

ROCKWELL MEDICAL, INC.
Form 10-Q
May 10, 2018
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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 March 31, 2018

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 (State or other jurisdiction of incorporation or organization)	38-3317208 (I.R.S. Employer Identification No.)
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30142 Wixom Road, Wixom, Michigan (Address of principal executive offices)	48393 (Zip Code)
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(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

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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 April 30, 2018
Common Stock, no par value	51,768,424 shares

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Rockwell Medical, Inc.

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

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of March 31, 2018 and December 31, 2017

(Unaudited)

	March 31, 2018	December 31, 2017
ASSETS		
Cash and Cash Equivalents	\$ 3,278,087	\$ 8,406,917
Investments Available for Sale	24,821,682	24,648,459
Accounts Receivable, net of a reserve of \$3,400 in 2018 and \$11,000 in 2017	5,993,708	6,355,566
Inventory	8,544,854	7,637,384
Other Current Assets	1,607,440	1,779,992
Total Current Assets	44,245,771	48,828,318
Property and Equipment, net	2,572,619	2,548,978
Inventory, Non-Current	3,722,901	5,986,752
Intangible Assets	3,940	4,028
Goodwill	920,745	920,745
Other Non-current Assets	490,703	490,819
Total Assets	\$ 51,956,679	\$ 58,779,640
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 4,012,341	\$ 4,222,159
Accrued Liabilities	4,191,501	4,715,712
Customer Deposits	235,078	205,303
Total Current Liabilities	8,438,920	9,143,174
Deferred License Revenue	16,150,609	16,723,318

Shareholders' Equity:

Common Shares, no par value, 51,768,424 and 51,768,424 shares issued and outstanding	274,386,910	273,210,907
Accumulated Deficit	(246,791,897)	(240,262,376)
Accumulated Other Comprehensive Income	(227,863)	(35,383)
Total Shareholders' Equity	27,367,150	32,913,148
Total Liabilities And Shareholders' Equity	\$ 51,956,679	\$ 58,779,640

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

For the three months ended March 31, 2018 and March 31, 2017

(Unaudited)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Sales	\$ 14,948,579	\$ 14,592,254
Cost of Sales	14,919,072	12,234,782
Gross Profit	29,507	2,357,472
Selling, General and Administrative	5,061,955	6,100,715
Research and Product Development	1,666,356	1,214,851
Operating Income (Loss)	(6,698,804)	(4,958,094)
Interest and Investment Income	169,283	216,071
Income (Loss) Before Income Taxes	(6,529,521)	(4,742,023)
Income Tax Expense	—	—
Net Income (Loss)	\$ (6,529,521)	\$ (4,742,023)
Basic Earnings (Loss) per Share	\$ (0.13)	\$ (0.09)
Diluted Earnings (Loss) per Share	\$ (0.13)	\$ (0.09)

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three months ended March 31, 2018 and March 31, 2017

(Unaudited)

	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
Net Income (Loss)	\$ (6,529,521)	\$ (4,742,023)
Unrealized Gain (Loss) on Available-for-Sale Investments	(189,995)	112,002
Foreign Currency Translation Adjustments	(2,485)	505
Comprehensive Income (Loss)	\$ (6,722,001)	\$ (4,629,516)

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For the three months ended March 31, 2018

(Unaudited)

	COMMON SHARES		ACCUMULATED	ACCUMULATED	TOTAL
	SHARES	AMOUNT	DEFICIT	OTHER COMPREHENSIVE INCOME (LOSS)	SHAREHOLDER'S EQUITY
Balance as of December 31, 2017	51,768,424	\$ 273,210,907	\$ (240,262,376)	\$ (35,383)	\$ 32,913,148
Net Loss	—	—	(6,529,521)	—	(6,529,521)
Unrealized (Loss) on Available-for-Sale Investments	—	—	—	(189,995)	(189,995)
Foreign Currency Rate Changes	—	—	—	(2,485)	(2,485)
Issuance of Common Shares	—	—	—	—	—
Shares Issued in Exchange for Services	—	68,653	—	—	68,653
Stock Option Based Expense	—	616,273	—	—	616,273
Stock Tendered in Satisfaction of Tax Liabilities	—	—	—	—	—
Restricted Stock Amortization	—	491,077	—	—	491,077
Balance as of March 31, 2018	51,768,424	\$ 274,386,910	\$ (246,791,897)	\$ (227,863)	\$ 27,367,150

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended March 31, 2018 and March 31, 2017

(Unaudited)

	2018	2017
Cash Flows From Operating Activities:		
Net (Loss)	\$ (6,529,521)	\$ (4,742,023)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	129,076	130,215
Share Based Compensation—Non-employee	68,654	19,071
Share Based Compensation—Employees	1,107,349	2,259,316
Increase in Inventory Reserves	1,296,954	—
Loss on Disposal of Assets	3,083	3,350
Loss on Sale of Investments Available for Sale	2,892	—
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	295,973	(344,500)
Decrease (Increase) in Inventory	59,427	(2,291,108)
Decrease in Other Assets	238,438	160,406
(Decrease) in Accounts Payable	(209,208)	(1,914,780)
(Decrease) Increase in Other Liabilities	(494,969)	2,160,268
(Decrease) in Deferred License Revenue	(504,528)	(498,120)
(Decrease) in Deferred Drug License Revenue	(68,181)	(93,181)
Changes in Assets and Liabilities	(683,048)	(2,821,015)
Cash (Used In) Operating Activities	(4,604,561)	(5,151,086)
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(1,416,665)	—
Sale of Investments Available for Sale	1,050,554	31,123
Purchase of Equipment	(155,712)	(162,003)
Proceeds on Sale of Assets	—	450
Cash (Used In) Investing Activities	(521,823)	(130,430)
Cash Flows From Financing Activities:		
Cash (Used In) Provided By Financing Activities	—	—
Effects of exchange rate changes	(2,446)	632
(Decrease) In Cash	(5,128,830)	(5,280,884)

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Cash At Beginning Of Period	8,406,917	17,180,594
Cash At End Of Period	\$ 3,278,087	\$ 11,899,710

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

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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”. In 2017, we supplied approximately 25% of the United States domestic market with dialysis concentrates. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. The majority of our sales occur in the United States.

We are regulated by the United States 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 of 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, 2017 has been derived from our audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of our management, all adjustments have been included that are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three months ended March 31, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2017 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 includes a description of our significant accounting policies.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard, ASC 606 Revenue from Contracts with Customers, which requires recognition of revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. The new standard supersedes U.S. GAAP guidance on revenue recognition and requires the use of more estimates and judgments than the former standards.

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The new revenue standard became effective for us on January 1, 2018, and was adopted using the modified retrospective method. The adoption of the new revenue standard as of January 1, 2018, did not change our revenue recognition as the majority of our revenues continue to be recognized when the customer takes control of our product. As we did not identify any accounting changes that impacted the amount of reported revenues with respect to our product revenues or licensing agreements, no adjustment to retained earnings was required upon adoption.

In accordance with the standard, revenue is measured based on consideration transferred as specified in a contract with a customer, and excludes any sales incentives or rebates. We recognize revenue when it satisfies a performance obligation by transferring control over a product or service to a customer. We recognize revenues following the five step model prescribed under ASU No. 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligations.

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight related to contracts with customers are accounted for as a fulfillment cost and are included in cost of sales when control of the goods transfers to the customer.

Nature of goods and services

The following is a description of principal activities from which we generate our revenue.

Product sales – Product sales are tracked in two reportable segments – Drug Products and Concentrate Products. We account for individual products and services separately if they are distinct (i.e., if a product or service is separately identifiable from other items and if a customer can benefit from it on its own or with other resources that are readily available to the customer). The consideration, including any discounts, is allocated between separate products and services based on their stand-alone selling prices. The stand-alone selling prices are determined based on the cost plus margin approach.

Drug and concentrate products are sold directly to dialysis clinics and to wholesale distributors in both domestic and international markets. Distribution and license agreements for which upfront fees are received are evaluated upon execution or modification of the agreement to determine if the agreement creates a separate performance obligation from the underlying product sales. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the product sales. In instances where regulatory approval of

the product has not been established and we do not have sufficient experience with the foreign regulatory body to conclude that regulatory approval is probable, the revenue for the performance obligation is recognized over the term of the license agreement (over time recognition). Conversely, when regulatory approval already exists or is probable, revenue is recognized at the point in time that control of the product transfers to the customer.

We have received upfront fees under two distribution and license agreements that have been deferred as a contract liability. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. (“Wanbang”) are recognized as revenue over the estimated term of the distribution and license agreement as regulatory approval was not received and we did not have sufficient experience in China to determine that regulatory approval was probable as of the execution of the agreement. The amounts received from Baxter are recognized as revenue at the point in time that the estimated product sales under the agreement occur.

For the business under our distribution agreement with Baxter Healthcare Corporation (the “Baxter Agreement”) and for the majority of our international customers we recognize revenue at the shipping point, which is generally our plant or warehouse. For other business, we recognize revenue based on when the customer takes control of the product. The amount of revenue recognized is based on the purchase order less returns and adjusted for any rebates, discounts, chargebacks or other amounts paid to customers. There were no such adjustments for the periods reported. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while distributor payment terms averaging 45 days.

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Disaggregation of revenue

In the following table, revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

In thousands of US dollars (\$)	Three Months Ended		
	March 31, 2018		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenue Segment			
License Fee – Over time	\$ 68	\$ -	\$ 68
Concentrate Products			
Product Sales – Point-in-time	14,376	12,472	1,904
License Fee – Point-in-time	504	504	-
Total Concentrate Products	14,880	12,976	1,904
Net Revenue	\$ 14,948	\$ 12,976	\$ 1,972

Contract balances

The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers.

In thousands of US dollars (\$)	March 31, 2018	December 31, 2017
Receivables, which are included in ‘Trade and other receivables’	\$ 5,684	\$ 5,544
Contract liabilities	\$ 16,151	\$ 16,723

There were no impairment losses recognized related to any receivables arising from our contracts with customers for the quarter ending March 31, 2018.

For the three months ended March 31, 2018, we had no material bad-debt expense and there were no material contract assets recorded on the Consolidated Balance Sheet as of March 31, 2018. We do not generally accept returns of our concentrate products and no reserve for returns of concentrate products was established as of March 31, 2018 or December 31, 2017.

The contract liabilities primarily relate to upfront payments / consideration received from customers that are received in advance of the customer assuming control of the related products.

Transaction price allocated to remaining performance obligations

For the three months ended March 31, 2018, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled \$16,151,000 as of March 31, 2018. The amount relates primarily to upfront payments / consideration received from customers that are received in advance of the customer assuming control of the related products. We apply the practical expedient in paragraph 606-10-50-14 and do not disclose information about remaining performance obligations that have original expected durations of one year or less. The Baxter Agreement includes minimum commitments of product sales over the duration of the agreement. Unfulfilled performance obligations related to the Baxter Agreement are product sales of \$12,742,000 through expiration of the agreement on October 2, 2024.

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.

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Investments Available for Sale

Investments Available for Sale are short-term investments, consisting of investments in short-term notes and 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 \$24,821,682 as of March 31, 2018. 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 \$216,256 and gross unrealized gains were \$26,260 as of March 31, 2018. There were realized gains of \$1,425 and realized losses of \$4,417 in the first quarter of 2018.

The Company has evaluated the near term interest rate environment and the expected holding period of the investments along with the duration of the portfolio assets in assessing the severity and duration of potential impairments. Based on our evaluation, the Company does not consider those investments to be other-than-temporarily impaired at March 31, 2018.

Research and Product Development

We recognize research and product development expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately \$1.7 million and \$1.2 million for the three months ended March 31, 2018 and 2017, 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 March 31, 2018	Three Months Ended March 31, 2017
Basic Weighted Average Shares Outstanding	51,288,424	50,686,044
Effect of Dilutive Securities	—	—
Diluted Weighted Average Shares Outstanding	51,288,424	50,686,044

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3. Inventory

Components of inventory, net of reserves as of March 31, 2018 and December 31, 2017 are as follows:

	March 31, 2018	December 31, 2017
Raw Materials	\$ 9,403,198	\$ 10,604,232
Work in Process	124,534	212,505
Finished Goods	2,740,023	2,807,399
Total	\$ 12,267,755	\$ 13,624,136

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As of March 31, 2018, we classified \$3,722,901 of inventory as non-current all of which related to the active pharmaceutical ingredient for Triferic. As of March 31, 2018, we had total Triferic finished goods inventory aggregating \$5,903,000 against which we had reserved \$4,758,000.

4. Baxter Distribution Agreement

As of October 2, 2014, we entered into the Baxter Agreement, pursuant to which Baxter became our exclusive agent for sales, marketing and distribution activities for our hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years ending on October 2, 2024. The Baxter Agreement does not include any of our drug products. We retain sales, marketing and distribution rights for our hemodialysis concentrate products in specified foreign countries in which we have an established commercial presence. During the term of the Baxter Agreement, Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products.

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," "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 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, “Item 1A — Risk Factors” in our Form 10-K for the year ended December 31, 2017 and from time to time in our other reports filed with the SEC.

Risks Related To Our Drug Business

- There can be no assurance of if or when we might receive separate reimbursement status for Triferic from CMS.

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- Although Triferic has been approved by the FDA, we may not be able to commercialize it successfully, especially if Triferic is not approved for separate reimbursement status by CMS.
- If we are unable to use our Triferic inventory before its shelf life expires, we will have to recognize additional reserves which could have a material adverse effect on our results of operations, financial condition and cash flows.
- 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.
- If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our business may be harmed.
- Defending our proprietary rights could be expensive, we may not always be successful in protecting our intellectual property, licenses and other proprietary rights and we could be prevented from selling products, forced to pay royalties and damages and compelled to defend against litigation if we infringe the rights of a third party.
- 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 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 business, results of operations and financial position.
- 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.
- If our products are approved and marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.
- 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.
- 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.
- 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.
- It may be difficult for us to capture market share for Calcitriol in the highly competitive generic drug market.
- Inventory obsolescence due to finite shelf lives could adversely affect our business.

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.
- A few customers account for a substantial portion of the end user sales of our concentrate products. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our concentrate business.
- The concentrate market is competitive and has a large competitor with substantial resources.
- We may be affected materially and adversely by increases in raw material costs.

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, results of operation, financial position and cash flows.

- Our business could be impacted as a result of actions by activist shareholders, including as a result of a potential proxy contest for the election of directors at our annual meeting.
- Health care reform could adversely affect our business.
- We depend on key personnel, the loss of which could harm our ability to operate.
- 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.

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- 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.
- 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.
 - We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.
- Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.
- We may be unable to obtain secured debt financing because of borrowing restrictions under the Baxter Agreement.
- We may need to raise additional equity or debt capital in the near future to help ensure we have sufficient liquidity to fund our operations.
- Any adverse conclusions from our ongoing SEC inquiry could result in fines, criminal penalties and have an adverse effect on our business.

Risks Related To Our Common Stock

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

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

Overview

We are 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. 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 on 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 separate reimbursement, which is available for new, innovative therapies. We believe Triferic therapy provides improved clinical benefits to patients and significant cost savings to dialysis providers.

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Although we cannot be certain, we believe that Triferic has the potential to be granted separate reimbursement by CMS as a result of our extensive efforts in working with policy makers to secure separate reimbursement. We have had in-depth discussions with high level officials within the current administration, key members of Congress, patient advocacy groups and industry stakeholders regarding the merits of Triferic and about why this innovative therapy should receive separate reimbursement. Our efforts have resulted in strong support for separate reimbursement for Triferic. We have submitted information to CMS that highlights the improved clinical benefits that Triferic provides to patients, as well as the significant cost savings Triferic delivers to both Medicare and dialysis providers. We cannot predict the outcome or timing of CMS's process and there can be no assurance of if or when we might receive separate reimbursement for Triferic from CMS.

Until the separate reimbursement issue is resolved for Triferic, we do not anticipate realizing significant revenues from Triferic sales. In the meantime, we continue marketing to, and educating our customers about, Triferic and the valuable benefits 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-date to its positive clinical and cost saving benefits. Our marketing and education efforts to nephrologists and nurses, as well as to patients, have been well received.

We have built and previously invested in significant inventory of Triferic in anticipation of receiving separate reimbursement status. However, if we are unable to successfully commercialize Triferic and achieve sufficient sales volumes over the next one to two years, we will have to write off a significant portion of our inventory investment in Triferic, which would not have a material negative impact on our cash flow but would have a material adverse effect on our results of operations and financial position. As of March 31, 2018, we had \$5.9 million of Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved \$4.8 million. In the first quarter of 2018, we reserved an additional \$1.3 million (included within our \$4.8 million reserve) resulting in a remaining net book value of \$1.1 million of Triferic finished goods inventory as of March 31, 2018. We also have approximately \$7.5 million of Triferic Active Pharmaceutical Ingredient ("API") and have classified \$3.7 million of Triferic API as non-current inventory as of March 31, 2018. We believe we have produced sufficient supplies of Triferic API to meet prospective demand in 2018 and 2019. If CMS does not award us separate reimbursement for Triferic during 2018 or further extends its review of Triferic for separate reimbursement or should we not realize commercial sales during 2018 or 2019, some or all of our current investment in Triferic finished goods inventory and some of our Triferic API inventory will likely need to be written off, which would not have a material negative impact on our cash flow but would have a material adverse impact on our reported results of operations and financial position.

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. 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 sell our dialysis concentrates in the United States and certain foreign markets under the agreement with Baxter. We receive a pre-defined gross profit margin on our concentrate products sold pursuant to the Baxter Agreement, subject to an annual true-up of costs.

We are also working to begin marketing Calcitriol, an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis. Calcitriol is FDA approved under an Abbreviated New Drug Application which is manufactured for us through a contract manufacturing organization ("CMO"). We submitted a manufacturing update to the FDA to approve the CMO and FDA has provided a target date for their response of no later than August 19, 2018. The stability data that was provided in the Calcitriol submission remains within

specification. There can be no assurance the FDA will grant approval of our submission. If we are permitted to begin marketing Calcitriol, we do not anticipate Calcitriol sales will have a material impact on our results of operations during 2018.

Results of Operations for the Three Months Ended March 31, 2018 and March 31, 2017

Sales

Our sales in the first quarter of 2018 were \$14.9 million, \$0.4 million or 2.4% higher than the first quarter of 2017. The increase was primarily due to higher domestic concentrate sales of \$0.4 million which was primarily due to increased pass through delivery costs billed to Baxter. Our international sales increased 1.6% over the first quarter of 2017. Revenue recognized from licensing fees was slightly lower than the first quarter of 2017.

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Gross Profit

Gross profit in the first quarter of 2018 was slightly positive as the gross profit from our concentrate business was offset by expenses related to our drug business. Gross profit was negatively impacted by \$1.6 million in costs related to our drug business which included an increase in our Triferic inventory reserve of \$1.3 million. Our concentrate gross profit was approximately \$1.7 million and decreased by \$0.7 million in the first quarter of 2018 compared to the first quarter of 2017. The decrease in our concentrate business gross profit was largely due to increased concentrate distribution costs and lower pricing under the Baxter Agreement, which was partially offset by increased unit volume growth. Recently implemented government regulation in the trucking industry has further negatively impacted a nationwide driver shortage resulting in increased costs for both incoming materials and shipments within the United States. We expect this trend to continue to increase costs in the near term.

Selling, General and Administrative Expense

Selling, general and administrative expense during the first quarter of 2018 was \$5.1 million compared to \$6.1 million in the first quarter of 2017. The \$1.0 million expense decrease was primarily due to lower equity compensation expense of \$1.1 million. Equity grants awarded to our independent directors and non-executive employees during the first quarter were made expressly contingent upon shareholder approval of our proposed 2018 Long Term Incentive Plan (the "Plan") at our scheduled June 21, 2018 annual meeting of shareholders. If our shareholders approve the Plan, we will begin to amortize \$1.7 million of equity compensation expense associated with these awards at that time, with approximately \$830,000 expected to be recognized during the remainder of 2018. We incurred lower legal and litigation costs during the quarter, which was partially offset by a settlement payment to an activist investor group of \$428,000. See Part II – Item 1 – Legal Proceedings. We expect our selling, general and administrative expense will increase significantly in the second half of the year to help support our expected increased Triferic commercialization efforts.

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 compared to \$1.2 million in the first quarter of 2017. Research and product development costs incurred in the first quarter of 2018 were largely related to Triferic testing and development costs for use in other clinical indications and delivery presentations.

Interest and Investment Income, Net

Our net interest and investment income in the first quarter of 2018 was \$0.2 million and was at the same level as the first quarter of 2017.

Income Tax Expense

We recognized no income tax expense in the first quarter of 2018 or 2017.

Liquidity and Capital Resources

We believe we currently have adequate capital resources and liquidity to pursue our business strategy in 2018. In addition to operating our concentrate business, our business strategy is centered on developing, marketing and licensing high potential drug products, in particular Triferic. The actual amount of cash that we will need to execute our business strategy is subject to many factors, including, but not limited to, the timing and magnitude of cash received from drug product sales, the timing and expenditures associated with the commercialization of Triferic and Calcitriol, the timing and expenditures associated with the build-up of related inventory and whether, and to what extent, separate reimbursement for Triferic is approved by CMS.

As of March 31, 2018, we had current assets of \$44.2 million and net working capital of \$35.8 million. We have approximately \$28.1 million in cash and investments as of March 31, 2018. Our uses of cash have primarily been for operating expenses and research and product development expenses. Cash used in operating activities was \$4.6 million in the first quarter of 2018, which included research and development expenses of \$1.7 million. A settlement payment to an activist group of \$428,000 was paid in the first quarter of 2018.

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We are in discussions with multiple potential business development partners to out license rights to our drug products outside the United States. Such licensing arrangements may include a combination of 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.

We are currently using cash to fund our operations and, we believe we have sufficient cash to fund our operations for at least the next twelve months. Until we are able to generate sufficient cash from our commercial business activities, we will need to seek additional financing to provide the cash necessary to execute our business strategy, including working capital needs. Our capital raising activities may include, but may not be limited to, the issuance of common stock or other securities via private placement or public offerings or the issuance of debt. While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all. In particular, our Baxter Agreement prohibits us from entering into a contract that would encumber the assets used in our concentrate business without the prior written consent of Baxter. Due to the fact that the assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own other than our drug inventory, we may not, or find it difficult, to obtain secured debt financing without the consent of Baxter. Furthermore, additional equity financings may be dilutive to our stockholders and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have invested \$24.8 million in available for sale securities that are invested in short-term bonds which typically yield higher returns than the interest realized in money market funds. While these bonds are 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.

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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

Richmond Matters

Our Board of Directors was unable to reach agreement to appoint a seventh director by February 15, 2018 in breach of our prior settlement agreement with Richmond Brothers, Inc. (“RBI”), David S. Richmond (“Richmond”) and others. Accordingly, on February 27, 2018, RBI and Richmond delivered a letter to us nominating Lisa Colleran, Benjamin Wolin and Richmond for election to our Board of Directors at our 2018 annual meeting of shareholders. Thereafter, on March 7, 2018, we entered into a letter agreement with RBI and Richmond to memorialize the parties’ mutual agreement on certain corporate governance matters (the “Letter Agreement”). The Letter Agreement provided, among other things, that: (a) by March 7, 2018, our Board would increase its size from six directors to eight directors and would appoint: (i) Benjamin Wolin as a Class I director to serve for a term expiring at the Company’s 2019 annual meeting of shareholders and as the lead independent director of the Board and (ii) Lisa Colleran as a Class II director to serve for a term expiring at the 2020 annual meeting of shareholders; and (b) if the Company complied with the provisions of the Letter Agreement by March 7, 2018, then RBI would withdraw its proposal to separately nominate any directors for election at the 2018 annual meeting of shareholders. As a result, on March 9, 2018, RBI and Richmond withdrew their proposal to separately nominate directors for election at our 2018 annual meeting of shareholders. Mr. Wolin was subsequently appointed by our Board as Chairman of the Board. Additionally, our Board approved the payment to Richmond of \$428,000 in the first quarter of 2018 related to reimbursement of legal expenses and other expenses as required by the Letter Agreement.

Other Proceedings

As a follow up to their prior letters dated February 13, 2017 and April 5, 2017, we received a letter dated April 24, 2018 from the Securities and Exchange Commission requesting certain information generally with respect to the status of CMS's determination of separate reimbursement status for Triferic and our current decision not to actively market and sell Triferic without such separate reimbursement. We are cooperating and responding to this request.

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

Other than the foregoing, there have been no material changes to the risk factors set forth in our annual report for the year ended December 31, 2017 under "Item 1A — Risk Factors".

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Item 6. Exhibits

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 INDEX

Exhibit No.	Description
10.73	<u>Letter Agreement, dated March 7, 2018, by and among the Company, Richmond Brothers, Inc. and David S. Richmond. (Company's Form 8-K filed on March 13, 2018).</u>
*10.74	<u>Executive Employment Agreement, dated March 7, 2018, between Rockwell Medical, Inc. and Robert L. Chioini. (Company's Form 8-K filed on March 13, 2018).</u>
*10.75	<u>Executive Employment Agreement, dated March 7, 2018, between Rockwell Medical, Inc. and Thomas E. Klema. (Company's Form 8-K filed on March 13, 2018).</u>
*10.76	<u>Approval of Independent Director Compensation and Form of Contingent Option Agreement for Directors (Company's Form 8-K filed March 21, 2018).</u>
10.77	<u>Amendment No. 1 to Letter Agreement, dated April 17, 2018, by and among the Company, Richmond Brothers, Inc. and David S. Richmond (Company's Form 8-K filed April 19, 2018).</u>
31.1	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934</u>
31.2	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934</u>
32.1	<u>Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934</u>
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

*Current management contracts or compensatory plans or arrangements.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ROCKWELL MEDICAL, INC.
(Registrant)

Date: May 10, 2018 /s/ ROBERT L. CHIOINI
Robert L. Chioini
President and Chief Executive Officer
(principal executive officer) (duly authorized officer)

Date: May 10, 2018 /s/ THOMAS E. KLEMA
Thomas E. Klema
Vice President and Chief Financial Officer
(principal financial officer and principal accounting officer)