

ROCKWELL MEDICAL, INC.

Form 424B3

November 28, 2012

Table of Contents

PROSPECTUS SUPPLEMENT NO. 4

Filed Pursuant to Rule 424(b)(3)

To Prospectus dated January 29, 2008

Registration No. 333-148601

1,159,169 SHARES OF COMMON STOCK

This Prospectus Supplement No. 4 supplements the prospectus dated January 29, 2008 relating to the resale by the Selling Shareholders identified in this prospectus supplement and the accompanying prospectus, or their pledgees, donees, transferees or other successors-in-interest, of up to 1,159,169 shares of our common stock, including shares of common stock issuable upon the exercise of warrants but excluding 2,158,337 shares previously sold by the Selling Shareholders. The Selling Shareholders, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. We will not receive any proceeds from the sale of shares of our common stock by Selling Shareholders. Upon any exercise for cash of the warrants, the warrant holders will pay us the exercise price specified in the warrants for the underlying shares. We have agreed to pay certain expenses in connection with the registration of the shares and to indemnify the Selling Shareholders against certain liabilities.

This prospectus supplement is being filed to update various information that has changed since the date of the accompanying prospectus and the prior prospectus supplement. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the accompanying prospectus. Unless otherwise specified or the context otherwise requires, references in this prospectus supplement to the prospectus mean the accompanying prospectus as updated and modified by this prospectus supplement.

Our common stock is listed on the NASDAQ Global Market and traded under the symbol RMTI. On November 23, 2012, the closing sale price of our common stock on NASDAQ was \$7.19 per share. You are urged to obtain current market quotations for the common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-5.

This prospectus supplement should be read in conjunction with the accompanying prospectus and this prospectus supplement is qualified in its entirety by reference to the accompanying prospectus except to the extent that the information contained herein modifies or supersedes the information contained in the accompanying prospectus. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference as of the date of this prospectus supplement, on the other hand, the information in this prospectus supplement shall control. Capitalized terms used in this prospectus supplement and not otherwise defined herein shall have the meanings specified in the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 28, 2012.

Table of Contents

TABLE OF CONTENTS

Prospectus Supplement No. 4

| | Page |
|--|-------------|
| <u>Where You Can Get More Information</u> | i |
| <u>Documents Incorporated by Reference</u> | ii |
| <u>Prospectus Supplement Summary</u> | S-1 |
| <u>Cautionary Statement Regarding Forward-Looking Statements</u> | S-4 |
| <u>Risk Factors</u> | S-5 |
| <u>Selling Shareholders</u> | S-12 |
| <u>Description of Common Stock</u> | S-15 |
| <u>Experts</u> | S-16 |
| Prospectus | |

| | Page |
|--|-------------|
| <u>Where You Can Get More Information</u> | 2 |
| <u>Documents Incorporated by Reference</u> | 2 |
| <u>Prospectus Summary</u> | 4 |
| <u>The Offering</u> | 5 |
| <u>Cautionary Statement Regarding Forward-Looking Statements</u> | 5 |
| <u>Risk Factors</u> | 6 |
| <u>Use of Proceeds</u> | 9 |
| <u>Selling Shareholders</u> | 10 |
| <u>Plan of Distribution</u> | 12 |
| <u>Legal Matters</u> | 15 |
| <u>Experts</u> | 15 |

Rockwell Medical, Inc.'s principal executive offices are located at 30142 Wixom Road, Wixom, Michigan 48393, our telephone number at that address is (248) 960-9009 and our Internet address is www.rockwellmed.com. The information on our Internet website is not incorporated by reference in this prospectus supplement, and you should not consider it to be a part of this document. Our website address is included as an inactive textual reference only. Unless the context otherwise requires, references in this prospectus supplement to Rockwell, we, us, and our refer to Rockwell Medical, Inc. (formerly known as Rockwell Medical Technologies, Inc.).

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. The Selling Shareholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus supplement is accurate only as of the date of this prospectus supplement, regardless of the time of delivery of this prospectus or of any sale of common stock.

WHERE YOU CAN GET MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the SEC). You can inspect and copy such reports 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.

We have filed with the SEC a Registration Statement on Form S-3 to register the common shares that are being offered in this prospectus supplement. This prospectus supplement is part of the Registration Statement. This prospectus supplement does not include all of the information contained in the Registration Statement. For further information about us and the common shares offered in this prospectus supplement, you should review the Registration Statement. You can inspect or copy the Registration Statement, at prescribed rates, at the SEC's public reference facilities at the address listed above.

Table of Contents

DOCUMENTS INCORPORATED BY REFERENCE

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, 2011.

Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2012, June 30, 2012 and September 30, 2012.

Current Reports on Form 8-K filed January 27, 2012, February 10, 2012, February 15, 2012, March 7, 2012, April 20, 2012, May 16, 2012, May 30, 2012, June 14, 2012, August 3, 2012, August 15, 2012 and November 28, 2012.

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.

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).

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-5, 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, as you determine whether an investment is appropriate for you.*

Our Company

We are an integrated biopharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products and services for the treatment of iron deficiency and secondary hyperparathyroidism. We are an established manufacturer and supplier of high-quality hemodialysis dry and liquid dialysate concentrates to dialysis providers and distributors in the U.S. and abroad, which is currently our primary business. Hemodialysis is a treatment that duplicates kidney function for patients with failed kidneys resulting from End Stage Renal Disease, or ESRD. Our dialysis products are used to maintain human life by removing toxins and replacing critical nutrients in the hemodialysis patient's bloodstream.

Our lead drug candidate for iron therapy treatment is soluble ferric pyrophosphate, or SFP. We have licensed exclusive global rights for SFP. SFP delivers iron 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. To realize a commercial benefit from SFP, we must complete clinical trials and obtain U.S. Food and Drug Administration, or FDA, approval. We also plan to seek foreign market approval for this product or to license the technology to a pharmaceutical company who will seek market approval in the licensed markets. We believe this product will substantially improve iron therapy and, if approved, will compete for the global hemodialysis iron therapy market. We are conducting ongoing Phase III clinical trials on SFP, which we refer to as CRUISE-1 and CRUISE-2. 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. There can be no assurance, however, that SFP will be approved by the FDA or, if approved, that it will be successfully marketed.

The Company has acquired an approved Abbreviated New Drug Application for Calcitriol injection, a generic FDA-approved drug. Calcitriol is an active vitamin D analogue indicated for the treatment of secondary hyperparathyroidism. The majority of ESRD patients receive a form of vitamin D on a routine basis. We are required to gain FDA regulatory approval for changes in manufacturing location prior to marketing Calcitriol. We anticipate obtaining the necessary approval in the first half of 2013 and to begin marketing Calcitriol commercially thereafter. Based on manufacturers' reports and industry estimates, we believe the market size in the United States for vitamin D therapy for ESRD patients is in excess of \$350 million per year.

Dialysis patients, or ESRD stage 5 patients, are those patients whose kidneys no longer function properly and must receive routine dialysis treatments to survive. Most of these chronic patients receive hemodialysis treatments three times per week, or 156 times per year. Most chronic patients have their dialysis treatment performed at a free-standing clinic while those patients with temporary or acute kidney failure generally have their treatments performed at hospitals. In either setting, a dialysis machine dilutes concentrated solution, such as our liquid or dry concentrate products, with purified water. The resulting solution is called dialysate. Dialysate is pumped through an artificial kidney machine (or dialyzer) while the patient's blood is pumped through a semi-permeable membrane inside the dialyzer in the opposite direction from the dialysate. The dialysate infuses dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and either acetic acid or citric acid into the patient's blood while removing water and waste. The patient's physician chooses the proper concentrations required for each patient based on each particular patient's needs. In addition to using concentrate products, which must be replaced for each use for each patient, 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

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, orUSRDS, we estimate that there are approximately 5,800 Medicare-certified hemodialysis treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 65% of the domestic hemodialysis market. According to industry statistics published by USRDS, at the end of 2009, 387,000 patients in the United States were receiving dialysis treatments. The domestic dialysis industry has experienced steady patient population growth over the last several decades. U.S. patient population growth has averaged approximately 4% per year over the last five years.

ESRD incidence rates vary by country. Based on industry reports, the global ESRD population receiving some form of dialysis treatment is estimated to be over two million and to be growing at a rate of approximately 6% annually. The three major 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 area is projected to experience rapid growth in the incidence of kidney disease over the decade ahead.

Our Recent Financial Results

Our results of operations for the years ended December 31, 2011 and 2010 and the nine months ended September 30, 2012, and our total assets as of the end of each of these periods, are as follows:

| (in thousands) | Nine Months Ended Sept. 30, 2012 | Years Ended December 31, | |
|----------------|---|-------------------------------------|-------------|
| | | 2011 | 2010 |
| Net Loss | \$ (40,348) | \$ (21,445) | \$ (2,683) |
| | As of Sept. 30, 2012 | As of December 31, | |
| Total Assets | \$ 24,221 | \$ 31,940 | \$ 36,967 |

We commenced our Phase III clinical development program for SFP, our lead drug product, in 2011 and our research and development costs have increased substantially in 2011 and the first nine months of 2012 over 2010 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 decreased at September 30, 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. Total assets at December 31, 2011 decreased compared to December 31, 2010 due to the cash used in operations to fund the increased research and development spending, partially offset by positive cash flow generated from our operations excluding research and development spending and \$4.8 million in proceeds primarily from the exercise of outstanding common stock purchase warrants.

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 results of operations and financial position.

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.

Table of Contents

The Offering

| | |
|--|---|
| Common Stock offered by Selling Shareholders | 1,159,169 shares of our common stock (excluding shares previously sold by the Selling Shareholders), including 1,159,169 shares issuable upon the exercise of warrants. |
| Use of proceeds | Proceeds received from the issuance of shares upon exercise of warrants will be used for general corporate purposes. We will not receive any proceeds from the sale of shares in this offering by the Selling Shareholders. |
| NASDAQ Global Market symbol | RMTI |
| Risk Factors | See the section of this prospectus supplement captioned "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. |

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus supplement. 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, intend or similar expressions, or m 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

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

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 in particular accounted for 48% of our sales in 2011 and has accounted for 42% to 52% 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. 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.

Our clinical trials might not prove successful. Positive results in early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in earlier-stage development. We cannot assure you that the phase 3 clinical trial will achieve positive results.

In addition, the FDA may order the temporary or permanent discontinuation of a clinical trial at any time. Many products that undergo clinical trials are never approved for patient use. Thus, it is possible that our new proprietary products may never be approved to be marketed. If we are unable to obtain marketing approval, our entire investment in new products may be worthless, our licensing rights could be forfeited and the price of our common stock could substantially decline.

Table of Contents

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

We are seeking FDA approval to manufacture and market our lead drug candidate, SFP, for which late-stage clinical trials are ongoing. We are also seeking FDA approval for a change in manufacturing location for our approved generic drug called Calcitriol. While we anticipate timely manufacturing approval for Calcitriol, if we encounter manufacturing delays with our contract manufacturer, FDA approval could be delayed.

Even if SFP and the manufacturing change for Calcitriol are approved by the FDA, the commercial success of these drugs will be affected by a number of factors, including the following:

Both drugs will have to compete against existing products, including some that currently dominate their respective markets, and others that later enter the markets;

it may be difficult to gain market acceptance of the new products;

nephrologists, anemia managers and dialysis chains may be slow to change their clinical practice protocols for new products or may not change their protocols at all;

achieving and maintaining compliance with all applicable regulatory requirements;

the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization of these drugs;

a continued acceptable safety profile of SFP following FDA approval; and

changes to government reimbursement practices that could adversely affect dialysis providers' ability to purchase or pay for our drug products.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenues through the sale of SFP or Calcitriol. If we are not successful in commercializing our drugs, it would have a material adverse effect on our financial position and results of operations and the market value of our common shares.

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

A significant portion of our costs are for chemicals and fuel which are subject to pricing volatility based on demand and are highly influenced by the overall level of economic activity in the U.S. and abroad. These costs rose during 2010 and 2011 and had a negative effect on our gross margins. We may realize future cost and pricing pressure which may cause our gross profit margins to decrease further and have a material adverse effect on our results of operations.

Our products are distribution-intensive, resulting in a high cost to deliver relative to the selling prices of our products. The cost of diesel fuel represents a significant operating cost for us. If oil costs increase or if oil prices spike upward, we may be unable to recover those increased costs through higher pricing. Also, as we increase our business in certain markets and regions, which are farther from our manufacturing facilities than we have historically served, we may incur additional costs that are greater than the additional revenue generated from these initiatives. Our customer mix may change to a less favorable customer base with lower gross profit margins.

Our competitors have often used bundling techniques to sell a broad range of products and have often offered low prices on dialysis concentrate products to induce customers to purchase their other higher margin products, such as dialysis machines and dialyzers. It may be difficult for us to raise prices due to these competitive pressures.

Edgar Filing: ROCKWELL MEDICAL, INC. - Form 424B3

Our suppliers may increase their prices faster than we are able to raise our prices to offset such increases. We may have limited ability to gain a raw material pricing advantage by changing vendors for certain chemicals and packaging materials.

As we increase our manufacturing and distribution infrastructure we may incur costs for an indefinite period that are greater than the incremental revenue we derive from these expansion efforts.

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

S-6

Table of Contents

We incurred a net loss in each of the last several years and, as of December 31, 2011, our accumulated deficit was \$56.0 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products. We expect to continue to incur operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

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.

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.

Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, 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.

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 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.

We depend on government funding of health care.

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare and Medicaid funding to be viable businesses. A variety of changes to health insurance and reimbursement are included in health reform legislation enacted by Congress in recent years. Some of these changes could have a negative impact on Medicare and Medicaid funding, which fund the majority of dialysis costs in the United States, and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, our customers would be severely impacted, increasing our risk of not being paid in full by our customers. An increase in our exposure to uncollectible accounts could have a material adverse effect on our financial position, results of operations and cash flows.

In the United States, the Medicare Improvements for Patients and Providers Act of 2008 or MIPPA changed the dialysis reimbursement method from the prior practice of separately billed services and medications to a single bundled rate, which became effective on January 1, 2011. Most dialysis providers have adopted this method of reimbursement, which provides for a single payment per dialysis treatment compared to the current method consisting of a composite rate payment and separately billed drugs and services. This change in reimbursement practice was intended to reduce Medicare funding costs and to prompt dialysis providers to reduce their cost of dialysis services. This change increases the burden on dialysis treatment providers to effectively manage their cost of treatment and operations and may put more pressure on suppliers such as us to reduce providers' costs. As a result, we may see increased pressure to reduce the prices of our products, which would have a negative impact on our revenue and gross profit margins. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to this change in reimbursement practice which could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

As a result of these changes to Medicare reimbursement, industry observers also anticipate increased consolidation in the dialysis provider market which has been largely unchecked by the Federal Trade Commission to date. Continued consolidation in providers will likely result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry.

Health care reform could adversely affect our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. The federal Medicare and Medicaid programs are facing financial challenges and are looking at ways to reduce the costs of the Medicare and Medicaid programs. Similarly, many states have large deficits which may prove unsustainable, resulting in defaults on state debt obligations which may ultimately result in the reduction or curtailment of health care benefits or state Medicaid reimbursement.

In the United States, Congress enacted health reform legislation in 2010 that will make significant changes to the health care payment and delivery system. The health reform legislation requires employers to provide employees with insurance coverage that meets minimum eligibility and coverage requirements or face penalties. The legislation also includes provisions that will impact the number of individuals with insurance coverage, the types of coverage and level of health benefits that will be required and the amount of payment providers performing health care services will receive. The legislation imposes implementation effective dates beginning in 2010 and extending through 2020. Many of the changes require additional guidance from government agencies or federal regulations. The proposed changes in the Medicare and Medicaid programs could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations. In addition, the health reform legislation imposes fees or excise taxes on pharmaceutical and device manufacturers based on their revenues that could also have a material adverse effect on the Company.

Beginning in 2013, the legislation imposes requirements on device manufacturers to report annually to the FDA regarding certain financial relationships they have with physicians and hospitals. This reporting requirement will increase governmental scrutiny on our contractual relationships with physicians and hospitals and will increase the risk of inadvertent violations resulting in liability under the Medicare fraud and abuse laws, which could have a material adverse effect on our results of operations, financial position and cash flows.

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

Our revenue from international distributors may not recur consistently or at all. Such revenue is often dependent upon the availability of government funding in those nations and there may be local, regional or geopolitical changes that impact funding of healthcare expenditures in those nations. This inconsistency could result in significant fluctuations in our revenues from period to period and make our revenues hard to predict. Negative fluctuations could have a material adverse effect on our results of operations and financial condition.

We depend on key personnel.

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, Dr. Ajay Gupta MD, our Chief Scientific Officer, Dr. Raymond Pratt, our Chief Medical Officer and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for managing our sales and marketing efforts. Dr. Gupta is primarily responsible for discovery and development of new technologies. Dr. Pratt is primarily responsible for the clinical development, testing and regulatory approval of our products. None of our executive management are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini, Dr. Gupta, Dr. Pratt or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

Our business is highly regulated.

Table of Contents

The testing, manufacture and sale of the products we manufacture and distribute are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before medical devices can be commercially marketed in the United States, the FDA must give either 510(k) clearance or pre-market approval for the devices. If we do not comply with these requirements, we may be subject to a variety of sanctions, including fines, injunctions, seizure of products, suspension of production, denial of future regulatory approvals, withdrawal of existing regulatory approvals and criminal prosecution. Our business could be adversely affected by any of these actions.

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding manufacturing quality. In addition, our new products will be subject to review and approval by the FDA. The process of obtaining such approval is time-consuming and expensive. In addition, changes in applicable regulatory requirements could significantly increase the costs of our operations and may reduce our profitability if we are unable to recover any such cost increases through higher prices.

We depend on contract research organizations 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.

We utilize contract research organizations to conduct our clinical trials in accordance with study specific protocols. We also contract with other third party service providers for clinical trial material production, packaging and labeling, lab testing, data management services as well as a number of other services. There can be no assurance that these organizations will fulfill their commitments to us on a timely basis or that the accuracy and quality of the clinical data they provide us will not be compromised by their failure to fulfill their obligations. If these service providers do not perform as contracted, our development plans could be adversely affected.

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

The approval procedures for the marketing of our new drug products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Additional studies may be required to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

We may not have sufficient products liability insurance.

As a supplier of medical products, we may face potential liability from a person who claims that he or she suffered harm as a result of using our products. We maintain products liability insurance in the amount of \$5 million per occurrence and \$5 million in the aggregate. We cannot be sure that it will remain economical to retain our current level of insurance, that our current insurance will remain available or that such insurance would be sufficient to protect us against liabilities associated with our business. We may be sued, and we may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by product liability litigation and that could harm our marketing ability. Any litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. Our business, financial condition and results of operations could be adversely affected by an uninsured or inadequately insured product liability claim in the future.

Our Board of Directors is subject to potential deadlock.

Our Board of Directors presently has four members, and under our bylaws, approval by a majority of the Directors is required for many significant corporate actions. It is possible that our Board of Directors may be unable to obtain majority approval in certain circumstances, which would prevent us from taking action.

Table of Contents

RISKS RELATED TO OUR COMMON STOCK

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

Our future sales of common shares may have a negative effect on the market price of our common shares from time to time. Sales of substantial amounts of our common shares (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. As of December 31, 2011 an additional 2,507,440 shares may be issued upon exercise of outstanding warrants. An additional, 100,000 shares may be issued after December 31, 2013. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares.

In addition, as of December 31, 2011, there were 3,952,802 shares issuable upon the exercise of outstanding and exercisable stock options, 1,529,333 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 701,331 additional shares available for grant under our 2007 Long Term Incentive Plan. Additional grants have been made in 2012. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options.

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.

SEC rules require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each year, and to include a management report assessing the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K. In our annual assessment of internal controls over financial reporting that management performed for the year ended December 31, 2011, we identified a material weakness in our internal control over financial reporting. Although we believe this material weakness has been remedied, it is possible, due to the small size of our accounting staff, that we may identify other control deficiencies in the future that constitute one or more material weaknesses. If our internal control over financial reporting or disclosure controls and procedures are not effective, there may be errors in our financial statements and in our disclosure that could require restatements. Investors may lose confidence in our reported financial information and in our disclosure, which could lead to a decline in our stock price.

No system of internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

The market price of our securities may be volatile.

The historically moderate to lower trading volume of our common shares may cause the market price of the common shares to fluctuate significantly in response to relatively few trades or transactions.

Table of Contents

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

As of December 31, 2011, to our knowledge, our officers and directors beneficially owned approximately 25% of our voting shares (assuming the exercise of exercisable options granted to such officers and directors). Accordingly, they may be able to exert influence over matters requiring shareholder approval, including the election of our Board of Directors and approval of significant corporate transactions. Our shareholders do not have the right to cumulative voting in the election of directors. In addition, the Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we may become subject to Michigan statutes regulating business combinations which might also hinder or delay a change in control. Anti-takeover provisions that could be included in the preferred stock when issued and the Michigan statutes regulating business combinations can have a depressive effect on the market price of our common shares and can limit shareholders' ability to receive a premium on their shares by discouraging takeover and tender offers.

Our directors serve staggered three-year terms, and directors may not be removed without cause. Our Articles of Incorporation also set the minimum and maximum number of directors constituting the entire Board at three and fifteen, respectively, and require approval of holders of a majority of our voting shares to amend these provisions. These provisions could have an anti-takeover effect by making it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common shares and do not anticipate paying such dividends in the foreseeable future. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations and, therefore, it is highly unlikely we will pay cash dividends.

Table of Contents

SELLING SHAREHOLDERS

The shares of common stock originally to be sold by the Selling Shareholders consisted of:

2,158,337 shares of our common stock that we issued to certain selling shareholders (the Offering Selling Shareholders) in a private placement on November 28, 2007;

1,079,169 shares of our common stock issuable upon exercise of warrants to purchase common stock that we issued to the Offering Selling Shareholders in connection with their purchase of shares of our common stock in a November 28, 2007 private placement; and

80,000 shares of our common stock issuable upon exercise of warrants to purchase common stock that we issued to a sales agent in a November 28, 2007 private placement.

Throughout this prospectus, when we refer to the Selling Shareholders, we mean the persons listed in the table below, as well as the pledgees, donees, assignees, transferees, successors and others who later hold any of the Selling Shareholders' interests, and when we refer to the shares of our common stock being offered by this prospectus supplement, we are referring to the shares of our common stock sold and the shares of our common stock issuable upon the exercise of the warrants issued in the private placement.

In connection with the registration rights we granted to the Offering Selling Shareholders, we filed with the SEC a registration statement on Form S-3, of which this prospectus supplement forms a part, with respect to the resale or other disposition of the shares of common stock offered by this prospectus supplement or interests therein from time to time on the NASDAQ Global Market, in privately negotiated transactions or otherwise. We have also agreed to prepare and file amendments and supplements to the registration statement to the extent necessary to keep the registration statement effective for the period of time required under our agreement with the Offering Selling Shareholders. The outstanding warrants held by the Offering Selling Shareholders were amended between November 23 and 27, 2012 to extend the expiration date from November 28, 2012 to January 28, 2013. The outstanding warrant held by RJ Aubrey IR Services LLC was amended on November 22, 2012 to extend the expiration date from November 28, 2012 to November 28, 2013. The warrants held by the Selling Shareholders became exercisable on November 28, 2008.

The actual number of shares of common stock covered by this prospectus supplement, and included in the registration statement of which this prospectus supplement forms a part, includes additional shares of common stock that may be issued with respect to the shares of common stock described herein as a result of stock splits, stock dividends, reclassifications, recapitalizations, combinations or similar events.

The table below sets forth, to our knowledge, information about the Selling Shareholders as of November 1, 2012, except as noted in the footnotes to the table. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares of our common stock. The number representing the number of shares of common stock beneficially owned by each Selling Shareholder includes (i) all shares held by a Selling Shareholder, plus (ii) all options, warrants, or other derivative securities which are exercisable within 60 days of November 1, 2012 or the applicable date set forth in the footnotes to the table, including the warrants issued in the private placement, held by a Selling Shareholder. Under the terms of the warrants, Selling Shareholders may not exercise the warrants to the extent such conversion or exercise would cause such Selling Shareholder, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 9.99% of our then outstanding shares of common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrants which have not been exercised. The percentages of shares owned after the offering are based on 21,298,820 shares of our common stock outstanding as of November 2, 2012, which includes the outstanding shares of common stock offered by this prospectus supplement. Unless otherwise indicated below, to our knowledge, all persons named in this table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership by the person named below.

We do not know when or in what amounts a Selling Shareholder may offer shares for sale. The Selling Shareholders might not sell any or all of the shares offered by this prospectus supplement. Because the Selling Shareholders may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the Selling Shareholders after completion of the offering. However, for purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus supplement will be held by the Selling Shareholders.

Table of Contents

The Selling Shareholders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of their shares of common stock since the date on which the information in the table below is presented. Information about the Selling Shareholders may change over time.

| Name of Selling Shareholder | Shares of Common Stock Beneficially Owned | | Number of Shares of Common Stock Being Offered | Shares of Common Stock to be Beneficially Owned After Offering | |
|---|---|------------|--|--|------------|
| | Number | Percentage | | Number | Percentage |
| Entities affiliated with Berlin Financial, Ltd. | 150,788(1) | * | 41,667 | 109,121 | * |
| OTA LLC | 104,167(2) | * | 104,167 | 0 | 0 |
| David Hagelstein Revocable Living Trust | 2,673,754(3) | 12.1 | 862,502 | 1,811,252 | 8.5 |
| RJ Aubrey IR Services LLC | 117,400(4) | * | 80,000 | 37,400 | * |
| The DCB Trust | 245,069(5) | 1.1 | 60,833 | 184,236 | * |
| Johnny A. Swanson | 10,000(6) | * | 10,000 | 0 | * |

* Less than one percent.

- (1) Consists of 41,667 shares of common stock issuable upon the exercise of warrants held by Thomas G. Berlin acquired from J George Investments LLC (J George), who was an Offering Selling Shareholder now or previously named in this prospectus, and 109,121 shares of common stock for which Berlin Financial, Ltd, the general partner of J George, and Thomas G. Berlin hold sole voting and investment control. Mr. Berlin expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (2) Consists of 104,167 shares issuable upon the exercise of warrants held by OTA, LLC (OTA) acquired from Offering Selling Shareholders now or previously named in this prospectus. Ira Leventhal, a senior managing director of OTA, has sole voting and investment control over the securities beneficially owned by OTA. Mr. Leventhal expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (3) Consists of 862,502 shares issuable upon the exercise of warrants held by the David A. Hagelstein Revocable Living Trust, dated October 27, 1993 (the Revocable Trust) acquired from an Offering Selling Shareholder now or previously named in this prospectus, 1,372,430 shares of common stock owned by the Revocable Trust, and 438,822 shares of common stock owned by the David Hagelstein Charitable Remainder Unitrust, dated November 20, 2003 (the Charitable Trust). Mr. Hagelstein is the sole trustee and beneficiary of the Revocable Trust and is the sole trustee of the Charitable Trust. Mr. Hagelstein has sole voting and dispositive power with respect to all such shares.
- (4) Consists of 22,400 shares of common stock owned by RJ Aubrey IR Services LLC (RJ Aubrey), 15,000 shares issuable upon exercise of a warrant not covered by this prospectus, and 80,000 shares of common stock issuable upon the exercise of warrants by RJ Aubrey acquired for services as a sales agent in the November 2007 offering. Ronald J. Aubrey is the sole member of RJ Aubrey and expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (5) Consists of 60,833 shares issuable upon the exercise of warrants held by the DCB Trust acquired from Offering Selling Shareholders now or previously named in this prospectus and 184,236 shares of common stock held by the DCB Trust. Doug C. Burns, the trustee of the DCB Trust, has sole voting and investment control over the securities beneficially owned by the DCB Trust. Mr. Burns expressly disclaims beneficial ownership of the securities, other than to the extent of his pecuniary interest therein.

Table of Contents

- (6) Consists of 10,000 shares issuable upon the exercise of warrants held by Johnny A. Swanson acquired from Offering Selling Shareholders now or previously named in this prospectus.

Relationships with Selling Shareholders

RJ Aubrey acted as a sales agent in the Company's November 2007 private placement and has acted as a non-employee consultant providing various advisory services, including without limitation investor relations consulting services, introducing the Company to potential licensing partners and acquisition candidates and acting as a liaison to the equity investment community. Except as otherwise disclosed in the preceding sentence, none of the Selling Shareholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years.

Table of Contents

DESCRIPTION OF COMMON STOCK

Our authorized capital stock is 40,000,000 shares of common stock and 3,416,664 shares of preferred stock (including 1,416,664 shares of Series A Preferred Shares which were previously issued and cancelled and which are not available for issuance). At November 2, 2012, 21,298,820 shares of common stock and no shares of preferred stock were outstanding. This description is subject to, and qualified in its entirety by, the provisions of our amended and restated articles of incorporation and bylaws, as well as the provisions of any applicable laws. A copy of our amended and restated articles of incorporation (Articles) was filed with the SEC as Exhibit 3.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008. A copy of our amended and restated bylaws (Bylaws) was filed with the SEC as Exhibit 3.2 to our Current Report on Form 8-K filed on November 25, 2008.

Holders of our common stock are entitled to one vote for each share held of record on all matters on which shareholders are generally entitled to vote. The vote of the holders of a majority of the stock represented at a meeting at which a quorum is present is generally required to take shareholder action, unless a greater vote is required by law. Directors are elected by a plurality of the votes cast at any election and there is no cumulative voting of shares.

Holders of our common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available for the payment of dividends. Upon the liquidation, dissolution or winding up of the Company, holders of common stock are entitled to share pro rata in any assets available for distribution to shareholders after payment of all obligations of the Company and after provision has been made with respect to each class of stock, if any, having preference over the common stock. Holders of common stock do not have cumulative voting rights or preemptive, subscription or conversion rights and shares of common stock are not redeemable. The shares of common stock presently outstanding are duly authorized, validly issued, fully paid and non-assessable.

The directors of the Company serve staggered three-year terms. Directors may not be removed without cause. The Articles also set the minimum and maximum number of directors constituting the entire Board at three and fifteen, respectively, with the exact number to be determined by the board from time to time.

Our Articles and Bylaws contain provisions that could have the effect of delaying, deterring or preventing a merger, tender offer or other takeover attempt. Our Articles authorize the Board to issue up to 40 million shares of common stock (less shares already outstanding or reserved for issuance) and up to two million shares of preferred stock without shareholder approval. In addition, the Articles provide that shareholder action without a meeting requires the unanimous consent of the shareholders unless the action has been approved by the Board prior to execution of the shareholder consent. Our Bylaws permit incumbent directors to fill any vacancies on the board of directors, however occurring, whether by an increase in the number of directors, death, resignation, retirement, disqualification, removal from office or otherwise. Furthermore, our Bylaws require shareholders to give advance notice of director nominations and proposals to be presented at meetings of shareholders.

These provisions may delay shareholder actions with respect to business combinations and the election of new members to our Board. As such, the provisions could discourage open market purchases of our common stock because a shareholder who desires to participate in a business combination or elect a new director may consider them disadvantageous.

Chapter 7A of the MBCA provides that a business combination subject to Chapter 7A between a covered Michigan corporation or any of its subsidiaries and a beneficial owner of shares entitled to 10% or more of the voting power of such corporation generally requires the affirmative vote of 90% of the votes of each class of stock entitled to vote, and not less than two thirds of the votes of each class of stock entitled to vote (excluding voting shares owned by such 10% or more owner), voting as a separate class. These requirements do not apply if (1) the corporation's board of directors approves the transaction before the 10% or more owner becomes such or (2) the transaction satisfies certain fairness standards, certain other conditions are met and the 10% or more owner has been such for at least five years. Chapter 7A business combinations include, among other transactions, mergers, significant asset transfers, certain disproportionate issuances of shares to an interested shareholder, certain reclassifications and recapitalizations disproportionately favorable to such shareholder, and the adoption of a plan of liquidation or dissolution in which such a shareholder would receive anything other than cash. We are currently not subject to Chapter 7A but may opt in at any time by resolution of our Board.

Table of Contents

Listing

Our common stock is listed and traded on the NASDAQ Stock Market under the symbol RMTI.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company.

EXPERTS

The financial statements incorporated in this prospectus by reference from Rockwell's Annual Report on Form 10-K for the year ended December 31, 2011 have been audited by Plante & Moran, PLLC, independent auditors, as stated in their report which is incorporated in this prospectus supplement by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

S-16

Table of Contents

PROSPECTUS

3,317,506 SHARES OF COMMON STOCK

This Prospectus relates to resales of shares of our common stock, including shares of common stock issuable upon the exercise of warrants, that we issued to the selling shareholders identified in this prospectus (collectively, the Selling Shareholders) in connection with (i) our private placement of securities on November 28, 2007 and (ii) our private placement of securities to a service provider on November 28, 2007. We will not receive any proceeds from the sale of shares of our common stock by Selling Shareholders. Upon any exercise for cash of the warrants, the warrant holders will pay us an exercise price of such warrants. We have agreed to pay certain expenses in connection with the registration of the shares and to indemnify the Selling Shareholders against certain liabilities.

The Selling Shareholders identified in this prospectus, or their pledgees, donees, transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices.

Our common stock is listed on the Nasdaq Global Market and traded under the symbol RMTI. On January 9, 2008, the closing sale price of our common stock on Nasdaq was \$6.97 per share. You are urged to obtain current market quotations for the common stock.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 29, 2008.

Table of Contents

TABLE OF CONTENTS

| | Page |
|--|-------------|
| <u>Where You Can Get More Information</u> | 2 |
| <u>Documents Incorporated by Reference</u> | 2 |
| <u>Prospectus Summary</u> | 4 |
| <u>The Offering</u> | 5 |
| <u>Cautionary Statement Regarding Forward-Looking Statements</u> | 5 |
| <u>Risk Factors</u> | 6 |
| <u>Use of Proceeds</u> | 9 |
| <u>Selling Shareholders</u> | 10 |
| <u>Plan of Distribution</u> | 12 |
| <u>Legal Matters</u> | 15 |
| <u>Experts</u> | 15 |

Rockwell Medical Technologies, Inc.'s principal executive offices are located at 30142 Wixom Road, Wixom, Michigan 48393, our telephone number at that address is (248) 960-9009 and our Internet address is www.rockwellmed.com. The information on our Internet website is not incorporated by reference in this prospectus, and you should not consider it to be a part of this document. Our website address is included as an inactive textual reference only. Unless the context otherwise requires references in this prospectus to Rockwell, we, us, and our refer to Rockwell Medical Technologies, Inc.

We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. The Selling Shareholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

WHERE YOU CAN GET MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the SEC). You can inspect and copy such reports 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.

We have filed with the SEC a Registration Statement on Form S-3 to register the common shares that are being offered in this Prospectus. This prospectus is part of the Registration Statement. This prospectus does not include all of the information contained in the Registration Statement. For further information about us and the common shares offered in this prospectus, you should review the Registration Statement. You can inspect or copy the Registration Statement, at prescribed rates, at the SEC's public reference facilities at the address listed above.

DOCUMENTS INCORPORATED BY REFERENCE

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, and any information filed with the SEC subsequent to this prospectus 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-KSB for the fiscal year ended December 31, 2006.

Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2007, June 30, 2007, and September 30, 2007.

Table of Contents

Current Reports on Form 8-K filed May 31, 2007, October 9, 2007, December 4, 2007 and December 20, 2007.

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 Securities and Exchange Commission on January 23, 1998, including any amendment or reports filed for the purpose of updating such description.

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 but before the termination of this offering are deemed to be incorporated by reference into this prospectus and will constitute a part of the prospectus from the date of filing of those documents.

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

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, 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).

Table of Contents

PROSPECTUS SUMMARY

This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk Factors.

ROCKWELL MEDICAL TECHNOLOGIES, INC.

We manufacture hemodialysis concentrate solutions and dialysis kits, and we sell, distribute and deliver these and other ancillary hemodialysis products primarily to hemodialysis providers in the United States as well as internationally primarily in Latin America, Asia and Europe. Hemodialysis duplicates kidney function in patients with failing kidneys also known as End Stage Renal Disease (ESRD). ESRD is an advanced stage of chronic kidney disease characterized by the irreversible loss of kidney function. Without properly functioning kidneys, a patient's body cannot get rid of excess water and toxic waste products. Without frequent and ongoing dialysis treatments these patients would not survive.

Our dialysis solutions (also known as dialysate) are used to maintain life, removing toxins and replacing nutrients in the dialysis patient's bloodstream. We have licensed and are currently developing proprietary renal drug therapies for both iron-delivery and carnitine/vitamin-delivery, utilizing dialysate as the delivery mechanism. These exclusive renal drug therapies support disease management initiatives to improve the quality of care for dialysis patients and are designed to deliver safe and effective therapy to patients while decreasing nursing time and supply cost. The Company offers the proprietary Dri-Sate® Dry Acid Concentrate Mixing System, RenalPure® Liquid Acid Concentrate, SteriLyte® Liquid Bicarbonate Concentrate, RenalPure® Powder Bicarbonate Concentrate, Blood Tubing Sets, Fistula Needles and a wide range of ancillary dialysis items.

Hemodialysis treatments are generally performed in independent clinics or hospitals with the majority of dialysis services performed by regional and national for-profit dialysis chains. The two largest national for-profit dialysis chains service approximately 60% of the domestic hemodialysis market. According to the latest industry statistics published by the U.S. Renal Data Systems (USRDS), 341,000 patients in the United States were receiving dialysis treatments at the end of 2005. The domestic dialysis industry has experienced steady patient population growth over the last two decades. In the last five years, however, the patient growth rate has decreased with the patient population increasing between 3-5% per year. Population segments with the highest incidence of ESRD are also among the fastest growing within the U.S. population including the elderly, Hispanic and African-American population segments. Recent U.S. demographic projections indicate that the incidence of ESRD is expected to increase in the years ahead and will exceed current incidence levels.

ESRD incidence rates vary by country with some higher and some lower than the United States. Based on industry reports, the global ESRD population is estimated to be over 2 million and to be growing approximately 5-6% annually. The three major dialysis markets are the United States, the European Union and Japan representing approximately 60% of the global treatments based on industry estimates.

Our strategy is to develop our dialysis concentrate and supply business and to develop drugs, nutrients and vitamins to be delivered by our dialysis concentrate products. Our long term objectives are to increase our market share, expand our product line, expand our geographical selling territory and improve our profitability by implementing the following strategies:

increasing our revenues through new innovative products, such as our Dri-Sate® Dry Acid Concentrate Mixing System and SteriLyte® Liquid Bicarbonate Concentrate,

gaining FDA approval to market innovative products such as iron supplemented dialysate,

acting as a single source supplier to our customers for the concentrates, chemicals and supplies necessary to support a hemodialysis provider's operation,

increasing our revenues by expanding our ancillary product line,

Edgar Filing: ROCKWELL MEDICAL, INC. - Form 424B3

offering our customers a higher level of delivery and customer service by using our own delivery vehicles and drivers, and

expanding our market share in target regions, including regions where our proximity to customers will provide us with a competitive cost advantage and allow us to provide superior customer service levels.

Table of Contents

THE OFFERING

| | |
|--|---|
| Common Stock offered by Selling Shareholders | 3,317,506 shares of our common stock, including 1,079,169 shares issuable upon the exercise of warrants. |
| Use of proceeds | Proceeds received from the issuance of shares upon exercise of warrants will be used for general corporate purposes. We will not receive any proceeds from the sale of shares in this offering by the Selling Shareholders. |
| Nasdaq Global Market symbol | RMTI |

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements relating to our anticipated future financial condition, operating results, cash flows and our current business plans. 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.

These forward-looking statements represent our outlook only as of the date of this prospectus. 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. 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, including under Risk Factors section beginning on page 6, and in our reports filed from time to time 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. While we believe that the forward-looking statements in this prospectus are reasonable, you should not place undue reliance on any forward-looking statement. 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.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

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 revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. If we were to lose a significant portion of our business with major national and regional dialysis chains, it could have a substantial negative impact on our cash flow and operating results. If we were to lose a substantial portion of our business, it may 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 substantially larger competitors with greater resources.

There is intense competition in the hemodialysis product market and most of our competitors are large diversified companies which have substantially greater financial, technical, manufacturing, marketing, research and development and management resources than we do. We may not be able to successfully compete with these other companies. Our national competitors have 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 competitors, we may be at a disadvantage in competing against their marketing strategies.

Our new drug product 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. 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 be able to raise sufficient funds to complete the clinical trials to obtain marketing approval. Our clinical trials might not prove successful. In addition, the FDA may order the temporary or permanent discontinuation of a clinical trial at any time. Many products that undergo clinical trials are never approved for patient use. Thus, it is possible that our new proprietary products may never be approved to be marketed. If we are unable to obtain marketing approval, our entire investment in new products may be worthless and our licensing rights could be forfeited.

Even if our new drug product is approved by the FDA it may not be successfully marketed.

Several drugs currently dominate treatment for iron deficiency and new drugs treating this indication will have to compete against existing products. It may be difficult to gain market acceptance of a new product. Nephrologists, anemia managers and dialysis chains may be slow to change their clinical practice protocols for new products or may not change their protocols at all.

Dialysis providers are dependent upon government reimbursement practices for the majority of their revenue. Even if we obtain FDA approval for our new product, there is no guarantee that our customers would receive reimbursement for the new product, even though the current treatment method is reimbursed by the government. Without such reimbursement, it is unlikely that our customers would adopt a new treatment method. There is a risk that our new product may not receive reimbursement or may not receive the same level of reimbursement that is currently in place.

We depend on government funding of healthcare.

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare funding to be viable businesses. If Medicare funding were to be materially decreased, our customers would be severely impacted and could be unable to pay us.

Table of Contents

We may not be successful in improving our gross profit margins and our business may remain unprofitable.

Our products are distribution intensive resulting in a high cost to deliver relative to the selling prices of our products. As we increase our business in certain markets and regions, which are further from our manufacturing facilities than we have historically served, we may incur additional costs that are greater than the additional revenue generated from these initiatives. Our customer mix may change to a less favorable customer base with lower gross profit margins.

Our competitors have often used bundling techniques to sell a broad range of products and have often offered low prices on dialysis concentrate products to induce customers to purchase their other higher margin products such as dialysis machines and dialyzers. It may be difficult for us to raise prices due to these competitive pressures.

Our suppliers may increase their prices faster than we are able to raise our prices to offset such increases. We may have limited ability to gain a raw material pricing advantage by changing vendors for certain raw materials.

As we increase our manufacturing and distribution infrastructure we may incur costs for an indefinite period that are greater than the incremental revenue we derive from these expansion efforts.

The cost of diesel fuel represents a significant operating cost for us. If oil costs continue to increase or if oil prices spike upward, we may be unable to recover those increased costs through higher pricing.

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

Our revenue from international distributors may not recur consistently or may not recur at all. Such revenue is often dependent upon government funding in those nations and there may be local, regional or geopolitical changes that may impact funding of healthcare expenditures in those nations.

We depend on key personnel.

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for managing our sales and marketing efforts, which has driven our growth. We maintain key man life insurance on Mr. Chioini in the amount of \$1 million. Neither Mr. Chioini nor Mr. Klema are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini or Mr. Klema, our business, financial condition and results of operations could be adversely affected.

Our business is highly regulated.

The testing, manufacture and sale of the products we manufacture and distribute are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before medical devices can be commercially marketed in the United States, the FDA must give either 510(k) clearance or premarket approval for the devices. If we do not comply with these requirements, we may be subject to a variety of sanctions, including fines, injunctions, seizure of products, suspension of production, denial of future regulatory approvals, withdrawal of existing regulatory approvals and criminal prosecution. Our business could be adversely affected by any of these actions.

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding manufacturing quality, known as Good Manufacturing Practices, or GMP. In addition, our new products will be subject to review as a pharmaceutical drug by the FDA. Changes in applicable regulatory requirements could significantly increase the costs of our operations and may reduce our profitability if we are unable to recover any such cost increases through higher prices.

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

Table of Contents

The approval procedures for the marketing of our new drug products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Additional studies may be required to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

Health care reform could adversely affect our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results.

We may not have sufficient cash to fund SFP development in future years.

Our research and development plan for SFP is expected to result in significant cash outlays in 2008 and 2009. We expect to spend between \$5-6 million in 2008 on SFP product development and approval. We expect that our cash resources are adequate to fund our cash requirements in 2008. We believe we have adequate sources of liquidity to fund the testing and regulatory approval for SFP. However, if additional testing is required that is beyond that which we have planned for, we may not have adequate cash resources to fund our product development and approval efforts. If our clinical trial efforts do not achieve acceptable results, we may have to do more testing and, depending on the scope and duration of any additional testing, our available cash resources may not be sufficient to fund that additional testing.

We may not have sufficient products liability insurance.

As a supplier of medical products, we may face potential liability from a person who claims that he or she suffered harm as a result of using our products. We maintain products liability insurance in the amount of \$3 million per occurrence and \$3 million in the aggregate. We cannot be sure that it will remain economical to retain our current level of insurance, that our current insurance will remain available or that such insurance would be sufficient to protect us against liabilities associated with our business. We may be sued, and we may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by product liability litigation and that could harm our marketing ability. Any litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. Our business, financial condition and results of operations could be adversely affected by an uninsured or inadequately insured product liability claim in the future.

Our Board of Directors is subject to potential deadlock.

Our Board of Directors presently has four members, and under our bylaws, approval by a majority of the Directors is required for many significant corporate actions. It is possible that our Board of Directors may be unable to obtain majority approval in certain circumstances, which would prevent us from taking action.

RISKS RELATED TO OUR COMMON STOCK

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

We are unable to predict the effect, if any, that future sales of common shares, or the availability of our common shares for future sales, will have on the market price of our common shares from time to time. Sales of substantial amounts of our common shares (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. 9,807,510 of the Company's common shares are freely tradable as of December 31, 2007, and an additional 1,632,837 shares are tradable subject to the resale limitations contained in Rule 144 under the Securities Act. In addition, as of December 31, 2007, 4,052,035 shares were available for future issuance under our 1997 Stock Option Plan, including 3,052,035 shares issuable upon the exercise of outstanding stock options, all of which were exercisable and 1,000,000 shares under our 2007 Long Term Incentive Plan of which 755,000 options have been granted, but are not vested or exercisable. In the future, we may issue additional shares in connection with investments, repayment of our debt or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares.

Table of Contents

The market price of our securities may be volatile.

The historically low trading volume of our common shares may also cause the market price of the common shares to fluctuate significantly in response to a relatively low number of trades or transactions.

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

As of December 31, 2007, our officers and directors beneficially owned approximately 21.6% of our voting shares (assuming the exercise of exercisable options granted to such officers and directors). Accordingly, they may be able to effectively control our affairs. Our shareholders do not have the right to cumulative voting in the election of directors. In addition, the Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we are subject to Michigan statutes regulating business combinations, takeovers and control share acquisitions which might also hinder or delay a change in control. Anti-takeover provisions that could be included in the preferred stock when issued and the Michigan statutes regulating business combinations, takeovers and control share acquisitions can have a depressive effect on the market price of the Company's securities and can limit shareholders' ability to receive a premium on their shares by discouraging takeover and tender offer offers.

Our directors serve staggered three-year terms, and directors may not be removed without cause. The Company's Articles of Incorporation also set the minimum and maximum number of directors constituting the entire Board at three and fifteen, respectively, and require approval of holders of a majority of the Company's voting shares to amend these provisions. These provisions could have an anti-takeover effect by making it more difficult to acquire the Company by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

The Company does not anticipate paying dividends in the foreseeable future.

Since inception, the Company has not paid any cash dividend on its common shares and it does not anticipate paying such dividends in the foreseeable future. The payment of dividends by the Company is within the discretion of its Board of Directors and depends upon the Company's earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. The Company intends to retain earnings, if any, to finance its operations.

Outstanding options may affect the market price of the common shares.

In addition to the common shares offered in this prospectus, we have reserved 4,052,035 common shares for issuance upon exercise of options under our 1997 Stock Option Plan and our 2007 Long Term Incentive Plan, under which we have granted options to acquire an aggregate of 3,807,035 common shares through December 31, 2007. As of December 31, 2007, options to purchase 3,807,035 common shares remain outstanding. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options. Further, while the options are outstanding, we may be unable to obtain additional financing on favorable terms.

USE OF PROCEEDS

Upon any exercise for cash of the warrants, the warrant holders will pay us the exercise price of the warrants as set forth in the following table. We will use any cash we receive upon the exercise of the warrants for general corporate purposes. There is no assurance that all or any of the warrants will be exercised prior to their expiration nor any assurance of the timing of the receipt of exercise proceeds. Assuming that all of the warrants are exercised, we expect to receive proceeds of approximately \$8.6 million. We will not receive any proceeds from the sale of shares by the Selling Shareholders.

Table of Contents

| Number of Shares | Per Share Exercise Price | Total |
|------------------------|--------------------------------|--------------|
| Underlying Warrants | | |
| 1,079,169 | \$ 7.18 | \$ 7,748,433 |
| 80,000 | \$ 10.00 | \$ 800,000 |
| 1,159,169 | | \$ 8,548,433 |

The Selling Shareholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Shareholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Shareholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq Global Market listing fees and fees and expenses of our counsel and our accountants.

SELLING SHAREHOLDERS

The shares of common stock being sold by the Selling Shareholders consist of:

2,158,337 shares of our common stock that we issued to certain selling shareholders (the Offering Selling Shareholders) in a private placement on November 28, 2007;

1,079,169 shares of our common stock issuable upon exercise of warrants to purchase common stock that we issued to the Offering Selling Shareholders in connection with their purchase of shares of our common stock in a November 28, 2007 private placement; and

80,000 shares of our common stock issuable upon exercise of warrants to purchase common stock that we issued to a sales agent in a November 28, 2007 private placement.

Throughout this prospectus, when we refer to the Selling Shareholders, we mean the persons listed in the table below, as well as the pledgees, donees, assignees, transferees, successors and others who later hold any of the Selling Shareholders' interests, and when we refer to the shares of our common stock being offered by this Prospectus, we are referring to the shares of our common stock sold and the shares of our common stock issuable upon the exercise of the warrants issued in the private placement.

In connection with the registration rights we granted to the Offering Selling Shareholders, we filed with the SEC a registration statement on Form S-3, of which this prospectus forms a part, with respect to the resale or other disposition of the shares of common stock offered by this prospectus or interests therein from time to time on the Nasdaq Global Market, in privately negotiated transactions or otherwise. We have also agreed to prepare and file amendments and supplements to the registration statement to the extent necessary to keep the registration statement effective for the period of time required under our agreement with the Offering Selling Shareholders. The warrants held by the Offering Selling Shareholders are exercisable at any time on or after November 28, 2008, in whole or in part and expire on November 28, 2012.

The actual number of shares of common stock covered by this prospectus, and included in the registration statement of which this Prospectus forms a part, includes additional shares of common stock that may be issued with respect to the shares of common stock described herein as a result of stock splits, stock dividends, reclassifications, recapitalizations, combinations or similar events.

The table below sets forth, to our knowledge, information about the Selling Shareholders as of December 31, 2007. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares of our common stock. The number representing the number of shares of common stock beneficially owned prior to the offering for each Selling Shareholder includes (i) all shares held by a Selling Shareholder prior to the private placement, plus (ii) all shares purchased by the Selling Shareholder pursuant to the private placement and being offered pursuant to the prospectus or acquired thereafter as well as (iii) all options, warrants, or other derivative securities which are exercisable within 60 days of December 31, 2007, including the warrants issued in the private placement, held by a Selling Shareholder. Under the terms of the warrants, Selling Shareholders may not exercise the warrants to the extent such conversion or exercise would cause such Selling

Table of Contents

Shareholder, together with its affiliates, to beneficially own a number of shares of common stock which would exceed 9.99% of our then outstanding shares of common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of the warrants which have not been exercised. The percentages of shares owned after the offering are based on 13,815,186 shares of our common stock outstanding as of December 31, 2007, which includes the outstanding shares of common stock offered by this prospectus. Unless otherwise indicated below, to our knowledge, all persons named in this table have sole voting and investment power with respect to their shares of common stock, except to the extent authority is shared by spouses under applicable law. The inclusion of any shares in this table does not constitute an admission of beneficial ownership by the person named below.

We do not know when or in what amounts a Selling Shareholder may offer shares for sale. The Selling Shareholders might not sell any or all of the shares offered by this prospectus. Because the Selling Shareholders may offer all or some of the shares pursuant to this offering, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, we cannot estimate the number of the shares that will be held by the Selling Shareholders after completion of the offering. However, for purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the Selling Shareholders.

The Selling Shareholders may have sold or transferred, in transactions exempt from the registration requirements of the Securities Act, some or all of their shares of common stock since the date on which the information in the table below is presented. Information about the Selling Shareholders may change over time.

| Name of Selling Shareholder | Shares of Common Stock Beneficially Owned Prior to Offering | | Number of Shares of Common Stock Being Offered | Shares of Common Stock to be Beneficially Owned After Offering | |
|---|---|------------|--|--|------------|
| | Number | Percentage | | Number | Percentage |
| Entities affiliated with RA Capital Management, LLC | 2,050,001(1) | 14.8 | 2,050,001 | 0 | * |
| Entities affiliated with Berlin Capital | 785,566(2) | 5.7 | 250,002 | 535,564 | 3.9 |
| RRC Bio Fund, LP | 125,001(3) | * | 125,001 | 0 | * |
| Camber Capital Fund L.P. | 187,500(4) | 1.4 | 187,500 | 0 | * |
| Mediphase Offshore Master Fund, L.P. | 125,001(5) | * | 125,001 | 0 | * |
| Boxer Capital LLC | 500,001(6) | 3.6 | 500,001 | 0 | * |
| RJ Aubrey IR Services LLC | 118,385(7) | * | 80,000 | 38,385 | * |

* Less than one percent.

- (1) Consists of 1,350,267 shares of common stock owned by RA Capital Biotech Fund, L.P. (Fund I) and 675,134 shares of common stock issuable upon the exercise of warrants held by Fund I; 16,400 shares of common stock owned by RA Capital Biotech Fund II, L.P. (Fund II) and 8,200 shares of common stock issuable upon the exercise of warrants held by Fund II. RA Capital Management, LLC is the general partner of each of Fund I and Fund II, and Richard H. Aldrich and Peter Kolchinsky are the sole managers of RA Capital Management, LLC. Each of the above persons expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (2) Consists of 288,856 shares of common stock owned by Berlin Capital Growth L.P. (Berlin Capital) and 41,667 shares of common stock issuable upon the exercise of warrants held by Berlin Capital; 413,376 shares of common stock owned by J George Investments LLC (J George) and 41,667 shares of common stock issuable upon the exercise of warrants held by J George. Berlin Financial, Ltd. is the general partner of Berlin Capital and J George. Thomas G. Berlin is the managing member of Berlin Financial, Ltd. and expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.

Table of Contents

- (3) Consists of 83,334 shares of common stock owned by RRC Bio Fund, LP (RRC) and 41,667 shares of common stock issuable upon the exercise of warrants held by RRC. RRC Management, LLC is the general partner of RRC and James Silverman is the sole manager of RRC Management, LLC. Each of the above persons expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (4) Consists of 125,000 shares of common stock owned by Camber Capital Fund, L.P. (Camber) and 62,500 shares of common stock issuable upon the exercise of warrants held by Camber. Camber Capital Partners LLC is the general partner of Camber. Stephen Du Bois is the sole manager of Camber Capital Partners LLC and expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (5) Consists of 83,334 shares of common stock owned by Mediphase Offshore Master Fund, L.P. (Mediphase) and 41,667 shares of common stock issuable upon the exercise of warrants held by Mediphase. Mediphase Capital Partners, LLC is the general partner of Mediphase and Lawrence G. Miller and Paul A. Howard are the sole managers of Mediphase Capital Partners, LLC. Each of the above persons expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (6) Consists of 333,334 shares of common stock owned by Boxer Capital LLC (Boxer) and 166,667 shares of common stock issuable upon the exercise of warrants held by Boxer. Andrew Gitkin and Shehan Dissanayake are the managing members of Boxer. Each of the above persons expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.
- (7) Consists of 38,385 shares of common stock owned by RJ Aubrey IR Services LLC (RJ Aubrey) and 80,000 shares of common stock issuable upon the exercise of warrants by RJ Aubrey. Ronald J. Aubrey is the sole member of RJ Aubrey and expressly disclaims beneficial ownership of the securities, other than to the extent of his or its pecuniary interest therein.

Relationships with Selling Shareholders

None of the Selling Shareholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years.

PLAN OF DISTRIBUTION

Selling Shareholders

The Selling Shareholders of the common shares covered by this prospectus or any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common shares on any stock exchange market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed, negotiated or market prices. The Selling Shareholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the date of this prospectus;

broker-dealers may agree with the Selling Shareholder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

Table of Contents

any other method permitted pursuant to applicable law.

The Selling Shareholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus. Broker-dealers engaged by the Selling Shareholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Shareholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the common shares or interests therein, the Selling Shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common shares in the course of hedging the positions they assume. The Selling Shareholders may also, on or after the date of this prospectus, sell the common shares short and deliver these securities to close out their short positions, or loan or pledge the common shares to broker-dealers that in turn may sell these securities. The Selling Shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Any broker-dealers or agents that are involved in selling or distributing the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Shareholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common shares.

The Company is required to pay the fees and expenses incurred by the Company incident to the registration of the shares as well as certain of the fees and expenses of the Selling Shareholders. The Company has agreed to indemnify the Selling Shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. The Selling Shareholders have agreed to indemnify the Company against certain losses, claims, damages and liabilities, including liabilities under the Securities Act arising out of or based upon any untrue statement of any material fact contained in the registration statement, or solely arising out of or relating to the omission to state a material fact required to be stated in this registration statement or necessary to make the statements herein not misleading, in each case to the extent that such untrue statement or alleged untrue statement or omission or alleged omission was made in the registration statement in reliance upon and in conformity with written information furnished by such Selling Shareholders expressly for use in connection with the registration statement.

In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each Selling Shareholder has advised us that it has not entered into any written or oral agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Shareholders.

We agreed to keep this prospectus effective for a period ending on the earlier to occur of (i) the date that all of the common shares have been sold or (ii) the second anniversary of the mandatory effective date of 60 calendar days after the filing date of this registration statement, if the SEC determines not to review the registration statement, or 120 calendar days after the filing date of this registration statement, if the SEC determines to review the registration statement; provided, that in either case such date shall be extended by the amount of time of any suspension period, as described in the registration rights agreement. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common shares for a period of two business days prior to the commencement of the distribution. In addition, the Selling Shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations

Table of Contents

thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common shares by the Selling Shareholders or any other person. We will make copies of this prospectus available to the Selling Shareholders and have informed it of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

Warrants

The following description is a summary of material provisions of the warrants issued in our private placements on November 28, 2007. It does not restate the terms of the warrants in their entirety. We urge you to read the forms of warrant because they, and not this description, define the rights of the holders of the warrants.

Offering Selling Shareholder Warrants

The warrants issued to the Offering Selling Shareholders (the Offering Selling Shareholder Warrants) in our private placement on November 28, 2007, when exercised, entitle the Offering Selling Shareholders to receive an aggregate of 1,079,169 shares of common stock at an exercise price of \$7.18 per share, subject to adjustment. The Offering Selling Shareholder Warrants are exercisable at any time during the period from November 28, 2008 to November 28, 2012. Generally, an Offering Selling Shareholder Warrant, or a part thereof, is not exercisable, if, upon such exercise, the number of shares of common stock held or beneficially owned by such Offering Selling Shareholder would exceed 9.99% of the number of shares of Common Stock then issued and outstanding. This restriction, however, can be waived by the Offering Selling Shareholder upon written notice to the Company.

The exercise price and the number of shares of common stock purchasable upon exercise of the Offering Selling Shareholder Warrants both will be subject to adjustment in certain events including:

- (a) stock dividend payable in common stock, stock split, or subdivision of our common stock;
- (b) reclassification of our common stock or any reorganization, consolidation, merger, or sale, lease, license, exchange or other transfer of all or substantially all, of the business and/or assets of the Company.

Agent Warrants

The warrants issued to RJ Aubrey in a private placement on November 28, 2007 (the Agent Warrants), when exercised, entitle RJ Aubrey to receive 80,000 shares of common stock at an exercise price of \$10.00 per share, subject to adjustment. The Agent Warrants are exercisable at any time during the period from November 28, 2008 to November 28, 2012. The Agent Warrants, or a part thereof, are not exercisable, if, upon such exercise, the number of shares of common stock held or beneficially owned by RJ Aubrey would exceed 9.99% of the number of shares of Common Stock then issued and outstanding. This restriction, however, can be waived by RJ Aubrey upon written notice to the Company. This restriction, however, can be waived by RJ Aubrey upon written notice to the Company.

The exercise price and the number of shares of common stock purchasable upon exercise of the Agent Warrants both will be subject to adjustment in certain events including:

- (a) stock dividend payable in common stock, stock split, or subdivision of our common stock;
- (b) reclassification of our common stock or any reorganization, consolidation, merger, or sale, lease, license, exchange or other transfer of all or substantially all, of the business and/or assets of the Company.

Expenses

The following table sets forth the estimated amounts of expenses to be borne by the Company in connection with the issuance and distribution of the common shares being registered, other than underwriting discounts and commissions:

| | |
|---|--------------|
| Securities and Exchange Commission Registration Fee | \$ 916.00 |
| Accounting Fees and Expenses | \$ 10,000.00 |

Edgar Filing: ROCKWELL MEDICAL, INC. - Form 424B3

| | |
|--|---------------|
| Legal Fees and Expenses | \$ 120,000.00 |
| Transfer Agent's and Registrar's Fees and Expenses | \$ 2,000.00 |
| Miscellaneous Expenses | \$ 11,250.00 |
| Total | \$ 144,166.00 |

Table of Contents

None of these expenses will be borne by the Selling Shareholders. All of these expenses, except the Securities and Exchange Commission Registration Fee, represent estimates only.

LEGAL MATTERS

The validity of the issuance of the common stock offered by this prospectus will be passed upon for us by Dykema Gossett PLLC.

EXPERTS

The financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-KSB for the year ended December 31, 2006, have been audited by Plante & Moran, PLLC, independent auditors, as stated in their report which is incorporated in this prospectus by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.