinical trials for a potential new drug, filing an NDA with the FDA and receiving a decision from the FDA is expected to take several years, with no guarantee of approval. Clinical trials typically take years to complete and early promising clinical trial results may not necessarily be indicative of later results or demonstrate sufficient safety and efficacy to support an NDA filing. Clinical trials and the NDA approval process for any new drug candidate are also very expensive. Similarly, the FDA approval process for a new indication of Triferic would require us to pay substantial review fees, may require clinical trials and could take years to complete.

There is no guarantee the FDA will approve our new drug candidates. Once trials are completed and the NDA is submitted to the FDA, the FDA may find deficiencies that raise safety or efficacy concerns or may otherwise require additional clinical testing or impose other requirements, which could significantly delay approval or result in us not receiving approval at all. In addition, varying interpretations of the data obtained from testing could delay, limit or prevent regulatory approval. If approval is not granted for any new products or new indications submitted for approval, 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.

Our drug business depends 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. Congress continuously enacts a variety of changes to health insurance and reimbursement, some of which 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.

Since 2011, CMS has continued to modify reimbursement policies for dialysis under the ESRD prospective payment system generally resulting in lower payment to dialysis providers. 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.

The new presidential administration and members of the U.S. Congress have introduced legislation in both the House of Representatives and Senate to repeal and/or replace all or part of the Patient Protection and Affordable Care Act, or PPACA, including potential changes or repeal of the Medicaid expansion, coverage for pre-existing coverages and insurance coverage minimum benefits. The likelihood of passage and the impact of this legislation is uncertain but could potentially impact reimbursement by the Medicare and Medicaid programs for our drug products and dialysis and the ability of certain individuals to obtain coverage. Other state and federal healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or change the methods used by Medicare and Medicaid to reimburse providers, including the

"bundled" payment model and the availability of transitional add-on reimbursement, any of which could result in reduced demand for our products once approved or pricing pressures.

As a result of these changes to Medicare and Medicaid 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.

It may be difficult for us to capture market share for Calcitriol in the highly competitive generic drug market.

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. Dialysis service providers may seek alternative forms of treatment for this indication. Any of these outcomes could have an adverse effect on our ability to successfully commercialize Calcitriol.

RISKS RELATED TO OUR CONCENTRATE BUSINESS

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 things, termination due to an uncured material breach by us. A Refund Trigger Event would obligate us to refund $6.6 million of the $20 million upfront fee (and any portion of the West Coast facility fee that may have been paid by Baxter) if termination occurs in 2017 or 2018, and $5.0 million of the $20 million upfront fee (and any portion of the West Coast facility fee that may have been paid by Baxter) if termination occurs in 2019, 2020 or 2021.

If Baxter terminates the Distribution Agreement because it has been enjoined by a court of competent jurisdiction from selling in the United States 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. In any such event, our financial condition, results of operations, and cash reserves could be materially and adversely affected.

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.

Sales of our products are highly concentrated in a few customers. One customer accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. The loss of any of these significant customers could adversely affect our results of operations, financial condition and cash flows.

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

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 a competitive strategy to capture market share of the concentrate products we sell. We and Baxter may be at a disadvantage in competing against their strategies to sell concentrate products. Furthermore, the primary competitor is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 36% of all U.S. patients through its clinics. This competitor has routinely acquired smaller clinic chain operations which we supply through Baxter and may acquire more of the customers we service in the future.

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 United States 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 has the option to terminate the Distribution Agreement and obtain a refund of a portion of the fees we received from Baxter. Any such termination or refund could have a material adverse effect on our business, results of operations, financial position and cash flows.

RISKS RELATED TO OUR BUSINESS AS A WHOLE

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.

Our businesses are highly regulated. The testing, manufacture and sale of the products we manufacture directly or through third party CMOs are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before drugs or medical devices, such as our concentrate products, can be commercially marketed in the United States, the FDA must give either premarket approval or 510(k) clearance. Even after a product is approved, regulatory authorities may still impose significant restrictions on a product's indicated uses or marketing or impose requirements for potentially costly post-marketing studies. In addition, our products are subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and reporting of safety and other post-market information, including both federal and state requirements in the United States and in other jurisdictions where they are marketed. In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current cGMP and applicable state laws. As such, we and our CMOs are subject to continual review and periodic inspections to assess compliance with cGMP and state laws. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas to achieve and maintain regulatory compliance. We are also required to report certain adverse reactions and production problems, if any, to the FDA, state agencies and foreign regulatory authorities, when applicable, and to comply with requirements concerning advertising and promotion for our products.

If non-compliant inventory is sold or if a regulatory agency determines that we do not comply with any applicable regulatory requirements, we may be subject to warnings from, or enforcement action by, state and federal government authorities that may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, injunctions and criminal prosecution. If regulatory sanctions are applied, the value of our Company and our operating results could be materially and adversely affected. Our business could also be adversely affected by delays in obtaining necessary regulatory approvals and any restrictions placed by the FDA on our intended marketing or the use of our products.

Our failure to comply with applicable regulations could also result in product liability litigation against us. In addition, our failure to comply with respect to our concentrate products could constitute a breach by us of the Distribution Agreement, providing Baxter with various remedies that would be material and adverse to us. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations, which, 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.

Health care reform could adversely affect our business.

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.

The United States government faces structural deficits that may require changes to government funded healthcare programs such as Medicare and Medicaid which may negatively impact us directly or indirectly through the customers of our products. 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. Legislative and administrative efforts to repeal or modify the PPACA are underway and in January 2017, President Trump signed an Executive Order directing federal agencies with authority and responsibility under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We cannot predict how repeal or replacement of PPACA, the Executive Order or

other health care reform will affect our business and any such changes could substantially modify the methodology for reimbursing medical services, drugs and devices or the number of patients eligible for reimbursement or otherwise adversely affect our ability to successfully develop and commercialize our products.

Device and pharmaceutical manufacturers are required to report annually to the Department of Health and Human Services regarding certain financial relationships they have with physicians and teaching hospitals. This reporting requirement imposes governmental scrutiny on our contractual relationships with physicians and teaching hospitals and creates risk that inadvertent violations will 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.

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. Raymond D. Pratt, our Chief Medical Officer, Dr. Ajay Gupta, our Chief Scientific Officer and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for making major corporate decisions, managing the overall operations and resources of the Company and leading the development and execution of the Company's long term strategy. Dr. Pratt is primarily responsible for the clinical development, testing and regulatory approval of our products. Dr. Gupta is primarily responsible for discovery and development of new technologies. No member of our executive management team has an employment agreement with the Company. If we lose the services of Mr. Chioini, Dr. Pratt, Dr. Gupta or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

Defending our intellectual property rights could be expensive, we may not always be successful in protecting our exclusive rights and 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, particularly with our drug products, 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. 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 manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. If Baxter is prevented from selling 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.

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.

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. Following FDA approval, if we or others later identify previously unknown undesirable side effects caused by our drug or concentrate products, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for such products or any products perceived to be similar to such products, the FDA or other applicable regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications, may suspend or withdraw their approval of the product, may require it to be removed from the market or may impose restrictions on the distribution or use of the product. Such side effects may also result in litigation against us by private litigants.

We maintain products liability insurance in the amount of $10 million per occurrence and $10 million in the aggregate. We cannot be sure that such insurance would be sufficient to protect us against liabilities associated with any

of these events in view of our expanding business or that such insurance will remain available at economical levels. We may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by such sanctions or product liability litigation and that could harm our marketing ability. Any such sanctions or litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. In any such event, our business, financial condition and results of operations could be materially adversely affected.

Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners' critical information technology systems or infrastructure.

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property, proprietary business information, proprietary information of our customers and business partners in the information technology systems of the Company and those of our current CMOs and other current or future contractors and consultants. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, intentional theft of confidential information or reputational damage from espionage attacks, malware, ransomware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities and business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be subject to legal claims or proceedings, liability under personal privacy laws and regulatory penalties. In any such event, our business, financial condition and results of operations could be materially adversely affected.

We may be unable to obtain secured debt financing in the future as a result of our Distribution Agreement with Baxter.

The Distribution Agreement prohibits us from entering into a 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 tangible assets we own. If our development activities require substantial cash resources in the future in excess of our liquid resources on hand and if our cash flows are not sufficient 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 this type of debt financing, our business and our future development and expansion strategies may be adversely affected.

RISKS RELATED TO OUR COMMON STOCK

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

Any future sales by us of substantial amounts of our common shares, or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares and may dilute the economic value and voting rights of existing shareholders.

In addition, as of June 30, 2017, there were 6,557,834 shares issuable upon the exercise of outstanding and exercisable stock options with an average exercise price of $7.77 and 1,147,667 shares issuable upon the exercise of outstanding stock options that are not yet exercisable with an average exercise price of $8.18. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options.

The market price for our common stock is volatile.

Our stock price, like the market price of many stocks in the specialty pharmaceutical, biotechnology and pharmaceutical industries, is volatile. Events such as announcements around clinical testing results or regulatory approval of a product, as well as the reporting of sales, operating results and cash resources, may cause significant fluctuations in our share price. In addition, third parties may engage in trading strategies that result in intentional volatility to and control over our share price.

Our ability to use our net operating loss carryforwards to offset potential taxable income and related income taxes that would otherwise be due may be limited.

We have substantial net operating loss carryforwards, or NOLs, available to reduce future taxable income. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs. In addition to uncertainty regarding our future profitability, our use of the NOLs may be subject to annual limitations under the "ownership change" provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which may result in the expiration of some or all of the NOLs before they can be used. In general, an "ownership change" occurs if, during a rolling three-year period, there is a greater than 50% change in the percentage ownership of the corporation by 5% owners (and persons treated as 5% owners), as defined in Section 382 and related regulations. We may experience an ownership change in the future as a result of future changes in our stock ownership. The inability to use our NOLs to reduce federal taxable income could result in increased future tax liability to us and reduce the cash that would otherwise be available to our business.

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.

SEC rules require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each year, and to include a management report assessing the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K. It is possible, due to the small size of our accounting staff, that we may identify control deficiencies in the future that constitute one or more material weaknesses. If our internal control over financial reporting or disclosure controls and procedures are not effective, there may be errors in our financial statements and in our disclosure that could require restatements. In addition, if a restatement were to occur, investors may lose confidence in our reported financial information and in our disclosure, which could lead to a decline in our stock price.

No system of internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

Structural and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.

The Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock, or rights to acquire preferred stock, having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance or potential issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we may become subject to Michigan statutes regulating business combinations or our Board may take other actions which might also hinder or delay a change in control. Any such actions can have a depressive effect on the market price of our common shares and can limit shareholders' ability to receive a premium on their shares by discouraging takeover and tender offers.

Our shareholders do not have the right to cumulative voting in the election of directors. Moreover, our directors serve staggered three-year terms, and directors may not be removed without cause. These provisions could have an anti-takeover effect by making it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could also delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common shares and do not anticipate paying such dividends in the foreseeable future. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations. Therefore, it is highly unlikely we will pay cash dividends.

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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Repurchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs
April 2017	---	---	n/a	n/a
May 2017	---	---	n/a	n/a
June 2017	317,671	$7.20	n/a	n/a
Total	317,671	$7.20	n/a	n/a

Under the provisions of the Company's 2007 Long Term Incentive Plan, 317,671 shares were tendered to the Company in satisfaction of withholding tax liabilities associated with the vesting of restricted stock awards. The Company has no publicly announced share repurchase program.

Item 6. Exhibits

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

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: August 9, 2017

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

Date: August 9, 2017

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

10-Q EXHIBIT INDEX

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated. Exhibits not required for this report have been omitted. Our Commission file number is 000-23661.

Exhibit No.	Description
10.68	First Amendment to Exclusive Distribution Agreement, dated as of June 23, 2017, by and between the Company and Baxter Healthcare Corporation (with certain portions redacted pursuant to a confidential treatment request)
10.69	First Amendment to Investment Agreement, dated as of June 23, 2017, by and between the Company and Baxter Healthcare Corporation
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

[* *] Portions of this exhibit have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

FIRST AMENDMENT TO
EXCLUSIVE DISTRIBUTION AGREEMENT

This First Amendment to the Exclusive Distribution Agreement (this "First Amendment") is executed this 23rd day of June, 2017, by and between Rockwell Medical, Inc., a Michigan corporation (the "Company") and Baxter Healthcare Corporation, a Delaware corporation ("Distributor").

RECITALS

A. Distributor and the Company are parties to that certain Exclusive Distribution Agreement, effective as of October 2, 2014 (the "Agreement").

B. Distributor and the Company are parties to an arbitration to settle certain disputes arising out of the Agreement and desire to enter into this First Amendment in connection with a settlement of their disputes.

AGREEMENT

In consideration of the foregoing and mutual covenants and agreements contained in this First Amendment and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

1. Section 1.1 of the Agreement is amended by adding paragraph (f) as follows:

> (f) Notwithstanding anything in this Agreement to the contrary, it shall not be a breach of the Agreement if the Company discusses, negotiates or enters into an amendment or other modification to the Designated Customer's Original Customer Contract that increases the prices paid by the Designated Customer to the Company thereunder; provided that such amendment or other modification shall not otherwise modify such contract without Distributor's prior written consent, which consent shall not be unreasonably withheld.

2. Section 1.3 of the Agreement is amended and restated in its entirety as follows:

> **Original Customer Contracts**. As and when requested by the Distributor, the Company shall assign to the Distributor (to the extent assignable without further Third Party consent) the Company's rights under the Original Customer Contracts to Commercialize the Products in the Territory during the Term. The Distributor shall assume the Company's obligations under each assigned Original Customer Contract, but only to the extent that such obligations are required to be performed after the effective date of the assignment. With respect to the Designated Customer's Original Customer Contract, until (a) the Company has assigned such Original Customer Contract to Distributor with the Designated Customer's consent, or (b) Distributor enters into a replacement contract for Concentrate Products with the Designated Customer (or its Affiliate), the Company shall retain all Economic Losses arising from such Original Customer Contract and the Company shall pay to the Distributor the amount equivalent to the Economic Gains from such Original Customer Contract. "Economic Losses" for this purpose shall be the amount by which (i) the fees and costs

relating to Support Services rendered under Exhibit C with respect to Products shipped to the Designated Customer under the Original Customer Contract using the allocation method set forth in Exhibit C exceed (ii) (A) the aggregate price paid for Products by the Designated Customer minus (B) the Contract Price for Products ordered by the Designated Customer. "Economic Gains" for this purpose shall be the amount by which the aggregate price paid for Products by the Designated Customer exceeds the aggregate of (i) the Contract Price for Products ordered by the Designated Customer and (ii) the fees and costs relating to Support Services rendered under Exhibit C with respect to the Products shipped to the Designated Customer under the Original Customer Contract using the allocation method set forth in Exhibit C . For the avoidance of doubt, this Section 1.3 shall impose on the Distributor no obligation to make any payment to the Company relative to the Designated Customer's Original Customer Contract. Distributor shall use reasonable commercial efforts to negotiate a new contract with a price increase directly with the Designated Customer (or its Affiliate) to replace the Designated Customer's Original Customer Contract.

3. Section 3.8 of the Agreement is amended and restated in its entirety as follows:

(a)(1) Subject to the terms of this Section 3.8, the exclusive Distributor Rights granted to the Distributor under Section 1.1, other than with respect to the Designated Customer, shall become non-exclusive at the option of the Company if the quantity of Concentrate Products, measured in gallons, ordered by the Distributor (or directly by its customers) in the United States during any Calendar Year is less than the relevant minimum order threshold for such Calendar Year determined as follows (each, a "Minimum Order Threshold"):

Calendar Year	Minimum Order Threshold
2017	[* *]
2018	[* *]
2019	[* *]
2020	[* *]
2021	[* *]
2022	[* *]
2023	[* *]
2024	[* *]
2025 and each Calendar Year thereafter during the Term	[* *]% of the Baseline Amount for Calendar Year 2025, and an incremental [* *]% increase for each Calendar Year thereafter during the Term (resulting in a Minimum Order Threshold of [* *]% of the Baseline Amount for final Calendar Year).

For purposes of determining whether the Minimum Order Threshold has been achieved for any Calendar Year, except as provided in clause (a)(3) of this Section 3.8, gallons ordered by or on behalf of the Designated Customer, or by Distributor, its Affiliates, Marketing Partners, sub-distributors or otherwise for resale or distribution, directly or indirectly, to Designated Customer or its Affiliates shall not at any time be counted as gallons ordered.

(2) Subject to the terms of this Section 3.8, the exclusive Distributor Rights granted to the Distributor under Section 1.1 with respect to the Designated Customer shall become non-exclusive at the option of the Company if, after (A) the Company obtains consent from the Designated Customer and the Designated Customer's Original Customer Contract has been assigned to Distributor, or (B) Distributor enters into a new contract for Concentrate Products with the Designated Customer (or its Affiliate if such Affiliate has executed such new contract instead of the Designated Customer), the quantity of Concentrate Products, measured in gallons, ordered by (i) Designated Customer (or its Affiliate if such Affiliate has executed such new contract) or (ii) the Distributor, its Affiliates, Marketing Partners, sub-distributors or otherwise for resale or distribution, directly or indirectly, to Designated Customer or its Affiliates during any Calendar Year following the Designated Customer Baseline Year is less than the relevant minimum order threshold for such Calendar Year (each, a "**Designated Customer Minimum Order Threshold**"). The Designated Customer Minimum Order Threshold shall be [* *]% of the Designated Customer Baseline Amount in the first Calendar Year after the Designated Customer Baseline Year, and shall increase [* *]% per year thereafter ([* *]%, [* *]% etc.) through 2024, and thereafter shall increase in a similar manner by [* *]% each Calendar Year until the end of the Term of the Agreement. For purposes of determining whether the Designated Customer Minimum Order Threshold has been achieved for any Calendar Year, except as provided in clause (a)(3) of this Section 3.8, gallons ordered other than by or on behalf of the Designated Customer, or by Distributor, its Affiliates, Marketing Partners, sub-distributors or otherwise for resale or distribution, directly or indirectly, to Designated Customer or its Affiliates shall not at any time be counted as gallons ordered.

(3) For purposes of this Section 3.8 and the related definitions, Concentrate Products in powder form shall be measured in gallons by applying the conversion ratios set forth in **Exhibit E** hereto. The Company represents and warrants that such conversion ratios are consistent with (i) the mixing instructions provided by the Company to its customers as of the Effective Date, and (ii) any mixing information set forth in the Regulatory Approvals for such Concentrate Products.

To the extent that the gallons of Concentrate Products ordered for any Calendar Year exceed the Minimum Order Threshold or Designated Customer Minimum Order Threshold for such Calendar Year, the excess may be applied against the other Threshold for the same Calendar Year or may be carried forward and applied against the Minimum Order Threshold or Designated Customer Minimum Order Threshold, at Distributor's option, without duplication, for future Calendar Years until the entire excess has been fully-credited. Solely for illustration purposes, if the Minimum Order Threshold for Calendar Year 2 is [* *] and the gallons of Concentrate Product ordered in Calendar Year 2 other than by or on behalf of the Designated Customer, or by Distributor, its Affiliates, Marketing Partners, sub-distributors or otherwise for resale or distribution, directly or indirectly, to Designated Customer or its Affiliates are [* *], then a total of [* *] gallons may be applied, at the Distributor's option, against the Designated Customer Minimum Order Threshold for Calendar Year 2 or against the Minimum Order Threshold or Designated Customer Minimum Order

Threshold for Calendar Year 3 and future years until the [* *] gallons has been fully-credited.

(b) Notwithstanding any other provision hereof, if the Distributor's Commercialization of any Concentrate Product (or Concentrate Products) in any Calendar Year is materially and adversely impacted by a Disruptive Event for a period of at least [* *] days during such Calendar Year, then (i) the Distributor shall have no obligation to achieve the Minimum Order Threshold or Designated Customer Minimum Order Threshold, whichever is applicable, for such Calendar Year, and (ii) the Minimum Order Threshold or Designated Customer Minimum Order Threshold, whichever is applicable, for the following Calendar Year shall be the Minimum Order Threshold or Designated Customer Minimum Order Threshold, whichever is applicable, in effect during the Calendar Year in which the Disruptive Event occurred and the schedule of Minimum Order Thresholds or Designated Customer Minimum Order Thresholds, whichever is applicable, for future Calendar Years shall be adjusted accordingly. The Distributor shall notify the Company in writing as soon as possible if it discovers facts or circumstances that are reasonably likely to materially and adversely impact its Commercialization of a Concentrate Product (or Concentrate Products) for purposes of this Section 3.8(b).

(c)(1) If the Distributor fails to achieve the Minimum Order Threshold for any Calendar Year and if the Company believes that the Distributor has not been excused from achieving the Minimum Order Threshold by reason of any Disruptive Event as set forth in Section 3.8(b), then the Company shall notify the Distributor in writing within [* *] days after the end of such Calendar Year. Upon receipt of such notice, the Distributor shall have a period of [* *] days (the "Shortfall Cure Period") to submit one or more Firm Orders to make up for any shortfall and, upon so doing, the gallons of Concentrate Product reflected in such Firm Orders shall count (without duplication) toward the Distributor's satisfaction of the Minimum Order Threshold for such Calendar Year.

(2) If the Distributor fails to achieve the Designated Customer Minimum Order Threshold for any Calendar Year and if the Company believes that the Distributor has not been excused from achieving the Minimum Order Threshold by reason of any Disruptive Event as set forth in Section 3.8(b), then the Company shall notify the Distributor in writing within [* *] days after the end of such Calendar Year. Upon receipt of such notice, the Distributor shall have the Shortfall Cure Period to submit one or more Firm Orders to make up for any shortfall and, upon so doing, the gallons of Concentrate Product reflected in such Firm Orders shall count (without duplication) toward the Distributor's satisfaction of the Designated Customer Minimum Order Threshold for such Calendar Year.

(3) If the Company assigns the Designated Customer's Original Customer Contract to Distributor, or Distributor enters into a new contract for Concentrate Products with the Designated Customer (or its Affiliate if such Affiliate has executed such new contract instead of the Designated Customer), and, in either case, such contract is terminated before a Designated Customer Baseline Amount is established and the termination is not caused by, or attributable to any action taken or the failure to take any

action, by the Company, and the termination is caused by the Distributor's breach of its agreement with the Designated Customer, then the Company's sole remedy shall be is to render non-exclusive the Distributor Rights as to the Designated Customer. In order to exercise its right to render such Distributor Rights non-exclusive, the Company must notify the Distributor in writing thereof within [* *] days after it has been made aware of such termination. If the Company fails to so notify the Distributor within such [* *]-day period, such Distributor Rights shall remain exclusive. If the Company so notifies the Distributor within such [* *]-day period, then the Distributor Rights shall be non-exclusive as to the Designated Customer effective as of the date the Distributor receives such notice from the Company; provided, however, that if the Distributor contends that the condition set forth in this Section 3.8(c)(3) has not been satisfied, then the Distributor Rights shall remain exclusive until the dispute is resolved in accordance with Section 11.15.

(d)(1) The Company's sole remedy for the Distributor's failure to achieve the Minimum Order Threshold under Section 3.8(a)(1) is to render non-exclusive the Distributor Rights as to all customers other than the Designated Customer. In order to exercise its right to render the Distributor Rights as to all customers other than the Designated Customer non-exclusive, the Company must notify the Distributor in writing thereof within [* *] days after the expiration of the Shortfall Cure Period. If the Company fails to so notify the Distributor within such [* *]-day period, the Distributor Rights as to all customers other than the Designated Customer shall remain exclusive. If the Company so notifies the Distributor within such [* *]-day period, then the Distributor Rights as to all customers other than the Designated Customer shall be non-exclusive effective as of the date the Distributor receives such notice from the Company; provided, however, that if the Distributor contends that the applicable Minimum Order Threshold has been satisfied or that such Minimum Order Threshold does not apply by reason of a Disruptive Event, then the Distributor Rights as to all customers other than the Designated Customer shall remain exclusive until the dispute is resolved in accordance with Section 11.15.

(2) The Company's sole remedy for the Distributor's failure to achieve the Designated Customer Minimum Order Threshold is to render non-exclusive the Distributor Rights as to the Designated Customer. In order to exercise its right to render such Distributor Rights non-exclusive, the Company must notify the Distributor in writing thereof within [* *] days after the expiration of the Shortfall Cure Period. If the Company fails to so notify the Distributor within such [* *]-day period, such Distributor Rights shall remain exclusive. If the Company so notifies the Distributor within such [* *]-day period, then the Distributor Rights shall be non-exclusive as to the Designated Customer effective as of the date the Distributor receives such notice from the Company; provided, however, that if the Distributor contends that the applicable Designated Customer Minimum Order Threshold has been satisfied or that such Designated Customer Minimum Order Threshold does not apply by reason of a Disruptive Event, then the Distributor Rights shall remain exclusive until the dispute is resolved in accordance with Section 11.15.

4. The introductory language at the beginning of Section 4.5 of the Agreement is amended and restated in its entirety as follows

> **West Coast Facility Fee**. The following shall apply if the Company and the Distributor have determined to establish a West Coast Facility, such determination is set forth in writing and signed by the Parties and the Company has complied with Section 3.9:

5. Section 4.6 of the Agreement is amended by adding a new paragraph (d) as follows:

> (d) In the event Distributor believes in good faith Rockwell has breached Section 1.1 and such breach does not entitle Distributor to terminate the Agreement under Section 10.2(b) or Distributor otherwise chooses not to pursue termination as a remedy, Distributor may give written notice of such alleged breach to the Company under this Section 4.6(d). If the Company disputes such alleged breach, it shall notify Distributor of such dispute within ten Business Days after receipt of such notice, in which case such dispute shall be resolved in accordance with Section 11.15. If the Company does not dispute such alleged breach or if upon resolution of a dispute in accordance with Section 11.15, it is determined that such breach exists, then Rockwell shall have [* *] days after receipt of such notice or determination of breach, as applicable, in which to remedy such default. If such default is not remedied in the time period set forth above, Distributor shall have the right to receive liquidated damages in the amount of $[* *] and Distributor reserves the right to take the position that certain breaches (such as a breach of exclusivity) cannot be cured.

6. Section 9.3 of the Agreement is amended and restated in its entirety as follows:

> **Obligations**. The recipient of Confidential Information shall (a) use such Confidential Information solely and exclusively in connection with the exercise of its rights and the discharge of its obligations under this Agreement and (b) not disclose such Confidential Information without the prior written consent of the disclosing Party to any Person other than (x) those of its agents and representatives who need to know such Confidential Information for such permitted use and who are bound by obligations of confidentiality with respect thereto and (y) potential financing sources, underwriters, placement agents and potential advisors, in each case who are bound by obligations of confidentiality with respect thereto. Notwithstanding the foregoing, the recipient of Confidential Information may disclose it to the extent necessary to comply with Applicable Laws or with an Order issued by a court or regulatory body with competent jurisdiction; provided that, in connection with such disclosure, the recipient shall (i) provide reasonable advance notice of such disclosure to the disclosing Party; (ii) limit the disclosure to the information that is legally required to be disclosed, and (iii) use commercially reasonable efforts to obtain confidential treatment or an appropriate protective order, to the extent available, with respect to such Confidential Information. The obligations under this Section 9.3 shall remain in effect from the Effective Date through the fifth anniversary of the termination or expiration of this Agreement.

7. The second bullet in Section 10.3 of the Agreement is amended and restated in its entirety as follows:

- Articles 7, 8, 9, 10 and 11 (excluding Section 11.17); and

8. Section 11.15 of the Agreement is amended and restated in its entirety as follows:

(a) Any and all disputes, claims or controversies ("disputes") arising out of or relating to this Agreement, including without limitation, any dispute as to the existence, validity, performance, breach or termination of this Agreement, shall be resolved in the following manner. A party must first send written notice of the dispute to the other party for attempted resolution by negotiation between executives who have authority to settle the controversy. Negotiations must be conducted within 14 days after such notice is received (all references to "days" in this provision are to calendar days). If the parties fail to meet or if the matter has not been resolved within 14 days, the parties shall mediate their dispute within 30 days after the 14 day period has expired. If the mediation fails to resolve all disputes or if the mediation has not been scheduled within 30 days, either party may initiate arbitration with respect to the matters submitted to negotiation and mediation by filing a written demand for arbitration. Disputes shall be settled by final and binding arbitration administered by the International Institute for Conflict Prevention & Resolution (CPR) in accordance with its rules. The place of arbitration shall be Chicago, IL. Notwithstanding the foregoing, to the extent a party is seeking injunctive relief either party may immediately bring a proceeding seeking preliminary injunctive relief or a temporary restraining order in a court having jurisdiction, and this relief shall remain in effect until the parties reach a resolution or so long as the arbitrator(s) feel as appropriate.

(b) For disputes under $[* *], one arbitrator shall either be mutually agreed by the parties or appointed in accordance with the arbitrator's rules. For disputes over $[* *], a panel of three arbitrators shall be appointed in accordance with the arbitrator's rules. Within 30 days following the initiation of an arbitration proceeding, the arbitrator(s) will be selected. No later than 60 days after selection, the arbitrator(s) shall hold a hearing to resolve each of the issues identified by the parties. All arbitration proceedings shall be conducted in the English language. At least 7 days prior to the hearing, each party shall submit the following to the other party and the arbitrator(s):

- A copy of all exhibits on which such party intends to rely in any oral or written presentation to the arbitrator(s);

- A list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

- A proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or of any legal arguments. The parties agree that neither side shall seek as part of its remedy any punitive damages; and

- A brief in support of such party's proposed rulings and remedies, provided the brief shall not exceed 20 pages.

(c) Within 14 days following completion of the hearing, each party may submit to the other party and the arbitrator(s) a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed 10 pages. The arbitrator(s) shall rule on each disputed issue within 21 days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the parties on each disputed issue and may adopt one party's proposed rulings and remedies on some issues and the other parties proposed rulings and remedies on other issues. The arbitrator(s) shall not adopt any written opinion or otherwise explain the basis of the ruling. If the arbitrator(s) rule in favor of one party on all disputed issues, the losing party shall pay the prevailing party's fees and expenses (including attorneys' fees). If the arbitrator(s) rule in favor of one party on some issues and the other party on other issues, the arbitrator(s) shall allocate fees and expenses in a way that bears a reasonable relationship to the ruling. The rulings of the arbitrator(s) and the allocation of fees and expenses shall be binding, non-reviewable and non-appealable, and may be entered as a final judgment in any court having jurisdiction. Except as required by law, the parties agree to keep confidential the existence of the arbitration, the submissions made by the parties (including exhibits, testimony, proposed rulings and briefs) and the decisions made by the arbitrator(s), including its awards.

9. Exhibit A of the Agreement is amended by deleting the definition of "Excluded Claim," amending and restating the definition of Baseline Amount and adding the definitions of "Calendar Year," "Designated Customer," "Designated Customer Baseline Amount," "Designated Customer Baseline Year," "Designated Customer Minimum Order Threshold" and "Threshold" as follows:

"**Baseline Amount**" means [* *] gallons of Concentrate Products, which represents total orders in gallons for the year ended December 31, 2016, excluding the Designated Customer.

"Calendar Year" means a year ending December 31.

"**Designated Customer"** means [* *]

"**Designated Customer Baseline Amount**" means the total amount of gallons of Concentrate Products ordered during the Designated Customer Baseline Year by (i) Designated Customer (or its Affiliate if such Affiliate has executed such new contract) or (ii) the Distributor, its Affiliates, Marketing Partners, sub-distributors or otherwise for sale or transfer to the Designated Customer (or its Affiliate if such Affiliate has executed such new contract).

"**Designated Customer Baseline Year** " means the first full Calendar Year following the year in which the Designated Customer's Original Customer Contract is assigned to Distributor or in which Distributor enters into a new contract for Concentrate Products with the Designated Customer (or its Affiliate if such Affiliate has executed such new contract instead of the Designated Customer).

"**Designated Customer Minimum Order Threshold**" has the meaning set forth in Section 3.8(a).

"**Threshold**" means each of the Minimum Order Threshold and the Designated Customer Minimum Order Threshold and "Thresholds" means the Minimum Order Threshold and the Designated Customer Minimum Order Threshold, together.

10. Exhibit C of the Agreement is hereby amended by the following paragraph at the end thereof:

Allocation

To the extent that the cost of Transportation Services must be allocated between orders relating to the Designated Customer and other customers, such costs shall be allocated based upon the ratio of the weight of Concentrate Products sold to the Designated Customer compared to the weight of Concentrate Products sold to other customers, effective January 1, 2017. To the extent that the cost of Customer Services must be allocated between orders relating to the Designated Customer and other customers, such costs shall be allocated based upon the number of orders of Concentrate Products by the Designated Customer compared to the number of orders of Concentrate Products by Distributor for other customers, effective January 1, 2017.

11. Exhibit J of the Agreement is hereby amended by amending and restating the section entitled "Target Margins – Concentrate Products" as follows:

Target Margins – Concentrate Products			
	Target Margin		
Year	**[* *]**	**[* *] and [* *]**	**Other Domestic**
2014	**[* *]%**	**[* *]%**	**[* *]%**
2015	**[* *]%**	**[* *]%**	**[* *]%**
2016	**[* *]%**	**[* *]%**	**[* *]%**
2017	**[* *]%**	**[* *]%**	**[* *]%**
2018	**[* *]%**	**[* *]%**	**[* *]%**
2019	**[* *]%**	**[* *]%**	**[* *]%**
2020	**[* *]%**	**[* *]%**	**[* *]%**
2021	**[* *]%**	**[* *]%**	**[* *]%**
2022	**[* *]%**	**[* *]%**	**[* *]%**
2023	**[* *]%**	**[* *]%**	**[* *]%**
2024	**[* *]%**	**[* *]%**	**[* *]%**
2025	**[* *]%**	**[* *]%**	**[* *]%**
2026	**[* *]%**	**[* *]%**	**[* *]%**
2027	**[* *]%**	**[* *]%**	**[* *]%**
2028	**[* *]%**	**[* *]%**	**[* *]%**
2029	**[* *]%**	**[* *]%**	**[* *]%**

* Effective as of date of First Amendment.

For purposes of this Exhibit J, "[* *]" means [* *] and "[* *]" means [* *].

12. Governing Law. All issues and questions concerning the construction, validity, enforcement, and interpretation of this First Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the laws of the State of Delaware.

13. No Other Changes. Except as expressly modified in this First Amendment, all other terms and conditions of the Agreement remain unchanged and in full force and effect and shall govern and apply to all matters contemplated by this First Amendment.

14. Interpretation. The term "Agreement" as used herein shall mean the Agreement as amended, modified, and supplemented by this First Amendment and all other capitalized terms used herein but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

15. Counterparts and Facsimile/PDF Signatures. This First Amendment may be executed in any number of counterparts, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The parties hereto agree that facsimile transmission or PDF of original signatures shall constitute and be accepted as original signatures.

16. Severability. In the event that any provision of this First Amendment shall be held to be invalid or unenforceable in any respect, such provision shall be enforced to the fullest extent permitted by law and the remaining provisions of this First Amendment shall remain in full force and effect. If any such invalid portion constitutes a material term of this First Amendment, the parties hereto shall meet and in good faith seek to mutually agree to modify this First Amendment so as to retain, if possible, the overall essential terms of this First Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to be executed by their duly authorized representatives and effective as of the date first above written.

COMPANY:	**DISTRIBUTOR:**
ROCKWELL MEDICAL, INC.	**BAXTER HEALTHCARE CORPORATION**
By: /s/ Robert Chioini	By: /s/ Gavin Campbell
Print Name: Robert Chioini	Print Name: Gavin Campbell
Title: Chief Executive Officer	Title: General Manager, US Renal

FIRST AMENDMENT TO
INVESTMENT AGREEMENT

This First Amendment to the Investment Agreement (this "First Amendment") is executed this 23rd day of June, 2017, by and between Rockwell Medical, Inc., a Michigan corporation (the "Company") and Baxter Healthcare Corporation, a Delaware corporation ("Purchaser").

RECITALS

A. Purchaser and the Company are parties to that certain Investment Agreement, effective as of October 2, 2014 (the "Agreement"), which was entered into in connection with their execution of the Exclusive Distribution Agreement (the "EDA") of the same date between the parties.

B. Purchaser and the Company are parties to an arbitration to settle certain disputes arising out of the EDA and desire to enter into this First Amendment in connection with a settlement of their disputes.

AGREEMENT

In consideration of the foregoing and mutual covenants and agreements contained in this First Amendment and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

1. Section 7.1(b) of the Agreement is amended and restated in its entirety as follows:

> (b) Notwithstanding any other provision herein to the contrary, the Purchaser shall not sell, transfer, assign, donate, pledge or otherwise dispose of the Restricted Shares until the date which is the earlier of one year after the date hereof or the day immediately following the Company's 2018 annual meeting of shareholders. On or before the earlier of (i) the occurrence of the date specified in the immediately preceding sentence and (ii) the expiration or termination of the Distribution Agreement, the Company shall direct its transfer agent to reissue the Purchaser's stock certificate representing the Restricted Shares without any legends (the "**Replacement Stock Certificate**") and the Company agrees it will thereafter place no stop orders or restrictions on the Restricted Shares for any reason.

2. Section 7.1(c) of the Agreement is amended and restated in its entirety as follows:

> (c) Any new certificate representing Restricted Shares (other than the Replacement Stock Certificate) shall bear a legend substantially in the following form:
>
> The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be offered, sold or otherwise transferred, pledged or hypothecated unless and until such shares are registered under such Securities Act or an opinion of counsel satisfactory to the Company is obtained to the effect that such registration is not required. Such shares are also subject to a restriction on transfer contained in an Investment Agreement, dated as of October 2, 2014 (and amended on June 23, 2017). A copy of the Investment Agreement is available at the Company's principal executive offices.

3. Section 7.2(a)(iii) of the Agreement is amended and restated in its entirety as follows:

> (iii) (A) fail to (1) grant a proxy to the Company's designee(s) authorizing such designee(s) to vote with respect to, or (2) otherwise vote, all shares of Common Stock owned as of the relevant record date, in either case, on each director-nominee and proposal in the manner recommended by the Company Board in its proxy statement filed with the SEC in connection with the solicitation of proxies for a meeting of shareholders, (B) fail to give consent as a shareholder, as to all shares of Common Stock owned as of the relevant record date, with respect to each director-nominee and proposal in the manner recommended by the Company Board in its consent statement filed with the SEC in connection with the solicitation of consents in lieu of a meeting of shareholders, or (C) grant a proxy or otherwise transfer, or allow to be transferred, the right to vote any shares of Common Stock other than to the Company's designee(s);

4. Governing Law. All issues and questions concerning the construction, validity, enforcement, and interpretation of this First Amendment shall be governed by and construed in accordance with the laws of the State of Michigan, without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of Michigan or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the laws of the State of Michigan.

5. No Other Changes. Except as expressly modified in this First Amendment, all other terms and conditions of the Agreement remain unchanged and in full force and effect and shall govern and apply to all matters contemplated by this First Amendment.

6. Interpretation. The term "Agreement" as used herein shall mean the Agreement as amended, modified, and supplemented by this First Amendment and all other capitalized terms used herein but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

7. Counterparts and Facsimile/PDF Signatures. This First Amendment may be executed in any number of counterparts, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The parties hereto agree that facsimile transmission or PDF of original signatures shall constitute and be accepted as original signatures.

8. Severability. In the event that any provision of this First Amendment shall be held to be invalid or unenforceable in any respect, such provision shall be enforced to the fullest extent permitted by law and the remaining provisions of this First Amendment shall remain in full force and effect. If any such invalid portion constitutes a material term of this First Amendment, the parties hereto shall meet and in good faith seek to mutually agree to modify this First Amendment so as to retain, if possible, the overall essential terms of this First Amendment.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this First Amendment to be executed by their duly authorized representatives and effective as of the date first above written.

COMPANY:	**PURCHASER:**
ROCKWELL MEDICAL, INC.	**BAXTER HEALTHCARE CORPORATION**
By: /s/ Robert Chioini	By: /s/ Gavin Campbell
Print Name: Robert Chioini	Print Name: Gavin Campbell
Title: Chief Executive Officer	Title: General Manager, US Renal

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: August 9, 2017

/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: August 9, 2017

/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 June 30, 2017 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: August 9, 2017

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

Dated: August 9, 2017

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