ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10-K
March 12, 2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 000-23661
ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

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

(248) 960-9009
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, no par value	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act:
(None)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

The aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2009 (computed by reference to the closing sales price of the registrant s Common Stock as reported on the NASDAQ Global Market on such date) was $87,376,165. For purposes of this computation, shares of common stock held by our executive officers, directors and common shareholders with 10% or more of the outstanding shares of Common Stock were excluded. Such determination should not be deemed an admission that such officers, directors and beneficial owners are, in fact, affiliates.

Number of shares outstanding of the registrant s Common Stock, no par value, as of February 28, 2010: 17,202,108 shares.

Documents Incorporated by Reference

Portions of the Registrant s definitive Proxy Statement pertaining to the 2010 Annual Meeting of Shareholders (the Proxy Statement) to be filed pursuant to Regulation 14A are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

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PART I

References to the Company, we, us and our are to Rockwell Medical Technologies, Inc. and its subsidiaries unless otherwise specified or the context otherwise requires.

Forward Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue , predict , fo intend or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the potential for the Centers for Medicare and Medicaid Services, or CMS, to change its reimbursement policies and the effect on our business if such change is made, 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 report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, including without limitation in Item 1A Risk Factors, and from time to time in our other 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. 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 required by law.

Item 1. *Description of Business.*

General

Rockwell Medical Technologies, Inc., incorporated in the state of Michigan in 1996, manufactures 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 (CKD) 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. Iron supplementation is routinely

administered to more than 90% of patients receiving treatment for anemia. We have licensed a drug therapy for the delivery of iron supplementation for anemic dialysis patients which we refer to as dialysate iron and more specifically as soluble ferric pyrophosphate (SFP). To realize a commercial benefit from this therapy, and pursuant to the licensing agreement, we must complete clinical trials and obtain U.S. Food and Drug Administration (FDA) approval to market iron supplemented dialysate. We also plan to seek foreign market approval for this product. We believe this product will substantially improve iron maintenance therapy and, if approved, will compete for the global market for iron maintenance therapy. Based on reports from manufacturers of intravenous

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(IV) iron products and industry estimates, the market size in the United States for IV iron therapy for all indications is approximately $560 million per year. We estimate the global market for IV iron therapy is in excess of $850 million per year. We cannot, however, give any assurance that this product will be approved by the FDA or, if approved, that it will be successfully marketed.

We have also entered into a licensing agreement related to a patent for the delivery of carnitine and vitamins via our hemodialysis solutions. To realize a commercial benefit of this product we must obtain regulatory approval of this product. We seek to add other renal therapies to our pipeline in the future.

Our Business Strategy

Our strategy is to become a leading biopharmaceutical company focused on renal indications. The following are the key elements of our business strategy:

Obtain Regulatory Approval of our Lead Drug Candidate, SFP, Indicated for the Treatment of Iron Deficiency Anemia.

We intend to initiate late stage clinical trials for SFP and obtain FDA regulatory approval to market SFP. We intend to market SFP using our existing operating business infrastructure which currently serves approximately 25% of the U.S. dialysis market.

Develop our Product Portfolio of Renal and Anemia Drugs, Including Extensions of SFP.

We intend to initiate clinical development and obtain FDA regulatory approval to market other extensions of drug products based upon the SFP technology. We believe our SFP technology can be leveraged into other applications. Another developmental candidate in our portfolio is a licensed product that includes carnitine and vitamins delivered via dialysate.

Identify Novel Drug Targets to Address Unmet Market Opportunities.

Our objective is to identify and validate novel drug targets for CKD, ESRD and other therapeutic areas.

Obtain Partners to Achieve Global Development and Commercialization of our Products.

We seek commercial collaborations to develop our products, obtain regulatory approval and realize financial benefits on an international or global basis. We intend to leverage the development, regulatory and commercialization expertise of potential business partners to accelerate the development of certain potential products through licensing of selected technologies.

Acquire Rights to Complementary Drug Candidates and Technologies.

We intend to continue to selectively pursue and acquire rights to drug products in various stages of development while leveraging our dialysis market position.

Continue Development of our Commercial Business and Market Position.

We intend to continue to develop our market presence in our dialysis products business, which will provide a broader platform from which we can sell new products to the dialysis market.

Our Markets

How Hemodialysis Works

Hemodialysis patients generally receive their treatments at independent hemodialysis clinics or at hospitals. A hemodialysis provider such as a hospital or a free standing clinic uses a dialysis station to treat patients. A dialysis station contains a dialysis machine that takes concentrate solutions primarily consisting of nutrients and minerals, such as our liquid concentrate solutions or our concentrate powders mixed with purified water, and accurately dilutes those solutions with purified water. The resulting solution, known as dialysate, is then pumped through a

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device known as a dialyzer (artificial kidney), while at the same time the patient s blood is pumped through a semi-permeable membrane within the dialyzer. Excess water and chemicals from the patient s blood pass through the membrane and are carried away in the dialysate while certain nutrients and minerals in the dialysate penetrate the membrane and enter the patient s blood to maintain proper blood chemistry. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and acetic acid. The patient s physician chooses the formula required for each patient based on each particular patient s needs, although most patients receive one of eight common formulations.

In addition to using concentrate solutions and chemical powders (which must be replaced for each use for each patient), a dialysis provider also requires various other ancillary products such as blood tubing, fistula needles, specialized custom kits, dressings, cleaning agents, filtration salts and other supplies, many of which we sell.

Dialysis Industry Trends

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 (USRDS) we estimate that there are approximately 5,400 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 63% of the domestic hemodialysis market. According to industry statistics published by USRDS at the end of 2007, 358,000 patients in the United States were receiving dialysis treatments. The domestic dialysis industry has experienced steady patient population growth over the last two decades. U.S. patient population growth has averaged 4% per year over the last five years.

ESRD incidence rates vary by country with some higher and most lower than the United States. Based on industry reports, the global ESRD population is estimated to be over 2 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 between approximately 55-60% of the total global treatments based on industry estimates.

Our Products

We manufacture, sell, distribute and deliver hemodialysis concentrates as well as a full line of ancillary hemodialysis products to hemodialysis providers and distributors located in 37 states and territories as well as a number of foreign countries, primarily in Latin America, Asia and Europe. Hemodialysis concentrates are comprised of two primary product types, which are generally described as acidified dialysate concentrate, also known as acid concentrate, and bicarbonate.

Renal Pure Liquid Acid Concentrate

Acid concentrate generally contains sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. Acid concentrate products are manufactured in three basic series to reflect the dilution ratios used in various types of dialysis machines. We supply all three series and currently manufacture approximately 60 different liquid acid concentrate formulations. We supply liquid acid concentrate in both 55 gallon drums and in cases containing four one gallon containers.

Dri-Sate® Dry Acid Concentrate & Mixing System

We have 510(k) clearance from the FDA to market Dri-Sate Dry Acid Concentrate & Mixing System. Our Dri-Sate Dry Acid Concentrate & Mixing System allows a clinic to mix its acid concentrate on-site. The clinical technician, using a specially designed mixer, adds pre-measured packets of the necessary ingredients to 50 or 100 gallons of purified water (AMII standard). Once mixed, the product is equivalent to the acid concentrate provided to our

customers in liquid form. Clinics using Dri-Sate Dry Acid Concentrate realize numerous advantages, including lower cost per treatment, reduced storage space requirements, reduced number of deliveries and more flexibility in scheduling deliveries. In addition to the advantages to our customers, our freight costs are lower for Dri-Sate Dry Acid Concentrate than for acid concentrate in the liquid form. We can also realize greater productivity from our truck fleet resources delivering dry products.

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RenalPure Powder Bicarbonate Concentrate

Bicarbonate is generally sold in powder form and each clinic generally mixes bicarbonate on site as required. We offer 9 different bicarbonate powder products covering all three series of generally used bicarbonate dilution ratios.

SteriLyte® Liquid Bicarbonate Concentrate

We have 510(k) clearance from the FDA to market SteriLyte Liquid Bicarbonate. Our SteriLyte Liquid Bicarbonate is used in both acute care and chronic care settings. Our SteriLyte Liquid Bicarbonate offers the dialysis community a high-quality product and provides the clinic a safe supply of bicarbonate.

Ancillary Products

We offer a wide range of ancillary products including blood tubing, fistula needles, specialized custom kits, dressings, cleaning agents, filtration salts and other supplies used by hemodialysis providers.

Iron Supplemented Dialysate

We have licensed the exclusive right to manufacture and sell SFP, a product that we believe, when approved by the FDA, will substantially improve the treatment of dialysis patients with iron deficiency, which is pervasive in the dialysis patient population. Iron deficiency in dialysis patients typically results from the demands placed upon the body by current dialysis drug therapies. Most dialysis patients receive replacement therapy of recombinant human erythropoietin commonly referred to as erythropoiesis stimulating agents, or ESA. An ESA is an artificial hormone that acts in the bone marrow to increase the production of red blood cells, which carry oxygen throughout the body to nourish tissues and sustain life. Hemoglobin, an important constituent of red blood cells, is composed largely of iron and protein.

Treatment with ESA therapy requires adequate amounts of iron, as well as the rapid mobilization of iron reserves, for new hemoglobin synthesis and new red blood cell formation. The demands of this therapy can outstrip the body s ability to mobilize iron stores. An ESA is commonly administered as a large IV injection on an intermittent basis, which creates an unnatural strain on the iron release process when the need for iron outstrips its rate of delivery, called functional iron deficiency. In addition, the majority of dialysis patients also suffer from iron deficiency resulting from blood loss from dialysis treatments and reduced dietary intake of iron. Accordingly, iron supplementation is required to maintain proper iron balance and ensure good therapeutic response from ESA treatments. The liver is the site of most stored iron. Iron stores typically will be depleted before the production of iron-containing proteins, including hemoglobin, is impaired. Most dialysis patients receiving ESA therapy also receive iron supplement therapy in order to maintain sufficient iron stores and to achieve the full benefit of ESA treatments.

Current iron supplement therapy involves IV parenteral iron compounds, which deposit their iron load into the liver rather than directly to blood plasma to be carried to the bone marrow. The liver slowly processes these iron deposits into a useable form. As a result of the time it takes for the liver to process a dosage of IV iron into useable form, there can be volatility in iron stores, which can reduce the effectiveness of ESA treatments.

Our iron supplemented dialysate is distinctly different from IV iron compounds because our product transfers iron in a useable form directly from dialysate into the blood plasma, from which it is carried directly to the bone marrow for the formation of new red blood cells. The kinetic properties of our iron compound allows for the rapid uptake of iron in blood plasma by molecules that transport iron called transferrin. The frequency and dosage of our iron supplemented dialysate is designed and intended to maintain iron balance in a steady state. We believe that this more direct method of iron delivery will be more effective at maintaining iron balance in a steady state and achieving superior therapeutic

response from ESA treatments.

Iron supplemented dialysate has other benefits that we believe are important. Iron administered by our product bypasses the liver altogether and thereby avoids causing oxidative stress to the liver, which we believe is a significant risk of current iron supplement therapies. In addition, we believe that clinics may realize significant drug

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administration savings due to decreased nursing time for administration and elimination of supplies necessary to administer IV iron compounds.

We are currently conducting the testing required to obtain FDA approval to market SFP in the United States. A Phase IIa clinical trial on our licensed iron supplemented dialysate product under an Investigational New Drug (IND) exemption was completed by our licensor prior to us licensing the product. We completed our Phase IIb human clinical trial at the end of 2009. The Phase IIb study showed SFP was well-tolerated without apparent toxicity and there was overwhelming evidence of dose-dependent SFP-derived iron transfer and uptake based on iron parameters as surrogate markers of efficacy. One of the primary endpoints of the study, a decrease in hemoglobin of at least 1.0 g/dL, was not met primarily due to problems with the study design and the iron-replete nature of enrolled patients, coupled with the control group being unexpectedly and substantially more iron replete than the rest of the test population at the beginning of the study. The other primary endpoint was achieved with the demonstration of safety across all dose groups.

It is our intention to commence our Phase III clinical program after we review the results of our Phase II study and our Phase III clinical design with the FDA.

Distribution and Delivery Operations

The majority of our domestic sales are delivered by our subsidiary, Rockwell Transportation, Inc. Rockwell Transportation, Inc. operates a fleet of trucks which are used to deliver products to our customers. A portion of our deliveries, primarily to medical products distributors, is provided by common carriers chosen by us based on rates.

We perform services for customers that are generally not available from common carriers, such as stock rotation, non-loading-dock delivery and drum pump-offs. Certain of our competitors use common carriers and/or do not perform the same services upon delivery of their products. We believe we offer a higher level of service to our customers because of the use of our own delivery vehicles and drivers.

Our Dri-Sate Dry Acid Concentrate provides an economic incentive to our customers to migrate from liquid acid dialysate in drums to our dry acid concentrate as a result of distribution synergies realized from Dri-Sate. As an example, a pallet containing four drums of liquid acid concentrate contains 220 gallons of liquid acid concentrate. On a pallet containing our Dri-Sate Dry Acid Concentrate, we can ship the equivalent of 1,200 gallons of acid concentrate in powder form. The potential distribution savings offered with Dri-Sate coupled with other advantages over drums make Dri-Sate an attractive alternative for many customers.

Sales and Marketing

We primarily sell our products directly to domestic hemodialysis providers through direct salespeople employed by us and through several independent sales representation companies. Our President and Chief Executive Officer leads and directs our sales efforts to our major accounts. We also utilize several independent distributors in the United States. Our products are sold to certain international customers through independent sales agents and distributors.

Our sales and marketing initiatives are directed at purchasing decision makers at large for-profit national and regional hemodialysis chains and toward independent hemodialysis service providers. Our marketing efforts include advertising in trade publications, distribution of product literature and attendance at industry trade shows and conferences. We target our sales and marketing efforts to clinic administrators, purchasing professionals, nurses, medical directors of clinics, hospital administrators and nephrologists.

Competition

Dialysis Concentrate and Supplies Competition

We compete against larger more established competitors with substantially greater financial, technical, manufacturing, marketing, research and development and management resources. We had three major competitors until one of our major competitors, Gambro Healthcare, Inc. (Gambro), exited the hemodialysis concentrate market at the end of 2006. Our largest competitor is a subsidiary of Fresenius Medical Care AG& Co. KGaA

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(Fresenius), which is primarily in the business of operating dialysis clinics but also manufactures and markets dialysis devices, drugs and supplies. Globally, Fresenius is vertically integrated, manufacturing a broad range of dialysis products, marketing several dialysis related drugs, and selling a more comprehensive line of dialysis equipment, supplies and services than we sell.

Fresenius treats over 127,500 dialysis patients in North America and operates approximately 1,700 clinics. It also has a renal products business that manufactures a broad array of equipment and supplies, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. In addition to its captive customer base in its own clinics, Fresenius also serves other clinic chains and independent clinics with its broad array of products where it commands a market leading position in its key product lines. Fresenius manufactures its concentrate in its own regional manufacturing facilities. Fresenius operates an extensive warehouse network in the United States serving its captive customer base and other independent clinics.

Gambro manufactures and sells hemodialysis machines, dialyzers and other ancillary supplies. Until the end of 2006, Gambro marketed its concentrate solutions to dialysis chains and independent clinics. Gambro sold products to its own clinics until October 2005 when it sold those clinics to DaVita, Inc. (DaVita), our largest customer. Concurrent with Gambro s exit from the concentrate business in late 2006, we began to service many of the DaVita clinics previously serviced by Gambro. DaVita currently services approximately 117,000 patients in 1,500 clinics.

We also compete against Cantel Medical Corp. s subsidiary, Minntech Corporation (Minntech). Minntech s Renal Systems division primarily sells dialysis concentrates and Renalin, a specialty reuse agent for sanitizing dialyzers. Minntech has one domestic manufacturing facility located in Minnesota. We believe Minntech primarily sells its liquid concentrate products to domestic customers within a 300 mile radius of its facility.

In addition, we compete against other distributors with respect to certain ancillary products and supplies.

Iron Maintenance Therapy Market Competition

We intend to enter the iron maintenance therapy market for the treatment of dialysis patients with anemia. We must obtain FDA approval for our iron supplemented dialysate to enter this market. The iron therapy market for IV iron in the United States presently has several competitors and is dominated by two second generation IV iron drugs, Venofer® and Ferrlecit®. Venofer® is the global market leader for IV iron therapy. Venofer® is owned by Switzerland-based Galenica. Galenica has also developed a new product, Ferinject®, for which it is seeking FDA approval. Ferinject® is not approved for marketing in the United States.

In the U.S. and Canada, Galenica exclusively licenses Venofer® and Injectafer® (US brand name for Ferinject®) to Luitpold Pharmaceuticals, Inc., a wholly owned US subsidiary of Daiichi Sankyo Company Ltd., which has entered into a corresponding ten year sublicense agreement with Fresenius Medical Care to manufacture and distribute Venofer® to the dialysis market in the US and Canada. Venofer® is currently being marketed by Fresenius in the United States to the dialysis market while Luitpold, through its subsidiary American Regent, Inc., markets Venofer for other markets and indications including the pre-dialysis CKD market.

Sanofi-Aventis did not renew its US marketing license of Ferrlecit® with Watson Pharmaceutical, Inc. (Watson) and plans to market Ferrlecit® in the United States beginning in 2010. Ferrlecit® is an injectable iron supplement made of sodium ferric gluconate complex in sucrose.

Watson intends to market a generic version of Ferrlecit® in the future. Watson also markets a product called IN-FeD® which is an injectable iron supplement made of dextran and ferric hydroxide. Watson is a large manufacturer of both generic and branded drugs.

In 2009, AMAG Pharmaceuticals, Inc. obtained FDA approval to market ferumoxytol, a parenteral iron product, and began marketing it, under the brand name Feraheme® in late 2009 to both pre-dialysis and chronic dialysis patients. We believe that both Feraheme® and Ferinject® are primarily intended to target the pre-ESRD markets and other indications such as oncology but they may compete in the ESRD market as well.

The markets for drug products are highly competitive. Competition in drug delivery systems is generally based on marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by dialysis providers and nephrologists is also critical to the success of a product. The

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first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share. In a highly competitive marketplace and with evolving technology, additional product introductions or developments by others might render our products or technologies noncompetitive or obsolete. In addition, pharmaceutical and medical device companies are largely dependent upon health care providers being reimbursed by private insurers and government payors. Drugs approved by the FDA might not receive reimbursement from private insurers or government payors. Even if approved by the FDA, providers of dialysate iron maintenance therapy might not obtain reimbursement from insurers or government payors. If providers do not receive reimbursement for dialysate iron maintenance therapy, the commercial prospects and marketability of the product would be severely diminished.

CMS has historically paid providers for dialysis treatments under the Medicare program in two parts: the composite rate and separately reimbursed drugs and services. The composite rate is payment for the complete dialysis treatment except for physicians professional services, separately billed laboratory services, separately billed drugs. CMS reimbursement practices are changing, which we think may benefit our marketing efforts. CMS will begin implementation of a fully bundled reimbursement rate on January 1, 2011 and is intended to be fully implemented by 2014. This change is expected to result in a single composite rate per treatment, thereby eliminating reimbursement for individual drugs and services to providers. While the precise terms and structure of the reimbursement procedures under this capitated rate program are not expected to be fully known until closer to implementation, we believe that the provider market may find the potential economic advantages of our iron supplemented dialysate to be an attractive alternative to IV iron drugs. Providers may be attracted to SFP over IV iron products due to the lower cost of administration and the potential for improved therapeutic response from costly ESA treatments.

Quality Assurance and Control

We place significant emphasis on providing quality products and services to our customers. Quality management plays an essential role in determining and meeting customer requirements, identifying, preventing and correcting variance from specifications and improving our products. We have implemented quality systems that involve control procedures that result in rigid conformance to specifications. Our quality systems also include assessments of suppliers of raw materials, packaging components and finished goods, and quality management reviews designed to inform management of key issues that may affect the quality of products, assess the effectiveness of our quality systems and identify areas for improvement.

Technically trained professionals at our production facilities develop and implement our quality systems which include specific product testing procedures and training of employees reinforcing our commitment to quality and promoting continuous process improvements. To assure quality and consistency of our concentrates, we conduct specific analytical tests during the manufacturing process for each type of product that we manufacture. Our quality control laboratory at each facility conducts analytical tests to verify that the chemical properties of the concentrates comply with the specifications required by industry standards. Upon verification that a batch meets those specifications, we then package those concentrates. We also test packaged concentrates at the beginning and end of each production run to assure product consistency during the filling process. Each batch is assigned a lot number for tracking purposes and becomes available for shipment after verification that all product specifications have been met.

We use automated testing equipment in order to assure quality and consistency in the manufacture of our concentrates. The equipment allows us to analyze the materials used in the hemodialysis concentrate manufacturing process, to assay and adjust the in-process hemodialysis concentrate, and to assay and certify that the finished products are within the chemical and biological specifications required by industry regulations. Our testing equipment provides us with a high degree of accuracy and efficiency in performing the necessary testing.

Government Regulation

The testing, manufacture and sale of our hemodialysis concentrates and the ancillary products we distribute are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Under the Federal Food, Drug and Cosmetic Act (the FD&C Act), and FDA regulations, the

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FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and marketing of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution.

We plan to develop and commercialize selected drug candidates by ourselves such as our iron supplemented dialysate product. The development and regulatory approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy and uncertain. Before marketing in the United States, any pharmaceutical or therapeutic product must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FD&C Act.

Moreover, the FDA imposes substantial requirements on new product research and the clinical development, manufacture and marketing of pharmaceutical products, including testing and clinical trials to establish the safety and effectiveness of these products.

Medical Device Approval and Regulation

A medical device may be marketed in the United States only with prior authorization from the FDA unless it is subject to a specific exemption. Devices classified as Class I devices (general controls) or Class II devices (general and special controls) are eligible to seek 510(k) clearance from the FDA. Such clearance generally is granted when submitted information establishes that a proposed device is substantially equivalent to a legally marketed device that is not subject to premarket approval. A legally marketed device is a pre-amendment device that was legally marketed prior to May 28, 1976. The FDA in recent years has been requiring a more rigorous demonstration of substantial equivalence than in the past, including requiring clinical trial data in some cases. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new 510(k) submissions. We have been advised that it usually takes from three to six months from the date of submission to obtain 510(k) clearance, and may take substantially longer. Our hemodialysis concentrates, liquid bicarbonate and other ancillary products are categorized as Class II devices.

A device which sustains or supports life, prevents impairment of human health or which presents a potential unreasonable risk of illness or injury is categorized as a Class III device. A Class III device generally must receive approval through a pre-market approval (PMA) application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We have been advised that it usually takes from one to three years to obtain approval after filing the request, and may take substantially longer.

If human clinical trials of a device are required, whether for a 510(k) submission or a PMA application, and the device presents a significant risk, the sponsor of the trial (usually the manufacturer or the distributor of the device) will have to file an investigational device exemption (IDE) application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is approved by the FDA and one or more appropriate Institutional Review Boards (IRBs), the device may be shipped for the purpose of conducting the investigations without compliance with all of the requirements of the FD&C Act and human clinical trials may begin. The FDA will specify the number of investigational sites and the number of patients that may be included in the investigation. If the device does not present a significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the study by one or more appropriate IRBs without the need for FDA approval.

Any devices manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA and certain state agencies. As a manufacturer of medical devices for marketing in the United States we are required to adhere to regulations setting forth detailed good manufacturing practice (GMP) requirements, which include testing, control and documentation requirements. We must also comply with medical device reporting regulations which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Labeling and

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promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

We are subject to routine inspection by the FDA and certain state agencies for compliance with GMP requirements and other applicable quality system regulations. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, transportation and disposal of hazardous or potentially hazardous substances.

We have 510(k) clearance from the FDA to market hemodialysis concentrates in both liquid and powder form. In addition, we have received 510(k) clearance for our Dri-Sate Dry Acid Concentrate Mixer.

We must comply with the FD&C Act and related laws and regulations, including GMP, to retain 510(k) clearances. We cannot assure you that we will be able to maintain our 510(k) clearances from the FDA to manufacture and distribute our products. If we fail to maintain our 510(k) clearances, we may be required to cease manufacturing and/or distributing our products, which would have a material adverse effect on our business, financial condition and results of operations. If any of our FDA clearances are denied or rescinded, sales of our products in the United States would be prohibited during the period we do not have such clearances.

In addition to the regulations for medical devices covering our current dialysate products, our new product development efforts will be subject to the regulations pertaining to pharmaceutical products. We have signed a licensing agreement for iron supplemented dialysate to be included in our dialysate products. Water soluble iron supplements when coupled with our dialysate are intended to be used as an iron maintenance therapy for dialysis patients, and we have been advised that this dialysate iron product will be considered a drug/device combination by the FDA. As a result, our iron maintenance therapy product will be subject to the FDA regulations for both pharmaceutical products and medical devices.

Drug Approval and Regulation

The marketing of pharmaceutical products, such as our new iron maintenance therapy product, in the United States requires the approval of the FDA. The FDA has established regulations, guidelines and safety standards which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of our new iron maintenance therapy product and other pharmaceutical products. The process of obtaining FDA approval for our new product may take several years and involves the expenditure of substantial resources. The steps required before a pharmaceutical product can be produced and marketed for human use include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of a New Drug Application (NDA) or, in some cases, an Abbreviated New Drug Application (ANDA); and (v) review and approval of the NDA or ANDA by the FDA. An NDA generally is required for products with new active ingredients, new indications, new routes of administration, new dosage forms or new strengths. An NDA requires that complete clinical studies of a product s safety and efficacy be submitted to the FDA, the cost of which is substantial. The costs are often less, however, for new delivery systems which utilize already approved drugs than for drugs with new active ingredients.

An ANDA is a marketing application filed as part of an abbreviated approval process that is available for generic drug products that have the same active ingredient(s), indication, route of administration, dosage form and dosage strength as an existing FDA-approved product, if studies have demonstrated bio-equivalence of the new product to the FDA-approved product. Under applicable regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on the approved product s patent or that such patent has expired. If the

applicant certifies that its product does not infringe on the approved product s patent, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent, and the FDA may not finally approve the ANDA until a court finally determines that the applicable patent is invalid or would not be infringed by the applicant s product.

Pre-clinical studies are conducted to obtain preliminary information on a pharmaceutical product s efficacy and safety in animal or in vitro models. The results of these studies are submitted to the FDA as part of the IND and

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are reviewed by the FDA before human clinical trials begin. Human clinical trials may begin 30 days after receipt of the IND by the FDA unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase I trials consist of testing the product primarily for safety in a small number of patients or healthy volunteers at one or more doses. In Phase II trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase I trials with the primary intent of determining the effective dose range. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at a large number of test sites. A clinical plan, or protocol, accompanied by documentation from the institutions participating in the trials, must be received by the FDA prior to commencement of each of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or an ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or an ANDA in a timely manner. The FDA may deny an NDA or an ANDA if applicable regulatory criteria are not satisfied or it may require additional testing, including pre-clinical, clinical and or product manufacturing tests. Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA or an ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

Manufacturing facilities are subject to periodic inspections for compliance with regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may also have similar regulations. We expend significant time, money and effort in the area of quality assurance to fully comply with all applicable requirements. FDA approval to manufacture a drug is site specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations. Manufacturers and distributors must comply with various post-market requirements, including adverse event reporting, re-evaluation of approval decisions and notices of changes in the product.

Other government regulations

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. Recent health reform proposals, if enacted, are likely to result in material changes to the Medicare and Medicaid programs and levels of reimbursement and possibly the imposition of fees or excise taxes on pharmaceutical and device manufacturers based on revenues. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations.

The approval procedures for the marketing of our 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. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries which typically do not require additional testing for products that have received FDA approval.

However, since medical practice and governmental regulations differ across regions, further testing may be needed to support market introduction in some foreign countries. Some foreign regulatory agencies may require additional studies involving patients located in their countries. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Issues related to import and export can delay product

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introduction. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Product License Agreements

We entered into two license agreements with an entity covering drugs and vitamin additives to dialysate. These license agreements cover both issued patents and pending patent applications in the United States and abroad. We entered into these license agreements in 2002 and 2006. The U.S. and foreign license rights extend until approximately 2023.

We are a party to a product license agreement for an issued U.S. patent and pending international patent applications for a combination drug and vitamin supplement to be delivered by dialysate. This product license includes a complex of carnitine and vitamins. The license agreement requires us to seek and to fund U.S. regulatory approval. The license agreement calls for ongoing royalties for any product sales following regulatory approval during the life of the patent and a reduced royalty rate for ten years thereafter.

We are also a party to a license agreement for SFP that covers issued patents in the United States, the European Union and Japan, as well as patent and pending patent applications in other foreign jurisdictions. The license agreement continues for the duration of the underlying patents in each country, or until August 14, 2016 in the United States, and may be extended thereafter. Patents were issued in the United States in 1999 and 2004. The European patent was issued in 2005 and extends through 2017. The Japanese patent was issued in 2007 and extends through 2017.

Our SFP license agreement requires us to obtain and pay the cost of obtaining FDA approval of the product in order to realize any benefit from commercialization of the product. In addition to funding safety pharmacology testing, clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product. The milestone payments include a payment of $50,000 which will become due upon completion of Phase III clinical trials, a payment of $100,000 which will become due upon FDA approval of the product and a payment of $175,000 which will become due upon issuance of a reimbursement code covering the product.

Trademarks & Patents

We have several trademarks and servicemarks used on our products and in our advertising and promotion of our products, and we have applied for U.S. registration of such marks. Most such applications have resulted in registration of such trademarks and servicemarks.

We were issued patents in the U.S. and Canada for our Dri-Sate Dry Acid Concentrate method and apparatus for preparing liquid dialysate which expire on September 17, 2019.

In addition to the patent protection afforded SFP under our licensing agreement, we have a pending patent application which covers SFP s active pharmaceutical ingredient, its synthesis and its manufacture.

Suppliers

We believe the raw materials and packaging materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products distributed by us are generally available from several potential suppliers. Our principal suppliers include Roquette, Inc., Church & Dwight Co. Inc. and US Salt Company. Key suppliers of services for our clinical trials, including contract research organizations, lab testing services and other service providers, are available from a number of potential vendors.

Customers

We operate in one market segment which involves the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process to hemodialysis clinics. For the years ended December 31, 2009, 2008 and 2007, one customer, DaVita, Inc., accounted for 50%, 51% and 52% of our sales, respectively. Our accounts receivable from this customer were $1,267,500 and $2,620,000 as of

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December 31, 2009 and 2008, respectively. We are dependent on this key customer and the loss of its business would have a material adverse effect on our business, financial condition and results of operations. No other customers accounted for more than 10% of our sales.

The majority of our international sales in each of the last three years were sales to domestic distributors that were resold to end users outside the United States. Our sales to foreign customers and distributors amounted to less than 5% of our total sales in each of those years and we have no assets outside the United States. Our total international sales, including sales to domestic distributors for resale outside the United States, aggregated 12%, 10% and 5% of overall sales in 2009, 2008 and 2007, respectively.

Employees

As of December 31, 2009, we had approximately 300 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an at-will basis.

Research & Development

We are required to pay the cost of obtaining FDA approval to market SFP in order to realize any benefit from commercialization of the product, which we expect will take several years and be costly to us. We completed our pre-clinical testing in 2007 and our Phase IIb dose ranging study in late 2009. We engaged outside service providers, contract research organizations, consultants and legal counsel to assist us with clinical trials, product development and obtaining regulatory approval. In addition, we incurred ongoing expenses related to obtaining additional protection of the intellectual property underlying our licensing agreements. In 2009, 2008 and 2007, we incurred aggregate expenses related to the commercial development of SFP of approximately $6.5 million, $3.8 million and $3.3 million, respectively.

We estimate that it will cost approximately $15 million to complete our clinical testing and obtain FDA approval to market SFP. We estimate that we will spend $18 million or more on product development and other research activities over the next two years, including our SFP expenditures. These costs will have a material impact on us and we are likely to incur annual losses for the duration of the clinical trials. Our current level of capital resources is expected to be adequate to fund our expected funding requirements. However, if we need to do more testing than expected, we may need to raise additional capital at some future date.

Where You Can Get Information We File with the SEC

Our internet address is http://www.rockwellmed.com. You can access free of charge on our web site all of our reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports. These reports are available as soon as practicable after they are electronically filed with the SEC.

The SEC also maintains a website on the internet that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. The address of the SEC s Web site is http://www.sec.gov.

Item 1A. ***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.

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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 one of our customers that accounts for a substantial portion of our sales. The loss of this customer would have a material adverse affect 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 a majority of our total sales during each of the last three 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 substantially larger competitors with greater resources.

There is intense competition in the hemodialysis product market and 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 have 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, we may not be able to market it successfully.

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 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. While our gross profit margins improved substantially in 2009 due to a variety of factors including product mix shifts to less expensive products,

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reductions in fuel and chemical costs and increased product pricing, we may realize future cost and pricing pressure which may cause our gross profit margins to decrease.

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.

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.