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 with, or submit to, the SEC and in other public communications we make,

Compliance with applicable governmental laws, rules and regulations,

The prompt internal reporting of violations of the Code of Business Conduct and Ethics to the appropriate person or persons, and

Accountability for adherence to the Code of Business Conduct and Ethics.

Our Code of Business Conduct and Ethics is posted on our website at www.rockwellmed.com and is an exhibit to our Annual Report on Form 10-K. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendments to, or a waiver from, a provision of the Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics definition enumerated in the applicable SEC rule by posting such information on our website at www.rockwellmed.com within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation.

Compensation Discussion and Analysis

Our Compensation Objectives

Our Compensation Committee (composed of independent directors Bagley, Boyd, and Holt) is responsible for establishing and administering the policies governing compensation for our executive officers. The key objectives established by our compensation committee for our compensation program are to:

a) Attract and retain superior caliber key executive personnel;

b) Motivate and reward executives who are critical to our success; and

c) Provide a competitive compensation package that aligns the interests of our management with the interests of our shareholders and encourages the creation of shareholder value.

In order to position the Company for its development as a specialty bio-pharmaceutical company and to meet the foregoing objectives, the Compensation Committee provides the executive officers with competitive short term cash compensation in the form of salary and bonus to attract and retain key personnel and provides appropriate long term compensation through equity-based compensation awards that align shareholder and management interests to motivate management to optimize shareholder value. References in this discussion to the named executive officers, or NEOs, are to the individuals listed in the Summary Compensation Table.

Basis for Our Compensation Structure

Our Board of Directors believes that the Company has a unique opportunity to create substantial shareholder value as an evolving specialty bio-pharmaceutical company. The Company's strategy to reposition itself as a specialty bio-pharmaceutical company developing high potential pharmaceuticals is a longer term, multi-year strategy. In order to execute on this strategy, we recognized the need to build our organizational structure and particularly the need for a broader management team with more diverse skills who could lead and direct our development efforts. An important element of this strategy was to develop a comprehensive and longer term compensation strategy for the executive team that would help us attract and retain quality leaders.

In early 2008, the Compensation Committee commissioned a study in anticipation of the future recruitment of key officers to lead and direct the Company's drug development efforts. Based on this study, prepared by management from publicly available data from over 230 biotech, specialty pharmaceutical and other medical device companies, the Compensation Committee determined appropriate compensation ranges for current and future executives in their respective positions relative to this peer review at that time. The companies included in the study represented a cross section of those companies in our industry that management believed were the most similarly situated to our current size and business or the size and business we expect to attain in the next few years based on

the strategy described above. Due to the Company's unique position across these multiple segments and sectors, the Committee believes that this analysis provided a comprehensive and balanced perspective. The Company completed an updated compensation analysis in 2010 of approximately 50 life science companies and used this analysis as an additional background reference. This analysis included life science companies with market capitalization in the $175 $350 million range. The Compensation Committee believes this range is appropriate for compensation planning purposes and is consistent with its expectations for the Company's valuation potential in the current compensation planning cycle. While the data from these studies were reviewed and considered by the Compensation Committee as general reference points in making informed judgments on executive compensation and competitive pay plans, and to provide perspective for developing competitive compensation opportunities, the Compensation Committee did not formally benchmark the compensation of individual executives to any particular amount or range based upon such data. In making its evaluation, analysis and assessment of executive compensation, the Compensation Committee assesses other factors, including the executive's role or roles with the Company, the breadth of knowledge and skill the executive possesses, the executive's ability to influence the development of the business, demonstrated leadership in the executive's area of expertise, leadership continuity and executive retention and motivation as well as other factors that the Compensation Committee determines are important and relevant to the executive's compensation.

We also have in place the Amended and Restated 2007 Long Term Incentive Plan, which permits the Compensation Committee to award a wide variety of incentive awards, including equity-based awards in various forms such as stock options and restricted stock. The Committee uses equity-based awards under this plan to provide the NEOs with long term incentives intended to align their interests with shareholder value creation. The long term incentive compensation strategy has been to issue equity-related compensation primarily in the form of nonqualified stock options with vesting in installments over a three year period and an exercise price equal to the fair market value of our common shares on the grant date. Structured in this way, the options have value only to the extent our stock price increases during the ten year term of the options. The structure also encourages retention, as unvested portions of the options are forfeited upon termination of employment other than in connection with death, disability or change in control and vested portions must be exercised within an abbreviated time frame following termination. The phased three year vesting period retains the long term element of equity-based incentives while enabling earlier rewards if achievements result in a higher stock value. We have tended to grant proportionately more equity-based compensation than cash compensation in part because of its long term motivational aspects and also as a means of conserving our cash resources during this period of development and operational losses. The Compensation Committee makes situational assessments of both the timing and frequency of equity compensation awards based upon the developmental status and progress of the business in achieving its goals and objectives and input from management and typically makes the assessments and grants on an annual basis, but occasionally makes them more or less frequently based on specific development milestones and events.

The other aspects of our compensation program also reflect our preference to keep operating expenses to a minimum to conserve cash resources. The Company offers a 401(k) plan for individual retirement savings opportunities for executives, but the plan is non-contributory by the Company and we have no other pension or retirement plan or deferred compensation arrangement for our named executive officers. Personal savings and assets realized from long term equity incentives are expected to be the primary sources of assets to fund post retirement income for the management team.

The perquisites we offer our named executive officers are modest, as we believe our NEOs are fairly compensated through the other parts of the compensation package. The Company provides long term disability insurance for the NEOs at a nominal cost per covered executive. In addition, Mr. Chioini receives a vehicle allowance consistent with our historical practice since the Company's

inception. The Compensation Committee believes this element helps to make his compensation package overall more competitive.

We have no employment, termination, severance or change in control agreements or arrangements with our NEOs at this time. We believe the equity-based awards held by the NEOs, which will vest upon a change in control, provide sufficient incentive for them to remain engaged should the Company be sold. The Compensation Committee may determine in the future that it is appropriate to enter into such agreements with the NEOs to accomplish the objectives set forth above.

In view of the substantial beneficial ownership of our common shares by our NEOs, we currently do not have any established stock ownership guidelines.

Key Elements of Compensation for 2012

In establishing cash and equity-based compensation, the Compensation Committee took into account a number of factors, including the compensation study data, the Company's business results and accomplishments, the unique skills and attributes of the executive in his leadership role, the respective importance of the executive's position and the executive's performance, contributions and leadership demonstrated. In this regard, the Compensation Committee relies on input from the chief executive officer regarding the performance of the other NEOs and its own assessment of the chief executive officer's performance. In light of the overwhelming shareholder support for our executive compensation practices expressed at last year's annual meeting through the advisory vote on compensation, the Compensation Committee maintained our existing compensation program and philosophy in 2012 but continues to review and evaluate executive compensation trends and practices and may modify the program or philosophy from time to time as it deems necessary or appropriate.

Salaries. In March 2012, based on the chief executive officer's recommendation, the Compensation Committee approved salary increases of approximately 8% for Mr. Chioini, 8% for Mr. Klema and 8% for Dr. Gupta in light of 2011 business results and accomplishments. Based on our 2010 compensation study, executive officers' salaries are estimated to be within a range of 10% of the median salaries for similar positions. While the Committee has not targeted a specific level for compensation in comparison to these studies, it believes current compensation levels are necessary in order to meet the key objectives of our compensation program. The Compensation Committee considered factors including experience, skills, knowledge, breadth of responsibility and effectiveness in executing the executive's functional role in determining salary levels. The chief executive officer was not present for the deliberations or voting by the Compensation Committee on the determination of the chief executive officer's compensation but did provide recommendations to the Committee with respect to compensation matters for the other executive officers.

Bonuses. Bonus potential for executive positions was set at 50% of base salary by the Compensation Committee for 2012. The Compensation Committee increased the bonus potential range from 25% of base salary in 2011 based on recognition of the high potential to develop and contribute to building shareholder value over the next several years and with the objective of making bonus compensation more competitive. The Compensation Committee believes it is important to recognize the opportunity for the executive team to create value for the shareholders and for the Compensation Committee to have the latitude to recognize achievement of business development goals and objectives. The Compensation Committee's objective is to align shareholder and management interests in longer term value creation, while, to a lesser degree, reward achievement of short term goals and objectives. The Compensation Committee also retained the flexibility of recognizing exceptional outcomes in development, job performance and value creation through supplemental discretionary bonuses separate from the targeted bonus levels. The proportion of the bonus potential to be awarded and whether to award any bonuses at all was based on the subjective judgment of the Compensation Committee based on its evaluation of the executive team's contributions during 2012 to the development of the Company

and its progress toward meeting key objectives for the Company's growth and development and on informal input from the chief executive officer. The Compensation Committee has not yet determined whether to pay bonus awards for 2012 performance.

Equity Compensation. The Compensation Committee granted options to our current NEOs in January 2012 and June 2012. All grants were made on the terms included in our standard executive option grant form agreement. All awards have an exercise price equal to fair market value on the date of the award. The options become exercisable in equal installments over three years beginning on the first anniversary of the grant date and have a term of ten years. The amounts were recommended by the chief executive officer based on each NEO's level of responsibility, success at achieving strategic and business objectives and influence the NEO has had and is expected to have on creating or increasing the value of our business. In determining whether to award option grants and the size of the equity awards to NEOs, the Compensation Committee also considered factors such as overall performance of the Company and the executive, progress toward stated objectives, contributions to overall corporate development as well as anticipated future contributions to corporate development, non-cash financial expense, tax implications of the equity awards and their potential to increase shareholder value. Dr. Pratt, who was hired in April 2012, received a grant of options shortly after his hiring based upon similar considerations and with his input as part of the negotiation of his initial compensation package but did not receive other grants during the year.

In order to facilitate our strategy of broadening our management team and recruiting life science executives to our Company, we determined last year to increase the number of shares subject to the Amended and Restated 2007 Long Term Incentive Plan. As discussed in this proxy statement under "Proposal to Approve Amendment to Amended and Restated 2007 Long Term Incentive Plan," the Board of Directors has determined to further increase the number of shares subject to that plan so that an adequate number of shares will continue to be available for grants to both current and newly hired executives in accordance with the program described above. The Compensation Committee approved grants in January 2013 to certain NEOs on the same terms as the 2012 grants.

The Compensation Committee made restricted stock grants in 2012 based on the overall progress in corporate development to Mr. Chioini, Dr. Gupta and Mr. Klema who were granted 100,000, 75,000 and 60,000 shares, respectively. The Compensation Committee selected a two year cliff vesting for these grants. The Compensation Committee believes that there is high potential to develop and increase shareholder value over this period. The Compensation Committee wants to provide incentive and to motivate senior management to optimize shareholder value during this critical development period and believes these incentives will provide alignment between shareholder and management objectives.

On May 14, 2012, with the approval of the Compensation Committee and the award holders, we further amended the terms of restricted stock awards issued in November 2008 to Mr. Chioini and Mr. Klema to postpone the vesting of the remainder of the awards (50,000 shares for Mr. Chioini and 25,000 shares for Mr. Klema) from May 15, 2012 to March 1, 2013. Similarly, in March 7, 2012, we amended the terms of restricted stock awards issued in August 2010 to Mr. Chioini, Mr. Klema, and Dr. Gupta so that the vesting of the portion of each award that was scheduled to vest on March 10, 2012 (50,000 shares for Mr. Chioini, 30,000 shares for Mr. Klema and 37,500 shares for Dr. Gupta) was postponed to August 6, 2012 and on July 31, 2012 we amended the terms of these same restricted stock awards to vest on March 8, 2013. The deferral of the vesting of these awards was determined to be in the best interests of the Company as the likely sale of shares by the award holders in order to fund tax liabilities resulting from the vesting of these awards may have resulted in an adverse impact on the market price of our common shares during time periods immediately preceding or following an equity offering of our common shares.

Deductibility of Executive Compensation

Section 162(m) of the Internal Revenue Code of 1986, as amended, restricts the deductibility of executive compensation paid to our chief executive officer and any of our four other most highly compensated executive officers at the end of any fiscal year to not more than $1 million in annual compensation (including gains from the exercise of certain stock option grants). Qualifying performance-based compensation, including gains from option exercises, is exempt from this limitation if it complies with the various conditions described in Section 162(m) and the accompanying regulations. The Amended and Restated 2007 Long Term Incentive Plan contains provisions intended to cause compensation realized in connection with the exercise of options granted thereunder to be exempt from the Section 162(m) restrictions.

Our compensation program may result in payments from time to time that are subject to these restrictions on deductibility, but we do not believe the effect of these restrictions on us is currently material. It may be appropriate to exceed the limitation on deductibility to ensure that executive officers are compensated in a manner that is consistent with our best interests, the best interests of our shareholders and our executive compensation philosophy and objectives, and we reserve the authority to approve non-deductible compensation in appropriate circumstances.

Compensation Committee Report

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis contained in this proxy statement with management. Based on the Committee's review of, and the discussions with management with respect to, the Compensation Discussion and Analysis, the Committee has recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this proxy statement, and in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

COMPENSATION COMMITTEE:
Patrick J. Bagley
Ronald D. Boyd
Kenneth L. Holt

Summary Compensation Table

The following table summarizes compensation paid to or earned by the Company's executive officers who were serving as such at December 31, 2012, whom we refer to collectively as our NEOs, during the last three years.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)(a)	Stock Awards ($)(b)	Option Awards ($)(c)	All Other Compensation ($)(d)	Total ($)
Robert L. Chioini	2012	$ 545,000	$ 136,250	$ 945,000	$ 1,448,585	$ 20,256	3,095,091
Chairman, President and	2011	$ 505,000	126,250		1,260,850	20,675	1,912,775
Chief Executive Officer	2010	495,000	198,750	$ 586,180	1,011,955	20,231	2,312,116
Thomas E. Klema							
	2012	325,000	81,250	567,000	566,735		1,539,985
Chief Financial Officer,	2011	301,000	75,250		504,340		880,590
Secretary and Treasurer	2010	295,000	73,750	351,708	475,644		1,196,102
Dr. Ajay Gupta(e)							
	2012	383,000	95,750	708,750	860,685		2,048,185
Chief Scientific Officer	2011	355,000	88,750		756,510		1,200,260
	2010	348,000	87,000	439,635	528,791		1,403,426
Dr. Raymond D. Pratt(f)							
Chief Medical Officer	2012	212,308	49,750		775,800		1,037,858

(a)

These bonus amounts were approved by the Compensation Committee following the year end, but constitute compensation earned for services rendered in the year shown.

(b)

The amounts reported in this column represent grant date fair values of restricted stock awards computed in accordance with FASB ASC Topic 718. These restricted stock awards were valued at the closing market price on the date of grant, or $5.8618 per share for 2010 and $8.73 per share for the 2012 grant.

(c)

The amounts reported in this column represent grant date fair values of stock option grants made during such year determined using the Black Scholes option pricing model, excluding any forfeiture reserves. The assumptions used to determine fair value are set forth in the table below:

Year	Dividend Yield	Risk Free Rate	Volatility	Expected Life
2012	0.0%	0.8-1.2%	64-65%	6 years
2011	0.0%	1.1-2.3%	63-64%	6 years
2010	0.0%	1.8-2.8%	66%	6 years

(d)

For Mr. Chioini, the amounts reported reflect payments made by the Company under its lease car program of $17,092, $16,935 and $16,779, and premiums for long-term disability insurance of $3,165, $3,740 and $3,452 in 2012, 2011 and 2010, respectively. The incremental cost to the Company of perquisites provided to the other NEOs did not exceed $10,000 and, therefore, has been excluded pursuant to applicable SEC rules.

(e)

Dr. Gupta joined the Company in June 2009.

(f)

Dr. Pratt joined the Company in May 2012 at an annual base salary of $345,000.

Grants of Plan-Based Awards

The NEOs received the equity-based awards set forth in the table below under the Amended and Restated 2007 Long Term Incentive Plan, or LTIP, during 2012.

Grants of Plan-Based Awards Table for 2012

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise Price of Option Awards ($/sh)	Grant Date Fair Value of Stock and Option Awards ($)
Robert Chioini	1/5/2012		225,000	$ 10.04	1,322,775
	6/4/2012		25,000	$ 8.73	125,810
	6/11/2012	100,000			945,000
Ajay Gupta					
	1/5/2012		125,000	$ 10.04	734,875
	6/4/2012		25,000	$ 8.73	125,810
	6/11/2012	75,000			708,750
Thomas Klema					
	1/5/2012		75,000	$ 10.04	440,925
	6/4/2012		25,000	$ 8.73	125,810
	6/11/2012	60,000			567,000
Raymond Pratt					
	5/1/2012		150,000	$ 8.93	775,800

The option grants were made pursuant to terms stated in an option agreement adopted under the LTIP by the Compensation Committee. The option agreements provide that the options become exercisable in three equal annual installments beginning on the one year anniversary of the grant date as long as the grantee remains employed by us. The options become fully exercisable immediately upon (i) the grantee's death or permanent disability or (ii) upon a "change in control" (as defined in the LTIP). The Compensation Committee has the right to accelerate vesting or extend the time for exercise. The exercise price of the options is the fair market value per share of our common shares on the grant date as determined under the LTIP. The grantee may pay the exercise price in cash, with previously acquired shares that have been held at least six months or pursuant to a broker-assisted cashless exercise method. The stock options will expire 10 years after the grant date and will immediately terminate to the extent not yet exercisable if the grantee's employment with us is terminated for any reason other than death or disability. If the grantee's employment is terminated other than due to death or disability on or after the date the options first become exercisable, then the grantee has the right to exercise the option for three months after termination of employment to the extent exercisable on the date of termination. If the grantee's employment terminates due to death or disability, the grantee or the grantee's estate has the right to exercise the option at any time during the remaining term to the extent it was not previously exercised. The option agreement also provides that options issued to the grantee may not be transferred by the grantee except pursuant to a will or the applicable laws of descent and distribution or transfers to which the Compensation Committee has given prior written consent. Until the issuance of common shares pursuant to the exercise of stock options, holders of stock options granted under the option agreement have no rights of holders of our common shares.

The restricted stock grants were made under the LTIP pursuant to terms stated in a restricted stock award agreement adopted under the LTIP by the Compensation Committee. The restricted stock award agreements provide that, so long as the grantee remains employed by us, the restricted stock fully vests upon the earlier of (i) on the second anniversary of the grant date (ii) subject to the right of the Compensation Committee to declare otherwise, a "change in control" (as defined in the LTIP). If the grantee's employment is terminated for any reason prior to the restricted stock becoming fully vested, the grantee forfeits the restricted stock, unless otherwise determined by the Compensation Committee. The restricted stock agreement also provides that restricted stock issued to the grantee may not be transferred by the grantee in any manner prior to vesting. Grantees otherwise have all rights of

holders of our common shares, including voting rights and the right to receive dividends. Restricted stock grants made prior to 2012 vested in two installments, one-half on the 18 month anniversary of the grant date and the remainder on the three year anniversary of the grant date, but otherwise have the same terms.

On May 14, 2012, with the approval of the Compensation Committee and the award holders, we further amended the terms of restricted stock awards issued in November 2008 to Mr. Chioini and Mr. Klema to postpone the vesting of the remainder of the awards (50,000 shares for Mr. Chioini and 25,000 shares for Mr. Klema) from May 15, 2012 to March 1, 2013. Similarly, in March 7, 2012, we amended the terms of restricted stock awards issued in August 2010 to Mr. Chioini, Mr. Klema, and Dr. Gupta so that the vesting of the portion of each award that was scheduled to vest on March 10, 2012 (50,000 shares for Mr. Chioini, 30,000 shares for Mr. Klema and 37,500 shares for Dr. Gupta) was postponed to August 6, 2012 and on July 31, 2012, we further amended the terms of these same restricted stock awards to vest on March 8, 2013.

A "change in control" is generally defined in the LTIP as any of the following events:

(i) If the Company consolidates with or merges into any other corporation or other entity and is not the continuing or surviving entity of such consolidation or merger;

(ii) If the Company permits any other corporation or other entity to consolidate with or merge into the Company and the Company is the continuing or surviving entity but, in connection with such consolidation or merger, the common shares are changed into or exchanged for stock or other securities of any other corporation or other entity or cash or any other assets;

(iii) If the Company dissolves or liquidates;

(iv) If the Company effects a share exchange, capital reorganization or reclassification in such a way that holders of common shares shall be entitled to receive stock, securities, cash or other assets with respect to or in exchange for the common shares;

(v) If any one person, or more than one person acting as a group, acquires ownership of common shares possessing 35% or more of the total voting power of the common shares;

(vi) If a majority of members on the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election; or

(vii) If there is a change in the ownership of a substantial portion of the Company's assets, which shall occur on the date that any one person, or more than one person acting as a group acquires assets from the Company that have a total gross fair market value equal to or more than 40% of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions.

The table below shows the value of the unvested options and restricted stock that would have become vested at December 31, 2012 if a change in control had occurred on such date or, in the case of options, if the named executive officers' employment had terminated on such date due to death or disability. The value is based upon the closing price on December 31, 2012 and, in the case of options, the spread between such price and the exercise price of the options that would have become exercisable.

Name	Change in Control	Death or Disability
Robert Chioini	$ 2,131,439	$ 118,939
Ajay Gupta	1,225,900	18,400
Thomas Klema	1,229,414	62,164
Raymond Pratt		

Employment Agreements

Each of our executive officers is employed at will, and we have no employment, termination or change in control agreements with our executive officers. We do not pay any benefits to our executive officers under any plan that provides for retirement benefits or payments in connection with resignation, retirement or other termination, except as described above with respect to restricted shares and stock options or as the Board or the Compensation Committee may determine at the time of any such termination.

Outstanding Equity Awards At Fiscal Year-End

The following table shows certain information regarding outstanding equity awards at December 31, 2012 for the NEOs.

Outstanding Equity Awards at Fiscal Year-End

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares That Have Not Vested (#)	Market Value of Shares That Have Not Vested ($)(j)
Robert Chioini(k)	300,000		1.81	6/18/2013		
	25,000		3.06	9/17/2013		
	105,000		4.05	1/13/2014		
	335,000		2.79	12/22/2014		
	375,000		4.55	12/15/2015		
	250,000		6.50	12/17/2017		
	75,000		6.50	04/03/2018		
	175,000		3.09	11/19/2018		
	225,000		6.74	6/18/2019		
	100,000	50,000(a)	7.13	1/15/2020		
	66,667	33,333(b)	5.8618	8/13/2020		
	83,333	166,667(c)	8.47	1/11/2021		
		225,000(d)	10.04	1/5/2022		
		25,000(e)	8.73	6/4/2022		
					250,000(g)	$ 2,012,500
Thomas Klema	150,000		1.81	6/18/2013		
	25,000		3.06	9/17/2013		
	85,000		4.05	1/13/2014		
	115,000		2.79	12/22/2014		
	187,500		4.55	12/15/2015		
	175,000		6.50	12/17/2017		
	80,000		3.09	11/19/2018		
	125,000		6.74	6/18/2019		
	40,000	20,000(a)	7.13	1/15/2020		
	40,000	20,000(b)	5.8618	8/13/2020		
	33,333	66,667(c)	8.47	1/11/2021		
		75,000(d)	10.04	1/5/2022		
		25,000(e)	8.73	6/4/2022		
					145,000	$ 1,167,250

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares That Have Not Vested (#)	Market Value of Shares That Have Not Vested ($)(j)
Ajay Gupta	200,000		$ 6.74	6/18/2019		
	40,000	20,000(a)	7.13	1/15/2020		
	50,000	25,000(b)	5.8618	8/13/2020		
	50,000	100,000(c)	8.47	1/11/2021		
		125,000(d)	10.04	1/5/2022		
		25,000(e)	8.73	6/4/2022		
					150,000(i)	$ 1,207,500
Raymond Pratt		150,000(f)	8.93	5/1/2022		

(a) These options vest in three equal annual installments beginning January 15, 2011. The options would become immediately exercisable upon death, disability or a change in control.

(b) These options vest in three equal annual installments beginning August 13, 2011. The options would become immediately exercisable upon death, disability or a change in control.

(c) These options vest in three equal annual installments beginning January 11, 2012. The options would become immediately exercisable upon death, disability or a change in control.

(d) These options vest in three equal annual installments beginning January 5, 2013. The options would become immediately exercisable upon death, disability or a change in control.

(e) These options vest in three equal annual installments beginning June 4, 2013. The options would become immediately exercisable upon death, disability or a change in control.

(f) These options vest in three equal annual installments beginning May 1, 2013. The options would become immediately exercisable upon death, disability or a change in control.

(g) 50,000 of these shares vest on each of March 1, 2013, March 8, 2013 and August 13, 2013 and 100,000 vests on June 4, 2014 or immediately upon a change in control.

(h) 25,000 of these shares vest on March 1, 2013, 30,000 vest on each of March 8, 2013 and August 13, 2013 and 60,000 on June 4, 2014, and all vest immediately upon a change in control.

(i) 37,500 of these shares vest on each of March 8, 2013 and August 13, 2013 and 75,000 vests on June 4, 2014, or immediately upon a change in control.

(j) Value was determined by multiplying the number of shares that have not vested by the closing price of our common shares as of December 31, 2012 ($8.05).

(k) 143,000 of the options subject to a grant with a $0.55 per share exercise price expiring in December 2012 were transferred during 2012 pursuant to a 2007 domestic relations order.

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Option Exercises and Stock Vested

The following table provides information with respect to options exercised by the NEOs during 2012. No shares of restricted stock held by the NEOs vested during 2012.

Option Exercises and Stock Vested for 2012

	Option Awards	
Name	**Number of Shares Acquired on Exercise (#)**	**Value Realized on Exercise ($)**
Robert Chioini		
Thomas Klema	68,000	$ 319,600
Ajay Gupta		
Raymond Pratt		

Director Compensation

In 2012, non-employee directors of the Company did not receive any cash compensation. No fees were paid for attendance at any Board or committee meetings, but the non-employee directors were reimbursed for their expenses incurred in attending Board and committee meetings in accordance with Company policy.

The non-employee directors are eligible to receive grants under the LTIP. The making of any such grants and the terms of such grants are determined by the Compensation Committee. On January 5, 2012, each non-employee director was granted options to purchase 25,000 common shares at an exercise price equal to the closing market price on the grant date ($10.04). The options vest in three equal annual installments beginning one year after the date of grant and expire ten years after the date of grant. The amount in the table below represents the grant date fair value of such grants determined in accordance with FASB ASC Topic 718 using the Black Scholes option pricing model, excluding any forfeiture reserves. We assumed a dividend yield of 0.0%, risk free interest rate of 1.2%, volatility of 65% and expected lives of 6 years.

2012 Director Compensation

Name	Option Awards ($)(a)	Total ($)
Patrick J. Bagley	146,975	146,975
Kenneth L. Holt	146,975	146,975
Ronald D. Boyd	146,975	146,975

(a)

The following table shows certain information regarding outstanding equity awards at December 31, 2012 for the non-employee directors.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Ronald D. Boyd	25,000		$ 1.81	6/18/2013
	25,000		3.06	9/17/2013
	10,000		4.05	1/13/2014
	25,000		2.79	12/22/2014
	25,000		4.55	12/15/2015
	50,000		6.50	12/17/2017
	25,000		3.09	11/19/2018
	25,000		6.74	6/18/2019
	16,667	8,333	7.13	1/15/2020
	16,667	8,333	5.8618	8/13/2020
	16,667	33,333	8.47	1/11/2021
		25,000	10.04	1/5/2022
Kenneth L. Holt	25,000		$ 3.06	9/17/2013
	10,000		4.05	1/13/2014
	25,000		4.55	12/15/2015
	50,000		6.50	12/17/2017
	25,000		3.09	11/19/2018
	25,000		6.74	6/18/2019
	16,667	8,333	7.13	1/15/2020
	16,667	8,333	5.8618	8/13/2020
	16,667	33,333	8.47	1/11/2021
		25,000	10.04	1/5/2022
Patrick J. Bagley	25,000		$ 4.55	12/15/2015
	50,000		6.50	12/17/2017
	25,000		3.09	11/19/2018
	25,000		6.74	6/18/2019
	16,667	8,333	7.13	1/15/2020
	16,667	8,333	5.8618	8/13/2020
	16,667	33,333	8.47	1/11/2021
		25,000	10.04	1/5/2022

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information regarding the ownership of the common shares as of March 6, 2013 (unless otherwise indicated) with respect to

each current director and nominee,

each of the persons named in the Summary Compensation Table,

all current directors and executive officers as a group, and

each person known to us to be the beneficial owner of more than five percent of the common shares outstanding on March 6, 2013.

The number of shares beneficially owned is determined under rules of the Securities and Exchange Commission, or SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire on March 6, 2013 or within 60 days thereafter through the exercise of any stock option or other right. The persons named in the table have sole voting power and sole dispositive power with respect to the common shares beneficially owned, except as otherwise noted below.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership(a)	Percent of Class
Patrick J. Bagley	386,284	1.8
Ronald D. Boyd	293,334	1.3
Robert L. Chioini(b)	3,379,666	14.2
Kenneth L. Holt	229,843	1.1
Thomas E. Klema (b)	1,579,304	7.0
Raymond D. Pratt	50,000	0.2
Ajay Gupta	606,882	2.8
All directors and current executive officers as a group (7 persons)	6,525,313	24.9
David A. Hagelstein and related entities(c)	2,673,754	12.0
Richmond Brothers, Inc.(d)	2,903,381	13.5

(a) Includes restricted shares subject to forfeiture to us under certain circumstances and shares that may be acquired upon exercise of stock options as set forth in the table below. Also includes 856,333 shares owned by Mr. Chioini, 323,138 shares owned by Mr. Klema and 21,509 shares owned by Mr. Holt that are pledged as collateral under standard margin loan arrangements.

	Restricted Shares	Option Shares
Patrick J. Bagley	0	208,334
Ronald D. Boyd	0	293,334
Robert L. Chioini	200,000	2,323,333
Kenneth L. Holt	0	208,334
Thomas E. Klema	120,000	1,134,166
Raymond D. Pratt	0	50,000
Ajay Gupta	150,000	451,667
All directors and current executive officers as a group	470,000	4,669,168

(b) The address for Mr. Chioini and Mr. Klema is 30142 Wixom Road, Wixom, Michigan 48393.

(c) Based on a Form 4 filed January 28, 2013, by David A. Hagelstein and the David Hagelstein Charitable Remainder Unitrust, (the "Charitable Trust"), on showing ownership as of January 28,

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2013. As of that date, Mr. Hagelstein beneficially owned 2,673,754 common shares, 2,247,363 of which are owned by the David A. Hagelstein Revocable Living Trust, dated October 27, 1993 (the "Revocable Trust"), and 426,391 of which are owned by the Charitable Trust. Of the common shares beneficially owned by the Revocable Trust, 862,502 are common shares underlying currently exercisable warrants. Mr. Hagelstein is the sole trustee and beneficiary of the Revocable Trust and is the sole trustee of the Charitable Trust. Mr. Hagelstein has sole voting and dispositive power with respect to all such shares. The address for Mr. Hagelstein and the Charitable Trust is 36801 Woodward Avenue, Suite 313, Birmingham, Michigan 48009.

(d)

Based on a Schedule 13G filed March 11, 2013 by Richmond Brothers, Inc., reporting ownership as of that date. Richmond Brothers, Inc. has sole dispositive power over the reported common shares but has no voting power with respect to such shares. The address for Richmond Brothers, Inc. is 7415 Foxworth Court, Jackson, Michigan 49201.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans, including individual compensation arrangements, under which our equity securities are authorized for issuance as of December 31, 2012:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	5,989,200	$ 5.95	1,284,665
Equity compensation plans not approved by security holders	291,000	$ 9.28	
Total	6,280,200	$ 6.11	1,284,665

From 2007 through 2010, we issued warrants to purchase common shares pursuant to compensation arrangements with various non-employee consultants who provide (or provided) services to us, including providing investor relations consulting services and introducing the Company to potential licensing partners and acquisition candidates and acting as a liaison to the equity investment community. These were not issued under a preexisting plan and shareholder approval for these transactions was not required or sought. The exercise price and the number of shares of common stock purchasable upon exercise of the warrants are subject to adjustment in certain events including: (a) a stock dividend payable in common stock, stock split, or subdivision of our common stock; and (b) reclassification of our common stock or any reorganization, consolidation, merger, or sale, lease, license, exchange or other transfer of all or substantially all of the business and/or assets of the Company.

On November 28, 2007, we entered into an agreement pursuant to which we issued warrants to acquire 80,000 Common Shares at an exercise price of $10.00 per share, exercisable for cash at any time during the period from November 28, 2008 to November 28, 2012. These warrants were extended until November 28, 2013. The Common Shares underlying these warrants have been registered for resale by the holder under the Securities Act of 1933.

On May 28, 2008, we entered into an advisory agreement pursuant to which we issued warrants to acquire 100,000 Common Shares. The warrants were immediately earned and became exercisable on May 28, 2009. The warrants would have expired on May 28, 2012. The warrants had an exercise price of $9.00 per share and may be exercised on a cashless basis or for cash. The Common Shares underlying these warrants have been registered for resale by the holder under the Securities Act of 1933. During 2010, we agreed to extend the term and revise the exercise price of these warrants in consideration for additional services. The exercise price of these warrants was reduced to $8.00 from $9.00 and their term extended by one year to May 28, 2013.

On March 8, 2010, we entered into an advisory agreement pursuant to which we issued warrants to acquire 20,000 Common Shares. The warrants were issued as compensation for investor relations consulting services. The advisory agreement was scheduled to terminate on December 31, 2010 but could be terminated by either party upon 30 days prior written notice. The warrants were to be earned in 5,000 share increments on March 8, 2010, April 1, 2010, July 1, 2010, and October 1, 2010. The agreement was terminated prior to the final installment being earned, such that only 15,000 of the warrants became earned. The warrants became exercisable on March 8, 2011, may be exercised in whole or in part at any time until their expiration by the submission of an exercise notice accompanied by payment of the exercise price in cash or certified check or by cashless exercise and expired March 8, 2013. The warrants had an exercise price of $6.14 per share.

On September 1, 2010, we issued 5,000 warrants with an exercise price of $8.00 as consideration for services. The warrants became exercisable on September 1, 2011 and may be exercised in whole or in part at any time until their expiration by the submission of an exercise notice accompanied by payment of the exercise price in cash or certified check or by cashless exercise. The warrants will expire on May 28, 2013.

Item 13. Certain Relationships and Related Transactions and Director Independence.

Related Party Transactions

Pursuant to its charter, the Audit Committee is charged with monitoring and reviewing transactions and relationships involving independence and potential conflicts of interest with respect to our directors and executive officers. To the extent any such transactions are proposed, they would be subject to approval by the Board of Directors in accordance with applicable law and the NASDAQ Marketplace Rules, which require that any such transactions required to be disclosed in our proxy statement be approved by a committee of independent directors of our Board of Directors. In addition, our Code of Business Conduct and Ethics generally requires directors and employees to avoid conflicts of interest. There were no transactions since January 1, 2012, and there is no currently proposed transaction, in which the Company was or is to be a participant, the amount involved exceeded or will exceed $120,000, and in which any director, executive officer, 5% shareholder of the Company or any immediate family member of any of such persons had or will have a direct or indirect material interest, except as described below.

SFP License

We are party to a license agreement, dated January 7, 2002, with Charak LLC and its owner, Dr. Ajay Gupta, for our SFP product that covers issued patents in the United States, the European Union and Japan, as well as patent and pending patent applications in other foreign jurisdictions. Dr. Gupta is our Chief Scientific Officer. The license agreement continues for the duration of the underlying patents in each country, or until August 14, 2016 in the United States and 2017 in Europe and Japan, and may be extended thereafter. If we are successful in obtaining FDA approval we may apply for an extension of our patent exclusivity for up to five years. The license agreement requires us to obtain and pay the cost of obtaining FDA approval of the SFP 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. In addition to payments made prior to Dr. Gupta joining us as an executive officer, the milestone payments include a payment of $50,000 which will become due upon completion of Phase III clinical trials, a payment of $100,000 which will become due upon FDA approval of the product and a payment of $175,000 which will become due upon issuance of a reimbursement code covering the product. This agreement was negotiated on an arm's length basis before Dr. Gupta had any material relationship with us.

Warrant Extensions

In November 2012, the Company agreed with all of the holders of the warrants it issued on November 28, 2007 to purchase its common shares at $7.18 per share to extend the expiration date from November 28, 2012 to January 28, 2013. In January 2013, the Company agreed to further extend the expiration date of such warrants to July 31, 2013. Both extensions were unanimously approved by the Board of Directors. There was no consideration given or received by the Company in connection with either extension and no other terms of the warrants were modified. David Hagelstein, who is the beneficial owner of more than 5% of the Company's outstanding common shares but not otherwise affiliated with the Company, owns 862,502 of these warrants.

Independence

Based on the absence of any material relationship between them and us, other than in their capacities as directors and shareholders, the Board of Directors has determined that each of Messrs. Boyd, Bagley and Holt are independent as independence is defined in the applicable NASDAQ Stock Market and SEC rules.

Item 14. Principal Accountant Fees and Services.

The following table presents aggregate fees billed for each of the years ended December 31, 2012 and 2011 for professional services rendered by Plante & Moran, PLLC, our independent registered public accounting firm for those years, in the following categories:

	Fiscal Year Ended December 31	
	2012	2011
Audit Fees(a)	$ 212,148	$ 178,785
Audit-Related Fees(b)	$ 9,280	$ 12,255
Tax Fees(c)	$ 51,940	$ 23,580
All Other Fees	$ -0-	$ -0-

(a) Consists of fees for the audit of our annual financial statements, review of our Form 10-K, review of our quarterly financial statements included in our Forms 10-Q, services provided in connection with our proxy statement and services in connection with other regulatory filings, including our registration statements filed with the SEC under the Securities Act of 1933 and our recent equity financing. Fees also include work in connection with Plante & Moran, PLLC's audit of our internal control over financial reporting.

(b) Represents consultation on financial accounting and reporting matters.

(c) Consists of tax return preparation fees.

The Audit Committee of the Board does not consider the provision of the services described above by Plante & Moran, PLLC to be incompatible with the maintenance of Plante & Moran, PLLC's independence.

Before Plante & Moran, PLLC is engaged by us to render audit or non-audit services, the engagement is approved by our Audit Committee. All of the services performed by Plante & Moran, PLLC for the Company during 2012 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The financial statements and schedule filed herewith are set forth on the Index to Financial Statements and Schedule of the separate financial section of this annual report, which is incorporated herein by reference.

(b) Exhibits

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated. Exhibits not required for this report have been omitted. Our Commission file number is 000-23661.

3.1	Amended and Restated Articles of Incorporation, dated as of May 24, 2012 (Company's Form 10-Q filed August 7, 2012).
3.2	Amended and Restated Bylaws (Company's Form 8-K filed November 25, 2008).
4.1	Form of Warrant (Company's Form 8-K filed December 4, 2007).
4.2	RJ Aubrey Warrant Agreement, dated November 28, 2007 (Company's Form 8-K filed December 4, 2007).
4.3	Form of Investor Warrant to Purchase Common Stock issuable by the Company to the investor signatories to the Subscription Agreement, filed as exhibit F to the Placement Agency Agreement (Company's Form 8-K filed September 30, 2009).
4.4	Form of Placement Agent Warrant issuable by the Company to JMP Securities LLC and Wedbush Securities Inc. (Company's Form 8-K filed September 30, 2009).
4.5	Warrant issued to RJ Aubrey IR Services LLC as of September 30, 2008 (Company's Form S-3 (file no. 333-160710)).
4.7	Warrant issued to Capitol Securities Management, Inc. as of May 28, 2008 (Company's Form S-3 (file no. 333-160710)).
4.8	Warrant issued to Emerald Asset Advisors, LLC as of November 5, 2008 (Company's Form S-3 (file no. 333-160710)).
4.9	Form of Warrant issued to Messrs. Rick, Pizzirusso, Ries, Meyers and Pace as of July 17, 2009 (Company's Form S-3 (file no. 333-160710)).
4.10	Warrant issued to RJ Aubrey IR Services LLC as of March 8, 2010. (Company's Form 10-Q filed May 7, 2010).
4.11	Warrant issued to Capitol Securities Management, Inc. as of September 1, 2010 (Company's Form 8-K filed September 2, 2010).
4.12	Form of Amended and Restated Warrant issued to Messrs. Rick, Pizzirusso, Ries, Meyers, Pace and Bailey as of September 1, 2010 (Company's Form 8-K filed September 2, 2010).

4.13	Warrant issued to DaVita Inc. as of February 16, 2011 (Company's Form 8-K filed February 23, 2011).
4.14	Amendment to Warrant issued to Emerald Asset Advisors, LLC as of November 1, 2011 (Company's Form 8-K filed November 4, 2011).
4.15	Form of Amendment to Common Stock Warrant, dated November 23, 26 or 27, 2012, amending warrants issued in private offering in November 2007 (Company's Form 8-K filed November 28, 2012).
4.16	Amendment to Common Stock Warrant, dated November 22, 2012, amending warrant issued to RJ Aubrey IR Services LLC in November 2007 (Company's Form 8-K filed November 28, 2012).
4.17	Form of Amendment to Common Stock Warrant, dated as of January 28, 2013, amending warrants issued in private offering in November 2007 (Company's Form 8-K filed January 28, 2013).
*10.1	Rockwell Medical, Inc. 1997 Stock Option Plan (Company's Proxy Statement filed April 17, 2006).
10.2	Lease Agreement dated March 12, 2000 between the Company and DFW Trade Center III Limited Partnership (Company's Form 10-KSB filed March 30, 2000.)
10.3	Lease Agreement dated October 23, 2000 between the Company and International-Wixom, LLC (Company's Form 10-KSB filed April 2, 2001.)
10.4	Licensing Agreement between the Company and Charak LLC and Dr. Ajay Gupta dated January 7, 2002 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934) (Company's Form 10-KSB filed April 1, 2002).
10.10	Second Amendment of Industrial Lease Agreement between Rockwell Medical, Inc. and DCT DFW, LP dated August 17, 2005 (Company's Form 8-K filed August 19, 2005).
10.11	Amending Agreement made the 16th day of January, 2006, by and between Dr. Ajay Gupta, Charak LLC and Rockwell Medical, Inc. (Company's Form 10-KSB filed March 31, 2006).
10.17	Consulting Agreement, dated as of October 3, 2007 (Company's Form 8-K filed October 9, 2007).
10.18	Common Stock Purchase Agreement, dated November 28, 2007, between the Company and certain Purchasers (Company's Form 8-K filed December 4, 2007).
10.19	Registration Rights Agreement, dated November 28, 2007, between the Company and certain Purchasers (Company's Form 8-K filed December 4, 2007).
*10.20	Form of Nonqualified Stock Option Agreement (Director Version) (Company's Form 8-K filed December 20, 2007).
*10.21	Form of Nonqualified Stock Option Agreement (Employee Version) (Company's Form 8-K filed December 20, 2007).
10.22	Lease Agreement dated March 19, 2008 between the Company and EZE Management Properties Limited Partners (Company's Form 10-K filed March 24, 2008).
10.24	Advisory Agreement dated May 28, 2008 between the Company and Capitol Securities Management, Inc. (Company's Form 10-Q filed August 12, 2008).

10.25	Mutual Release and Settlement Agreement dated September 24, 2008 by and among the Company, FWLL, LLC and ST Holdings, Inc. (Company's Form 10-Q filed November 13, 2008).
10.26	Advisory Agreement dated September 30, 2008 between the Company and RJ Aubrey IR Services LLC (Company's Form 10-Q filed November 13, 2008).
10.27	Advisory Agreement dated November 5, 2008 between the Company and Emerald Asset Advisors, LLC (Company's Form 10-Q filed November 13, 2008).
*10.28	Form of Restricted Stock Award Agreement (Executive Version) (Company's Form 8-K filed November 25, 2008).
10.29	Amendment to Advisory Agreement dated November 21, 2008 between the Company and Emerald Asset Advisors, LLC (Company's Form 10-K filed March 16, 2009).
10.30	Lease Renewal dated August 21, 2008 between the Company and International-Wixom, LLC with respect to the Lease Agreement dated October 23, 2000 (Company's Form 10-K filed March 16, 2009).
10.31	Second Amendment dated November 18, 2008 to the Supply Agreement between the Company and DaVita, Inc. dated May 5, 2004 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934) (Company's Form 10-K filed March 16, 2009).
10.33	Placement Agency Agreement with JMP Securities LLC and Wedbush Securities Inc. dated September 29, 2009 (including the form of Subscription Agreement included as Exhibit A thereto) (Company's Form 8-K filed September 30, 2009).
10.34	Advisory Agreement dated March 8, 2010 between the Company and RJ Aubrey IR Services LLC (Company's Form 10-Q filed May 7, 2010).
10.35	Third Amendment to Industrial Lease Agreement between Rockwell Medical, Inc. and DCT DFW, LP dated July 7, 2010 (Company's Form 8-K filed on July 13, 2010).
10.36	Amendment No. 3 to Rockwell Medical, Inc. 2007 Long Term Incentive Plan (Company's Proxy Statement filed April 15, 2010).
10.37	Lease Renewal Agreement dated August 27, 2010, by and between Rockwell Medical, Inc. and International-Wixom, LLC (Company's Form 8-K filed September 2, 2010).
10.38	Advisory Agreement dated September 1, 2010 between the Company and Capitol Securities Management, Inc. (Company's Form 8-K filed September 2, 2010).
10.39	Products Purchase Agreement dated February 16, 2011, by and between Rockwell Medical, Inc. and DaVita Inc. (with certain portions deleted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934) (Company's Form 10-K/A filed May 27, 2011).
10.40	Agreement to Extend the Lease Agreement, Options to Purchase and Option to Lease dated February 17, 2011, by and between Rockwell Medical, Inc. and EZE Management Properties Limited Partnership (Company's Form 8-K filed February 24, 2011).
*10.42	Form of Amendment to 2008 Restricted Stock Award Agreement as of November 17, 2011 with Robert L. Chioini and Thomas E. Klema (Company's Form 8-K filed November 22, 2011)

*10.43	Form of Amendment to 2010 Restricted Stock Award Agreement as of March 7, 2012 with Robert L. Chioini, Thomas E. Klema, and Dr. Ajay Gupta (Company's Current Report on Form 8-K dated March 7, 2012)
*10.44	Form of Amendment to 2008 Restricted Stock Award Agreement as of May 14, 2012 with Robert L. Chioini and Thomas E. Klema (Company's Current Report on Form 8-K dated May16, 2012)
*10.45	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 24, 2012 (incorporated by reference to the Company's Proxy Statement for the 2012 Annual Meeting of Shareholders filed on April 13, 2012).
*10.46	Form of restricted stock award agreement (Company's Current Report on Form 8-K dated June 14, 2012).
*10.47	Form of Amendment to 2010 Restricted Stock Award Agreement as of August 3, 2012 with Robert L. Chioini, Thomas E. Klema, and Dr. Ajay Gupta (Company's Current Report on Form 8-K filed August 3, 2012).
10.48	Lease Renewal Agreement dated August 14, 2012, by and between Rockwell Medical, Inc. and International-Wixom, LLC (Company's Current Report on Form 8-K filed August 15, 2012).
10.49	Lease Renewal Agreement dated November 30, 2012, by and between Rockwell Medical, Inc. and EZE Management Properties Limited Partners (Company's Current Report on Form 8-K filed December 4, 2012).
14.1	Rockwell Medical, Inc. Code of Ethics (Company's Proxy Statement filed April 23, 2004).
21.1	List of Subsidiaries (Company's Form SB-2 (file No. 333-31991)).
23.1	Consent of Plante & Moran, PLLC.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a).
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101. INS**	XBRL Instance Document
101. SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase
101.DEF**	XBRL Taxonomy Extension Definition Database
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase

* Current management contracts or compensatory plans or arrangements.

** XBRL (Extensible Business Reporting Language) information is furnished and not filed herewith, is not a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ROCKWELL MEDICAL, INC. (Registrant)

By: /s/ ROBERT L. CHIOINI

Robert L. Chioini
President and Chief Executive Officer

Date: March 18, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ ROBERT L. CHIOINI Robert L. Chioini	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2013
/s/ THOMAS E. KLEMA Thomas E. Klema	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 18, 2013
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 18, 2013
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 18, 2013
/s/ PATRICK J. BAGLEY Patrick J. Bagley	Director	March 18, 2013

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Rockwell Medical, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Rockwell Medical, Inc. and Subsidiary (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2012. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Rockwell Medical, Inc. and Subsidiary at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 16 to the consolidated financial statements, the Company has sustained recurring losses from operations, negative working capital, and insufficient liquidity, which raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 16. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Rockwell Medical, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 18, 2013 expressed an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 18, 2013

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Rockwell Medical, Inc. and Subsidiary

We have audited Rockwell Medical, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

In our opinion, Rockwell Medical, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Rockwell Medical, Inc. and Subsidiary (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2012 and related financial statement schedule and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 18, 2013

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
ASSETS		
Cash and Cash Equivalents	$ 4,711,730	$ 5,715,246
Investments Available for Sale		11,810,775
Accounts Receivable, net of a reserve of $26,000 in 2012 and $29,000 in 2011	4,431,932	4,222,816
Inventory	2,649,639	2,504,127
Other Current Assets	1,356,131	1,643,565
Total Current Assets	13,149,432	25,896,529
Property and Equipment, net	1,858,442	2,290,476
Intangible Assets	666,744	833,773
Goodwill	920,745	920,745
Other Non-current Assets	429,723	1,998,076
Total Assets	$ 17,025,086	$ 31,939,599
LIABILITIES AND SHAREHOLDERS' EQUITY		
Capitalized Lease Obligations	$ 2,280	$ 6,470
Accounts Payable	14,833,565	5,364,537
Accrued Liabilities	12,015,978	8,225,015
Customer Deposits	135,133	96,329
Total Current Liabilities	26,986,956	13,692,351
Capitalized Lease Obligations		2,280
Shareholders' Equity:		
Common Shares, no par value, 21,494,696 and 18,710,002 shares issued and outstanding	92,866,458	67,407,847
Common Share Purchase Warrants, 2,233,240 and 2,607,440 warrants issued and outstanding	7,178,929	7,103,975
Accumulated Deficit	(110,007,257)	(55,985,742)
Accumulated Other Comprehensive Loss		(281,112)
Total Shareholders' Equity (Deficit)	(9,961,870)	18,244,968
Total Liabilities And Shareholders' Equity	$ 17,025,086	$ 31,939,599

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For The Years Ended December 31, 2012, 2011 and 2010

	2012	2011	2010
Sales	$ 49,842,392	$ 48,966,231	$ 59,554,592
Cost of Sales	43,148,965	43,323,321	49,693,753
Gross Profit	6,693,427	5,642,910	9,860,839
Selling, General and Administrative	12,683,860	9,522,305	9,307,621
Research and Product Development	48,271,649	17,805,362	3,422,134
Operating Income (Loss)	(54,262,082)	(21,684,757)	(2,868,916)
Interest and Investment Income, net	241,518	244,049	195,218
Interest Expense	951	1,844	9,701
Income (Loss) Before Income Taxes	(54,021,515)	(21,442,552)	(2,683,399)
Income Tax Expense		2,005	
Net Income (Loss)	$ (54,021,515)	$ (21,444,557)	$ (2,683,399)
Basic And Diluted Earnings (Loss) Per Share	$ (2.65)	$ (1.21)	$ (.16)

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For The Years Ended December 31, 2012, 2011 and 2010

	2012	2011	2010
Net Income (Loss)	**$ (54,021,515)**	**$ (21,444,557)**	**$ (2,683,399)**
Reclassification of Losses Included in Net Loss	67,303	84,590	
Unrealized Gain (Loss) on Available-for-Sale Investments	213,809	(152,079)	(213,623)
Comprehensive Income (Loss)	**$ (53,740,403)**	**$ (21,512,046)**	**$ (2,897,022)**

The accompanying notes are an integral part of the combined financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For The Years Ended December 31, 2012, 2011 and 2010

	COMMON SHARES		PURCHASE WARRANTS			ACCUMULATED OTHER COMPREHENSIVE	TOTAL
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	INCOME (LOSS)	SHAREHOLDER'S EQUITY
Balance as of December 31, 2009	17,200,442	$53,545,394	3,318,569	$ 7,635,594	$ (31,857,786)	$	$ 29,323,202
Net Loss					(2,683,399)		(2,683,399)
Unrealized Losses on Available-for-Sale Investments						(213,623)	(213,623)
Issuance of Common Shares	313,166	90,448					90,448
Issuance of Purchase Warrants			20,000	639,915			639,915
Stock Option Based Expense		3,048,750					3,048,750
Restricted Stock Amortization		332,644					332,644
Balance as of December 31, 2010	17,513,608	$57,017,236	3,338,569	$ 8,275,509	$ (34,541,185)	$ (213,623)	$ 30,537,937
Net Loss					(21,444,557)		(21,444,557)
Reclassification of Losses Included in Net Loss						84,590	84,590
Unrealized (Loss) on Available-for-Sale Investments						(152,079)	(152,079)
Issuance of Common Shares	397,054	719,484					719,484
Issuance of Purchase Warrants			100,000	312,325			312,325
Exercise of Purchase Warrants	799,340	5,361,135	(831,129)	(1,483,859)			3,877,276
Additional Paid In Capital		244,289					244,289
Stock Option Based Expense		3,469,703					3,469,703
Restricted Stock Amortization		596,000					596,000
Balance as of December 31, 2011	18,710,002	$67,407,847	2,607,440	$ 7,103,975	$ (55,985,742)	$ (281,112)	$ 18,244,968
Net Loss					(54,021,515)		(54,021,515)
Reclassification of Losses Included in Net Loss						67,303	67,303
Unrealized Gain on Available-for-Sale Investments						213,809	213,809
Issuance of Common Shares	2,296,477	16,252,695					16,252,695
Shares Issued in Exchange for Services	200,000	1,854,000					1,854,000
Exercise of Purchase Warrants	288,217	2,372,192	(374,200)	(393,463)			1,978,729
Purchase Warrants Expense				468,417			468,417
Stock Option Based Expense		3,903,795					3,903,795
Restricted Stock Amortization		1,075,929					1,075,929
Balance as of December 31, 2012	21,494,696	$92,866,458	2,233,240	$ 7,178,929	$ (110,007,257)	$	$ (9,961,870)

The accompanying notes are an integral part of the consolidated financial statements.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2012, 2011 and 2010

	2012	2011	2010
Cash Flows From Operating Activities:			
Net (Loss)	**$ (54,021,515)**	**$ (21,444,557)**	**$ (2,683,399)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:			
Depreciation and Amortization	1,087,397	1,176,007	1,389,152
Share Based Compensation Non-employee	2,322,417	312,325	639,915
Share Based Compensation Employees	4,979,724	4,065,703	3,381,394
Loss (Gain) on Disposal of Assets	17,876	29,093	19,816
Loss on Sale of Investments Available for Sale	67,303	84,590	
Changes in Assets and Liabilities:			
(Increase) Decrease in Accounts Receivable	(209,116)	284,480	(1,014,674)
(Increase) Decrease in Inventory	(145,512)	432,751	151,474
(Increase) Decrease in Other Assets	1,855,787	(2,457,370)	(690,750)
Increase (Decrease)in Accounts Payable	9,469,028	1,705,030	270,750
Increase in Other Liabilities	3,829,767	5,028,846	637,236
Changes in Assets and Liabilities	14,799,954	4,993,737	(645,964)
Cash Provided By (Used) In Operating Activities	**(30,746,844)**	**(10,783,102)**	**2,100,914**
Cash Flows From Investing Activities:			
(Purchase) of Investments Available for Sale	(2,012,671)	(2,000,000)	(12,151,721)
Sale of Investments Available for Sale	14,037,255	1,975,244	
Purchase of Equipment	(507,788)	(421,043)	(772,364)
Proceeds on Sale of Assets	1,578	2,985	1,800
Purchase of Intangible Assets		(145,121)	
Cash (Used) In Investing Activities	**11,518,374**	**(587,935)**	**(12,922,285)**
Cash Flows From Financing Activities:			
Proceeds from Issuance of Common Shares and Purchase Warrants	18,231,424	4,841,049	90,448
Payments on Notes Payable and Capital Lease Obligations	(6,470)	(18,215)	(43,723)
Cash Provided By Financing Activities	**18,224,954**	**4,822,834**	**46,725**
Increase (Decrease) In Cash	(1,003,516)	(6,548,203)	(10,774,646)
Cash At Beginning Of Period	5,715,246	12,263,449	23,038,095
Cash At End Of Period	**$ 4,711,730**	**$ 5,715,246**	**$ 12,263,449**

Supplemental Cash Flow disclosure

	2012	2011	2010
Interest Paid	$ 951	$ 1,844	$ 9,701
Non-Cash Investing and Financing Activity			
Acquisition of Intangible Assets	$	$ 550,000	$
Equipment Acquired Under Capital Lease Obligations	$	$	$ 8,688

The accompanying notes are an integral part of the consolidated financial statements

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or "ESRD". We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients' blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States.

We are regulated by the Federal Food and Drug Administration ("FDA") under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders. We also have 510(k) approval to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

We have obtained global licenses for certain dialysis related drugs which we are developing and seeking FDA approval to market. We plan to devote substantial resources to the development, testing and FDA approval of our lead drug candidate.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc.

All intercompany balances and transactions have been eliminated in consolidation.

Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale. At December 31, 2012 and 2011 we had customer deposits of $135,132 and $96,329, respectively.

Shipping and Handling Revenue and Costs

Our products are generally priced on a delivered basis with the price of delivery included in the overall price of our products which is reported as sales. Separately identified freight and handling charges are also included in sales.

We include shipping and handling costs, including expenses of Rockwell Transportation, Inc., in cost of sales.

Cash and Cash Equivalents

We consider cash on hand, money market funds and unrestricted certificates of deposit with an original maturity of 90 days or less as cash and cash equivalents.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Investments Available for Sale

Investments Available for Sale are short-term investments, consisting principally of investments in short term duration bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense.

Accounts Receivable

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 accounts 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.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for normal maintenance and repairs are charged to expense as incurred. Property and equipment are depreciated using the straight-line method over their useful lives, which range from three to ten years. Leasehold improvements are amortized using the straight-line method over the shorter of their useful lives or the related lease term.

Licensing Fees

License fees related to the technology, intellectual property and marketing rights for dialysate iron covered under certain issued patents have been capitalized and are being amortized over the life of the related patents which is generally 17 years.

Goodwill, Intangible Assets and Long Lived Assets

The recorded amounts of goodwill and other intangibles from prior business combinations are based on management's best estimates of the fair values of assets acquired and liabilities assumed at the date of acquisition. Goodwill is not amortized; however, it must be tested for impairment at least annually. Amortization continues to be recorded for other intangible assets with definite lives over their 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.

An impairment review of goodwill, intangible assets, and property and equipment 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,

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

The useful lives of other intangible assets are based on management's best estimates of the period over which the assets are expected to contribute directly or indirectly to our future cash flows. Management annually evaluates the remaining useful lives of intangible assets with finite useful lives to determine whether events and circumstances warrant a revision to the remaining amortization periods. It is reasonably possible that management's estimates of the carrying amount of goodwill and the remaining useful lives of other intangible assets may change in the near term.

Income Taxes

We account for income taxes in accordance with the provisions of ASC 740-10, *Income Taxes.* A current tax liability or asset is recognized for the estimated taxes payable or refundable on tax returns for the year. Deferred tax liabilities or assets are recognized for the estimated future tax effects of temporary differences between book and tax accounting and operating loss and tax credit carryforwards. A valuation allowance is established for deferred tax assets if we determine it to be more likely than not that the deferred tax asset will not be realized. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

The effects of tax positions are generally recognized in the financial statements consistent with amounts reflected in returns filed, or expected to be filed, with taxing authorities. For tax positions that the Company considers to be uncertain, current and deferred tax liabilities are recognized, or assets derecognized, when it is probable that an income tax liability has been incurred and the amount of the liability is reasonably estimable, or when it is probable that a tax benefit, such as a tax credit or loss carryforward, will be disallowed by a taxing authority. The amount of unrecognized tax benefits related to tax positions is insignificant.

Research and Product Development

We recognize research and product development costs as expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including iron supplemented dialysate, aggregating approximately $48,272,000, $17,805,000, and $3,422,000 in 2012, 2011 and 2010, respectively.

We are conducting human clinical trials on iron supplemented dialysate and we recognize the costs of the human clinical trials as the costs are incurred and services performed over the duration of the trials.

Share Based Compensation

We measure the cost of employee services received in exchange for equity awards, including stock options, based on the grant date fair value of the awards in accordance with ASC 718-10, *Compensation Stock Compensation.* The cost of equity based compensation is recognized as compensation expense over the vesting period of the awards.

We estimate the fair value of compensation involving stock options utilizing the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

term, expected volatility of our stock price over the expected option term, and an expected forfeiture rate, and is subject to various assumptions. We believe the valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to ASC 718-10 requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants.

Employee Retirement Plans

We are the sponsor of a non-contributory 401(k) Employee Savings Plan.

Net Earnings per Share

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	2012	2011	2010
Basic Weighted Average Shares Outstanding	20,395,889	17,774,865	17,111,535
Effect of Dilutive Securities	-0-	-0-	-0-
Diluted Weighted Average Shares Outstanding	20,395,889	17,774,865	17,111,535

For 2012, 2011 and 2010, the dilutive effect of stock options and common share purchase warrants have not been included in the average shares outstanding for the calculation of diluted loss per share as the effect would be anti-dilutive as a result of our net loss in these periods. The table below summarizes potentially dilutive securities.

	2012	2011	2010
Stock Options	5,989,200	5,482,135	5,289,334
Range of Exercise Prices of Stock Options	$1.81 - $10.20	$0.55 - $10.20	$0.55 - $8.35
Common Share Purchase Warrants	2,233,240	2,607,440	3,338,569
Range of Exercise Prices of Warrants	$6.14 - $10.25	$6.14 - $10.25	$1.99 - $10.00
Unvested Restricted Common Shares	545,000	310,000	310,000

Disclosures About Fair Value of Financial Instruments

The carrying amounts of all significant financial instruments, comprising cash and cash equivalents, accounts receivable, and accounts payable approximate fair value because of the short maturities of these instruments.

Fair Market Value Measurements

Accounting standards require certain assets and liabilities be reported at fair value in the financial statements and provides a framework for establishing that fair value. The framework for determining

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

fair value is based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted in active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considering counterparty credit risk in its assessment of fair value. We value our available-for-sale investment securities, consisting solely of bond mutual funds, using Level 1 inputs in the fair value hierarchy. We do not have other financial assets that would be characterized as Level 2 or Level 3 assets.

The Company also has certain non-financial assets that under certain conditions are subject to measurement at fair value on a non-recurring basis. No such measurements were required in 2012 or 2011.

Other Comprehensive Income (Loss)

Accounting principles generally require that recognized revenue, expenses, gains, and losses be included in net income. Certain changes in assets and liabilities, however, such as unrealized gains and losses on available for sale securities, are reported as a direct adjustment to the equity section of the balance sheet. Such items, along with net income (loss), are considered components of comprehensive income (loss).

Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

New Accounting Pronouncement

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.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. INVESTMENTS IN AVAILABLE FOR SALE SECURITIES

As of December 31, 2012, we did not hold any investments in available for sale securities. In 2012, we sold securities with a market value of $14,037,255 with an average cost basis of $14,104,558. We realized gains of $10,436 and losses of $77,739 from sales of available-for-sale securities.

As of December 31, 2011, we held investments in available for sale securities in several short term bond funds. These funds generally held high credit quality short term debt instruments. These debt instruments were subject to changes in fair market value due to changes in interest rates. The market value of these investments was $11,810,775 as of December 31, 2011. In 2011 we sold securities with a market value of $2,000,000 with an average cost basis of $2,084,590 and we realized losses of $84,590 from rebalancing our portfolio of available-for-sale securities to shorter duration funds.

4. SIGNIFICANT MARKET SEGMENTS

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 customers accounted for more than 10% of our sales in the last three years.

The majority of our international sales in each of the last three years were sales to domestic distributors that were resold to end users outside the United States. Our sales to foreign customers and distributors were less than 5% of our total sales in 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.

5. INVENTORY

Components of inventory as of December 31, 2012 and 2011 are as follows:

	2012	2011
Raw Materials	$ 1,018,648	$ 819,523
Work in Process	179,922	171,842
Finished Goods	1,451,069	1,512,762
Total	$ 2,649,639	$ 2,504,127

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. PROPERTY AND EQUIPMENT

Major classes of property and equipment, stated at cost, as of December 31, 2012 and 2011 are as follows:

	2012	2011
Leasehold Improvements	$ 463,080	$ 446,164
Machinery and Equipment	6,046,055	5,848,306
Information Technology & Office Equipment	1,911,493	1,921,668
Laboratory Equipment	505,883	508,929
Transportation Equipment	383,711	417,493
	9,310,222	9,142,560
Accumulated Depreciation	(7,451,780)	(6,852,084)
Net Property and Equipment	$ 1,858,442	$ 2,290,476

Included in the table above are assets under capital lease obligations as follows:

	2012	2011
Assets under Capital Lease Obligations	$ 34,086	$ 84,832
Net Book Value of Assets under Capital Lease Obligations	11,557	29,269

Below is a summary of Depreciation expense by period:

	2012	2011	2010
Depreciation expense	$ 920,368	$ 1,141,545	$ 1,341,472

7. GOODWILL AND INTANGIBLE ASSETS

Total goodwill was $920,745 at December 31, 2012 and 2011. We completed our annual impairment tests as of November 30, 2012 and 2011, and determined that no adjustment for impairment of goodwill was required.

We have entered into a global licensing agreement for certain patents covering a therapeutic drug compound to be delivered using our dialysate product lines. We intend to seek FDA approval for this product. We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset.

During 2011, we acquired an abbreviated new drug application ("ANDA") for a generic version of an intravenous vitamin-D analogue, Calcitriol. After a one year period expiring July 13, 2012, the

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. GOODWILL AND INTANGIBLE ASSETS (Continued)

Company, at its option, paid $550,000 to retain the acquired ANDA and total capitalized costs related to this ANDA were approximately $695,000. These costs are being amortized over a five year period.

	2012	2011	2010
Capitalized Licensing Fees	$ 1,070,126	$ 1,070,126	$ 375,005
Accumulated Amortization	(403,382)	(236,353)	(208,348)
Capitalized Licensing Fees, Net of Amortization	$ 666,744	$ 833,773	$ 166,657
Amortization Expense	$ 167,029	$ 28,005	$ 47,299

Our policy is to amortize licensing fees over the life of the patents pertaining to certain licensing agreements. Estimated amortization expense for licensing fees for 2013 through 2016 is approximately $167,000 per year. Our SFP licensing agreement, which is with a company owned by our chief scientific officer, requires additional payments by the Company upon achievement of certain milestones.

8. OTHER CURRENT AND NON-CURRENT ASSETS

The Company has entered into contracts with contract research organizations for the purpose of conducting human clinical research trials and has advanced funds to contract research organizations to partially offset future service costs and expenses under these contracts. As of December 31, 2012, such advances classified as other current assets aggregated $852,555. As of December 31, 2011, such advances classified as non-current assets aggregated $1,497,000 and such advances classified as other current assets aggregated $852,000.

9. CAPITAL LEASE OBLIGATIONS

We have capital lease obligations related to financing certain equipment. These capital lease obligations require even monthly installments through 2013 and interest rates on the leases range from 8% to 15%. These obligations under capital leases had outstanding balances of $2,280 and $8,750 at December 31, 2012 and 2011, respectively.

Future minimum lease payments under capital lease obligations are:

Year Ending December 31, 2013	$ 2,410
Year Ending December 31, 2014	-0-
Total minimum payments on capital lease obligations	2,410
Interest	(130)
Present value of minimum lease payments	2,280
Current portion of capital lease obligations	(2,280)
Long-term capital lease obligations	$ -0-

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. ACCRUED LIABILITIES

We had the following accrued liabilities as of December 31, 2012 and 2011:

	2012	2011
Accrued Research & Development Expense	$ 9,832,357	$ 5,913,908
Accrued Compensation and Benefits	1,118,475	895,203
Other Accrued Liabilities	1,065,146	1,415,904
Total Accrued Liabilities	$ 12,015,978	$ 8,225,015

11. OPERATING LEASES

We lease our production facilities and administrative offices as well as certain equipment used in our operations. The lease terms range from monthly to five years. 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 February 2015 with an option to renew the lease for one year.

	2012	2011	2010
Lease Payments Under Operating Leases	$ 1,955,626	$ 2,001,094	$ 2,211,080

Future minimum rental payments under operating lease agreements are as follows:

Year ending December 31, 2013	$ 1,740,638
Year ending December 31, 2014	1,270,536
Year ending December 31, 2015	884,323
Year ending December 31, 2016	631,905
Year ending December 31, 2017	606,700
Year ending December 31, 2018 and thereafter	948,840
Total	$ 6,082,942

12. INCOME TAXES

A reconciliation of income tax expense at the statutory rate to income tax expense at our effective tax rate is as follows:

	2012	2011	2010
Tax Expense Computed at 34% of Pretax Income	$ (18,367,000)	$ (7,291,000)	$ (912,000)
Effect of Permanent Differences Principally Related to Non-taxable government grants			(83,000)
State Income Taxes		2,005	
Effect of Change in Valuation Allowance	(18,367,000)	(7,291,000)	(995,000)
Total Income Tax Expense	$ -0-	$ 2,005	$ -0-

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. INCOME TAXES (Continued)

The details of the net deferred tax asset are as follows:

	December 31,	
	2012	**2011**
Deferred tax assets:		
Net Operating Loss Carryforward	$ 33,016,000	$ 16,728,000
Stock Based Compensation	5,398,000	3,467,000
Accrued Expenses	274,000	78,000
Inventories	66,000	66,000
Prepaid Expenses	51,000	
Accounts Receivable	9,000	10,000
Subtotal	38,814,000	20,349,000
Deferred Tax Liabilities:		
Tax over Book Depreciation	276,000	323,000
Goodwill & Intangible Assets	272,000	297,000
Prepaid Expenses		3,000
Subtotal	548,000	623,000
Subtotal	38,266,000	19,726,000
Valuation Allowance	(38,266,000)	(19,726,000)
Net Deferred Tax Asset	$ -0-	$ -0-

Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $97,107,000 that expire between 2018 and 2032.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized upon the generation of future taxable income during the periods in which those temporary differences become deductible. We recognized no income tax expense or benefit for the years ended December 31, 2012, 2011 and 2010. Due to anticipated spending on research and development over the next several years, coupled with our limited history of operating income and our net losses in 2012, 2011 and 2010, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2012 and 2011. The portion of the valuation allowance resulting from excess tax benefits on share based compensation that would be credited directly to contributed capital if recognized in subsequent periods is $2.4 million.

The Company accounts for its uncertain tax positions in accordance with ASC 740-10, *Income Taxes* and the amount of unrecognized tax benefits related to tax positions is not significant at December 31, 2012 and 2011.

13. CAPITAL STOCK

Our authorized capital stock consists of 2,000,000 preferred shares, none of which were issued or outstanding at December 31, 2012, 2011 and 2010, 1,416,664 shares of 8.5% non-voting cumulative redeemable Series A Preferred Shares, $1.00 par value, of which none were issued outstanding at

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. CAPITAL STOCK (Continued)

December 31, 2012, 2011 and 2010, and 40,000,000 common shares, no par value per share, of which the following shares were outstanding:

	2012	2011	2010
Shares outstanding as of December 31,	21,494,696	18,710,002	17,513,608
Summary of Share Issuances:			
Shares Issuances related to Equity Compensation:			
Shares issued upon exercise of stock options by employees	216,477	397,054	78,166
Proceeds realized from stock option exercises	$ 132,026	$ 719,484	$ 90,448
Average exercise price of options exercised	$ 0.61	$ 1.81	$ 1.16
Restricted Stock Grants	235,000		235,000
Share issuances related to Warrant Exercises			
Shares issued upon the exercise of warrants	288,217	799,340	
Proceeds realized from warrant exercises	$ 1,978,729	$ 3,877,276	
Share issuances related to Equity Offerings			
Shares issued pursuant to equity offerings	1,845,000		
Proceeds realized from equity offerings	$ 16,120,669		
Share issuances in Exchange for Services			
Share issuances in Exchange for Services	200,000		
Value of Shares issued in Exchange for Services	$ 1,854,000		

Common Shares

Holders of the common shares are entitled to one vote per share on all matters submitted to a vote of our shareholders and are to receive dividends when and if declared by the Board of Directors. The Board is authorized to issue additional common shares within the limits of the Company's Articles of Incorporation without further shareholder action, subject to applicable stock exchange rules.

Warrants

We had 2,233,240 common share purchase warrants outstanding at December 31, 2012, of which 2,133,240 were exercisable as of December 31, 2012. During 2012, we agreed to extend the term of 1,079,169 common share purchase warrants until January 28, 2013 and incurred an expense of $280,600 related to the extension of these warrants. Subsequent to year end, we agreed to extend the term of 1,008,336 common share purchase warrants until July 31, 2013. We, also, extended the term of 80,000 common share purchase warrants until November 28, 2013 and incurred an expense of $33,600 related to the extension of the term of these warrants.

We had 2,607,440 common share purchase warrants outstanding at December 31, 2011 of which 2,507,440 were exercisable as of December 31, 2011. During 2011, we issued 100,000 warrants with an exercise price of $10.25 related to a supply agreement with a major customer and we recognized a reduction in revenue of $134,501 in 2011 related to those warrants. Those warrants are exercisable after December 31, 2013 and expire March 31, 2014. Also, during 2011, we agreed to extend the term of

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. CAPITAL STOCK (Continued)

245,000 warrants issued in November 2008 in consideration for services. The term was extended from November 5, 2011 to May 4, 2012 and 200,000 remained outstanding as of December 31, 2011. We recognized an expense of $165,850 related to the extension of the term of these warrants.

We had 3,338,569 common share purchase warrants outstanding at December 31, 2010 of which 3,318,569 were exercisable as of December 31, 2010. During 2010, we issued 5,000 warrants with an exercise price of $8.00 in exchange for services and incurred an expense of $4,000 in 2010. These warrants are exercisable on or after September 1, 2011 and expire on May 28, 2013. Also, pursuant to an agreement executed on March 8, 2010, we issued 15,000 warrants in exchange for services and incurred an expense of $46,600 in 2010 related to these warrants. These warrants are exercisable on or after March 8, 2011, have an exercise price of $6.14 and expire on March 8, 2013. Also during 2010, we agreed to extend the term and revise the exercise price of 100,000 warrants, issued in May 2008, in consideration for services. The exercise price of these warrants was lowered to $8.00 from $9.00 and their term extended by one year to May 28, 2013. We recognized an expense of $102,000 in 2010 related to the change in terms in for these warrants.

Warrants were valued using the Black Scholes model. In 2012, 2011 and 2010 we recognized $464,426, $312,000 and $640,000 in expense related to services and consideration provided in exchange for warrants. At December 31, 2012, the amount of unrecorded expense for warrants attributable to future periods was approximately $154,527 which is expected to be amortized to expense on a straight line basis in 2013.

Outstanding warrants by exercise price consisted of the following as of December 31, 2012, 2011 and 2010:

Exercise Price	Expiration Date	2012	2011	2010
$9.55	10/5/2014	883,071	883,071	1,079,200
$7.18	1/28/2013	1,059,169	1,079,169	1,079,169
$1.99	11/5/2011			300,000
$4.54	5/4/2012			200,000
$7.00	5/4/2012		200,000	200,000
$10.25	3/31/2014	100,000	100,000	
$8.00	5/28/2013	104,000	105,000	105,000
$7.00	10/3/2011			90,000
$9.55	10/5/2012		85,200	85,200
$10.00	11/28/2013	80,000	80,000	80,000
$7.50	10/3/2011			45,000
$6.14	3/8/2013	7,000	15,000	15,000
$6.50	9/30/2012		60,000	60,000
Total		2,233,240	2,607,440	3,338,569

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. LONG TERM INCENTIVE PLAN & STOCK OPTIONS

Long Term Incentive Plan & Stock Options

The Board of Directors adopted the Rockwell Medical, Inc., 2007 Long Term Incentive Plan ("LTIP") on April 11, 2007. The shareholders approved the LTIP on May 24, 2007 and approved amendments to the LTIP on May 23, 2008, May 21, 2009, May 27, 2010, May 26, 2011 and May 24, 2012. There are 6,250,000 common shares reserved for issuance under the LTIP. The Compensation Committee of the Board of Directors (the "Committee") is responsible for the administration of the LTIP including the grant of stock based awards and other financial incentives including performance based incentives to employees, non-employee directors and consultants.

Upon approval of the LTIP, the 1997 Stock Option Plan (the "Old Plan") was terminated as to future grants. No options were granted under the Old Plan after 2006.

The Committee determines the terms and conditions of options and other equity based incentives including, but not limited to, the number of shares, the exercise price, term of option and vesting requirements. The Committee approved stock option grants during 2012, 2011 and 2010 and restricted stock grants during 2012 and 2010 under the LTIP. The stock option awards were granted with an exercise price equal to the market price of the Company's stock on the date of the grant. The options expire 10 years from the date of grant or upon termination of employment and vest in three equal annual installments beginning on the first anniversary of the date of grant.

Restricted Stock Grants

We granted 235,000 restricted shares in both 2012 and 2010 under the LTIP. These restricted stock grants were valued at the market price on the date of grant. The 2012 grant vests two years after the date of grant with vesting conditioned upon continued employment with the Company. The 2010 restricted stock grant was granted with half the shares vesting after 18 months from the grant date and the remainder vesting 36 months from the grant date with vesting conditioned upon continued employment with the Company. Vesting terms of the 2010 grant were extended upon mutual agreement with the grantees to one half in March 2013 and one half in August 2013.

	2012	2011	2010
Restricted Shares Granted	235,000		235,000
Expense related to Grant of Restricted Shares	$ 1,075,929	$ 596,000	$ 332,644
Market Value Per Share on Grant Date	$ 9.45		$ 5.86
Unrecorded Stock Based Compensation for Restricted Stock Awards Attributable to Future Periods	$ 1,885,790		

Stock Option Grants

Our standard stock option agreement allows for the payment of the exercise price of vested stock options either through cash remittance in exchange for newly issued shares, or through non-cash exchange of previously issued shares held by the recipient for at least six months in exchange for our newly issued shares. The latter method results in no cash being received by us, but also results in a lower number of total shares being outstanding subsequently as a direct result of this exchange of shares. Shares returned to us in this manner would be retired.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

In 2012, 2011 and 2010, the Company received cash proceeds of $132,026, $719,484 and $90,448, respectively, in exchange for shares issued upon the exercise of options during the year. No income tax benefits were recognized during 2012, 2011 and 2010 related to stock option activity as the Company has a full valuation allowance recorded against its deferred tax assets. However, tax benefits for the excess of the value of the shares issued over the price paid of $494,000, $772,000 and $125,000 were created in 2012, 2011, and 2010. The cumulative excess tax benefit at December 31, 2012 is $2.4 million, which when realized, will be credited directly to stockholders' equity.

A summary of the status of the LTIP and the Old Plan is as follows:

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	AGGREGATE INTRINSIC VALUE
Outstanding at December 31, 2009	4,441,500	3.95	$ 16,604,310
Granted	938,000	6.70	
Exercised	(78,166)	1.16	$ 369,887
Forfeited	(12,000)	6.80	
Outstanding at December 31, 2010	5,289,334	4.52	$ 17,879,160
Granted	839,000	8.54	
Exercised	(416,201)	1.81	$ 2,571,874
Forfeited	(229,998)	6.61	
Outstanding at December 31, 2011	5,482,135	5.23	$ 17,761,008
Granted	871,000	9.62	
Exercised	(223,601)	0.59	$ 1,286,176
Forfeited	(140,334)	8.66	
Outstanding at December 31, 2012	5,989,200	5.95	$ 12,559,074

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICES	NUMBER OF OPTIONS	REMAINING CONTRACTUAL LIFE	WEIGHTED EXERCISE PRICE	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
$1.81 to $2.79	952,200	0.6 - 2.6 yrs.	$ 2.30	952,200	$ 2.30
$3.06 to $4.55	1,385,000	0.8 - 5.9 yrs.	$ 3.97	1,385,000	$ 3.97
$4.93 to $6.74	1,705,000	4.8 - 9.9 yrs.	$ 6.41	1,573,334	$ 6.45
$7.13 to $10.20	1,947,000	6.8 - 9.6 yrs.	$ 8.75	499,666	$ 7.81
Total	5,989,200	5.4 yrs.	$ 5.95	4,410,200	$ 4.93
Intrinsic Value	$ 12,559,074			$ 13,758,011	

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

	NUMBER OF UNVESTED OPTIONS	WEIGHTED AVERAGE FAIR MARKET VALUE AT GRANT DATE
As of December 31, 2009	1,305,000	
Granted	938,000	$ 4.07
Forfeited	(12,000)	
Vested	(621,889)	
As of December 31, 2010	1,609,111	
Granted	839,000	$ 5.06
Forfeited	(229,998)	
Vested	(688,780)	
As of December 31, 2011	1,529,333	
Granted	871,000	$ 5.93
Forfeited	(140,334)	
Vested	(680,999)	
As of December 31, 2012	1,579,000	

Assumptions used in Stock Option Valuation:

	2012	2011	2010
Volatility of share price	64 - 65%	63 - 64%	65 - 67%
Risk free interest rate	0.8 - 1.2%	1.1 - 2.6%	1.45 - 2.8%
Expected option life	6 yrs.	6 yrs.	6 yrs.
Dividend Yield	0.0%	0.0%	0.0%

We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to ASC 718-10 requirements. We primarily base our determination of expected volatility through our assessment of the historical volatility of our common shares. We do not believe that we are able to rely on our historical stock option exercise and post-vested termination activity to provide accurate data for estimating our expected term for use in determining the fair value of these options. Therefore, as allowed by Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment,* we have opted to use the simplified method for estimating the expected option term equal to the midpoint between the vesting period and the contractual term. The contractual term of the option is 10 years from the date of grant and the vesting term of the option is three years from date of grant. Risk free interest rates utilized are based upon published U.S. Treasury yield curves at the date of the grant for the expected option term.

For the years ended December 31, 2012, 2011 and 2010, we recognized compensation expense of $3,903,795, $3,469,703 and $3,048,750, respectively related to options granted to employees under the LTIP with a corresponding credit to common stock. At December 31, 2012, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately $4,963,000 which is expected to be amortized to expense over the remaining three year vesting period of the options.

As of December 31, 2012, the remaining number of common shares available for equity awards under the LTIP was 1,284,665.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. RISK MANAGEMENT

Insurance

We evaluate various kinds of risk that we are exposed to in our business. In our evaluation of risk, we evaluate options and alternatives to mitigating such risks. For certain insurable risks we may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For our subsidiary, Rockwell Transportation, Inc., we maintain a partially uninsured workers' compensation plan. Under the policy, the Company's self-insurance retention is $350,000 per occurrence and $747,193 in aggregate coverage for the policy year ending July 1, 2013. The total amount at December 31, 2012 by which retention limits exceed the claims paid and accrued is approximately $725,000 for the policy year ending July 1, 2013. Estimated additional future claims subject to payment by the Company of approximately $176,000 has been accrued for the year ended December 31, 2012.

At December 31, 2012, approximately $287,500 was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2012 amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

Litigation

From time to time in the ordinary course of business, we become involved in various lawsuits, claims and proceedings relating to the conduct of our business, including those pertaining to commercial, intellectual property and employment claims. While we cannot reasonably predict the outcome of any lawsuit, claim or proceeding, we intend to vigorously defend these matters. However, if we are unsuccessful in our defense, these matters could result in a material adverse impact to our financial position and results of operations. The Company is a defendant in various legal actions that have arisen in the ordinary course of business. In the opinion of management, eventual resolution of these claims will not have a material effect on the Company's financial position or results of operations.

16. MANAGEMENT PLAN OF ACTION

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern. However, the Company has sustained substantial operating losses in recent years and expects to continue to have operating losses in 2013. In addition, the Company has used and expects to continue to use substantial amounts of working capital to fund research and development costs. In view of these matters, realization of a major portion of the assets in the accompanying consolidated balance sheet is dependent upon the Company's ability to increase its liquidity and capital resources.

Management has developed plans and taken steps that it believes will enable the Company to continue its operations and meet operating and financing requirements. These plans include:

The Company has a multi-part financing plan to raise additional equity and debt financing to fund its research and development costs which are expected to be substantial. It is currently in negotiations for additional financing including equity and debt financing.

The Company is seeking partners for the development of its drug portfolio outside the U.S. and for other indications for SFP within the U.S.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. MANAGEMENT PLAN OF ACTION (Continued)

The Company plans to continue development of its dialysis concentrate and product supply business which generates positive cash flow based on earnings before interest, taxes, depreciation, amortization, research and development and non-cash charges for equity compensation.

In order to accelerate the development and national penetration of its concentrate business, the Company is seeking to partner its dialysis concentrate business in the United States with interested parties which may include joint ventures, partnerships or other arrangements to increase the value of its concentrate business operations.

The Company plans to begin selling Calcitriol, an intravenous vitamin D analogue targeted to the dialysis market, following FDA regulatory approval of a change in manufacturing location for the drug. Calcitriol is anticipated to provide substantial additional revenue and higher margins than the Company's current product lines.

17. QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2012 and 2011.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2012				
Sales	$ 12,028,417	$ 12,124,790	$ 12,689,339	$ 12,999,846
Cost of Sales	10,401,941	10,405,991	11,043,412	11,297,621
Gross Profit	1,626,476	1,718,799	1,645,927	1,702,225
Selling, General and Administrative	2,898,684	2,824,379	3,325,411	3,635,386
Research and Product Development	9,405,547	10,876,396	16,238,450	11,751,256
Operating Income (Loss)	(10,677,755)	(11,981,976)	(17,917,934)	(13,684,417)
Interest and Investment Income, net	111,097	77,091	42,296	11,034
Interest Expense	253	456	137	105
Income (Loss) Before Income Taxes	(10,566,911)	(11,905,341)	(17,875,775)	(13,673,488)
Income Tax Expense				
Net Income (Loss)	$ (10,566,911)	$ (11,905,341)	$ (17,875,775)	$ (13,673,488)
Basic And Diluted Earnings (Loss) Per Share	$ (.54)	$ (.58)	$ (.86)	$ (.66)

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. QUARTERLY RESULTS OF OPERATIONS (Continued)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2011				
Sales	$ 13,290,787	$ 11,802,307	$ 11,976,329	$ 11,896,808
Cost of Sales	11,639,242	10,731,258	10,600,144	10,352,677
Gross Profit	1,651,545	1,071,049	1,376,185	1,544,131
Selling, General and Administrative	2,246,553	2,372,597	2,271,350	2,631,805
Research and Product Development	2,402,596	3,313,762	4,221,118	7,867,886
Operating Income (Loss)	(2,997,604)	(4,615,310)	(5,116,283)	(8,955,560)
Interest and Investment Income, net	85,968	77,542	77,107	3,432
Interest Expense	601	504	408	331
Income (Loss) Before Income Taxes	(2,912,237)	(4,538,272)	(5,039,584)	(8,952,459)
Income Tax Expense			1,958	47
Net Income (Loss)	$ (2,912,237)	$ (4,538,272)	$ (5,041,542)	$ (8,952,506)
Basic And Diluted Earnings (Loss) Per Share	$ (.17)	$ (.26)	$ (.28)	$ (.49)

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions	(Deductions)	Balance at End of Period
Allowance for Doubtful Accounts:				
Year ended December 31, 2012	$ 29,473	$ 9,659	$ (12,875)	$ 26,257
Year ended December 31, 2011	$ 23,231	$ 8,527	$ (2,285)	$ 29,473
Year ended December 31, 2010	$ 31,472	$ 2,927	$ (11,168)	$ 23,231
Inventory Reserve:				
Year ended December 31, 2012	$ 39,803	$ 37,009	$ (49,233)	$ 27,579
Year ended December 31, 2011	$ 59,633	$ 18,501	$ (38,332)	$ 39,803
Year ended December 31, 2010	$ 32,455	$ 56,748	$ (29,570)	$ 59,633
Deferred Tax Asset Valuation Allowance:				
Year ended December 31, 2012	$ 19,726,000	$ 18,540,000	$	$ 38,266,000
Year ended December 31, 2011	$ 11,963,000	$ 7,763,000	$	$ 19,726,000
Year ended December 31, 2010	$ 10,930,000	$ 1,033,000	$	$ 11,963,000

Allowances and reserves are deducted from the accounts to which they apply.