ROCKWELL MEDICAL, INC.
Form 10-K
March 18, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012

OR

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

For the transition period from to
Commission file number 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

(248) 960-9009
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of each exchange on which registered:**
Common Stock, no par value	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act:

(None)

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

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

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 ý No o

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

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2012 (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 $140,024,066. 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 March 8, 2013: 21,559,138 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2013 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, Inc. and its subsidiaries unless otherwise specified or the context otherwise requires.

Forward Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as "may," might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue", "predict", "forecast", "projected," "intend" or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the timing and costs of obtaining FDA approval of our new products, statements regarding our new products and statements regarding our anticipated future financial condition, operating results, cash flows and business and financing 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 SEC. 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, Inc., incorporated in the state of Michigan in 1996, is a fully-integrated biopharmaceutical company targeting end-stage renal disease ("ESRD") and chronic kidney disease ("CKD") with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis (also referred to as "HD" or "dialysis").

Rockwell's lead investigational drug is in late stage clinical development for iron therapy treatment in CKD-HD patients. It is called Soluble Ferric Pyrophosphate ("SFP"). SFP delivers iron to the bone marrow in a non-invasive, physiologic manner to hemodialysis patients via dialysate during their regular dialysis treatment. The majority of ESRD patients receive iron on a routine basis. The Company intends to complete clinical trials and seek U.S. Food and Drug Administration ("FDA") market approval of SFP. We also plan to seek foreign market approval for this product and/or to license the technology to a company who will seek market approval in the licensed markets. We believe this product will substantially improve iron therapy and if approved will compete in the global iron therapy market treating hemodialysis patients. Currently, two Phase 3 clinical trials called CRUISE-1 and CRUISE-2 are being conducted for FDA submission for market approval. Recently, another SFP clinical study called the PRIME study was completed. The PRIME study was designed to show a reduction in the need for erythropoiesis stimulating agents ("ESA") in CKD-HD patients who receive

SFP during dialysis. The PRIME study was successful and demonstrated that with the use of SFP there is a significant reduction in the need for ESA. ESA is the most expensive drug used in dialysis. Based on reports from manufacturers of intravenous ("IV") iron products and industry estimates, the market size in the United States for IV iron therapy for ESRD patients is approximately $600 million per year. We estimate the global market for IV iron therapy is in excess of $1 billion per year. We cannot, however, give any assurance that this product will be approved by the FDA or, if approved, that it will be successfully marketed.

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

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

Our Business Strategy

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

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

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

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

We intend to obtain manufacturing approval from the FDA in 2013 for our FDA approved generic drug Calcitriol and thereafter to immediately begin marketing Calcitriol. The market potential is estimated to be approximately $350 million. We intend to market Calcitriol to our existing customer base that we service via our concentrate operating business, which currently serves approximately 27% of the U.S. concentrate dialysis market.

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

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

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

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

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

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

Identify Novel Drugs to Address Unmet Needs and Market Opportunities.

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

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

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

Our Markets

The Hemodialysis Market

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

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

Dialysis Industry Trends

Hemodialysis is the primary treatment modality employed in the United States with over 90% 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

the most recent industry statistics published by USRDS, there are approximately 400,000 dialysis patients in the United States. The U.S. patient population has grown steadily over the past several decades, and is expected to grow approximately 4-6% over the next several years.

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

Products (Operating Business)

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full line of ancillary products, to customers in the U.S. and abroad. Dialysate concentrates account for over 92% of our revenue and consist of two products known in the industry as "acid" and "bicarbonate" and are packaged as liquid or powder. All of our products are manufactured according to AAMI and GMP guidelines. Our concentrate products are used in conjunction and are diluted with clean water on-site at the clinic in the dialysis machine, creating dialysate, which works to clean the patient's blood.

CitraPure® Citric-Acid Concentrate

Our CitraPure® concentrate is 100% acetate-free, in contrast to the acetate-based products most widely used for many years. Acetate promotes inflammation so its removal is beneficial to the patient. Citrate has anticoagulant properties and has been shown in clinical studies to have the ability to reduce the need for heparin during dialysis treatment (CitraPure® is not indicated for heparin sparing). CitraPure® is packaged as a liquid and as a dry powder acid concentrate, for use with our Dry Acid Mixing System, containing citric acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply dry acid in 25 gallon cases and we supply liquid acid concentrate in both 55 gallon drums and in cases containing four-one gallon containers.

Dri-Sate® Dry Acid

Dry powder acid concentrate for use with our Dry Acid Mixing System, containing acetic acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply dry acid in 25 gallon cases.

Renal Pure® Liquid Acid Concentrate

Liquid acid concentrate containing acetic acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply liquid acid concentrate in both 55 gallon drums and in cases containing four-one gallon containers.

Dry Acid Concentrate Mixing System

Our Dry Acid Concentrate Mixing System is designed for our CitraPure® and Dri-Sate® Dry Acid product and allows a clinic to mix its acid concentrate on-site. The clinic technician, using a specially designed mixer, adds pre-measured packets of the necessary ingredients to purified water (AMII standard). Clinics using 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, while enabling the Company to reduce distribution and warehousing costs.

RenalPure® Powder Bicarbonate Concentrate

RenalPure® bicarbonate sold in powder form is used mainly in chronic settings. Each clinic mixes bicarbonate on-site as required.

SteriLyte® Liquid Bicarbonate Concentrate

SteriLyte® bicarbonate is sold in liquid form and is used mainly in acute care settings.

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.

Drug Products

We intend to obtain manufacturing approval from the FDA in 2013 for our FDA approved generic drug Calcitriol, and expect to immediately begin marketing Calcitriol commercially thereafter. We also intend to obtain FDA regulatory approval to market SFP, our investigational iron-delivery drug. We estimate filing our New Drug Application within the next 12 months and hope to receive FDA market approval to sell SFP commercially within 10 months from that date.

Calcitriol (Active Vitamin D) Injection; FDA Approved Generic Drug

Calcitriol is a generic active vitamin D and is indicated for the treatment of secondary hyperparathyroidism in dialysis patients. The majority of ESRD patients receive vitamin D on a routine basis using one of two branded drugs. Calcitriol is the only generic vitamin D and clinical data shows it to be clinically equivalent in safety and efficacy to the two branded drugs. We believe the lower cost of Calcitriol will entice dialysis providers to purchase it over current vitamin D options. We are in the process of obtaining regulatory approval for a change in manufacturing location and anticipate obtaining approval to begin marketing Calcitriol in 2013.

Soluble Ferric Pyrophosphate (SFP) Iron; Investigational Drug

We have licensed the exclusive right to manufacture and sell SFP. If approved by the FDA, we believe SFP will substantially improve iron therapy treatment for dialysis patients, which is pervasive in the CKD-HD patient population.

SFP is a unique iron compound that is delivered to the hemodialysis patient via dialysate, replacing the 5-7mg of iron that is lost during a dialysis treatment. SFP is introduced into the sodium bicarbonate concentrate that subsequently is mixed into dialysate. Once in the dialysate, SFP crosses the dialyzer membrane and enters the bloodstream where it immediately binds to apo-transferrin and is taken to the bone marrow. SFP mimics the way dietary iron is metabolized in the human body. In completed clinical trials to date, SFP has demonstrated that it can safely deliver iron and maintain hemoglobin levels, while decreasing ESA use without increasing iron stores.

To address iron deficiency, patients receive intravenous iron, and synthetic recombinant human erythropoietin, commonly referred to as erythropoiesis stimulating agent, or ESA. ESA is an artificial hormone that acts in the bone marrow, together with iron, 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.

Current iron therapy for CKD-HD patients is provided mainly with IV iron compounds, which are encased by a carbohydrate shell to prevent free-iron from circulating in the bloodstream. Due to the

carbohydrate shell, IV iron is taken up by the reticuloendothelial system and deposited primarily in the liver, rather than directly into blood plasma where it is to be carried to the bone marrow. An increase in inflammation during dosing causes a peptide called hepcidin to mobilize and block the IV iron from effectively leaving the liver, which can reduce the effectiveness of ESA treatments. The carbohydrate moiety in the IV iron compound is also believed to be responsible for anaphylactic reactions when they occur.

SFP is distinctly different from IV iron compounds. SFP enters the bloodstream through dialysate, and immediately binds to apo-transferrin (the body's natural binding site for iron) and is then carried directly to the bone marrow for the formation of new red blood cells, mimicking the way a healthy human body processes iron when received through food. Clinical data has shown that this more direct method of iron delivery is effective at maintaining a steady state of iron balance and achieves superior therapeutic response from ESA treatments, thereby lowering the need for ESA. SFP is an iron salt and contains no carbohydrate and, as a result, has demonstrated an excellent safety profile in clinical trials to date and has not been attributed to any anaphylactic episodes.

ESA is administered intravenously during dialysis treatments to help maintain hemoglobin levels. Iron supplementation is required to ensure good therapeutic response from ESA treatments. Most dialysis patients receive ESA therapy coupled with iron therapy in order to maintain hemoglobin levels and to achieve the full benefit of ESA treatments. ESAs are very expensive drugs and are known to have serious risks associated with their dosing to dialysis patients.

SFP, in place of IV iron, has shown it can lower the drug administration cost to dialysis providers. Along with the elimination of the needle and syringe normally used for IV iron administration, and the resulting substantial nursing time gained to deliver quality patient care, SFP clinical data has shown that it can greatly reduce ESA use.

In February 2013, top line results of our PRIME study demonstrated that SFP significantly reduces the need for ESA during dialysis. The PRIME study was a nine-month, prospective, randomized, placebo-controlled, double-blinded, multi-center study in the United States that randomized 108 patients equally to dialysate containing SFP-iron *versus* conventional dialysate. A total of 103 patients received blinded study drug (52 SFP, 51 Placebo). The PRIME study data showed a statistically significant 37.1% reduction in ESA usage compared to the control arm. The PRIME data demonstrated that SFP was able to maintain hemoglobin levels in the target range over the nine month study duration while the magnitude of ESA sparing, compared to the control arm, met statistical significance.

Our two SFP Phase 3 CRUISE efficacy studies required for FDA market approval began in 2011, and we expect to complete those studies and announce results in the second half of 2013. If those studies are successful, we will submit a New Drug Application to seek FDA approval to market SFP in the United States. We intend to use our current sales and distribution infrastructure (current operating business) as the channel to sell and deliver SFP to dialysis providers in the U.S. market, once FDA approved. We intend to license the rights to SFP for commercial development in markets outside of the United States, such as Europe and Asia.

Distribution and Delivery Operations

The majority of our domestic products are delivered through our subsidiary, Rockwell Transportation, Inc., which operates a fleet of trucks used to deliver products to our customers. We perform delivery services for customers that are generally not available from common carriers or our competitors, such as stock rotation, non-loading-dock delivery and drum pump-off service. As a result, we believe we offer a higher level of service to our customers.

Our Dry Acid Concentrate products require less storage space not only for our customers but for our warehousing as well. We are able to more effectively utilize warehouse and trailer space, as well transportation equipment, in our distribution process, resulting in a distribution savings.

Sales and Marketing

We sell our products direct to domestic hemodialysis providers using a small number of salespeople. Our Chief Executive Officer leads and directs our sales effort, and handles our major accounts. Our products are sold to international customers through independent sales agents, distributors and direct.

We market and advertise through trade publications, journals, product literature, the internet and industry trade conferences. We target our sales and marketing efforts to upper management of dialysis companies, providers, nephrologists, clinic administrators, nurses, medical directors and purchasing personnel.

Competition

Operating Business

There are just two, major concentrate suppliers servicing the US today. We compete against one larger and more established competitor with substantially greater financial, technical, manufacturing, marketing, research and development and management resources. Our largest competitor is US based Fresenius Medical Care NA, which is primarily in the business of operating dialysis clinics, as well as manufacturing and marketing dialysis devices, drugs and supplies. Fresenius operates approximately 1,800 clinics and treats over one third of the dialysis patients in the US. Fresenius is vertically integrated and manufactures and sells a full range of renal products, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. In addition to its captive customer base, Fresenius also services clinics owned by others with its products where it commands a market leading position in its key product lines. Fresenius manufactures its concentrate in its own regional manufacturing facilities.

Vitamin D Therapy Market Competition

We intend to market Calcitriol injection against two competitors with branded vitamin D products, as well as other generic drug competitors. Abbott Laboratories markets Zemplar® and Sanofi-Aventis, through its Genzyme subsidiary, markets Hectorol®. Other companies offer oral forms of vitamin D. A handful of other companies have historically marketed generic Calcitriol. We believe the dialysis reimbursement law that went into effect in January 2011, along with our current market share position, provides us an advantage to sell Calcitriol over other competitors in the market.

SFP Iron Therapy Market Competition

We intend to enter the iron delivery therapy market upon obtaining FDA approval for SFP. We expect SFP will be disruptive to the US IV iron market. Presently the IV iron drug Venofer® has the majority of the market for delivering iron to CKD-HD patients in the US. Venofer® is owned by Switzerland-based Galenica. Galenica is seeking FDA approval for a new product called Ferinject®, which does not appear to target the CKD-HD market. Fresenius has a sublicense agreement to manufacture and distribute Venofer® to the dialysis market in the US and Canada. Sanofi-Aventis markets the IV iron drug Ferrlecit® in the United States. Watson, a large manufacturer of both generic and branded drugs, introduced a generic IV iron in 2011 called Nulecit®.

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 could 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, the Centers for Medicare & Medicaid Services ("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 began implementation of a fully bundled reimbursement rate in 2011, which we believe should benefit our marketing efforts. The bundled rate is a single payment per treatment, thereby eliminating reimbursement for individual drugs and services to providers. As a result dialysis drugs are now viewed by providers as an additional cost rather than as a source of revenue. With FDA approval, we believe SFP, due to its potential for improved therapeutic response, ability to reduce the need for costly ESA and lower cost of administration, will be an attractive alternative to IV iron under this reimbursement landscape.

Quality Assurance and Control

We operate under FDA and GMP guidelines and place significant emphasis on providing quality products and services to our customers. Our quality management plays an essential role in meeting customer requirements and FDA guidelines. 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 maintain our quality system. 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. Prior to shipment, 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. Each product is assigned a lot number for tracking purposes.

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 our SFP iron. The development and regulatory approval process includes preclinical testing and human clinical trials and is lengthy and uncertain. Before marketing in the United States, any pharmaceutical

or therapeutic product must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FD&C Act.

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

Medical Device Approval and Regulation

A medical device may be marketed in the United States only with prior authorization from the FDA unless it is subject to a specific exemption. Devices classified as Class I devices (general controls) or Class II devices (general and special controls) are eligible to seek "510(k) clearance" from the FDA. Such clearance generally is granted when submitted information establishes that a proposed device is "substantially equivalent" 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, a device that has been reclassified from Class III to Class I or II, or a device which has been found substantially equivalent through the 510(k) process. 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 approximately one year 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 current 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. Under such a scenario, our products may be subject to voluntary recall by us or by required recall by

the FDA. 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 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 SFP. Our SFP and Calcitriol products will be subject to FDA drug regulations.

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

An ANDA is a marketing application filed as part of an abbreviated approval process that is available for generic drug products that have been determined to be "bioequivalent" to an FDA-approved drug. This requires that the generic drug product have the same amount of active ingredient(s) absorbed in the same amount of time, use indication, route of administration, dosage form and dosage strength as an existing FDA-approved product. In addition the generic drug product must be manufactured in accordance with GMP and meet requirements for batch identity, strength, purity and quality. 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 1 trials consist of testing the product primarily for safety, metabolism and pharmacologic action in a small number of patients or healthy volunteers at one or more doses. In Phase 2 trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase 1 trials with the primary intent of determining the effective dose range. Phase 3 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. Recently enacted health reform legislation has resulted in material changes to the Medicare and Medicaid

programs and levels of reimbursement, will impose excise taxes on medical devices and pharmaceutical products and will require medical device and pharmaceutical manufacturers to report certain relationships they have with physicians and teaching hospitals. 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 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 1999 and 2004. The European patent was issued in 2005 and extends through 2017. The Japanese patent was issued in 2007 and extends through 2017. 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 3 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.

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 have numerous patents connected to SFP and in prosecution in various countries.

We were also issued patents in the U.S. and Canada for our 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, 2012, 2011 and 2010, one customer, DaVita Inc., accounted for 49%, 48% and 42% of our sales, respectively. Our accounts receivable from this customer were $2,352,000 and $2,073,000 as of December 31, 2012 and 2011, 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. No other customer accounted for more than 10% of our sales in any of 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 2012, 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 11%, 13% and 23%, of overall sales in 2012, 2011 and 2010, respectively.

Employees

As of December 31, 2012, we had approximately 287 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 began our Phase 3 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 2012, 2011 and 2010, we incurred aggregate expenses related to research and development, nearly all of which were related to the commercial development of SFP, of approximately $48.3 million, $17.8 million and $3.4 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 effect on our results of operations and cash flow.

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

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

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

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

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

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 trials will achieve positive results. We are conducting two clinical trials related to SFP that we call CRUISE-1 and CRUISE-2. The results of CRUISE-1 and CRUISE-2 are expected to be announced in the second half of 2013.

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:

- one drug currently dominates treatment for iron deficiency and SFP will have to compete against it and other 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 for providers to use SFP 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 change in manufacturing location for Calcitriol so that we can begin marketing it, 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.

There is substantial doubt as to our ability to continue as a going concern.

Our audited consolidated financial statements at and for the year ended December 31, 2012 were prepared assuming that we will continue as a going concern, meaning that we will continue in operation for the foreseeable future and will be able to realize assets and discharge liabilities in the ordinary course of operations. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 contains an explanatory paragraph stating that our recurring losses and need for additional working capital raise substantial doubt about our ability to continue as a going concern. We incurred a net loss in each of the last several years and, as of December 31, 2012, our accumulated deficit was $110 million. As of December 31, 2012, our cash and investments were $4.7 million and our current liabilities exceeded our current assets by $13.8 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and we expect to continue to incur operating losses as we complete the clinical trial process and pursue regulatory approval of SFP, thereby creating substantial doubt in the absence of significant additional funding about our ability to continue as a going concern. This may make it more difficult for us to raise funds. If we are unable to obtain the level of funding we are seeking, we may be forced to delay, reduce, curtail, or cease our research and development efforts or our business operations as a whole. In such event, investors may lose a portion or all of their investment. Our consolidated financial statements contain no adjustment for the outcome of this uncertainty. Our ability to achieve profitability and positive cash flow from operations 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 require substantial additional financing to achieve our goals, and such financing may result in substantial dilution to shareholders or restrictions on our ability to operate our business. 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.

We are seeking additional funds 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. If we raise additional funds by issuing equity securities, substantial dilution to

existing shareholders is likely to result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

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 not be able to continue our operations as a going concern or 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.

If we are unable to continue operations as a going concern, investors may lose a portion or all of their investment.

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 have risen each year and have 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 in the future and have a material adverse effect on our results of operations.

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

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

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 depend on government funding of health care.

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

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

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. In addition, the health reform legislation imposes fees or excise taxes on pharmaceutical and device manufacturers based on their sales which could have a material adverse effect on the Company's financial results beginning in 2013. The U.S. government faces structural deficits that may require changes to government funded health care programs such as Medicare and Medicaid which may negatively impact customers of our products. Our sales, results of operations and cash flows could be materially impacted by future health care reform or reduced Medicare and Medicaid spending by the federal government.

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 federal fraud and abuse laws, which could have a material adverse effect on our results of operations, financial position and cash flows.

We depend on key personnel.

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

Our business is highly regulated.

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, 2012 an additional 2,133,240 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 and may dilute the economic value and voting rights of existing shareholders.

In addition, as of December 31, 2012, there were 4,410,200 shares issuable upon the exercise of outstanding and exercisable stock options, 1,579,000 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 1,284,665 additional shares available for grant under our 2007 Long Term Incentive Plan. Additional grants have been made in 2013. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options.

We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.

SEC rules require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each year, and to include a management report assessing the effectiveness of our

internal control over financial reporting in each Annual Report on Form 10-K. It is possible, due to the small size of our accounting staff, that we may identify control deficiencies in the future that constitute one or more material weaknesses. If our internal control over financial reporting or disclosure controls and procedures are not effective, there may be errors in our financial statements and in our disclosure that could require restatements. Investors may lose confidence in our reported financial information and in our disclosure, which could lead to a decline in our stock price.

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

The market price of our securities may be volatile.

Our relatively small public float and relatively low trading volume make it more likely that our stock price will fluctuate significantly in response to relatively few trades. We believe that we have been and may continue to be the target of third party short selling campaigns and other sophisticated trading strategies designed to reduce the market price of our common stock. Beginning in early 2013, the Company believes that certain stock trading firms have engaged in short selling programs to drive the share price of the Company's shares down with an expectation of covering those short positions by acquiring the Company's shares through or following an anticipated future common share offering. We have asked Nasdaq to initiate an investigation to determine if there was illegal trading activity in the Company's common shares. Such an investigation may not result in any definitive conclusions or in changes to the trading activity that has depressed the Company's share price. There is no guarantee that these trading strategies will not continue to have a negative impact on our share price and possibly limit our ability to raise sufficient capital to meet our financial needs.

In addition, we are expecting results from our two pivotal SFP clinical trials in the second half of 2013. The announcement of the results of these trials could create significant volatility in the market price of our common stock.

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

As of December 31, 2012, 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 2014. 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 2015 with an option to renew for one year.

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 2012 and 2011.

	Price Range	
	High	Low
2012		
Fourth Quarter	$ 8.38	$ 5.18
Third Quarter	9.60	7.64
Second Quarter	10.70	7.37
First Quarter	11.75	8.08
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

As of February 26, 2013, there were 28 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, 2007 with relative performance tracked through December 31, 2012. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Rockwell Medical Technologies, Inc., the Russell 2000 Index,
and the NASDAQ Biotechnology Index

*

$100 invested on 12/31/07 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012
Rockwell Medical	**100.00**	**58.36**	**107.10**	**110.03**	**117.97**	**112.12**
Russell 2000	**100.00**	**66.21**	**84.20**	**106.82**	**102.36**	**119.09**
NASDAQ Biotechnology	**100.00**	**93.40**	**103.19**	**113.89**	**129.12**	**163.33**

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,				
	2012	**2011**	**2010**	**2009**	**2008**
Net sales	$ 49,842,392	$ 48,966,231	$ 59,554,592	$ 54,729,505	$ 51,666,033
Cost of sales(2)	43,148,965	43,323,321	49,693,753	46,842,334	49,159,478
Gross profit(2)	6,693,427	5,642,910	9,860,839	7,887,171	2,506,555
Income from continuing operations before interest expense and income taxes(3)	(54,262,082)	(21,684,757)	(2,868,916)	(5,481,379)	(8,085,196)
Interest and Investment Income, net	240,567	242,205	185,517	(19,859)	221,139
Income from continuing operations before income taxes	(54,021,515)	(21,442,552)	(2,683,399)	(5,501,238)	(7,864,057)
Income taxes		2,005			
Net income	(54,021,515)	(21,444,557)	(2,683,399)	(5,501,238)	(7,864,057)
Earnings per common share:					
Basic	$ (2.65)	$ (1.21)	$ (0.16)	$ (0.37)	$ (0.57)
Diluted	$ (2.65)	$ (1.21)	$ (0.16)	$ (0.37)	$ (0.57)
Weighted average number of common shares and common share equivalents					
Basic	20,395,889	17,774,865	17,111,535	14,709,016	13,836,435
Diluted	20,395,889	17,774,865	17,111,535	14,709,016	13,836,435

	2012	**2011**	**2010**	**2009**	**2008**
Total assets	$ 17,025,086	$ 31,939,599	$ 36,966,907	$ 34,879,221	$ 18,959,982
Current assets	13,149,432	25,896,529	32,666,368	29,948,945	14,428,691
Current liabilities	26,986,956	13,692,351	6,420,220	5,536,957	7,097,836
Working capital	(13,837,524)	12,204,178	26,246,148	24,411,988	7,330,855
Long-term debt and capitalized lease obligations		2,280	8,750	19,062	41,203
Stockholders' equity(1)	(9,961,870)	18,244,968	30,537,937	29,323,202	11,820,943
Book value per outstanding common share	$ (0.46)	$ 0.98	$ 1.74	$ 1.70	$ 0.84
Common shares outstanding	21,494,696	18,710,002	17,513,608	17,200,442	14,104,690

(1) There were no cash dividends paid during the periods presented. Stockholders' equity reflects the proceeds of a public offering in each of 2009 and 2012.

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

(3) Increase in loss reflects significant increase in research and development expenses associated with Phase 3 clinical trials on SFP.

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 ESRD, CKD 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 $49.8 million in 2012. Our dialysis products business was cash flow positive in 2012, 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. Obtaining regulatory approval for a drug in the United States is expensive and can take several years. We expect to incur substantial costs relating to product testing and development over the next two years and expect to incur losses from operations in 2013. 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 the second half of 2013.

As of December 31, 2012 we had $4.7 million in cash.

In 2012, our sales increased $0.8 million or 1.8% compared to 2011. Our gross profit on sales increased $1.1 million or 18.6% compared to 2011 and gross profit margins increased to 13.4% from 11.5% in 2011. The increase in sales was a result of new business and reflected changes in customer and product mix to higher margin business and products. Our margins benefitted from our customers' shift from our liquid products to our dry concentrate products, conversion to our CitraPure product lines and the development of higher margin business.

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 the second half of 2013.

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. Our supply agreement with our largest domestic chain customer continues through the end of 2013 and is expected to be renewed for future periods.

Results of Operations

For the year ended December 31, 2012 compared to the year ended December 31, 2011

Sales

In 2012, our sales were $49.8 million compared to $49.0 million in 2011. Sales increased $0.8 million or 1.8% in 2012 compared to 2011. Domestic sales increased $1.7 million or 3.9% to $44.2 million while international sales decreased by $0.8 million or 12.1% to $5.6 million. International sales to a single international distributor decreased $1.4 million while all other international sales increased $0.6 million.

Domestic sales increased due to new business additions as well as changes in product mix to higher margin products including our CitraPure product lines and due to higher volume of our dry acid concentrate product lines. Dry acid concentrate lowers providers' cost per treatment and reduces our sales, but improves our gross profit margins due to a reduction in shipping costs.

Gross Profit

Our gross profit in 2012 was $6.7 million an increase of $1.1 million or 18.6% compared to 2011. Gross profit margins were 13.4% in 2012 compared to 11.5% in 2011. The increase in gross profit margins was due to increased sales of higher margin products and product lines including our CitraPure product lines along with conversions to dry acid concentrates. Margins also benefited from efforts to control operating costs in the face of inflationary cost increases for material, transportation operating costs and diesel fuel.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $12.7 million in 2012 compared to $9.5 million in 2011. The increase of $3.2 million was primarily due to an increase in non-cash charges for equity compensation of $2.9 million. Employee non-cash equity compensation aggregated $5.0 million in 2012 compared to $4.1 million in 2011. In addition, share based compensation for services increased $2.0 million to $2.3 million in 2012.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, primarily SFP, aggregating approximately $48.3 million and $17.8 million in 2012 and 2011, respectively. Costs incurred in both 2012 and 2011 were primarily for conducting human clinical trials of SFP and other SFP testing and development activities. Our spending increased considerably in 2012 for our Phase 3 clinical program as enrollment efforts and related testing activities increased dramatically and were in effect for the full year. We completed enrollment in our pivotal clinical studies during 2012 and expect to have results from our clinical studies during the second half of 2013.

Interest and Investment Income, Net

Net interest and investment income in 2012 was $242,000 compared to $244,000 in 2011. We earned higher rates of return on investable funds in 2012 compared to 2011 while overall investable funds were reduced throughout 2012 to fund our clinical development program.

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, 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 3 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.

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.

Going Concern.

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

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. In June 2011, the FASB issued Accounting Standards Update No. 2011-05, "Statement of Comprehensive Income" ("ASU 2011-05"), which requires entities to present net income and other comprehensive income in either a single continuous statement or in two separate, but consecutive, statements of net income and other comprehensive income. ASU 2011-05 was effective for our fiscal year beginning January 1, 2012. The standard did not impact our reported results of operations but did impact our financial statement presentation. We now present items of other comprehensive income in the Statement of Consolidated Comprehensive Income rather than in the Statement of Shareholders' Equity.

Liquidity and Capital Resources

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

spending to be significant as we execute our clinical program and complete the process of seeking regulatory approval for SFP in the United States.

Our cash resources include cash generated from our business operations and from proceeds of equity offerings, including the receipt of a net $16.0 million from an equity offering in February 2012. As of December 31, 2012, our cash and investments were $4.7 million and our current liabilities exceeded our current assets by $13.8 million.

Based on our recurring losses, negative cash flows from operations and working capital levels, we will need to raise substantial additional funds to finance our operations. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected. The report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2012 contains an explanatory paragraph stating that our recurring losses and need for working capital raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investments. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As the volume of testing activity increased during 2012, our accounts payable and accrued liabilities increased significantly with accrued liabilities related to research and development increasing from $5.9 million at the end of 2011 to $9.8 million at the end of 2012. As of December 31, 2012 our aggregate accounts payable was $14.8 million compared to $5.4 million at the end of 2011 and included invoiced amounts pending audit, review and approval for research and development services.

We expect to generate positive cash flow from operations in 2013, excluding research and development related expenditures. The Company intends to expand its customer relationships and to introduce Calcitriol during the second half of 2013 which may result in increased cash availability and higher future cash flows if successful. We believe that cash flow from operations will increase substantially upon marketing of Calcitriol which will offset a portion of the cash requirements to fund research and development expenditures.

The Company is actively seeking additional financing and is currently in negotiations for additional financing including equity and debt financing. The Company is also in discussion with potential business development partners to license rights to its products outside the United States and to partner its dialysis business with interested parties including joint ventures, partnerships and other arrangements.

While the Company believes it will be successful in completing financing transactions that will permit it to execute and complete its business plans, it is possible that the Company may not realize the funding it is seeking or may not realize an adequate amount of funding in the time frame it may be needed. If the Company is unable to obtain the level of funding it is seeking it may be forced to delay, reduce, curtail, or cease its research and development efforts and its business operations as a whole.

Contractual Obligations

The following table details our contractual obligations as of December 31, 2012:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Capital leases	$ 2,410	$ 2,410			
Operating leases	6,082,942	1,740,638	2,154,859	1,238,605	948,840
Purchase obligations					
Total	$ 6,085,352	$ 1,743,048	$ 2,154,859	$ 1,238,605	$ 948,840

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

We did not have any material exposure to interest rate risk as of December 31, 2012.

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 and other information required by this item are set forth on pages F-1 through F-25 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 disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management

necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2012. In making its assessment of internal control over financial reporting, management used the criteria described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing of the design and operating effectiveness of our internal control over financial reporting. Based on this evaluation, we concluded that the Company's internal control over financial reporting was effective as of December 31, 2012.

Plante & Moran, PLLC, an independent registered public accounting firm, as auditors of our consolidated financial statements, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2012. Plante & Moran, PLLC's report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting, is included herein.

Changes in Internal Controls

There was no change in our internal control over financial reporting identified in connection with the Company's evaluation of such internal controls that occurred during our fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors

The name and age of each director, his business experience, and the year each became a director, according to information furnished by such directors, are set forth below.

Class I Director

Ronald D. Boyd, age 50, has been a director since March 2000. Mr. Boyd has over 26 years of experience in the dialysis industry, including the ownership and operation of dialysis clinics as well as experience in dialysis product design, product development, regulatory approval and marketing. He has also been a private investor for many years. He currently is an owner and managing partner of Southeast Acute Services, LLC and Southern Renal Administrations, LLC, which is primarily in the business of acute dialysis services, since 2001. He was a founder and Managing Partner of East Georgia Regional Dialysis Center, an outpatient, freestanding dialysis center located in southern Georgia from 2001 until 2005. He was a founder of Diatek, Inc. in 2001 where he developed, designed and holds the patent to the Cannon Cath., the first "retrograde" dual lumen dialysis catheter in the market. The company has since been sold. He was a founder and co-owner of Classic Medical, Inc., a dialysis and medical products company, and served as the Executive Vice President of Classic Medical, Inc. from its inception in November 1993 until April 2007 when he sold his interest in that company. From May 1993 to November 1993, Mr. Boyd served as a consultant for Dial Medical of Florida, Inc., a manufacturer and distributor of dialysis products. From 1990 to 1993, Mr. Boyd served as a Regional Sales Manager for Future Tech, Inc., a dialysis products distributor. With his extensive experience in the dialysis industry, Mr. Boyd brings to the Board entrepreneurial experience and expertise in marketing, product development and strategy. Mr. Boyd's term as a director will expire at the 2013 annual meeting of shareholders and upon the election and qualification of his successor.

Class II Director

Kenneth L. Holt, age 60, has been a director since March 2000. Mr. Holt has over 25 years of experience in the dialysis industry, including the management and operation of dialysis clinics, and has also been a private investor for many years. He is currently an owner and a managing partner of two firms that provide contractual dialysis services; Southeast Acute Services, LLC and Southern Renal Administrators, since 2001. He was a founder and co-owner of Charleston Renal Care, LLC, a kidney disease management company specializing in the treatment of end-stage renal disease, until its sale in 2005. He was a founder and co-owner of Savannah Dialysis Specialists, LLC, a disease management company specializing in the treatment of end-stage renal disease, and served as the Managing Partner from October 1999 until its sale in 2004. From 1996 to October 1999, Mr. Holt served as Vice President for Gambro Healthcare, Inc., in its Carolinas Region, and held the same position at Vivra Renal Care, Inc., its predecessor company, which was acquired in 1997 by Gambro Healthcare, Inc. From 1986 to 1996, Mr. Holt was also the co-owner and Managing Partner of five other dialysis clinics that he founded. With his extensive experience in the dialysis industry, Mr. Holt brings to the Board entrepreneurial experience and expertise in operations and strategy, as well as financial expertise. Mr. Holt also brings strong accounting and financial skills to our audit committee and Board, having supervised the accounting and finance function for several businesses, and is an "audit committee financial expert" as defined by applicable SEC and NASDAQ rules. Mr. Holt's term as a director will expire at the 2014 annual meeting of shareholders and upon the election and qualification of his successor.

Class III Directors

Robert L. Chioini, age 48, is a founder of the Company, has served as our Chairman of the Board since March 2000, has served as our President and Chief Executive Officer since February 1997, has been one of our directors since our formation in October 1996 and served as President of the Company's predecessor which he founded in January 1995. Including his time with the Company, Mr. Chioini has nearly 20 years of operational and sales experience in the dialysis industry. Mr. Chioini, as our current President and Chief Executive Officer, brings to the Board extensive knowledge regarding the Company, the dialysis industry and the current environment in which we operate, allowing him to provide critical insight into operational requirements and strategic planning. In that position, he is also able to promote the flow of information between the Board and management and provide management's perspective on issues facing the Board. Mr. Chioini's term as a director will expire at the 2015 annual meeting of shareholders and upon the election and qualification of his successor.

Patrick J. Bagley, age 48, has been a director since July 2005. Mr. Bagley is Senior Partner of the law firm Bagley and Langan, P.L.L.C. and has been a practicing attorney since 1995, with a focus on general legal matters and litigation. Since 1987, Mr. Bagley has also been a licensed insurance agent licensed and certified in property and casualty insurance as well as life, accident and health insurance. Mr. Bagley has started and managed numerous businesses, including three different national franchises of retail service businesses. In addition, since 1988, Mr. Bagley has been a licensed real estate agent, real estate developer and real estate investor. Mr. Bagley brings strong risk management skills, substantial entrepreneurial experience and keen analytical abilities to the Board. His background as a lawyer provides a valuable perspective to the Board on legal, litigation and risk management matters. Mr. Bagley's term as a director will expire at the 2015 annual meeting of shareholders and upon the election and qualification of his successor.

The audit committee is comprised of Messrs. Holt, Bagley and Boyd. The Board has determined that Kenneth L. Holt, who is the Chairman of the Audit Committee, is an "audit committee financial expert," as defined by applicable SEC rules.

Executive Officers

The following information is provided for those officers currently designated as executive officers by the Board of Directors. The executive officers of the Company are elected or appointed annually and serve as executive officers of the Company at the pleasure of the Board of Directors. The Company's current executive officers are described below.

Robert L. Chioini's business experience is described above under "Class III Directors."

Thomas E. Klema, CPA/MBA, age 59, has served as the Company's Vice President, Chief Financial Officer, Treasurer and Secretary since January 1999. Prior to joining the Company, Mr. Klema was employed as Vice President of Finance and Administration at a specialty products division of Whistler Corporation from 1997 to 1998 and, from 1980 to 1996, held several management positions in the areas of finance, accounting, human resources, business planning, customer service and operations, including from 1993 to 1996 as a vice president, at Diversey Corporation, a subsidiary of the Molson Cos., until it was acquired by Unilever. Prior to 1980, Mr. Klema was employed as a certified public accountant. Mr. Klema holds both an MBA in finance and a BA in accounting from Michigan State University.

Ajay Gupta M.D., age 54, joined the Company as Chief Scientific Officer in June 2009. Prior to joining the Company, Dr. Gupta spent the prior seven years as an Associate Professor of Medicine at UCLA and Charles Drew University Schools of Medicine, Los Angeles, CA, where he had an active nephrology practice. Prior to that, Dr. Gupta served on the faculties of Henry Ford Hospital, Detroit, MI, University of Alabama, Birmingham, State University of New York, Syracuse and

Washington University, St. Louis. Dr. Gupta also completed a clinical fellowship in Nephrology from Wayne State University, Detroit, Michigan and a research fellowship in Nephrology from Washington University, St. Louis, Missouri. Dr. Gupta, who is the Founder and Chairman of the Indian Society for Bone and Mineral Research, earned his MBBS degree and completed his residency in Internal Medicine from All India Institute of Medical Sciences, New Delhi. Dr. Gupta is the inventor of dialysate iron therapy using Soluble Ferric Pyrophosphate (SFP) and is also the inventor of intravenous iron therapy using slow continuous infusion of SFP, including as an adjunct to parenteral nutritional admixtures. He has filed a number of patents in the areas of drugs, medical devices and diagnostic tests.

Raymond D. Pratt M.D., age 62, joined the company in April 2012 as its Chief Medical Officer. Prior to joining the Company, Dr. Pratt worked at Shire PLLC from 2003 to 2010 as Vice President Research and Development and as the scientific leader in its Emerging Business Unit and Renal Business Unit. Previous roles at Shire included Vice President Global Clinical Medicine and Global Clinical Affairs and head of US Clinical Development. Dr. Pratt served in a consulting role at Quintiles, a global biopharmaceutical services company, as a vice president of strategic drug development innovation since August 2011 and as an industry consultant during 2011 after leaving Shire. Prior to working at Shire, he was Senior Director, Clinical Research and Development at Eisai Medical Research from 1994 to 2003, where he was head of Central Nervous System and Internal Medicine clinical development.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten percent shareholders are required by regulation of the SEC to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of the Forms 3, 4 and 5 and any amendments thereto received by us, or written representations from certain reporting persons that no Forms 5 were required for those persons, we believe that, since January 1, 2012, our officers and directors and persons who own more than ten percent of a registered class of our equity securities have timely complied with all filing requirements under Section 16(a) of the Exchange Act except that Mr. Holt, a director, filed two late Form 4s disclosing a total of five transactions.

Code of Business Conduct and Ethics

Our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer or controller. Our Code of Business Conduct and Ethics contains written standards that we believe are reasonably designed to deter wrongdoing and to promote:

Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships,

Full, fair, accurate, timely and understandable disclosure in reports and documents that we file