ROCKWELL MEDICAL, INC.
Form 10-Q
November 09, 2012
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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 September 30, 2012

or

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

For the transition period from to

Commission File Number: 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

(248) 960-9009

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x 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). x 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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ 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 November 2, 2012
Common Stock, no par value	21,298,820 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 September 30, 2012 and December 31, 2011

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Cash and Cash Equivalents	$ 1,174,271	$ 5,715,246
Investments Available for Sale	10,078,094	11,810,775
Accounts Receivable, net of a reserve of $23,000 in 2012 and $29,000 in 2011	4,318,733	4,222,816
Inventory	2,672,067	2,504,127
Other Current Assets	1,761,200	1,643,565
Total Current Assets	20,004,365	25,896,529
Property and Equipment, net	1,940,555	2,290,476
Intangible Assets	708,500	833,773
Goodwill	920,745	920,745
Other Non-current Assets	646,849	1,998,076
Total Assets	$ 24,221,014	$ 31,939,599
LIABILITIES AND SHAREHOLDERS EQUITY		
Capitalized Lease Obligations	$ 3,078	$ 6,470
Accounts Payable	8,090,681	5,364,537
Accrued Liabilities	14,685,032	8,225,015
Customer Deposits	270,642	96,329
Total Current Liabilities	23,049,434	13,692,351
Capitalized Lease Obligations		2,280
Shareholders Equity:		
Common Shares, no par value, 21,298,820 and 18,710,002 shares issued and outstanding	90,631,586	67,407,847
Common Share Purchase Warrants, 2,346,440 and 2,607,440 warrants issued and outstanding	6,900,806	7,103,975
Accumulated Deficit	(96,333,769)	(55,985,742)
Accumulated Other Comprehensive Loss	(27,043)	(281,112)
Total Shareholders Equity	1,171,580	18,244,968
Total Liabilities And Shareholders Equity	$ 24,221,014	$ 31,939,599

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, 2012 and September 30, 2011

(Unaudited)

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Sales	**$ 12,689,339**	**$ 11,976,329**	**$ 36,842,546**	**$ 37,069,423**
Cost of Sales	11,043,412	10,600,144	31,851,344	32,970,644
Gross Profit	**1,645,927**	**1,376,185**	**4,991,202**	**4,098,779**
Selling, General and Administrative	3,325,411	2,271,350	9,048,474	6,890,500
Research and Product Development	16,238,450	4,221,118	36,520,393	9,937,476
Operating Income (Loss)	**(17,917,934)**	**(5,116,283)**	**(40,577,665)**	**(12,729,197)**
Interest and Investment Income, net	42,296	77,107	230,484	240,617
Interest Expense	137	408	846	1,513
Income (Loss) Before Income Taxes	(17,875,775)	(5,039,584)	(40,348,027)	(12,490,093)
Income Tax Expense		1,958		1,958
Net Income (Loss)	**$ (17,875,775)**	**$ (5,041,542)**	**$ (40,348,027)**	**$ (12,492,051)**
Basic Earnings (Loss) per Share	**($ .86)**	**($ .28)**	**($ 1.99)**	**($ .71)**
Diluted Earnings (Loss) per Share	**($ .86)**	**($ .28)**	**($ 1.99)**	**($ .71)**

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, 2012 and September 30, 2011

(Unaudited)

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Net Income (Loss)	**$ (17,875,775)**	**$ (5,041,542)**	**$ (40,348,027)**	**$ (12,492,051)**
Unrealized Gain (Loss) on Available-for-Sale Investments	148,907	(190,310)	254,069	(149,042)
Comprehensive Income (Loss)	**$ (17,726,868)**	**$ (5,531,852)**	**$ (40,093,958)**	**$ (12,641,093)**

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 Nine Months Ended September 30, 2012

(Unaudited)

	COMMON SHARES		PURCHASE WARRANTS				
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER S EQUITY
Balance as of December 31, 2011	18,710,002	$ 67,407,847	2,607,440	$ 7,103,975	$ (55,985,742)	$ (281,112)	$ 18,244,968
Net Loss					(40,348,027)		(40,348,027)
Unrealized Gain (Loss) on Available-for-Sale Investments						254,069	254,069
Issuance of Common Shares	2,128,601	16,193,845					16,193,845
Purchase Warrant Expense				111,683			111,683
Exercise of Purchase Warrants	260,217	2,104,852	(261,000)	(314,852)			1,790,000
Stock Option Based Expense		3,043,682					3,043,682
Restricted Stock Amortization		683,542					683,542
Shares Issued in Exchange for Services	200,000	1,854,000					1,854,000
Unearned Share Compensation		(656,182)					(656,182)
Balance as of September 30, 2012	21,298,820	$ 90,631,586	2,346,440	$ 6,900,806	$ (96,333,769)	$ (27,043)	$ 1,171,580

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 nine months ended September 30, 2012 and September 30, 2011

(Unaudited)

	2012	2011
Cash Flows From Operating Activities:		
Net (Loss)	**$ (40,348,027)**	**$ (12,492,051)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	828,676	928,208
Share Based Compensation Non-employee	1,309,502	105,274
Share Based Compensation- Employees	3,727,224	3,024,647
Loss (Gain) on Disposal of Assets	26,340	27,572
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	(95,917)	248,893
Decrease (Increase) in Inventory	(167,940)	702,193
(Increase) Decrease in Other Assets	1,233,592	(2,457,970)
Increase (Decrease) in Accounts Payable	2,726,145	(50,272)
Increase in Other Liabilities	7,184,330	2,714,301
Changes in Assets and Liabilities	10,880,210	1,157,145
Cash Provided By (Used) In Operating Activities	**(23,576,075)**	**(7,249,205)**
Cash Flows From Investing Activities:		
Purchase of Equipment	(381,400)	(344,250)
Proceeds on Sale of Assets	1,578	
Purchase of Intangible Assets	(550,000)	(144,023)
Sale of Investments Available for Sale	3,986,750	
(Purchase) of Investments Available for Sale	(2,000,000)	(24,757)
Cash (Used) In Investing Activities	**1,056,928**	**(513,030)**
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and exercise of Purchase Warrants	17,983,844	3,935,926
Payments on Notes Payable and Capital Lease Obligations	(5,672)	(15,225)
Cash Provided By Financing Activities	**17,978,172**	**3,920,701**
Increase (Decrease) In Cash	**(4,540,975)**	(3,841,534)
Cash At Beginning Of Period	5,715,246	12,263,449
Cash At End Of Period	**$ 1,174,271**	**$ 8,421,915**

Supplemental Cash Flow disclosure

	2012	2011
Interest Paid	$ 846	$ 1,513

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) 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 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. We also have 510(k) approval to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

We have obtained global licenses for certain dialysis related drugs which we are developing and for which we 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, 2011 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 nine month periods ended September 30, 2012 are not necessarily indicative of the results to be expected for the year ending December 31, 2012. You should read our unaudited interim financial statements together with the financial statements and related footnotes for the year ended December 31, 2011 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. Our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 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.

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Cash and Cash Equivalents

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

Investments Available for Sale

Investments Available for Sale are short-term investments, consisting principally of 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). 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. There were realized losses of $29,202 during the three and nine months ended September 30, 2012.

We hold investments in available for sale securities in short term bond funds. These funds generally hold high credit quality short term debt instruments. These debt instruments are subject to changes in fair market value due to changes in interest rates. The market value of these investments was $10,078,094 and $11,813,813 as of September 30, 2012 and 2011, respectively. Each of the bond funds is in an unrealized loss position and has been for more than 12 months. Total unrealized losses were $27,043 and $362,665 at September 30, 2012 and 2011, respectively. The Company evaluated the near term interest rate environment, 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, 2012.

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 iron supplemented dialysate drug candidate, Soluble Ferric Pyrophosphate, or SFP, aggregating approximately $36.5 million and $9.9 million for the nine months ended September 30, 2012 and 2011, 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 September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Basic Weighted Average Shares Outstanding	20,726,967	17,862,573	20,244,518	17,582,833
Effect of Dilutive Securities				
Diluted Weighted Average Shares Outstanding	20,726,967	17,862,573	20,244,518	17,582,833

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3. Inventory

Components of inventory as of September 30, 2012 and December 31, 2011 are as follows:

	September 30, 2012	December 31, 2011
Raw Materials	$ 1,072,396	$ 819,523
Work in Process	131,385	171,842
Finished Goods	1,468,286	1,512,762
Total	$ 2,672,067	$ 2,504,127

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 September 30, 2012, the amount included in other current assets was $1.2 million.

5. Other Non-Current Assets

Other non-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 September 30, 2012, the amount included in other non-current assets was $0.2 million.

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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 we, our and us are references to Rockwell Medical, Inc. and its subsidiaries.

Forward-Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, 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, 2011 and our Form 10-Q for the quarter ended March 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.

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

We have incurred net losses in each of the last several years and we may not achieve or sustain profitability.

We may require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We depend on government funding of healthcare.

Health care reform could adversely affect our business.

Orders from our international distributors may not result in recurring revenue.

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 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.

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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 operates in a single business segment as a specialty pharmaceutical company offering innovative products targeting hemodialysis chronic kidney disease. As an established manufacturer delivering high-quality hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad, we provide products used to maintain human life, remove toxins and replace critical nutrients in the dialysis patient s bloodstream.

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 drug candidates while also expanding our dialysis products business, which had sales of $36.8 million in the first nine months of 2012. Our dialysis products business is cash flow positive excluding research and development expenses, and provides an in-place sales and distribution infrastructure and conduit with established business relationships to sell our drug products into the dialysis market.

Our product development costs were primarily related to SFP, our lead drug candidate. We believe our SFP product has unique and substantive benefits compared to current treatment options and has the potential to compete in the iron delivery therapy market. Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We expect to incur substantial costs relating to product testing and development over the next several years and expect to incur losses from operations until SFP is approved and marketed. In addition to our SFP testing and approval process, we plan to spend additional amounts on drug development of extensions of SFP technology as well as on other opportunities.

In 2011, we acquired the right to manufacture Calcitriol, a generic vitamin D analogue, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We are in the process of obtaining FDA approval to make a change in manufacturing locations and expect to begin marketing Calcitriol in the first half of 2013.

As of September 30, 2012 we had $11.3 million in cash and investments.

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Results of Operations for the Three and Nine Months Ended September 30, 2012 and September 30, 2011

Sales

Sales in the third quarter of 2012 were $12.7 million compared to $12.0 million in the third quarter of 2011. Sales increased $0.7 million or 6.0% due to increased domestic sales of $0.7 million compared to the third quarter of 2011. Domestic sales were $0.7 million higher than the third quarter last year primarily due to improvements in product mix and increased volumes.

Sales in the first nine months of 2012 were $36.8 million compared to $37.1 million in the first nine months of 2011. The $0.3 million decrease in sales was attributable to lower sales to a single international distributor totaling $1.4 million in the first nine months of 2011. Other international sales increased 18% or $0.6 million while other domestic sales increased $0.5 million. Domestic sales were $0.5 million higher than the first nine months of last year primarily due to continuing changes in product and customer mix. Over the last year, many customers have converted to our dry acid concentrate product line, which lowers providers cost per treatment and reduces our sales, but improves our gross profit margins by reducing shipping costs.

Gross Profit

Gross profit margins in the third quarter of 2012 were 13.0% compared to 11.5% in the third quarter of 2011, an increase of 1.5 percentage points. Gross profit dollars in the third quarter were $1.6 million an increase of $0.3 million or 19.6% compared to the third quarter last year. This increase in gross profit was due to improving product mix, increased sales of our dry acid concentrate products, reduced operating expenses and other new business compared to the third quarter of 2011.

For the nine months ended September 30, 2012, gross profit was $5.0 million compared to $4.1 million in the first nine months of 2011. Gross profit margins were 13.5% compared to 11.1% in the first nine months of 2011. Gross profit increased by $0.9 million primarily due to an improving product and customer mix as well as lower operating costs. We realized lower operating costs due to lower personnel and insurance costs.

Selling, General and Administrative Expense

Selling, general and administrative expense during the third quarter of 2012 was $3.3 million, an increase of $1.1 million or 46.4% compared to the third quarter of 2011. The increase was due to non-cash equity compensation which was $1.1 million greater than the third quarter of 2011.

Selling, general and administrative expense for the first nine months of 2012 was $9.0 million compared to $6.9 million in the first nine months of 2011. The $2.1 million increase was largely due to non-cash equity compensation which was $1.9 million greater than for the first nine months of 2011.

Research and Development

Research and development costs were $16.2 million and $4.2 million in the third quarter of 2012 and 2011, respectively. Research and development costs for the first nine months of 2012 were $36.5 million compared to $9.9 million for the first nine months of 2011. Spending in both years was primarily for clinical testing and development of SFP with the increase in 2012 due to the increased testing associated with the SFP Phase III clinical program.

Interest and Investment Income, Net

Our net interest and investment income was $42,000 in the third quarter of 2012 compared to net interest and investment income of $77,000 in the third quarter of 2011. Our net interest and investment income for the first nine months of 2012 was $230,000 compared to $239,000 in the first nine months of 2011. The decrease in net interest and investment income in the first nine months of 2012 was primarily the result of slightly lower yields on our investments.

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Liquidity and Capital Resources

Our strategy is centered on obtaining regulatory approval to market SFP and developing other high potential drug candidates, while also expanding our dialysis products business. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions and other product development opportunities. These initiatives will require the expenditure of substantial cash resources. We expect our cash needs for research and development spending to be significant as we execute our clinical development program for SFP and other drug and business development initiatives.

Our cash resources include cash generated from our business operations and from proceeds of equity offerings. As of September 30, 2012, we had $11.3 million in cash and investments. In February 2012, we completed a common stock offering realizing $17.5 million in gross proceeds and approximately $16.2 million in net proceeds. We also realized approximately $1.8 million in proceeds from the exercise of warrants during the first nine months of 2012. We expect to generate additional cash from our business operations and from other sources, which may include the exercise of outstanding warrants, the possible out-licensing of SFP outside the United States, out-licensing of certain SFP uses outside the dialysis market and other capital raising alternatives as needed. We expect to generate positive cash flow from operations over the next year, excluding the effect of our research and development expenses, assuming relative stability in the markets for fuel and our key raw materials and relatively stable revenues.

During the first nine months of 2012, we used $23.6 million in cash in our operations. Our primary use of cash has been for development and testing expenditures related to SFP and those expenditures are expected to be substantial throughout 2013. We had capital expenditures of $0.4 million. We, also made the final cash payment of $550,000 in the third quarter of 2012 in connection with our acquisition of the right to market Calcitriol and funding will be necessary to obtain FDA approval for our contract manufacturer to manufacture the product for us. However, these expenditures relating to Calcitriol are not expected to have a material effect on our liquidity or financial position.

As of September 30, 2012, our current liabilities exceeded our current assets by $3.0 million. In order to meet our obligations as they are due and to complete our planned development activities, we expect to raise additional cash resources. We expect to obtain additional cash resources from a variety of potential sources including exercise of warrants, out-licensing arrangements, equity financing or debt financing arrangements. In addition, if we use more cash than anticipated for SFP development, if we are required to do more testing than expected, if the assumptions underlying our cash flow projections prove to be incorrect, or if we pursue opportunities to expand our business, we may need to obtain additional capital for those purposes as well. If we are not able to raise sufficient cash when needed, we may be required to delay, limit, reduce or suspend our product development and commercialization efforts for SFP.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our current exposure to interest rate risk is limited to changes in interest rates on short term investments of cash. As of September 30, 2012, we had $10.1 million invested in available for sale short term bond funds which typically yield higher returns than interest realized in money funds.

While these funds hold bonds of short term 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 or may not exceed the interest and dividends earned

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from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that an immediate 100 basis point increase or decrease in interest rates would 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

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

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

Remediation of Material Weakness

As discussed in the Company s Annual Report on Form-10-K for the year ended December 31, 2011, there was a material weakness in internal control over financial reporting identified by management relating to the timely recognition and recording of research and development expenses related to the Company s clinical trials. As a result of this material weakness at December 31, 2011, there were misstatements in accounts payable, accrued liabilities and research and development expense in the preliminary consolidated financial statements that were corrected prior to issuance of the Company s consolidated financial statements. The material weakness did not result in a material misstatement of any previously filed financial statements but posed the risk that it could result in a material misstatement that may not be prevented or detected on a timely basis.

During the first quarter of 2012, management addressed this control deficiency by assigning additional personnel resources to this activity to ensure accurate and timely recording of research and development expenditures by each vendor. Management changed its control procedures to ensure that all liabilities were identified and accurately calculated and that those calculations were properly reviewed. As a result of these changes and subsequent review and testing by management, management has concluded that the previously reported material weakness no longer existed as of March 31, 2012.

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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 5. Other Information

In June 2011, the Financial Accounting Standards Board (FASB) revised guidance on the presentation of comprehensive income in financial statements. Entities are required to report components of comprehensive income in either a continuous statement of comprehensive income or in two separate but consecutive statements. We adopted this standard as of January 1, 2012 and present net income and comprehensive income in two separate but consecutive statements. The table below reflects the retrospective application of this guidance for each of the three years ended December 31. The retrospective application did not have a material impact on our results of operations, cash flows or financial condition.

Components of Comprehensive Income

	Year ended December 31,		
	2011	**2010**	**2009**
Net Income	$ (21,444,557)	$ (2,683,399)	$ (5,501,238)
Other Comprehensive Income			
Unrealized Gain (Loss) on Available-for-Sale Investments	(67,489)	(213,623)	
Total Other Comprehensive Income or (Loss), net of tax	(67,489)	(213,623)	
Total Comprehensive Income or (Loss)	$ (21,512,046)	$ (2,897,022)	$ (5,501,238)

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, 2012

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

Date: November 9, 2012

/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
10.47	Form of Amendment to 2010 Restricted Stock Award Agreement as of August 3, 2012 with Robert L. Chioini, Thomas E. Klema, and Dr. Ajay Gupta (Company s Current Report on Form 8-K filed August 3, 2012)
10.48	Lease Renewal Agreement dated August 14, 2012, by and between Rockwell Medical, Inc. and International-Wixom, LLC (Company s Current Report on Form 8-K filed August 15, 2012)
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

* XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.