ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10-K
March 05, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

OR

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

Commission file number 000-23661

ROCKWELL MEDICAL 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 ¨ No x

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 ¨ No x

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 x No ¨

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 x No ¨

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. ¨

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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2011 (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 $191,629,578. 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 24, 2012: 20,707,886 shares.

Documents Incorporated by Reference

Portions of the Registrant s definitive Proxy Statement pertaining to the 2012 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.

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 , pr projected, intend or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the Centers for Medicare & Medicaid Services, or CMS, changes to its reimbursement policies and the effect on our business, statements regarding the timing and costs of obtaining FDA approval of our new products, statements regarding our new products 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 Asia, Latin America 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 renal drug therapies. Our lead drug development product, soluble ferric pyrophosphate (SFP), is for iron supplementation, a key element in the formation of new red blood cells. Iron supplementation is routinely administered to more than 90% of patients receiving treatment for anemia. We have licensed a drug therapy, SFP, for the delivery of iron supplementation for anemic dialysis patients. To market SFP and 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. 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 maintenance therapy and, if approved, will compete for the global market for iron maintenance therapy. Based on reports from manufacturers of intravenous (IV) iron products and industry estimates, the market size in the United States for IV iron therapy for all indications is approximately $600 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 acquired an Abbreviated New Drug Application (ANDA) allowing us to make calcitriol, a generic FDA- approved 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. Vitamin D is important in the regulation of calcium and phosphate in the bloodstream along with promoting bone health. Based on manufacturers reports and our own independent research, we believe the ESRD related vitamin D market in the United States to be over $350 million. Because we will be using a new location with a contract manufacturer to manufacture calcitriol, we will be required to gain FDA regulatory approval for changes in manufacturing prior to being able to market calcitriol. We anticipate gaining FDA regulatory approval in late 2012 and plan to begin marketing calcitriol thereafter.

Our Business Strategy

Our strategy is to become a leading biopharmaceutical company focused primarily 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 are conducting Phase III clinical trials for SFP and will seek to 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, such as peritoneal dialysis.

Identify Novel Drug Targets to Address Unmet Market Opportunities.

Our objective is to identify and validate novel drug targets for development for conditions such as chronic kidney disease and ESRD as well as other therapeutic areas.

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 and approval while leveraging our dialysis market position.

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

While we intend to commercialize SFP in the United States, we anticipate seeking 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.

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. We may seek to acquire approved medical devices or drugs, other dialysis related products or service businesses including clinical or other dialysis service businesses that we believe may be complementary to our overall development efforts.

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 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. Citric acid, which acts as an anticoagulant, may be used in place of 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 is the primary treatment modality employed in the United States with over 92% of all dialysis patients receiving hemodialysis. The Company does 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 (USRDS) we estimate that there are approximately 5,800 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 65% of the domestic hemodialysis market. According to 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 with some higher and most lower than the United States. Based on industry reports, the global ESRD population receiving some form of dialysis treatment is estimated to be over 2.1 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 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 36 states and territories as well as a

number of foreign countries, primarily in Asia. Latin America and Europe. Hemodialysis concentrates, which account for over 94% of our revenue, are comprised of two primary product types, which are generally described as acidified dialysate concentrate, also known as acid concentrate, and bicarbonate.

Renal Pure® & CitraPure® Liquid Acid Concentrate

Acid concentrate generally contains either citric acid or acetic acid, along with 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. Our acetate-free, citric-acid concentrate includes citrate which acts as an anticoagulant and has been known to reduce inflammation.

Dri-Sate ® Dry Acid Concentrate & Mixing System

We have 510(k) clearance from the FDA to market Dri-Sate® Dry Acid Concentrate and our Dri-Sate Mixer. Our Dri-Sate Dry Acid Concentrate and Dri-Sate Mixer allow 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.

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 liquid bicarbonate, which we sell under the trade name 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.

SFP Iron Therapy

We have licensed the exclusive right to manufacture and sell SFP, a product that we believe, if and 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 continual blood losses from the dialysis treatment coupled with 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. 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 therapy in order to maintain sufficient iron stores and to achieve the full benefit of ESA treatments.

Current iron therapy to the ESRD population is generally provided thorough IV parenteral iron compounds, which are ultimately taken up by the reticuloendothelial system and primarily deposited in 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. In addition, IV iron generally produces an inflammatory response limiting the amount of iron released from the liver.

Our SFP 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 allow for the rapid uptake of iron in blood plasma by molecules that transport iron called transferrin. The frequency and dosage of our SFP iron delivered via 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.

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

We started our Phase III clinical program for SFP in 2011 and expect those studies to be completed in the first half of 2013. If those studies are successful, we plan to submit a New Drug Application to seek FDA approval to market SFP in the United States. We intend to license SFP or seek a partner for commercial development of SFP for markets outside of the United States.

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 or otherwise do not perform the same services upon delivery of their products. We believe we offer a higher level of service to our customers because we use 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 independent sales representation companies. Our President and Chief Executive Officer leads and directs our sales efforts to our major accounts. We also utilize 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 and more established competitors with substantially greater financial, technical, manufacturing, marketing, research and development and management resources. We have two major competitors. Our largest competitor is a subsidiary of Fresenius Medical Care AG& Co. KGaA (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 130,000 dialysis patients in North America and operates approximately 1,800 clinics in the United States. 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.

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.

Vitamin D Therapy Market Competition

We intend to begin marketing an intravenous vitamin D drug, calcitriol, in late 2012 following receipt of FDA approval. There are two primary branded drug competitors in the IV vitamin D market and several generic drug competitors. The market leader is Abbott Laboratories, which markets Zemplar® and prior to introducing Zemplar® marketed Calcijex®, the branded version of calcitriol. Sanofi-Aventis, through its Genzyme subsidiary,

markets Hectorol® and several other companies offer oral forms of vitamin D. Several other companies have historically marketed calcitriol. We plan to compete against these various vitamin D analogues and other generic competitors who may market calcitriol. We believe that our dialysis market position, product offering and account relationships may provide us with an advantage over other competitors in this market.

Iron Maintenance Therapy Market Competition

We intend to enter the iron maintenance therapy market for the treatment of dialysis patients with anemia if we obtain FDA approval to market SFP. 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. We believe that Ferinject® is primarily intended to target the pre-ESRD markets and other indications such as oncology.

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 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 markets Ferrlecit® in the United States. Ferrlecit® is an injectable iron supplement made of sodium ferric gluconate complex in sucrose.

Watson, a large manufacturer of both generic and branded drugs, introduced a generic IV iron in 2011, Nulecit®. Watson also markets a product called IN-FeD® which is an injectable iron supplement made of dextran and ferric hydroxide.

Providers may be attracted to SFP over IV iron products due to the lower cost of administration and the potential for improved therapeutic response over more costly ESA treatments.

Bundled Reimbursement

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 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.

Prior to 2011, CMS had 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 and separately billed drugs. CMS reimbursement practices changed starting in 2011, which we believe may benefit our marketing efforts. CMS began implementation of a fully bundled reimbursement rate on January 1, 2011 which is intended to be fully implemented by 2014. This change has resulted in a single composite rate per treatment, thereby eliminating most separate charges for individual drugs and services to providers. With the implementation of a single bundled rate for dialysis treatments, most dialysis drugs will no longer receive

separate reimbursement. As a result, dialysis drugs will now likely be viewed by providers as a cost rather than as a source of revenue to the dialysis service provider. We believe that the provider market may find the potential economic advantages of SFP to be an attractive alternative to IV iron drugs. Similarly, calcitriol may provide potential cost advantages over branded vitamin D analogues.

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 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 SFP. 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) may be 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 in terms of safety and effectiveness 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 or a device that has been reclassified from Class III to Class I or II. 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 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, SFP 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 SFP, 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 SFP and our 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 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. Health reform legislation enacted in 2010 is likely to result in material changes to the Medicare and Medicaid programs and levels of reimbursement and will impose excise taxes on medical devices and pharmaceutical products. 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 introduction. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Product License Agreements

We are 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. We licensed the product from a company owned by Dr. Ajay Gupta who subsequently joined us as our Chief Scientific Officer. The license agreement continues for the duration of the underlying patents in each country, or until December 30, 2017 in the United States, and may be extended thereafter. Patents were issued in the United States in 2004. The European patent was issued in 2005 and extends through 2017. The Japanese patent was issued in 2007 and 2011 and extends through 2017. If we are successful in obtaining FDA approval we may apply for an extension of our patent exclusivity for up to five years. As noted below in Trademarks and Patents, the Company has also received patent protection on the pharmaceutical grade formulation of the active pharmaceutical ingredient in SFP which extends patent protection until 2029.

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.

We own an ANDA for calcitriol. We are in the process of obtaining FDA approval to market this product following manufacturing changes relating to a contract manufacturer that we have contracted with to manufacture calcitriol. The purchase agreement allows us until July 13, 2012, upon payment of an immaterial amount in cash, to return the ANDA to the seller should we decide not to market the drug. If we do not return the ANDA, we must make a final payment for the ANDA in the amount of $550,000.

Trademarks and 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 a U.S. patent on the synthesis and formulation of our pharmaceutical grade formulation of SFP. The U.S patent expires on April 17, 2029. Further patent applications are pending in other jurisdictions including Europe, Japan and Canada.

We were also 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.

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. 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, 2011, 2010 and 2009, one customer, DaVita Inc., accounted for 48%, 42% and 50%

of our sales, respectively. Our accounts receivable from this customer were $2,073,000 and $2,336,526 as of December 31, 2011 and 2010, 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. One distributor accounted for 15% of our sales in 2010 and 2% in 2011. Due to credit arrangements with this distributor no accounts receivable were due as of either December 31, 2010 or December 31, 2011. No other customers accounted for more than 10% of our sales in the last three years.

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 were less than 5% of our total sales in 2011 and 2010. We have no assets outside the United States. Our total international sales, including sales to domestic distributors for resale outside the United States, aggregated 13%, 23% and 12%, of overall sales in 2011, 2010 and 2009, respectively.

Employees

As of December 31, 2011, we had approximately 240 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 began our Phase III clinical program in 2011. 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 2011, 2010 and 2009, we incurred aggregate expenses related to the commercial development of SFP of approximately $17.4 million, $3.4 million and $6.5 million, respectively.

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.

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 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 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.

Even if our new drug products are approved by the FDA, we may not be able to market those successfully.

Even if SFP is approved by the FDA, the commercial success of SFP will depend on a number of factors, including the following:

- several drugs currently dominate treatment for iron deficiency and SFP 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;
- achieving and maintaining compliance with all regulatory requirements applicable to SFP;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization of SFP;
- our ability to avoid third party patent interference or patent infringement claims; and
- a continued acceptable safety profile of SFP following approval.

Furthermore, dialysis providers are dependent upon government reimbursement practices for the majority of their revenue. If we obtain approval for our SFP product, the product will be included as part of the single bundled payment rate implemented by Medicare in 2011 and will likely not require a separate reimbursement code as nearly all providers are expected to have adopted the single bundled payment rate prior to FDA approval to market SFP.

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. If we are not successful in commercializing SFP, or are significantly delayed in doing so, 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.

In addition, we are seeking FDA approval for a change in manufacturing location for a generic version of calcitriol, which we acquired from a third party. While we anticipate timely approval of these changes, we must meet certain regulatory requirements for product testing and stability. If we encounter testing that does not meet approvable standards or if we experience operational issues with our CMO, our introduction of calcitriol could be delayed beyond our expectations.

The market for generic drugs is generally very competitive. Even if the FDA approves our generic version of calcitriol for marketing, we may encounter a very competitive environment for calcitriol which may make it difficult for us to capture significant market share. If we do have success in capturing market share with calcitriol, it may attract other entrants to market their own generic version of calcitriol, which could have a material adverse effect on our future revenues and results of operations.

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.

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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.

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

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 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 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.

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 health reform legislation has been legally challenged in several jurisdictions. The cases have

been consolidated and are currently pending review by the United States Supreme Court. Therefore, it is difficult to determine at this time what impact the health reform legislation will have on us or our customers. 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. Annamaria Kausz, our Vice President of Drug Development and Medical Affairs 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. Kausz 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. Kausz or Mr. Klema, our business, product development efforts, 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 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.

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 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. We have identified a material weakness in our internal control over financial reporting in our annual assessment of internal controls over financial reporting that management performed for the year ended December 31, 2011, in which management has concluded that we did not have an adequate and accurate process for the timely recording and recognition of liabilities associated with certain of our clinical trial activities, resulting in a material weakness in our internal control in the timeliness of recording and recognizing liabilities related to these expenditures. 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. A material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause investors to lose confidence in our reported financial information, and lead to a decline in our stock price.

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.

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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We occupy a 51,000 square foot facility in Wixom, Michigan under a lease expiring in August 2012. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2015. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a lease expiring in February 2013.

We intend to use each of our facilities to manufacture and warehouse our products. All such facilities and their contents are covered under various insurance policies which management believes provide adequate coverage. We also use the office space in Wixom, Michigan as our principal administrative office. With our continued growth we expect that we will require additional office space, manufacturing capacity and distribution facilities to meet our business requirements.

Item 3. Legal Proceedings.

We are involved in certain legal proceedings before various courts and governmental agencies concerning matters arising in the ordinary course of business. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims that are considered probable of loss. The resolution of pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common shares trade on the Nasdaq Global Market under the trading symbol RMTI . The prices below are the high and low sale prices as reported by the Nasdaq Global Market in each quarter during 2011 and 2010.

	Price Range	
	High	**Low**
2011		
Fourth Quarter	$ 8.86	$ 6.80
Third Quarter	13.89	7.65
Second Quarter	16.91	8.76
First Quarter	9.70	7.73
2010		
Fourth Quarter	$ 8.74	$ 6.63
Third Quarter	7.65	4.75
Second Quarter	6.07	4.16
First Quarter	8.47	5.56

As of February 28, 2012, there were 30 holders of record of our common shares.

Dividends

Our Board of Directors has discretion whether or not to pay dividends. Among the factors our Board of Directors considers when determining whether or not to pay dividends are our earnings, capital requirements, financial condition, future business prospects and business conditions. We have never paid any cash dividends on our common shares and do not anticipate paying dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our operations.

Securities Authorized for Issuance Under Equity Compensation Plans

The information contained under Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters of this Annual Report on Form 10-K under the heading Securities Authorized for Issuance Under Equity Compensation Plans is incorporated herein by reference.

Performance Graph

The following graph compares the cumulative 5-year total return of holders of the Company s common stock with the cumulative total returns of the Russell 2000 index and the Nasdaq Biotechnology index. The graph tracks the performance of a $100 investment in our common stock and in each of the indexes (with reinvestment of all dividends, if any) on December 31, 2006 with relative performance tracked through December 31, 2011. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
Rockwell Medical	**100.00**	**100.70**	**58.77**	**107.85**	**110.80**	**118.79**
Russell 2000	**100.00**	**98.43**	**65.18**	**82.89**	**105.14**	**100.75**
NASDAQ Biotechnology	**100.00**	**102.53**	**96.57**	**110.05**	**117.19**	**124.54**

The information furnished under the heading Stock Performance Graph shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, and such information shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 6. Selected Financial Data.

The financial data in the following tables should be read in conjunction with the consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations included in this Form 10-K.

	For the Year Ended December 31,				
	2011	**2010**	**2009**	**2008**	**2007**
Net sales	$ 48,966,231	$ 59,554,592	$ 54,729,505	$ 51,666,033	$ 43,045,304
Cost of sales (2)	43,323,321	49,693,753	46,842,334	49,159,478	40,156,041
Gross profit (2)	5,642,910	9,860,839	7,887,171	2,506,555	2,889,263
Income from continuing operations before interest expense and income taxes	(21,684,757)	(2,868,916)	(5,481,379)	(8,085,196)	(3,608,353)
Interest and Investment Income, net	242,205	185,517	(19,859)	221,139	(110,542)
Income from continuing operations before income taxes	(21,442,552)	(2,683,399)	(5,501,238)	(7,864,057)	(3,718,895)
Income taxes	2,005				
Net income	(21,444,557)	(2,683,399)	(5,501,238)	(7,864,057)	(3,718,895)
Earnings per common share:					
Basic	$ (1.21)	$ (0.16)	$ (0.37)	$ (0.57)	$ (0.32)
Diluted	$ (1.21)	$ (0.16)	$ (0.37)	$ (0.57)	$ (0.32)
Weighted average number of common shares and common share equivalents					
Basic	17,774,865	17,111,535	14,709,016	13,836,435	11,771,381
Diluted	17,774,865	17,111,535	14,709,016	13,836,435	11,771,381

	As of December 31,				
	2011	**2010**	**2009**	**2008**	**2007**
Total assets	$ 31,939,599	$ 36,966.907	$ 34,879,221	$ 18,959,982	$ 22,803,134
Current assets	25,896,529	32,666,368	29,948,945	14,428,691	18,645,945
Current liabilities	13,692,351	6,420,220	5,536,957	7,097,836	4,637,271
Working capital	12,204,178	26,246,148	24,411,988	7,330,855	14,008,674
Long-term debt and capitalized lease obligations	2,280	8,750	19,062	41,203	204,837
Stockholders equity (1)	18,244,968	30,537,937	29,323,202	11,820,943	17,961,026
Book value per outstanding common share	$ 0.98	$ 1.74	$ 1.70	$ 0.84	$ 1.30
Common shares outstanding	18,710,002	17,513,608	17,200,442	14,104,690	13,815,186

(1) There were no cash dividends paid during the periods presented. Stockholders equity reflects the proceeds of a private placement in 2007 and a public offering in 2009.

(2) The Company has reclassified certain expenses from Selling, General and Administrative Expense to Cost of Sales in the 2008 and 2007 consolidated income statements to conform with current year presentation that was adopted in 2009. The impact of the change was not material.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview and Recent Developments

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

We are currently developing unique, proprietary renal drug therapies. These novel renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

Our strategy is to develop high potential drug candidates while also expanding our dialysis products business, which had sales of $49.0 million in 2011. Our dialysis products business was cash flow positive in 2011, excluding research and development expenses, and provides an in-place sales and distribution infrastructure and conduit with established business relationships to market pharmaceutical and additional products into the dialysis market.

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

In 2011, we acquired the right to manufacture the generic version of calcitriol, a vitamin D analogue, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We are in the process of obtaining FDA approval to make a change in manufacturing locations and intend to begin marketing calcitriol following regulatory approval of manufacturing changes, which is expected in late 2012.

As of December 31, 2011 we had $17.5 million in cash and investments. In February 2012, we completed a common stock offering for $17.5 million in gross proceeds and approximately $16.2 million in net proceeds.

In 2011, our sales were down compared to 2010 due to a reduction in sales to a single foreign distributor and, to a lesser extent, a loss of certain customers following their acquisition by competitors or by chains that buy product from our competitors, sales incentives and a shift in product mix from liquid to concentrate. Our margins benefitted from our customers shift from our liquid products to our concentrate products, but declined overall due to commodity and fuel cost increases coupled with lower overall sales volume. We anticipate that our gross profit margins will be favorably impacted by revenue from calcitriol once we obtain FDA approval for manufacturing changes, but we do not expect to begin selling calcitriol until late in 2012.

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

The majority of our business is with domestic clinics who order routinely. We renewed our supply agreement with our largest domestic chain customer through the end of 2013. Certain major distributors of our products internationally have not ordered consistently, however, resulting in variation in our sales from period to period. We anticipate that we will realize substantial orders from time to time from our largest international distributors but we expect the size and frequency of these orders to fluctuate from period to period. These orders may increase in future periods or may not recur at all.

Results of Operations

For the year ended December 31, 2011 compared to the year ended December 31, 2010

Sales

In 2011, our sales were $49.0 million compared to $59.6 million in 2010. Sales decreased $10.6 million or 17.8% with $7.6 million due to lower international sales and $2.8 million due to lower domestic sales and $0.2 million due to a government research grant received in 2010 that did not recur in 2011. International sales decreased due to lower sales to a single international distributor. Domestic sales decreased due to a change in product mix and due to lower sales volumes with approximately half of the sales decrease due to a loss of certain customers following their acquisition by competitors or by chains that buy product from our competitors.

Over the last year, customers have continued to convert to our Dri-Sate dry acid concentrate product line, which lowers providers cost per treatment and reduces our sales, but improves our gross profit margins due to a reduction in shipping costs. Our Dri-Sate dry acid concentrate displaced liquid acid concentrate volume, increasing to 58% of 2011 acid concentrate equivalent treatment gallons from 49% in 2010. We also experienced some downward pricing pressure with the implementation of the bundled reimbursement program by CMS (Medicare) in 2011.

Gross Profit

Our gross profit in 2011 was $5.6 million compared to $9.9 million in 2010. Gross profit margins were 11.5% in 2011 compared to 16.6% in 2010. The decreases in gross profit and margin were primarily due to lower sales volumes, increased sales incentives and inflationary cost increases to fuel, material and labor costs. Approximately $2.3 million of the decrease was due to the lower sales volumes generally and another $0.8 million was due to sales incentives net of other price changes and other product mix changes. Cost increases for fuel, material and labor net of operating expense decreases reduced gross profit approximately $1.1 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $9.5 million in 2011 compared to $9.3 million in 2010. The increase of $0.2 million was primarily due to an increase in non-cash charges for equity compensation, partially offset by lower information technology costs and related depreciation. Non-cash equity compensation aggregated $4.4 million in 2011 compared to $4.0 million in 2010.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including SFP, aggregating approximately $17.8 million and $3.4 million in 2011 and 2010, respectively. Costs incurred in both 2011 and 2010 were primarily for conducting human clinical trials of SFP and other SFP testing and development activities. Our spending increased considerably in 2011 as we initiated our Phase III clinical trial program which consists of several concurrent clinical studies.

Interest and Investment Income, Net

Net interest and investment income in 2011 increased by $57,000 compared to 2010 primarily due to an increase in interest income from our cash investments net of realized losses on investments.

Income Tax Expense

We have substantial tax loss carryforwards from our earlier losses. We have not recorded a federal income tax benefit from either our prior losses or our current year losses because we might not realize the carryforward benefit of the remaining losses.

For the year ended December 31, 2010 compared to the year ended December 31, 2009

Sales

In 2010, our sales were $59.6 million, an increase of $4.8 million or 8.8% over 2009. This increase was primarily due to increased international sales of $7.4 million or 113% partially offset by a $2.8 million or 5.8% decrease in domestic sales. Our international sales in 2010 were 23% of total sales compared to 12% of sales in 2009. The increase in our international sales was primarily due to increased sales to a single distributor. Our domestic sales were negatively impacted by customer conversions to lower cost formulations and conversions to Dri-Sate Dry Acid product line resulting in lower sales but at higher gross profit levels. Customers continue to migrate from liquid to dry acid concentrate with unit volumes up 28% in 2010 over 2009. In 2010, we received a research grant of $0.25 million from the U.S. government for SFP related research and testing which was recorded in sales.

Gross Profit

Our gross profit in 2010 was $9.9 million, an increase of $2.0 million or 25% over 2009. Our gross profit margins increased to 16.6% in 2010 compared to 14.4% in 2009. The improvement in our gross profit was primarily due to significant changes to our product mix over the last two years coupled with lower operating and procurement costs along with higher selling prices. Our product mix was favorably impacted by the continued conversion of customers to our Dri-Sate product line and to lower cost formulations of our dialysis concentrates. We also realized increased sales volumes in 2010 which contributed to the increase in our overall gross profit. These gains were partially offset by moderate increases in material, fuel and other operational costs over 2009.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $9.3 million in 2010 compared to $6.9 million in 2009, an increase of $2.4 million, which was primarily due to increases in non-cash charges for equity compensation ($1.7 million), compensation ($0.5 million) and other operating expenses ($0.2 million). Non-cash equity compensation aggregated $4.0 million in 2010 compared to $2.35 million in 2009 with approximately $0.25 million of the increase due to non-employee equity compensation.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including SFP, aggregating approximately $3.4 million and $6.5 million in 2010 and 2009, respectively. Costs incurred in both 2010 and 2009 were primarily for conducting human clinical trials of SFP and other SFP testing and development activities. During 2009, we conducted a Phase IIb study, which was completed in late 2009. Our SFP Phase III clinical program commenced in early 2011.

Interest Income and Expense, Net

Net interest income in 2010 increased by $205,000 compared to 2009 primarily due to a $190,000 increase in interest income from our cash investments as a result of higher investable funds resulting from the proceeds of the October 2009 equity offering.

Income Tax Expense

We have substantial tax loss carryforwards from our earlier losses. We have not recorded a federal income tax benefit from either our prior losses or our current year losses because we might not realize the carryforward benefit of the remaining losses.

Critical Accounting Estimates and Judgments

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. These accounting principles require us to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and contingencies. All significant estimates, judgments and assumptions are developed based on the best information available to us at the time made and are regularly reviewed and updated when necessary. Actual results will generally differ from these estimates. Changes in estimates are reflected in our financial statements in the period of change based upon on-going actual experience, trends, or subsequent realization depending on the nature and predictability of the estimates and contingencies.

Interim changes in estimates are generally applied prospectively within annual periods. Certain accounting estimates, including those concerning revenue recognition, allowance for doubtful accounts, impairments of long-lived assets, and accounting for income taxes, are considered to be critical in evaluating and understanding our financial results because they involve inherently uncertain matters and their application requires the most difficult and complex judgments and estimates. These are described below. For further information on our accounting policies, see Note 2 to our Consolidated Financial Statements.

Revenue recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Our products are generally sold domestically on a delivered basis and as a result we do not recognize revenue until delivered to the customer with title transferring upon completion of the delivery. For our international sales, we recognize revenue upon the transfer of title as defined by standard shipping terms and conventions uniformly recognized in international trade.

Allowance for doubtful accounts

Accounts receivable are stated at invoice amounts. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts that reflects our best estimate of accounts that may not be collected. We review outstanding trade account receivable balances and based on our assessment of expected collections, we estimate the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily on historical experience. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for doubtful accounts. If we underestimate the allowance, we would incur a current period expense which could have a material adverse effect on earnings.

Impairments of long-lived assets

We account for impairment of long-lived assets, which include property and equipment, amortizable and non-amortizable intangible assets and goodwill, in accordance with authoritative accounting pronouncements. An impairment review is performed annually or whenever a change in condition occurs which indicates that the carrying amounts of assets may not be recoverable. Such changes may include changes in our business strategies and plans, changes to our customer contracts, changes to our product lines and changes in our operating practices. We use a variety of factors to assess the realizable value of long-lived assets depending on their nature and use.

Goodwill is not amortized; however, it must be tested for impairment at least annually. The goodwill impairment analysis is based on the fair market value of our common shares. Amortization continues to be recorded for other intangible assets with definite lives over the estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or circumstances indicate that carrying amounts may not be recoverable based on future cash flows. If we determine that goodwill has been impaired, the change in value will be accounted for as a current period expense and could have a material adverse effect on earnings.

Accounting for income taxes

We estimate our income tax provision to recognize our tax expense and our deferred tax liabilities and assets for future tax consequences of events that have been recognized in our financial statements using current enacted tax laws. Deferred tax assets must be assessed based upon the likelihood of recoverability from future taxable income and to the extent that recovery is not likely, a valuation allowance is established. The allowance is regularly reviewed and updated for changes in circumstances that would cause a change in judgment about whether the related deferred tax asset may be realized. These calculations and assessments involve complex estimates and judgments because the ultimate tax outcome can be uncertain and future events unpredictable. If we determine that the deferred tax asset will be realized in the future, it may result in a material beneficial effect on earnings.

New Accounting Pronouncements

No new accounting pronouncements that were issued or became effective during the year have had or are expected to have a material impact on our Consolidated Financial Statements. For a discussion of new accounting pronouncements, see Note 2 to our Consolidated Financial Statements.

Liquidity and Capital Resources

Our strategy is centered on obtaining regulatory approval to market SFP and developing other high potential drug candidates, while also expanding our dialysis products business. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions and other product development opportunities. These initiatives will require the expenditure of substantial cash resources. We expect our cash needs for research and development spending to be significant over the next two years as we execute our clinical development program for SFP. We will invest in our Phase III clinical development program for SFP as well as other development initiatives over the next two years. We are also required to make an additional cash payment of $550,000 in connection with our acquisition of the right to market calcitriol and funding will be necessary to obtain FDA approval for our contract manufacturer to manufacture the product for us. However, these expenditures are not expected to have a material effect on our liquidity or financial position.

Our cash resources include cash generated from our business operations and from proceeds of equity offerings. As of December 31, 2011, we had $17.5 million in cash and investments. In February 2012, we completed a common stock offering for $17.5 million in gross proceeds and approximately $16.2 million in net proceeds. We expect to generate additional cash from our business operations and from other sources, which may include the exercise of warrants, the possible out-licensing of SFP outside the United States, out-licensing of certain SFP uses outside the dialysis market, and other capital raising alternatives as needed.

Our current assets exceeded our current liabilities by over $12.2 million as of December 31, 2011 and included $17.5 million in cash and short term investments. In 2011, we used $10.9 million in cash from operating activities which included research and product development costs of $17.8 million. In 2011, operational related liabilities net of assets increased by approximately $5.0 million primarily related to research and development activities. These liabilities will be paid in future periods. As of December 31, 2011, we have advanced $2.3 million in cash that will be used to offset future research and development costs. In 2011, we invested $0.4 million in capital expenditures compared to depreciation expense of $1.1 million. We also realized cash from financing activities aggregating $4.8 million, primarily from the exercise of warrants.

We believe our current and prospective sources of cash resources are sufficient to fund our anticipated research and development activities as well as our ordinary course operating cash requirements in 2012. We expect to generate positive cash flow from operations in 2012, excluding the effect of our research and development expenses, assuming relative stability in the markets for fuel and our key raw materials and relatively stable revenues. In addition, we may realize substantial cash proceeds from in-the-money warrants that expire in 2012 aggregating $11.2 million. However, if we use more cash than anticipated for SFP development, are required to

do more testing than expected, if the assumptions underlying our cash flow projections prove to be incorrect, or if we pursue opportunities to expand our business, we may need to obtain additional cash, such as through equity financing, debt financing of capital expenditures or a line of credit, to supplement our working capital. We explore opportunities from time to time to increase our cash resources, to reduce our liquidity risk and to have resources available to permit us to pursue expansion opportunities. Alternatively, we may seek to enter into product development arrangements with an international partner in order to fully execute our strategic plan. We may also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets and other potential funding sources.

Contractual Obligations

The following table details our contractual obligations as of December 31, 2011:

		Payments due by period			
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Capital leases	$ 9,561	$ 7,151	$ 2,410		
Operating leases	$ 2,516,898	$ 1,502,567	$ 788,222	$ 218,269	$ 7,840
Purchase obligations	$ 550,000	$ 550,000			
Total	$ 3,076,459	$ 2,059,718	$ 790,632	$ 218,269	$ 7,840

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a material effect on our financial condition.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

Our current exposure to interest rate risk is limited to changes in interest rates on short term investments of cash. As of December 31, 2011, we had $0.3 million in short term investments in a money market fund and $11.8 million in short term bond funds.

A hypothetical 100 basis point increase in market interest rates for short term liquid investments would increase our annualized interest income by an immaterial amount, assuming we invested $0.3 million in short term investments and that level remained constant for the year. We did not perform an analysis of a 100 basis point decrease in market interest rates as such an analysis would be meaningless.

We have invested $11.8 million in available for sale securities which are invested in short term bond funds which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short term duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

Foreign Currency Exchange Rate Risk

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders equity or net income.

Item 8. Financial Statements.

The Consolidated Financial Statements of the Registrant required by this item are set forth on pages F-1 through F-21 and incorporated herein by reference.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the dis