ROCKWELL MEDICAL, INC.
Form 10-Q
August 01, 2013
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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, 2013

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 o	Accelerated filer x
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 24, 2013**
Common Stock, no par value	39,916,961 shares

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Rockwell Medical, Inc.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of June 30, 2013 and December 31, 2012

	June 30, 2013 (Unaudited)	December 31, 2012
ASSETS		
Cash and Cash Equivalents	$ 40,952,067	$ 4,711,730
Accounts Receivable, net of a reserve of $32,500 in 2013 and $26,000 in 2012	4,576,492	4,431,932
Inventory	2,916,599	2,649,639
Other Current Assets	814,765	1,356,131
Total Current Assets	49,259,923	13,149,432
Property and Equipment, net	1,740,379	1,858,442
Intangible Assets	583,229	666,744
Goodwill	920,745	920,745
Other Non-current Assets	1,523,502	429,723
Total Assets	$ 54,027,778	$ 17,025,086
LIABILITIES AND SHAREHOLDERS EQUITY		
Capitalized Lease Obligations	$ 592	$ 2,280
Accounts Payable	8,303,965	14,833,565
Accrued Liabilities	8,455,508	12,015,978
Customer Deposits	29,007	135,133
Total Current Liabilities	16,789,072	26,986,956
Long Term Debt	20,000,000	
Shareholders Equity:		
Common Shares, no par value, 39,916,961 and 21,494,696 shares issued and outstanding	146,702,432	92,866,458
Common Share Purchase Warrants, 2,071,407 and 2,233,240 warrants issued and outstanding	7,786,474	7,178,929
Accumulated Deficit	(137,250,200)	(110,007,257)
Accumulated Other Comprehensive Loss		
Total Shareholders Equity (Deficit)	17,238,706	(9,961,870)
Total Liabilities And Shareholders Equity	$ 54,027,778	$ 17,025,086

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, 2013 and June 30, 2012

(Unaudited)

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Sales	**$ 12,984,164**	**$ 12,124,790**	**$ 25,320,538**	**$ 24,153,207**
Cost of Sales	11,299,099	10,405,991	22,354,493	20,807,932
Gross Profit	**1,685,065**	**1,718,799**	**2,966,045**	**3,345,275**
Selling, General and Administrative	3,237,974	2,824,379	7,154,757	5,723,063
Research and Product Development	10,222,721	10,876,396	22,977,239	20,281,943
Operating Income (Loss)	**(11,775,630)**	**(11,981,976)**	**(27,165,951)**	**(22,659,731)**
Interest and Investment Income, net	4,566	77,091	15,238	188,188
Interest Expense	92,155	456	92,230	709
Income (Loss) Before Income Taxes	(11,863,219)	(11,905,341)	(27,242,943)	(22,472,252)
Income Tax Expense				
Net Income (Loss)	**$ (11,863,219)**	**$ (11,905,341)**	**$ (27,242,943)**	**$ (22,472,252)**
Basic Earnings (Loss) per Share	**$ (.38)**	**$ (.58)**	**$ (1.04)**	**$ (1.12)**
Diluted Earnings (Loss) per Share	**$ (.38)**	**$ (.58)**	**$ (1.04)**	**$ (1.12)**

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, 2013 and June 30, 2012

(Unaudited)

	Three Months Ended June 30, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Net Income (Loss)	**$ (11,863,219)**	**$ (11,905,341)**	**$ (27,242,943)**	**$ (22,472,252)**
Unrealized Gain on Available-for-Sale Investments		4,453		105,162
Comprehensive Income (Loss)	**$ (11,863,219)**	**$ (11,900,888)**	**$ (27,242,943)**	**$ (22,367,090)**

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, 2013

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS			ACCUMULATED OTHER	TOTAL
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	COMPREHENSIVE INCOME (LOSS)	SHAREHOLDER S EQUITY
Balance as of December 31, 2012	21,494,696	$ 92,866,458	2,233,240	$ 7,178,929	$ (110,007,257)	$	$ (9,961,870)
Net Loss					(27,242,943)		(27,242,943)
Issuance of Common Shares	17,861,432	50,098,632					50,098,632
Shares Issued in Exchange for Services	200,000	196,000					196,000
Purchase Warrant Expense				1,004,786			1,004,786
Exercise of Purchase Warrants	50,833	762,222	(161,833)	(397,241)			364,981
Stock Option Based Expense		1,950,359					1,950,359
Restricted Stock Issuance	310,000						
Restricted Stock Amortization		828,761					828,761
Balance as of June 30, 2013	39,916,961	$ 146,702,432	2,071,407	$ 7,786,474	$ (137,250,200)	$	$ 17,238,706

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, 2013 and June 30, 2012

(Unaudited)

	2013	2012
Cash Flows From Operating Activities:		
Net (Loss)	**$ (27,242,943)**	**$ (22,472,252)**
Adjustments To Reconcile Net Loss To Net Cash Used In		
Operating Activities:		
Depreciation and Amortization	502,178	555,182
Share Based Compensation Non-employee	1,200,785	614,762
Share Based Compensation- Employees	2,779,121	2,393,609
Loss (Gain) on Disposal of Assets	5,516	25,340
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(144,560)	(133,189)
(Increase) in Inventory	(266,960)	(257,962)
Decrease in Other Assets	528,866	759,966
Increase (Decrease) in Accounts Payable	(6,529,600)	1,046,470
Increase (Decrease) in Other Liabilities	(3,666,596)	2,682,643
Changes in Assets and Liabilities	(10,078,850)	4,097,928
Cash Provided By (Used In) Operating Activities	**(32,834,193)**	**(14,785,431)**
Cash Flows From Investing Activities:		
Purchase of Equipment	(313,014)	(242,495)
Proceeds on Sale of Assets	6,898	1,578
(Purchase) of Investments Available for Sale		(2,000,000)
Cash (Used In) Investing Activities	**(306,116)**	**(2,240,917)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	50,463,613	17,785,640
Proceeds from the Issuance of Notes Payable	20,000,000	
Debt Issuance Costs	(1,081,279)	
Payments on Capital Lease Obligations	(1,688)	(4,626)
Cash Provided By Financing Activities	**69,380,646**	**17,781,014**
Increase (Decrease) In Cash	**36,240,337**	**754,666**
Cash At Beginning Of Period	4,711,730	5,715,246
Cash At End Of Period	**$ 40,952,067**	**$ 6,469,912**

Supplemental Cash Flow disclosure

	2013	2012
Interest Paid	$ 1,877	$ 709

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 (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis.

Rockwell s lead drug candidate, Soluble Ferric Pyrophosphate (SFP), in late-stage clinical development, is an iron replacement therapy for dialysis patients. The Company has completed the efficacy portion of its SFP Phase 3 clinical studies (CRUISE-1 and CRUISE-2).

Rockwell is preparing to launch its FDA approved generic drug called Calcitriol to treat secondary hyperparathyroidism in dialysis patients. Calcitriol active vitamin D injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. Rockwell intends to launch Calcitriol as soon as it receives FDA manufacturing approval.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. Rockwell s products are used to maintain human life, by removing toxins and replacing critical nutrients in the dialysis patient s bloodstream. Rockwell has three manufacturing and distribution facilities located in the U.S. and its operating infrastructure is a ready-made sales and distribution channel that is able to provide seamless integration into the commercial market for its drug products, Calcitriol and SFP upon FDA market approval.

We are regulated by the Federal Food and Drug Administration under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders and related equipment.

We have obtained global licenses for certain dialysis related drugs which we are developing and are seeking FDA approval to market. We plan to devote substantial resources to the development, testing and FDA approval of our lead drug candidate.

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, 2012 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 which 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, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013. You should read our unaudited interim

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financial statements together with the financial statements and related footnotes for the year ended December 31, 2012 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 includes a description of our significant accounting policies.

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.

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.

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 anemia related iron maintenance drug candidate, Soluble Ferric Pyrophosphate, or SFP, aggregating approximately $23.0 million and $20.3 million for the six months ended June 30, 2013 and 2012, respectively. We are conducting human clinical trials on SFP. We recognize the costs of the human clinical trials as the costs are incurred and services performed over the duration of the trials.

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, 2013	Three Months Ended June 30, 2012	Six Months Ended June 30, 2013	Six Months Ended June 30, 2012
Basic Weighted Average Shares Outstanding	31,191,079	20,568,133	26,243,526	20,001,975
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	31,191,079	20,568,133	26,243,526	20,001,975

3. Inventory

Components of inventory as of June 30, 2013 and December 31, 2012 are as follows:

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	June 30, 2013	December 31, 2012
Raw Materials	$ 1,257,690	$ 1,018,648
Work in Process	226,102	179,922
Finished Goods	1,432,807	1,451,069
Total	$ 2,916,599	$ 2,649,639

4. Other Current Assets

Other current assets includes amounts advanced to contract services providers. These advances will offset future liabilities incurred with contract services providers for services and travel related to our clinical trials. As of June 30, 2013, the amount included in other current assets was $0.3 million.

5. Loans Payable

As of June 14, 2013, the Company entered into a loan and security agreement (the Loan Agreement) with Hercules Technology III, L.P. (Hercules) pursuant to which the Company received a loan in the aggregate principal amount of $20.0 million. The Company is required to repay the aggregate principal balance under the Loan Agreement in 30 equal monthly installments of principal and interest commencing on September 1, 2014.

The loan will mature and become due on March 1, 2017, subject to adjustment as provided below, and will bear interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%. The Company will be required to make monthly interest only payments through August 31, 2014 (or May 31, 2014 if we fail to meet primary end points for both Phase 3 trials for our SFP drug prior to December 15, 2013). The Company met the primary endpoint on its first clinical trial, Cruise 1, and anticipates a confirmatory result on the Cruise 2 trial. If the interest only period is not extended, the maturity date for the loan would be December 1, 2016. Monthly principal and interest payments will be due on the loan following the interest only period through the maturity date. The loan may be prepaid at any time after June 14, 2014 without penalty and will mature and become due upon any change in control of the Company. The Company paid debt issuance costs totaling $1.1 million, including a fee of $0.2 million at closing to the Lender, which are recorded as a noncurrent asset, and is required to pay a fee of $1.1 million upon any prepayment or at maturity. The $1.1 million fee due upon any prepayment or at maturity is accrued using the effective interest rate method over the life of the loan. The effective interest rate of the loan is 14.5%.

In connection with the loan, the Company granted Hercules a security interest in substantially all of the Company s assets other than motor vehicles, real property and certain intellectual property and other interests. The Loan Agreement provides for standard indemnification of Hercules and contains representations, warranties and non-financial covenants of the Company. The Loan Agreement contains covenants that, among other things, limit the Company s ability to incur additional indebtedness, transfer assets, acquire assets of or merge with another entity and pay dividends to the Company s shareholders. The Loan Agreement defines event of default, to include, among other events, the occurrence of an event that results in a material adverse effect upon the Company s business operations, properties, assets or condition (financial or otherwise), the collateral or the perfection of the security interest, or the Company s ability to perform its obligations under the Loan Agreement. The Company was in compliance with the terms of the Loan Agreement and there was no event of default as of June 30, 2013.

The balance of the above debt matures as follows assuming the Company meets primary end points for both Phase 3 trials for its SFP drug prior to December 15, 2013:

2013	$	
2014		1,731,981
2015		7,492,371
2016		8,484,481
2017		2,291,167
Total Principal Payable	$	20,000,000

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Interest accrued on the loan payable through June 30, 2013 was $90,278.

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 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 the timing and costs of obtaining FDA approval of our new Soluble Ferric Pyrophosphate or SFP product 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 below and elsewhere 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, 2012.

- The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue. Our business is substantially dependent on a few customers that account for a substantial portion of our sales. The loss of any of these customers would have a material adverse effect on our results of operations and cash flow.

- We operate in a very competitive market against a substantially larger competitor with greater resources.

- Our lead drug candidate requires FDA approval and expensive clinical trials before it can be marketed.

- Even if we receive FDA approval to manufacture and market our new drug products, we may not be able to market them successfully.

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- We may require additional financing to achieve our goals, and such financing may result in dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain capital if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

- We may not be successful in maintaining our gross profit margins.

- We depend on government funding of health care.

- Health care reform could adversely affect our business.

- We depend on key personnel.

- Our business is highly regulated.

- We depend on contract research organizations and independent clinicians to manage and conduct our clinical trials and if they fail to follow our protocol or meet FDA regulatory requirements our clinical trial data and results could be compromised delaying our development plans or causing us to do more testing than planned.

- Foreign approvals to market our new drug products may be difficult to obtain.

- 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.

- We may not have sufficient products liability insurance.

- Our Board of Directors is subject to potential deadlock.

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

- 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.

- The market price of our securities may be volatile.

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

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

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

Overview and Recent Developments

Rockwell Medical, Inc. 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 U.S. and abroad.

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We are 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. Our dialysis products business has been cash flow positive, excluding research and development expenses, and provides a ready-made sales and distribution infrastructure to market our drugs and other related products used in dialysis.

Our product development costs were primarily related to SFP, our lead drug which is nearing completion of its Phase 3 clinical studies. The first efficacy study, Cruise-1, reported successful top line results in July 2013 having met its primary efficacy end point, all key secondary endpoints and demonstrated a very good safety profile. Cruise-2 results will be reported during the third quarter of 2013 and are anticipated to be confirmatory results to the identically designed Cruise-1 study.

Based upon clinical data to date, we believe SFP has unique and substantive benefits compared to current treatment options. Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We expect to incur substantial costs related to product testing and development in 2013 and to a lesser extent for regulatory approval in 2014. We expect to incur losses from operations in 2013 largely as a result of the cost of the SFP program.

We completed a multi-year extension of the supply agreement with our largest customer during the second quarter of 2013 and anticipate future volume and revenue growth from this agreement due to an increase in the minimum number of committed clinics, but do not expect a material change in gross profit margins.

As of June 30, 2013 we had $41.0 million in cash and cash equivalents. In May 2013, we completed a common stock offering for $40.3 million in gross proceeds and approximately $37.7 million in net proceeds. In June 2013 we entered into a loan agreement and borrowed $20,000,000. We believe these cash resources are adequate for the Company to complete the regulatory approval for SFP and through its commercialization. The Company expects to launch SFP immediately following FDA approval and to largely use its existing sales, marketing and business infrastructure in support of the SFP commercial development.

In 2011, we acquired an FDA approved generic vitamin D injection, Calcitriol, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We have submitted the necessary manufacturing data to the FDA to obtain commercial marketing approval and intend to begin marketing Calcitriol following regulatory approval from the FDA which we expect later this year. We anticipate that our gross profit margins will be favorably impacted by revenue from Calcitriol once we obtain FDA approval for manufacturing changes

We may experience changes in our customer and product mix in future quarters that could impact gross profit, since we sell a wide range of products with varying profit margins and to customers with varying order patterns. These changes in mix may cause our gross profit and our gross profit margins to vary period to period.

The majority of our business is with domestic clinics who order routinely. From time to time, we have experienced volatility in international orders.

Results of Operations for the Three and Six Months Ended June 30, 2013 and June 30, 2012

Sales

Sales in the second quarter of 2013 were $13.0 million compared to $12.1 million in the second quarter of 2012. Sales increased

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due to growth in our CitraPure® product lines, which increased significantly in the second quarter, reflective of increased market adoption and to a lesser extent, as a result of the multi-year supply agreement executed with our largest customer in May 2013. Domestic sales accounted for about half of the increase.

Sales in the first six months of 2013 were $25.3 million compared to $24.2 million in the first six months of 2012 an increase of $1.1 million or 4.8%. The increase was due to growth in CitraPure sales and, to a lesser extent, the execution of the multi-year supply agreement. Domestic sales accounted for nearly all of the increase.

Gross Profit

Gross profit dollars in the second quarter of 2013 and 2012 were $1.7 million while gross profit margins in the second quarter of 2013 were 13.0% compared to 14.2 % in the second quarter of 2012, a decrease of 1.2 percentage points which was due to inflationary cost increases for our raw materials.

Gross profit margins for the first six months of 2013 were 11.7 % compared to 13.9 % in the first six months of 2012. Gross profit dollars year to date were $3.0 million compared to $3.3 million in the first six months of 2012. The decrease in gross profit was primarily due to higher material costs coupled with increased operating costs compared to the first half of 2012. Operating costs increased due to inflation and increased costs due to government regulations.

Selling, General and Administrative Expense

Selling, general and administrative expense during the second quarter of 2013 was $3.2 million compared to $2.8 million in the second quarter of 2012. Non-cash equity compensation was $1.7 million in the second quarter of 2013 compared to $1.5 million in the second quarter of 2012. We recognized an increase of $0.2 million related to the mandated medical device tax in the second quarter of 2013.

Selling, general and administrative expense in the first half of 2013 was $7.2 million compared to $5.7 million in the first half of 2012. We incurred a non-cash charge of $0.9 million related to the extension of certain expiring common stock purchase warrants in 2013. We also recognized an increase in cost related to the recently mandated medical device tax of $0.5 million in the first half of 2013.

Research and Development

Research and development cost was $10.2 million in the second quarter of 2013 compared to $10.9 million in the second quarter of 2012. Research and development costs in the first six months of 2013 were $23.0 million compared to $20.3 million in the first six months of 2012. Spending in both years was primarily for clinical testing and development of SFP with the increase in 2013 due to increased testing associated

with the SFP Phase 3 clinical program. We anticipate substantial spending for clinical development and regulatory approval for SFP to continue into 2014 until the new drug application for SFP is submitted to the FDA.

Interest Expense, Net

Our net interest expense was $88,000 in the second quarter of 2013 compared to net interest and investment income of $77,000 in the second quarter of 2012. Year to date net interest expense was $77,000 compared to net interest and investment income of $188,000 in the first half of 2012. The increase in interest expense was due to the loan obligation entered into in June 2013. Reduced net interest and investment income was due to lower funds available for investment in 2013 compared to 2012.

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Liquidity and Capital Resources

We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP. SFP will require the expenditure of substantial cash resources over the next year as we execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States. Once completed, we expect these costs to decrease substantially. Costs for research and development were $23.0 million in the first half of 2013 compared to $20.3 in the first half of 2012. We also reduced our accounts payable by $6.3 million and other accrued liabilities by $3.3 million in the first half of 2013.

Our cash resources include cash generated from the proceeds of equity offerings, including the receipt of $12.0 million in net proceeds from an equity offering completed in March 2013 and $37.7 million in an equity offering completed in May of 2013. We also borrowed $20.0 million in June 2013. The repayment and other terms of the loan are described in Note 5 to the accompanying consolidated financial statements.

We had $41.0 million in cash as of June 30, 2013. Our current assets were $49.3 million and our current liabilities were $16.8 million as of June 30, 2013. In the first six months of 2013, our cash position increased by $36 million as a result of $69.7 million in capital raised in financing activities offset by our clinical development program for which we incurred $23 million in R&D expenses in the first half of 2013.

We believe we have adequate cash resources to fund our current development and commercialization plans for SFP. We are evaluating various business development and strategic partnering options which may provide additional financial resources.

Our contractual obligations are described in our Form 10-K for the year ended December 31, 2012. There have been no material changes to that information since December 31, 2012, other than the $20 million loan described in Note 5 to the accompanying consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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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 2012 Annual Report on Form 10-K. There have been no material changes to the risk factors described in such Form 10-K, except as described below.

The 2012 Form 10-K included a risk factor entitled There is substantial doubt as to our ability to continue as a going concern. Because of our recurring losses and the need for us to raise additional working capital, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 contains an explanatory paragraph stating that our recurring losses and need for additional working capital raise substantial doubt about our ability to continue as a going concern. Our losses have resulted principally from expenses incurred in research and development of our technology and products and we expect to continue to incur operating losses as we complete the clinical trial process and pursue regulatory approval of SFP. As of December 31, 2012, our cash and investments were $4.7 million and our current liabilities exceeded our current assets by $13.8 million. However, in the first six months of 2013, we have raised approximately $70 million in additional equity and debt capital, our current assets exceed our current liabilities by $32.5 million at June 30, 2013 and we believe we now have sufficient financing to execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States. As a result, we believe our potential inability to continue as a going concern is no longer a material risk.

In addition, as a result of the capital raised during the last six months, the risk factor entitled We require substantial additional financing to achieve our goals, and such financing may result in substantial dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts. is modified to read as follows:

We may require additional financing to achieve our goals, and such financing may result in dilution to shareholders or restrictions on our ability to operate our business. A failure to obtain capital, if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

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Over the last several years, we have dedicated a significant portion of our resources to the preclinical and clinical development of SFP. In particular, we are currently conducting a Phase 3 clinical program for SFP, which will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future developing SFP. These expenditures will include costs associated with research and development, conducting clinical trials, obtaining regulatory approvals and manufacturing products, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

We may seek additional funds through public or private equity or debt financings or other sources, such as strategic partnerships. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds by issuing equity securities, substantial dilution to existing shareholders could result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may not be able to continue as a going concern or may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates;

- delay, limit, reduce or terminate our research and development activities; or

- delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

The following risk factor is hereby added.

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

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We could incur substantial costs in seeking enforcement of our patent rights against infringement, and we cannot guarantee that such patents will successfully preclude others from using technology that we rely upon. We have no knowledge of any infringement or patent litigation, threatened or filed at this time. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our products infringes on the third party s patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from selling products, forced to pay damages and compelled to defend against litigation.

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 1, 2013	/s/ ROBERT L. CHIOINI Robert L. Chioini President and Chief Executive Officer (principal executive officer) (duly authorized officer)
Date: August 1, 2013	/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
3.1	Restated Articles of Incorporation, as amended as of May 1, 2013. (Company s Form 10-Q filed May 8, 2013).
4.18	Loan and Security Agreement dated as of June 14, 2013, among Rockwell Medical, Inc., Rockwell Transportation, Inc. and Hercules Technology III, L.P. (Company s Form 8-K filed June 20, 2013).
10.53	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective April 30, 2013 (appendix to Company s Proxy Statement for the 2013 Annual Meeting of Shareholders filed March 29, 2013).
10.54	Form of Restricted Stock Award Agreement June 2013 (Executive Version) (Company s Form 8-K filed June 19, 2013).
10.55	First Amended and Restated Products Purchase Agreement dated May 8, 2013, by and between Rockwell Medical, Inc. and DaVita Healthcare Partners, Inc. (with certain portions deleted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934).
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