ROCKWELL MEDICAL, INC.
Form 424B5
May 15, 2013

Table of Contents

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-181003

PROSPECTUS SUPPLEMENT TO PROSPECTUS DATED JUNE 13, 2012

Rockwell Medical, Inc.

11,475,410 Shares
Common Stock

$3.05 per share

We are offering 11,475,410 shares of our common stock, without par value, pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed on The NASDAQ Global Market and traded under the symbol RMTI. On May 13, 2013, the last reported sale price of our common stock on The NASDAQ Global Market was $3.74 per share.

Investing in our securities involves risks. See Risk Factors beginning on page S-7.

	Per Share	Total
Public offering price	$ 3.05	$ 35,000,000
Underwriting discounts and commissions (1)	$ 0.17	$ 1,925,000
Proceeds, before expenses, to us	$ 2.88	$ 33,075,000

(1) See Underwriting for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase an additional 1,721,311 shares solely to cover over-allotments. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $2,213,750 and the total proceeds to us, before expenses, will be $38,036,250.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

We expect to deliver the securities offered hereby on or about May 20, 2013.

Sole Book-Running Manager

Chardan Capital Markets, LLC

Lead Manager
Summer Street Research Partners

Co-Manager
C&Co/PrinceRidge

The date of this prospectus supplement is May 15, 2013.

Table of Contents

TABLE OF CONTENTS

Prospectus Supplement

Prospectus

Table of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is part of a registration statement that we filed with the Securities and Exchange Commission (the SEC), using a shelf registration process. This document has two parts. The first part is the prospectus supplement, which describes the specific terms of the offering. The second part is the accompanying prospectus, which describes more general information, some of which may not apply to the offering. You should read both this prospectus supplement and the accompanying prospectus, together with the additional information described under the heading Where You Can Get More Information.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, in the accompanying prospectus, in any other prospectus supplement and in any free writing prospectus filed by us with the SEC. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate only as of each of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates. To the extent that any statement that we make in this prospectus supplement differs from or is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein.

Unless the context otherwise requires, references in this prospectus supplement to Rockwell, we, us, and our refer to Rockwell Medical, Inc., and include its consolidated subsidiaries where the context so requires.

This prospectus supplement, the accompanying prospectus, and the information incorporated herein and therein by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

WHERE YOU CAN GET MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can inspect or copy all or any part of these materials, at prescribed rates, at the SEC s Public Reference Room at 100 F Street, N.E., Washington D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site at *www.sec.gov* that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC, including Rockwell.

The SEC allows Rockwell to incorporate by reference the information it files with the SEC. This permits us to disclose important information to you by referencing these filed documents. Any information referenced in this way is considered part of this prospectus supplement, and any information filed with the SEC subsequent to this prospectus supplement will automatically update and supersede this information. Rockwell incorporates by reference the documents listed below which have been filed with the SEC:

- Annual Report on Form 10-K for the fiscal year ended December 31, 2012 (including information from the Definitive Proxy Statement filed in connection with the Annual Meeting of Stockholders held on April 30, 2013, as filed with the SEC on March 29, 2013 incorporated therein by reference).

- Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013.

- Current Reports on Form 8-K filed January 29, 2013, February 5, 2013, March 20, 2013, March 26, 2013, May 2, 2013, May 9, 2013, May 14, 2013 and May 15, 2013.

- The description of our common shares included in our prospectus, dated July 24, 1997, included in our registration statement on Form SB-2 filed with the SEC on July 24, 1997, under the caption Description of Securities on pages 34 through 38 of the prospectus and incorporated by reference into our registration statement on Form 8-A filed with the SEC on January 23, 1998, including any amendment or reports filed for the purpose of updating such description.

Table of Contents

In addition, all documents filed by us under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 after the date of this prospectus supplement but before the termination of this offering are deemed to be incorporated by reference into this prospectus supplement and will constitute a part of this prospectus supplement from the date of filing of those documents.

Any statement contained in a document incorporated by reference or deemed to be incorporated by reference in this prospectus supplement shall be deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement or in any other subsequently filed document that is incorporated by reference modifies or supersedes such statement. Any statement that is so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

Rockwell will provide without charge, upon written or oral request, a copy of any or all of the documents which are incorporated by reference in this prospectus supplement, including any exhibits which are specifically incorporated by reference into such documents. Requests should be directed to Thomas E. Klema, Secretary, at our principal executive offices, located at 30142 Wixom Road, Wixom, Michigan 48393 (telephone number: (248) 960-9009).

INDUSTRY AND MARKET DATA

Industry and market data used throughout this prospectus supplement were obtained through company research, surveys and studies conducted by third parties, and industry and general publications. We have not independently verified any of the data from third party sources nor have we ascertained any underlying economic assumptions relied upon therein. While we are not aware of any misstatements regarding the industry data presented herein, estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading Risk Factors.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus supplement and the accompanying prospectus. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, predict, forecast, projected, 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 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 prospectus supplement 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 prospectus supplement, including under Risk Factors in this prospectus supplement, and from time to time in our reports filed with the Securities

and Exchange Commission.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows 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 law.

Table of Contents

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights certain information about us, this offering and selected information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus supplement and the accompanying prospectus, including the information incorporated by reference, carefully before making an investment decision. You should pay special attention to the information referred to under the heading Risk Factors in this prospectus supplement beginning on page S-7, and the risk factors and the financial statements and other information contained in our filings with the SEC which have been incorporated by reference in this prospectus supplement, when making an investment decision.

Our Company

We are a fully-integrated biopharmaceutical company targeting end-stage renal disease, or ESRD, and chronic kidney disease, or CKD, with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis (also referred to as HD or dialysis).

Our lead investigational drug is in late stage clinical development for iron therapy treatment in CKD-HD patients. It is called Soluble Ferric Pyrophosphate, or SFP. SFP delivers iron to the bone marrow in a non-invasive, physiologic manner to hemodialysis patients via dialysate during their regular dialysis treatment. The majority of ESRD patients receive iron on a routine basis. We intend to complete clinical trials and seek U.S. Food and Drug Administration, or FDA, market approval of SFP. We also plan to seek foreign market approval for this product and/or to license the technology to a company who will seek market approval in the licensed markets. We believe this product will substantially improve iron therapy and if approved will compete in the global iron therapy market treating hemodialysis patients. Currently, two Phase 3 clinical trials called CRUISE-1 and CRUISE-2 are being conducted for FDA submission for market approval. Recently, another SFP clinical study called the PRIME study was completed. The PRIME study was designed to show a reduction in the need for erythropoiesis stimulating agents, or ESA, in CKD-HD patients who receive SFP during dialysis. The PRIME study was successful and demonstrated that with the use of SFP there is a significant reduction in the need for ESA. ESA is the most expensive drug used in dialysis. Based on reports from manufacturers of intravenous, or IV, iron products and industry estimates, the market size in the United States for IV iron therapy for ESRD patients is approximately $600 million per year. We estimate the global market for IV iron therapy is in excess of $1 billion per year. We cannot, however, give any assurance that this product will be approved by the FDA or, if approved, that it will be successfully marketed.

We are also preparing to launch an FDA-approved generic drug called Calcitriol. Calcitriol is active vitamin D injection and indicated for the treatment of secondary hyperparathyroidism in dialysis patients. The majority of ESRD patients receive vitamin D on a routine basis. We are in the process of obtaining regulatory approval for a change in manufacturing location and anticipate obtaining approval to begin marketing Calcitriol in 2013. Based on manufacturers reports and industry estimates, we believe the market size in the United States for vitamin D therapy for ESRD patients is greater than $350 million per year.

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

Our Business Strategy

We intend to become a leading biopharmaceutical company focused primarily on renal indications, while leveraging our operating business infrastructure to market and sell approved drugs commercially. The following are the key elements of our business strategy:

Obtain Regulatory Approval of our Lead Drug Candidate SFP for the Treatment of Iron Deficiency in Hemodialysis Patients.

We are conducting Phase 3 clinical trials for our drug SFP and intend to obtain FDA regulatory approval to market SFP commercially. The market potential is estimated to be approximately $600 million per year. We intend to market SFP to our existing customer base that we service via our concentrate operating business, which currently serves approximately 27% of the U.S. concentrate dialysis market.

Table of Contents

Launch Calcitriol (Active Vitamin D) Injection for the Treatment of Secondary Hyperparathyroidism in Dialysis Patients.

We intend to obtain manufacturing approval from the FDA in 2013 for our FDA approved generic drug Calcitriol and thereafter to immediately begin marketing Calcitriol. The market potential is estimated to be approximately $350 million per year. We intend to market Calcitriol to our existing customer base that we service via our concentrate operating business.

Obtain License/Marketing Partners to Leverage Our Products Globally for Commercialization.

We seek commercial collaborations to license and develop our products and to realize financial benefits on an international basis. We intend to leverage the development, regulatory and marketing presence and expertise of potential business partners to accelerate the development of our products throughout the world.

Continue Development of our Commercial Concentrate Business and Market Position and to Leverage that Infrastructure to Sell our Renal Drugs Once Approved by the FDA.

We intend to continue to increase our market presence in our concentrate/dialysate products business in the U.S. and internationally by continuing to develop and offer innovative products that improve patient outcomes and lower provider costs. We intend to use this operating infrastructure to sell our renal drugs into the same market, with minimal additional expense.

Leverage Our SFP Technology to Develop Other Drugs for Other Indications in Iron Therapy Management.

We intend to pursue clinical development and/or business partnerships to leverage SFP iron delivery technology to address other indications for treating anemia in the U.S. and globally.

Identify Novel Drugs to Address Unmet Needs and Market Opportunities.

We will pursue opportunities to secure other drugs inside and outside the renal market that we believe hold great potential to address unmet needs, and that we believe will enable us to expand our reach further into drug development.

Acquire Rights to and Commercially Implement Complementary Drug Candidates and Technologies.

We intend to continue to selectively pursue and acquire rights to drug products in various stages of development, or FDA approved drugs, with the intention to commercialize and/or realize their business potential.

The Hemodialysis Market

The great majority of hemodialysis patients receive dialysis treatment three times per week, or 156 times per year. Most have their dialysis treatment performed at a free-standing clinic; these are called chronic patients. Some have their treatment performed at hospitals; these are called acute patients. A small percentage receive their treatment at home; these are called home patients. In each setting, a dialysis machine accurately dilutes concentrated solution, such as our concentrate products, with purified water. The resulting solution is called dialysate. Dialysate is pumped through an artificial kidney (or dialyzer) while the patient s blood is pumped through a semi-permeable membrane inside the dialyzer, in the opposite direction the dialysate is flowing. The dialysate infuses calcium and bicarbonate into the patient s blood while removing water and waste. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and acetic acid or citric acid. The patient s physician chooses the proper concentrations required for each patient based on each particular patient s needs.

In addition to using reusable concentrate products, a dialysis provider also uses other ancillary products such as blood tubing, fistula needles, specialized component kits, dressings, cleaning agents, filtration salts and other supplies, many of which we sell.

Table of Contents

Dialysis Industry Trends

Hemodialysis is the primary treatment modality employed in the United States with over 90% of all dialysis patients receiving hemodialysis. We do not compete in the peritoneal or home dialysis segments. Hemodialysis treatments are generally performed in independent clinics or hospitals with the majority of dialysis services performed by national and regional for profit dialysis chains. Based on data published by the U.S. Renal Data Systems, or USRDS, we estimate that there are approximately 5,800 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 65% of the domestic hemodialysis market. According to the most recent industry statistics published by USRDS, there are approximately 400,000 dialysis patients in the United States. The U.S. patient population has grown steadily over the past several decades, and is expected to grow approximately 4-6% over the next several years.

Based on industry reports, the global ESRD population receiving some form of dialysis treatment is estimated to be over 2.3 million patients. Incidence rates vary by country, growing approximately 6% in more mature dialysis populations and at a higher rate in developing countries. Today, the three largest dialysis markets are the United States, the European Union and Japan, which together represent approximately half of the total global treatments based on industry estimates. The Asia-Pacific market is projected to experience rapid growth in the incidence of kidney disease over the decade ahead.

Our results of operations for the quarters ended March 31, 2013 and 2012 and the years ended December 31, 2012 and 2011, and our current assets and total assets and total current liabilities as of March 31, 2013, December 31, 2012 and 2011, are as follows:

	Three Months Ended March 31,		Years Ended December 31,	
	2013	2012	2012	2011
(in thousands)	(unaudited)	(unaudited)	(audited)	(audited)
Sales	$ 12,336	$ 12,028	$ 49,842	$ 48,966
Research and Product Development Expense	$ 12,755	$ 9,406	$ 48,272	$ 17,805
Net Income (Loss)	$ (15,380)	$ (10,567)	$ (54,022)	$ (21,455)
Cash Provided By (Used) In Operating Activities	$ (11,308)	$ (8,302)	$ (30,747)	$ (10,783)

	As of March 31, 2013	As of December 31, 2012	2011
	(unaudited)	(audited)	(audited)
Current Assets	$ 14,188	$ 13,149	$ 25,897
Total Assets	$ 17,968	$ 17,025	$ 31,940
Total Current Liabilities	$ 28,474	$ 26,987	$ 13,692

We commenced our Phase 3 clinical development program for SFP, our lead drug product, in 2011 and our research and development costs and net loss have increased substantially in 2013 and 2012 over 2011 as a result. We expect our cash needs for research and development spending to be significant over the next two years as we execute our clinical development program for SFP and that we will continue to incur losses for the duration of the clinical program as a result of these higher costs.

Our total assets increased at March 31, 2013 as compared to December 31, 2012 due to cash received of $12.1 million in net proceeds from an offering of common stock completed in March 2013 which is described further below and positive cash flow generated from our operations, partially offset by cash used to fund research and development spending. Our total assets decreased at December 31, 2012 compared to December 31, 2011 due to the cash used in operations to fund the increased research and development spending, partially offset by the receipt of $16.2 million in net proceeds from an offering of common stock completed in February 2012 and positive cash flow generated from our operations excluding research and development spending.

As of March 31, 2013 and December 31, 2012 we had $5.8 million and $4.7 million in cash and investments, respectively.

Our current liabilities exceeded our current assets by $14.3 million and $13.8 million as of March 31, 2013 and December 31, 2012, respectively.

Table of Contents

On March 26, 2013, we announced the closing of the sale of 4,300,000 common shares at $3.00 per share in a registered direct offering for an aggregate offering amount of approximately $12.9 million. The net proceeds from the offering, after commissions and other estimated offering expenses, were approximately $12.1 million. We plan to use the net proceeds from the offering for general corporate purposes which may include research and development expenses, acquisition of intellectual property relating to complementary drug therapies, funding of clinical trials, and general administrative expenses.

Please refer to our most recent annual report on Form 10-K and our most recent quarterly report on Form 10-Q for further details regarding our financial position.

Going Concern

Due to our recurring losses and need for additional working capital, there is substantial doubt about our ability to continue as a going concern. Management is taking steps to improve our financial condition. The financial statements incorporated by reference herein and the accompanying footnotes have been prepared on a going concern basis, which contemplates the realization of assets and the discharge of liabilities in the normal course of business for the foreseeable future, and do not include any adjustment to reflect the possible future effects of our inability to raise the additional capital needed to continue as a going concern.

Corporate Information

We were incorporated in the State of Michigan in 1996. Our principal executive offices are located at 30142 Wixom Road, Wixom, Michigan 48393. Our telephone number is (248) 960-9009. Our website address is www.rockwellmed.com. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus supplement or the accompanying prospectus and should not be considered part of this prospectus supplement or the accompanying prospectus.

The Offering

Common Stock Offered	11,475,410 shares
Common Stock Outstanding After This Offering	37,534,548 shares (based on 26,059,138 common shares outstanding as of May 13, 2013 and assuming no exercise of outstanding options or warrants since that date)
Use of Proceeds	We expect to use the net proceeds from this offering to fund SFP clinical trials and for other general corporate purposes, which may include research and development expenses, acquisition of intellectual property relating to complementary drug therapies, and general and administrative expenses.
Risk Factors	See Risk Factors and other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Listing	Our common stock is listed on The NASDAQ Global Market under the symbol RMTI. The last reported price of our common stock on May 13, 2013 was $3.74 per share.

Unless otherwise stated, all information contained in this prospectus supplement assumes no exercise of the underwriters option to purchase of up to 1,721,311 additional shares.

Table of Contents

RISK FACTORS

In considering whether to purchase the securities, you should carefully consider all the information we have included or incorporated by reference in this prospectus supplement and the accompanying prospectus. In particular, you should carefully consider the following risk factors, as well as the factors listed in Cautionary Statement Regarding Forward-Looking Statements. You should carefully review all the information in this prospectus supplement and the accompanying prospectus about these securities.

RISKS RELATED TO OUR BUSINESS

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.

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. One customer, Davita Healthcare Partners, Inc., accounted for 49% of our sales in 2012 and has accounted for 42% to 51% of our revenues during each of the last five years. If we were to lose this customer or our relationship with any of our other major national and regional dialysis chain customers, it would have a substantial negative impact on our cash flow and operating results and could have a detrimental impact on our ability to continue our operations in their current form or to continue to execute our business strategy. If we lost a substantial portion of our business, we would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

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

There is intense competition in the hemodialysis product market and our primary competitor is a large diversified company which has substantially greater financial, technical, manufacturing, marketing, research and development and management resources than we do. We may not be able to successfully compete with them or other companies. Our primary competitor has historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell and as we do not manufacture or sell the same breadth of products as our primary competitor, we may be at a disadvantage in competing against their marketing strategies. Furthermore, our primary competitor is vertically integrated and is the largest provider of dialysis services in the United States with approximately one-third of all U.S. patients treated by this company through its clinics. This competitor has routinely acquired smaller clinic chain operations and may acquire some of our current customers in the future.

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

We are seeking FDA approval for SFP, a drug used in the treatment of anemia in hemodialysis patients. Obtaining FDA approval for any drug is expensive and can take a long time. We may not be successful in obtaining FDA approval for SFP. The FDA may change, expand or alter its requirements for testing, which may increase the scope, duration and cost of our clinical development plan. Clinical trials are expensive and time consuming to complete, and we may not have sufficient funds to complete the clinical trials to obtain marketing approval.