

ROCKWELL MEDICAL, INC.
Form 10-Q
November 09, 2015
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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 September 30, 2015

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.)

30142 Wixom Road, Wixom, Michigan
(Address of principal executive offices)

48393
(Zip Code)

(248) 960-9009

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year,
if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)

Accelerated filer
Smaller reporting company

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

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

| Class | Outstanding as of October 31, 2015 |
|----------------------------|------------------------------------|
| Common Stock, no par value | 51,077,877 shares |

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Rockwell Medical, Inc.

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****ROCKWELL MEDICAL, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

As of September 30, 2015 and December 31, 2014

(Unaudited)

| | September 30, 2015 | December 31, 2014 |
|--|-----------------------|----------------------|
| ASSETS | | |
| Cash and Cash Equivalents | \$ 33,172,740 | \$ 65,800,451 |
| Investments Available for Sale | 39,818,118 | 19,927,310 |
| Accounts Receivable, net of a reserve of \$88,000 in 2015 and \$52,000 in 2014 | 5,896,487 | 4,472,002 |
| Inventory | 7,415,281 | 3,920,185 |
| Other Current Assets | 1,601,211 | 587,201 |
| Total Current Assets | 87,903,837 | 94,707,149 |
| Property and Equipment, net | 1,341,795 | 1,496,912 |
| Intangible Assets | 207,415 | 332,686 |
| Goodwill | 920,745 | 920,745 |
| Other Non-current Assets | 542,223 | 542,224 |
| Total Assets | \$ 90,916,015 | \$ 97,999,716 |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| Accounts Payable | \$ 5,223,394 | \$ 5,294,515 |
| Accrued Liabilities | 2,937,245 | 4,325,997 |
| Customer Deposits | 313,082 | 183,890 |
| Total Current Liabilities | 8,473,721 | 9,804,402 |
| Deferred License Revenue | 18,012,839 | 19,492,520 |
| Shareholders Equity: | | |
| Common Shares, no par value, 50,227,877 and 50,284,007 shares issued and outstanding | 253,777,785 | 249,018,189 |
| Accumulated Deficit | (188,768,220) | (180,117,726) |
| Accumulated Other Comprehensive Income (Loss) | (580,110) | (197,669) |
| Total Shareholders Equity | 64,429,455 | 68,702,794 |

| | | | | | |
|---|---------------|-----------|-------------------|-----------|-------------------|
| Total Liabilities And Shareholders | Equity | \$ | 90,916,015 | \$ | 97,999,716 |
|---|---------------|-----------|-------------------|-----------|-------------------|

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three and nine months ended September 30, 2015 and June 30, 2014

(Unaudited)

| | Three Months Ended September 30, 2015 | Three Months Ended September 30, 2014 | Nine Months Ended September 30, 2015 | Nine Months Ended September 30, 2014 |
|--|--|--|---|---|
| Sales | \$ 14,378,528 | \$ 13,743,778 | \$ 41,218,065 | \$ 39,740,791 |
| Cost of Sales | 11,875,122 | 11,473,961 | 34,336,359 | 33,772,125 |
| Gross Profit | 2,503,406 | 2,269,817 | 6,881,706 | 5,968,666 |
| Selling, General and Administrative | 3,827,904 | 4,098,835 | 12,989,261 | 12,403,240 |
| Research and Product Development | 1,246,727 | 1,301,824 | 2,931,577 | 6,103,716 |
| Operating Income (Loss) | (2,571,225) | (3,130,842) | (9,039,132) | (12,538,290) |
| Interest and Investment Income, net | 156,672 | 55,263 | 388,638 | 199,113 |
| Interest Expense | | 892,027 | | 2,604,333 |
| Income (Loss) Before Income Taxes | (2,414,553) | (3,967,606) | (8,650,494) | (14,943,510) |
| Income Tax Expense | | | | |
| Net Income (Loss) | \$ (2,414,553) | \$ (3,967,606) | \$ (8,650,494) | \$ (14,943,510) |
| Basic Earnings (Loss) per Share | \$ (0.05) | \$ (0.10) | \$ (0.17) | \$ (0.37) |
| Diluted Earnings (Loss) per Share | \$ (0.05) | \$ (0.10) | \$ (0.17) | \$ (0.37) |

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the three and nine months ended September 30, 2015 and September 30, 2014

(Unaudited)

| | Three Months Ended September 30, 2015 | Three Months Ended September 30, 2014 | Nine Months Ended September 30, 2015 | Nine Months Ended September 30, 2014 |
|---|---|---|---|---|
| Net Income (Loss) | \$ (2,414,553) | \$ (3,967,606) | \$ (8,650,494) | \$ (14,943,510) |
| Unrealized Gain (Loss) on Available-for-Sale Investments | (270,017) | (58,848) | (382,441) | (40,003) |
| Comprehensive Income (Loss) | \$ (2,684,570) | \$ (4,026,454) | \$ (9,032,935) | \$ (14,983,513) |

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

Table of Contents**ROCKWELL MEDICAL, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY****For The Nine Months Ended September 30, 2015**

(Unaudited)

| | COMMON SHARES SHARES | AMOUNT | ACCUMULATED DEFICIT | ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS) | TOTAL SHAREHOLDER S EQUITY |
|---|-------------------------|-----------------------|-------------------------|--|----------------------------------|
| Balance as of December 31, 2014 | 50,284,007 | \$ 249,018,189 | \$ (180,117,726) | \$ (197,669) | \$ 68,702,794 |
| Net (Loss) | | | (8,650,494) | | (8,650,494) |
| Unrealized (Loss) on Available-For-Sale Securities | | | | (382,441) | (382,441) |
| Issuance of Common Shares | 233,998 | 1,575,333 | | | 1,575,333 |
| Stock Option Based Expense | | 3,487,107 | | | 3,487,107 |
| Restricted Stock Amortization | | 2,610,015 | | | 2,610,015 |
| Restricted Stock Tendered in Satisfaction of Tax Liabilities | (290,128) | (2,912,859) | | | (2,912,859) |
| Balance as of September 30, 2015 | 50,227,877 | \$ 253,777,785 | \$ (188,768,220) | \$ (580,110) | \$ 64,429,455 |

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

Table of Contents**ROCKWELL MEDICAL, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the nine months ended September 30, 2015 and September 30, 2014**

(Unaudited)

| | 2015 | 2014 |
|---|-----------------------|------------------------|
| Cash Flows From Operating Activities: | | |
| Net (Loss) | \$ (8,650,494) | \$ (14,943,510) |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: | | |
| Depreciation and Amortization | 608,152 | 767,386 |
| Share Based Compensation- Employees | 6,097,122 | 6,293,250 |
| Restricted Stock Tendered in Satisfaction of Tax Liabilities | (2,912,859) | |
| Amortization of Debt Issuance Costs | | 357,140 |
| Non-Cash Interest Expense | | 353,994 |
| Loss on Disposal of Assets | 4,292 | 4,827 |
| Loss on Sale of Investments, net | 58,095 | 1,223 |
| Changes in Assets and Liabilities: | | |
| (Increase) Decrease in Accounts Receivable | (1,424,485) | 388,653 |
| (Increase) in Inventory | (3,495,096) | (181,858) |
| (Increase) in Other Assets | (1,014,009) | (317,194) |
| (Decrease) in Accounts Payable | (71,121) | (3,514,762) |
| (Decrease) in Other Liabilities | (1,259,560) | (2,506,918) |
| Deferred License Revenue | (1,479,681) | |
| Changes in Assets and Liabilities | (8,743,952) | (6,132,079) |
| Cash Used In Operating Activities | (13,539,644) | (13,297,769) |
| Cash Flows From Investing Activities: | | |
| Purchase of Investments Available for Sale | (21,800,000) | (2,000,000) |
| Sale of Investments Available for Sale | 1,468,656 | 4,976,000 |
| Purchase of Equipment | (336,856) | (613,311) |
| Proceeds from Sale of Assets | 4,800 | |
| Cash Provided By (Used In) Investing Activities | (20,663,400) | 2,362,689 |
| Cash Flows From Financing Activities: | | |
| Payments on Notes Payable and Capital Lease Obligations | | (564,410) |
| Proceeds from the Issuance of Common Shares and Purchase Warrants | 1,575,333 | 2,634,876 |
| Cash Provided By Financing Activities | 1,575,333 | 2,070,466 |
| Increase (Decrease) In Cash | (32,627,711) | (8,864,614) |
| Cash At Beginning Of Period | 65,800,451 | 11,881,451 |
| Cash At End Of Period | \$ 33,172,740 | \$ 3,016,837 |

Supplemental Cash Flow disclosure

| | 2015 | 2014 |
|---------------|------|--------------|
| Interest Paid | \$ | \$ 1,906,022 |

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 obtained FDA approval of Triferic™, our branded dialysis iron maintenance therapy drug, in January 2015 and sales began in September 2015. We have also received 510(k) approval from the FDA to market hemodialysis solutions and powders, to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

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

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information and footnotes required by GAAP for complete financial statements. The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for complete financial statements.

In the opinion of our management, all adjustments have been included that are necessary to make the financial statements not misleading. All of these adjustments that are material are of a normal and recurring nature. Our operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2014 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 includes a description of our significant accounting policies.

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Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

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 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 investments in short term duration bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). These funds generally hold high credit quality short term debt instruments. These instruments are subject to changes in fair market value due primarily to changes in interest rates. The fair value of these investments was \$39,818,118 as of September 30, 2015. 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. Realized losses from repositioning our portfolio aggregated \$58,095 for the nine months ended September 30, 2015. Gross unrealized gains were \$18,493 and gross unrealized losses were \$598,603 as of September 30, 2015.

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 the potential impairment. Based on that evaluation the Company does not consider those investments to be other-than-temporarily impaired at September 30, 2015.

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, including our FDA approved iron maintenance therapy drug, Triferic , aggregating approximately \$1.2 million and \$1.3 million for the three months ended September 30, 2015 and 2014, respectively. Research and product development costs were \$2.9 million and \$6.1 million for the nine months ended September 30, 2015 and 2014, respectively.

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

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

The Company's Long Term Incentive Plan permits grantees to tender shares to the Company in satisfaction of liabilities related to the exercise of equity awards, including the exercise price of options and tax liabilities related to equity awards. During the first nine months of 2015, 290,128 shares were tendered to the Company in satisfaction of \$2,912,859 of such liabilities.

Net Earnings Per Share

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. The calculation of basic weighted average shares outstanding excludes unvested restricted stock. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

| | Three Months Ended September 30, 2015 | Three Months Ended September 30, 2014 | Nine Months Ended September 30, 2015 | Nine Months Ended September 30, 2014 |
|---|--|--|---|---|
| Basic Weighted Average Shares Outstanding | 50,222,787 | 40,405,693 | 49,988,684 | 40,063,399 |
| Effect of Dilutive Securities | | | | |
| Diluted Weighted Average Shares Outstanding | 50,222,787 | 40,405,693 | 49,988,684 | 40,063,399 |

3. Inventory

Components of inventory as of September 30, 2015 and December 31, 2014 are as follows:

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| | September 30, 2015 | | December 31, 2014 |
|-----------------|-----------------------|----|----------------------|
| Raw Materials | \$ 5,117,485 | \$ | 2,197,143 |
| Work in Process | 187,392 | | 197,106 |
| Finished Goods | 2,110,404 | | 1,525,936 |
| Total | \$ 7,415,281 | \$ | 3,920,185 |

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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, 2014.

Risks Related To Our Drug Business

- Although Triferic™ has recently been approved by the FDA, we may not be able to commercialize it successfully.
- Triferic™ is currently limited to use in 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. 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 consequences 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 and Recent Developments

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

We 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.

Our strategy is to develop high potential drugs while expanding our dialysis products business. In January 2015, we received FDA approval to market Triferic our lead branded drug. Based on our clinical trial results, we believe Triferic has the potential to capture significant market share due to its unique attributes and clinical benefits, including savings on nursing administration time, potential to reduce expensive ESA treatments and excellent safety profile. We began selling Triferic near the end of the third quarter of 2015.

In the fourth quarter of 2014, we strengthened our balance sheet to position the Company for future growth and development. We raised net proceeds of approximately \$55 million in a public offering of our common shares and sold \$15 million of common shares to Baxter in a private offering. We also received \$20 million in cash in connection with the signing of the Distribution Agreement with Baxter related to our concentrate products. We fully paid off our high interest rate long term debt in the fourth quarter of 2014 and we have no debt on our balance sheet at September 30, 2015. Overall, we had cash and investments of \$73.0 million as of September 30, 2015 and \$85.7 million as of December 31, 2014.

In addition to Triferic, we plan to begin marketing Calcitriol, which is a vitamin-D analogue used to treat secondary hyperparathyroidism. We expect to achieve profitability following the launch of our drug products and to generate positive cash flow from our business operations as a result.

Distribution Agreement

As discussed in Item 1 Business Distribution Agreement with Baxter in our 2014 Annual Report on Form 10-K, on October 2, 2014, we entered into the Distribution Agreement pursuant to which Baxter, a leading global dialysis products company, became our exclusive agent for sales, marketing and distribution activities for our concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. 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 Distribution Agreement, Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products. The Distribution Agreement

relates solely to our concentrate business and excludes any future drug related business.

Under the Distribution Agreement, Baxter purchases products from us at gross margin-based prices per unit, adjusted each year during the term and subject to an annual true up. We continue to manage customer service, transportation and certain other functions for our current customers through at least December 31, 2017, for which Baxter pays us an amount equal to our related costs to provide such functions plus a slight mark-up. The Distribution Agreement also requires Baxter to meet minimum annual gallon-equivalent purchase levels, subject to a cure period and certain other relief, in order to maintain its exclusive distribution rights. The minimum

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purchase levels increase each year over the term of the Distribution Agreement. Orders in any contract year that exceed the minimum will be carried forward and applied to future years' minimum requirements.

In light of the gross margin-based pricing terms, the arrangement for Baxter to reimburse us the cost of customer service, transportation and other functions performed for it through at least 2017, and Baxter's requirement to meet increasing minimum concentrate purchase levels, we expect the distribution relationship with Baxter under the Distribution Agreement to have a positive impact on our operating profit. Commencing with June 2015 activity for domestic accounts invoiced by Baxter, our revenue from dialysis concentrates and ancillary products reflect the lower wholesale prices paid by Baxter pursuant to our Distribution Agreement. Similarly, our distribution costs, which are included in costs of sales, and our administration costs, which are included in selling, general and administrative expenses, are being passed through to Baxter and are reduced accordingly. We expect the net effect of these changes to result in an improvement in gross profit of approximately \$1.2 million per annum compared to operating results for our domestic concentrate business prior to the Distribution Agreement. Included in the higher expected gross profit is recognition of deferred licensing revenue.

We expect our overall domestic and global concentrate sales to increase in the long term as a result of the expanded marketing channel provided by Baxter as well as the anticipated expansion of our manufacturing operations to the Western United States as a result of funding provided through the Distribution Agreement.

Results of Operations for the Three and Nine Months Ended September 30, 2015 and September 30, 2014

Sales

Our sales in the third quarter of 2015 were \$14.4 million, \$0.6 million or 4.6% higher than the third quarter of 2014. Domestic concentrate sales increased \$0.5 million or 4.2% compared to the third quarter of 2014 primarily due to higher concentrate unit volume sales aggregating \$0.4 million coupled with recognition of \$0.5 million in deferred license revenue partially offset by the lower wholesale prices paid by Baxter as a distributor.

Our sales for the first nine months of 2015 were \$41.2 million, an increase \$1.5 million or 3.7% over the first nine months of 2014. Concentrate sales increased 3.3% with international concentrate sales up 2.4% and domestic concentrate sales up 3.5% or \$1.2 million compared to the first nine months of 2014. The domestic concentrate sales increase was primarily due to the amortization of \$1.5 million of deferred license income related to the Distribution Agreement, partially offset by the lower wholesale prices paid by Baxter as a distributor and the cessation of contract manufacturing for a non-hemodialysis customer in the second quarter of 2015.

Gross Profit

Gross profit in the third quarter of 2015 was \$2.5 million, an increase of \$0.2 million or 10.3% over the third quarter of 2014. Gross profit margins increased to 17.4% from 16.5% in the third quarter of 2014. Gross profit was favorably impacted by the recognition of deferred license revenue under the Distribution Agreement of \$0.5 million in the third quarter of 2015.

Gross profit for the first nine months of 2015 was \$6.9 million compared to \$6.0 million in the first nine months of 2014. Gross profit was favorably impacted by the recognition of deferred license revenue under the Distribution Agreement of \$1.5 million. Gross profit margin was 16.7% for the first nine months of 2015 compared to 15.0% for the first nine months of 2014.

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Selling, General and Administrative Expense

Selling, general and administrative expenses during the third quarter of 2015 were \$3.8 million compared to \$4.1 million in the third quarter of 2014. The decrease of \$0.3 million was primarily a result of a \$0.8 million decrease in non-cash equity compensation to \$1.1 million in the third quarter of 2015 from the third quarter of 2014. The decrease was partially offset by increased costs of approximately \$0.5 million for personnel, marketing and other operating costs in support of the commercial launch of Triferic .

Selling, general and administrative expenses for the first nine months of 2015 were \$13.0 million compared to \$12.4 million for the first nine months of 2014. The increase was directly related to the Triferic product launch including increased spending on marketing, advertising, personnel and regulatory compliance.

Research and Product Development Costs

We incurred research and product development costs related to the commercial development, patent approval and regulatory approval of Triferic™ which was approved by the FDA in the first quarter of 2015. Research and product development costs declined to \$1.2 million in the third quarter of 2015 from \$1.3 million in the third quarter of 2014. Research and product development costs in the first nine months of 2015 declined to \$2.9 million from \$6.1 million in the first nine months of 2014 following FDA approval to market Triferic in January 2015. Future research and product development spending over the next year is expected to be related to other Triferic post approval studies and for developing other Triferic™ indications.

Interest and Investment Income, Net

Our net interest and investment income was \$0.2 million and \$0.4 million in the third quarter and first nine months of 2015, respectively, compared to a net interest expense of \$0.8 million and \$2.4 million in the comparable periods of 2014. The changes were a result of paying off our long term debt in the fourth quarter of 2014 and temporarily investing the remaining net proceeds from our capital raising activities in the fourth quarter of 2014 in short term investments.

Liquidity and Capital Resources

We have adequate capital resources and substantial liquidity to pursue our business strategy. Our strategy is centered on developing and licensing high potential drug candidates including Triferic™. We began selling Triferic late in the third quarter of 2015. We expect our business to become profitable and to generate positive cash flow in the year ahead as we achieve market penetration with our drug products.

As of September 30, 2015, we had \$87.9 million in current assets and net working capital of \$79.4 million. We had \$73.0 million in cash and investments including \$33.2 million in cash as of September 30, 2015. We had no debt outstanding as of September 30, 2015.

In the first nine months of 2015, we incurred \$2.9 million in research and product development costs and we increased our inventory by \$3.5 million in connection with the launch of our drug products. Other cash used in operations included approximately \$2.9 million for the satisfaction of tax obligations related to restricted stock tendered to the Company by restricted stock grantees. We intend to source our drug products from contract manufacturing organizations. Capital expenditures on our current facilities are not expected to materially exceed depreciation expense.

Future research and product development spending on the TrifericTM platform is expected to include clinical testing in connection with pediatric indications, peritoneal dialysis and certain other indications and is expected to be minor in relation to the Company's cash resources. Our near term cash requirements are anticipated to be

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primarily for working capital in support of drug sales including inventory and accounts receivable until the trade cycle related to our drug business begins to generate positive cash flows.

The Company is in discussions with multiple potential business development partners to out-license rights to our products outside the United States. We are 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, 2014. There have been no material changes to that information since December 31, 2014 except as described above.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We have temporarily invested \$39.8 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 which may exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

Foreign Currency Exchange Rate Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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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

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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 2014 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: November 9, 2015

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

Date: November 9, 2015

/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 |