ROCKWELL MEDICAL, INC.
Form 10-Q
August 09, 2016
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United States

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

or

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

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

(248) 960-9009

(Registrant s telephone number, including area code)

(Former name, former address and former fiscal year,

if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes o No

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

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

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

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Class	**Outstanding as of July 29, 2016**
Common Stock, no par value	51,526,877 shares

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of June 30, 2016 and December 31, 2015

(Unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
Cash and Cash Equivalents	$ 23,821,780	$ 31,198,182
Investments Available for Sale	40,612,423	39,482,732
Accounts Receivable, net of a reserve of $37,000 in 2016 and $75,000 in 2015	7,590,137	5,046,733
Inventory	11,009,676	7,871,780
Other Current Assets	943,173	1,026,889
Total Current Assets	83,977,189	84,626,316
Property and Equipment, net	1,561,913	1,646,568
Intangible Assets	82,351	165,657
Goodwill	920,745	920,745
Other Non-current Assets	600,687	462,839
Total Assets	$ 87,142,885	$ 87,822,125
LIABILITIES AND SHAREHOLDERS EQUITY		
Accounts Payable	$ 4,976,192	$ 3,995,216
Accrued Liabilities	4,122,854	3,831,356
Customer Deposits	79,822	264,879
Total Current Liabilities	9,178,868	8,091,451
Deferred License Revenue	20,333,845	17,410,852
Shareholders Equity:		
Common Shares, no par value, 51,526,877 and 51,501,877 shares issued and outstanding	263,073,468	257,773,494
Accumulated Deficit	(204,723,532)	(194,538,176)
Accumulated Other Comprehensive Income	(719,764)	(915,496)
Total Shareholders Equity	57,630,172	62,319,822
Total Liabilities And Shareholders Equity	$ 87,142,885	$ 87,822,125

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2016 and June 30, 2015

(Unaudited)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Sales	**$ 13,452,517**	**$ 12,955,576**	**$ 27,079,565**	**$ 26,839,537**
Cost of Sales	11,962,989	10,889,619	23,895,111	22,461,237
Gross Profit	**1,489,528**	**2,065,957**	**3,184,454**	**4,378,300**
Selling, General and Administrative	5,014,370	3,835,596	10,001,111	9,161,357
Research and Product Development	2,063,324	885,259	3,377,754	1,684,850
Operating Income (Loss)	**(5,588,166)**	**(2,654,898)**	**(10,194,411)**	**(6,467,907)**
Interest and Investment Income, net	227,020	118,151	413,582	231,966
Income (Loss) Before Income Taxes	(5,361,146)	(2,536,747)	(9,780,829)	(6,235,941)
Income Tax Expense			404,527	
Net Income (Loss)	**$ (5,361,146)**	**$ (2,536,747)**	**$ (10,185,356)**	**$ (6,235,941)**
Basic Earnings (Loss) per Share	**$ (0.11)**	**$ (0.05)**	**$ (0.20)**	**$ (0.12)**
Diluted Earnings (Loss) per Share	**$ (0.11)**	**$ (0.05)**	**$ (0.20)**	**$ (0.12)**

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three and six months ended June 30, 2016 and June 30, 2015

(Unaudited)

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net Income (Loss)	**$ (5,361,146)**	**$ (2,536,747)**	**$ (10,185,356)**	**$ (6,235,941)**
Unrealized Gain (Loss) on Available-for-Sale Investments	242,965	(182,623)	195,732	(112,424)
Comprehensive Income (Loss)	**$ (5,118,181)**	**$ (2,719,370)**	**$ (9,989,624)**	**$ (6,348,365)**

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

For The Six Months Ended June 30, 2016

(Unaudited)

	COMMON SHARES		ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER S
	SHARES	AMOUNT	DEFICIT	INCOME (LOSS)	EQUITY
Balance as of December 31, 2015	51,501,877	$ 257,773,494	$ (194,538,176)	$ (915,496)	$ 62,319,822
Net Loss			(10,185,356)		(10,185,356)
Unrealized Gain (Loss) on Available-For-Sale Securities				195,732	195,732
Issuance of Common Shares	25,000	77,250			77,250
Stock Option Based Expense		3,041,844			3,041,844
Restricted Stock Amortization		2,180,880			2,180,880
Balance as of June 30, 2016	**51,526,877**	**$ 263,073,468**	**$ (204,723,532)**	**$ (719,764)**	**$ 57,630,172**

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2016 and June 30, 2015

(Unaudited)

	2016	2015
Cash Flows From Operating Activities:		
Net (Loss)	**$ (10,185,356)**	**$ (6,235,941)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	395,990	408,327
Share Based Compensation- Employees	5,222,723	4,994,272
Restricted Stock Tendered in Satisfaction of Tax Liabilities		(2,912,859)
Loss on Disposal of Assets	258	2,424
(Gain) on Sale of Investments Available for Sale	(3,302)	
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(2,543,404)	533,187
(Increase) in Inventory	(3,137,896)	(2,394,836)
(Increase) in Other Assets	(54,132)	(338,954)
Increase (Decrease) in Accounts Payable	980,981	(974,672)
Increase (Decrease) in Other Liabilities	106,441	(1,797,325)
Deferred License Revenue	2,922,993	(986,454)
Changes in Assets and Liabilities	(1,725,017)	(5,959,054)
Cash (Used In) Operating Activities	**(6,294,704)**	**(9,702,831)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(9,259,648)	(20,300,000)
Sale of Investments Available for Sale	8,328,987	
Purchase of Equipment	(229,287)	(208,613)
Proceeds from Sale of Assets	1,000	4,800
Cash Provided By (Used In) Investing Activities	**(1,158,948)**	**(20,503,813)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares	77,250	1,552,068
Cash Provided By Financing Activities	**77,250**	**1,552,068**
Increase (Decrease) In Cash	**(7,376,402)**	**(28,654,576)**
Cash At Beginning Of Period	31,198,182	65,800,451
Cash At End Of Period	**$ 23,821,780**	**$ 37,145,875**

Supplemental Cash Flow disclosure	**2016**	**2015**

Interest Paid	$	$

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

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Rockwell Medical, Inc. and Subsidiary

Notes to Consolidated Financial Statements

1. Description of Business

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

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

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

We are regulated by the Federal Food and Drug Administration (FDA) under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We 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 subsidiary, Rockwell Transportation, Inc. All intercompany balances and transactions have been eliminated in consolidation. The accompanying consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America, or GAAP, and with the instructions to Form 10-Q and Securities and Exchange Commission Regulation S-X as they apply to interim financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2015 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial

statements.

In the opinion of our management, all adjustments have been included that are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2015 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Our

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Annual Report on Form 10-K for the fiscal year ended December 31, 2015 includes a description of our significant accounting policies.

Revenue Recognition

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

Consistent with these guidelines we recognize revenue at the time we transfer title to our products to our customers which generally occurs when our products are delivered to our customer s location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We apply judgment as we analyze each element of our contractual agreements to determine appropriate revenue recognition. The terms of our contractual agreements may include milestone payments if specified research and development objectives are achieved, non-refundable licensing fees, milestone payments on sales or royalties from product sales.

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

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

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

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

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

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

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale.

Cash and Cash Equivalents

We consider cash on hand, money market funds, unrestricted certificates of deposit and short term marketable securities with an original maturity of 90 days or less as cash and cash equivalents.

Investments Available for Sale

Investments Available for Sale are short-term investments, consisting of investments in short term bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). These funds generally hold high credit quality short term debt instruments. These instruments are subject to changes in fair market value due primarily to changes in interest rates. The fair value of these investments was $40,612,423 as of June 30, 2016. Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense. Gross unrealized gains were $42,758 and gross unrealized losses were $762,522 as of June 30, 2016. Realized gains in the second quarter of 2016 and year to date were $106,879 while realized losses were $103,577.

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, 2016.

Research and Product Development

We recognize research and product development expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately $2.1 million and $3.4 million for the three and six months ended June 30, 2016, respectively.

Share Based Compensation

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

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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, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Basic Weighted Average Shares Outstanding	50,676,877	50,069,729	50,674,954	49,869,693
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	50,676,877	50,069,729	50,674,954	49,869,693

3. Inventory

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

	June 30, 2016	December 31, 2015
Raw Materials	$ 8,060,417	$ 5,504,915
Work in Process	143,822	165,910
Finished Goods	2,805,437	2,200,955
Total	$ 11,009,676	$ 7,871,780

4. Contractual Agreement Revenue

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

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

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

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

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. References in this report to the Company, we, our and us are references to Rockwell Medical, Inc. and its subsidiary.

Forward-Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, projected, intend, or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding Triferic® also known as Ferric Pyrophosphate Citrate or SFP and Calcitriol and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

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

Risks Related To Our Drug Business

- Although Triferic® has been approved by the FDA and was recently made available for commercial use, we may not be able to commercialize it successfully.

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

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

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

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

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

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

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

- Health care reform could adversely affect our business.

Risks Related To Our Concentrate Business

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

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

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

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

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

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

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

Risks Related To Our Business As A Whole

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

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

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

- We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.

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

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

Risks Related To Our Common Stock

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

- The market price for our common stock is volatile.

- We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.

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

- We do not anticipate paying dividends in the foreseeable future.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flow and financial position. There can be no assurance that future results will meet expectations. We do not

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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.

Our business focus is on unique, proprietary renal drug therapies. These novel renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

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

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

We submitted and received a Medicare reimbursement code from the Centers for Medicare & Medicaid Services (CMS) in May 2015. Late in 2015, following the completion of their public comment period for 2016 reimbursement guidance, we met with CMS to evaluate the pathway for separate transitional add-on reimbursement for Triferic®. Since then, we have been actively working to obtain transitional add-on reimbursement for Triferic®, which would allow customers to receive a separate, higher reimbursement for Triferic® to cover their costs of converting to a new innovative therapy. We believe Triferic® meets the criteria for add-on reimbursement and that dialysis patients will greatly benefit from the use of Triferic®. If add-on reimbursement is granted, it is expected to be available for two years and may give dialysis providers additional incentive to adopt Triferic®.

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

In addition to marketing Triferic®, we are working to produce sufficient inventory to begin marketing Calcitriol, our FDA approved generic Vitamin-D injection. We are dependent upon contract manufacturing organizations to manufacture Calcitriol for us. On May 4, 2016 we announced that our third party contract manufacturer found that one of the inactive ingredients used in completed Calcitriol product earmarked for commercial sale was out of specification for stability. The stability issue was not related to the active pharmaceutical ingredient in Calcitriol, which is supplied by a different manufacturer. Rockwell is working closely with its contract manufacturer to resolve this issue in a timely manner. We expect to begin marketing Calcitriol as soon as production issues are addressed and product is produced within prescribed specifications and stability standards.

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

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Under our October 2014 Distribution Agreement with Baxter Healthcare Corporation, a leading global dialysis products supplier, Baxter is the exclusive distributor of our dialysis concentrates in the United States and certain foreign markets. Rockwell receives a pre-defined gross profit margin on its products sold pursuant to the Distribution Agreement which adjusts each year over the ten year term of the agreement and is subject to an annual true-up. Baxter must achieve certain growth targets to maintain its exclusivity under the Distribution Agreement. The Distribution Agreement does not include our drug products.

Recent Developments

We are making significant progress regarding our international business development efforts for Triferic®, including securing a licensing agreement with Wanbang Biopharmaceutical for the rights to commercialize our Triferic® and Calcitriol drugs for ESRD patients in the People s Republic of China. We believe that China will ultimately become a significant market for the Company due to its large and growing dialysis population with a hemodialysis market projected by some industry participants to become the largest in the world over the next several years. It is a market that we also expect will provide an ideal opportunity for our other Triferic® therapeutic indications. We have a strategy for each major market and region and we are actively pursuing other licensing and distribution arrangements.

Additionally, we received FDA approval for our Triferic® Powder Packet on April 25, 2016. This packaging presentation will reduce our future production and distribution costs considerably compared to our Triferic® solution in an ampule. We are developing additional presentations of Triferic® to meet the unique needs of targeted international markets.

Results of Operations for the Three and Six Months Ended June 30, 2016 and June 30, 2015

Sales

Our sales in the second quarter of 2016 were $13.5 million which was $0.5 million or 3.8% higher than the second quarter of 2015. Our domestic dialysis concentrate business revenue in the second quarter of 2016 was $0.9 million or 7.7% higher than the second quarter of 2015 with approximately 2% due to higher unit volume. Our international dialysis concentrate revenue was $0.4 million lower than the second quarter of 2015. Nearly all of our product sales were dialysis concentrate product sales and related ancillary items.

Our sales for the first six months of 2016 were $27.1 million, an increase of $0.2 million or 0.9% over the first six months of 2015. Our domestic concentrate business revenue increased $1.2 million or 5.2% compared to the first six months of 2015. Domestic unit volumes increased approximately 2.8% compared to the first six months of 2015. Our international concentrate business for the first six months of 2016 was $0.5 million or 12.5% lower than the first six months of last year. Third party contract manufacturing sales in the first six months of 2016 were $0.6 million lower due to the cessation of contract manufacturing for a certain non-hemodialysis customer in the second quarter of 2015.

While working to obtain transitional add on reimbursement for Triferic®, we continue to market to and educate our customer base on Triferic®. But until we obtain transitional add on reimbursement, or until we cease trying to obtain it, we expect Triferic® sales activity to be insignificant. Sales of Triferic® were not material in the first six months of 2016. We recognized approximately $0.1 million in deferred license revenue related the Wanbang Agreement during the first six months of 2016.

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Gross Profit

Gross profit in the second quarter of 2016 was $1.5 million which was $0.6 million less than in the second quarter of 2015. Manufacturing and regulatory expenses related to manufacturing of our drug products reduced gross profit by $0.5 million in the second quarter of 2016 compared to the second quarter of last year. Lower international sales volumes in the second quarter of 2016 resulted in lower gross profit but their effect was partially offset by higher gross profit on domestic business.

Gross profit for the first six months of 2016 was $3.2 million which was $1.2 million less than in the first six months of 2015. Gross profit decreased by $1.0 million due to higher manufacturing and other direct costs related to our drug products which included $0.3 million in value added taxes paid on the $4 million in licensing payments received on our international licensing agreement for China. The remainder of the decrease was due to lower gross profit on international sales due to lower international orders in the second quarter partially offset by the effect of higher domestic sales.

Selling, General and Administrative Expense

Selling, general and administrative expense during the second quarter of 2016 was $5.0 million compared to $3.8 million in the second quarter of 2015. The increase in expense was primarily due to non-cash equity compensation costs increasing by $0.8 million. Triferic® marketing expenses and legal fees also increased over the second quarter of 2015.

Selling, general and administrative expense for the first six months of 2016 were $10.0 million compared to $9.2 million in the first six months of 2015. The increase was primarily due to higher legal expenses of $0.3 million, increased personnel costs of $0.2 million, higher non-cash equity compensation of $0.2 million and increased Triferic® marketing expenses of $0.1 million.

Research and Product Development Expense

We incur research and product development costs related to the commercial development, patent approval and regulatory approval of new products, including Triferic® and other clinical indications for Triferic® in various markets and jurisdictions. Research and development expense was $2.1 million and $3.4 million in the second quarter and first six months of 2016, respectively, compared to $0.9 million and $1.7 million in the second quarter and first six months of 2015, respectively, reflecting additional clinical research work for other Triferic® indications.

Interest and Investment Income, Net

Our net interest and investment income was $0.2 million in the second quarter of 2016 compared to $0.1 million in the second quarter of 2015. For the first six months of 2016, our net interest and investment income was $0.4 million compared to $0.2 million in the first six months of 2015. The increases in net investment income were due to a higher level of invested funds.

Income Tax Expense

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

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Liquidity and Capital Resources

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

As of June 30, 2016, we had current assets of $84.0 million and net working capital of $74.8 million. We have approximately $64.4 million in cash and investments as of June 30, 2016. Our uses of cash have primarily been for research and product development, investments in inventory to support our product launches and for operating expenses. Cash flow from operations used $6.3 million in the first six months of 2016, which included research and development expenses of $3.4 million, and increases of $3.1 million in inventory and $2.5 million in accounts receivable. We also received $3.3 million net of taxes pursuant to the Wanbang Agreement. Our capital expenditures for the first half of 2016 were $0.2 million.

We anticipate that we will increase our inventory and accounts receivable as we increase our drug product sales. We also expect to invest in research and product development in 2016 as we work to expand potential uses for Triferic®, although spending on these indications is expected to be minor in relation to the Company s current cash resources. We believe that we have adequate capital resources to make these investments in accounts receivable, inventory and research and product development. We expect to generate positive cash flow from operations when sales of our drug products become significant.

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

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

The Company is in discussions with multiple potential business development partners to out-license rights to Rockwell s products outside the United States. Such licensing arrangements often include upfront fees, research and development milestones, other developmental milestone payments and royalties. If such licensing arrangements are negotiated for certain markets, we may receive such consideration in the future in addition to those we are already entitled to receive under existing agreements including our recently completed licensing agreement for China. In addition to the initial milestone payment under the Wanbang Agreement, we may receive up to an additional $35 million over the life of the agreement in regulatory and revenue milestone payments plus ongoing earnings. We are also considering other business development arrangements including joint ventures, partnerships and other transactions related to our products or other future products that we may develop or license.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Pending their use in the operating business, we have invested $40.6 million in available for sale securities that are invested in short term bond funds, which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses that exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

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Foreign Currency Exchange Rate Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rule 13a-15 of the Securities Exchange Act of 1934, as amended, that are designed to ensure that material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15 under the Exchange Act) during the most recently completed fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1A. Risk Factors

For information regarding risk factors affecting us, see Risk Factors in Item 1A of Part I of our 2015 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K.

Item 6. Exhibits

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

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SIGNATURES

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

ROCKWELL MEDICAL, INC.
(Registrant)

Date: August 9, 2016	/s/ ROBERT L. CHIOINI Robert L. Chioini President and Chief Executive Officer (principal executive officer) (duly authorized officer)
Date: August 9, 2016	/s/ THOMAS E. KLEMA Thomas E. Klema Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)

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10-Q EXHIBIT INDEX

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

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) of the Securities Exchange Act of 1934
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Database
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase