

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-K

March 12, 2010

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

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the fiscal year ended December 31, 2009**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the transition period from        to**

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

**Michigan**  
*(State or other jurisdiction of  
incorporation or organization)*

**38-3317208**  
*(I.R.S. Employer  
Identification No.)*

**30142 Wixom Road**  
**Wixom, Michigan**  
*(Address of principal executive offices)*

**48393**  
*(Zip Code)*

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

| <b>Title of Each Class:</b> | <b>Name of Each Exchange on Which Registered:</b> |
|-----------------------------|---|
| Common Stock, no par value  | Nasdaq Global Market                              |

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

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

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

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  No

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

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

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

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

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

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

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

### **Documents Incorporated by Reference**

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

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**PART I**

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

**Forward Looking Statements**

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue, predict, fo intend or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the potential for the Centers for Medicare and Medicaid Services, or CMS, to change its reimbursement policies and the effect on our business if such change is made, statements regarding the timing and costs of obtaining FDA approval of our new SFP product and statements regarding our anticipated future financial condition, operating results, cash flows and business plans.

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, including without limitation in Item 1A Risk Factors, and from time to time in our other reports filed with the Securities and Exchange Commission. Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows and financial position. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise except as required by law.

**Item 1. *Description of Business.***

**General**

Rockwell Medical Technologies, Inc., incorporated in the state of Michigan in 1996, manufactures hemodialysis concentrate solutions and dialysis kits, and we sell, distribute and deliver these and other ancillary hemodialysis products primarily to hemodialysis providers in the United States as well as internationally primarily in Latin America, Asia and Europe. Hemodialysis duplicates kidney function in patients with failing kidneys also known as End Stage Renal Disease ( ESRD ). ESRD is an advanced stage of chronic kidney disease ( CKD ) characterized by the irreversible loss of kidney function. Without properly functioning kidneys, a patient s body cannot get rid of excess water and toxic waste products. Without frequent and ongoing dialysis treatments, these patients would not survive. Our dialysis solutions (also known as dialysate) are used to maintain life, removing toxins and replacing nutrients in the dialysis patient s bloodstream.

We have licensed and are currently developing proprietary renal drug therapies for both iron-delivery and carnitine/vitamin-delivery, utilizing dialysate as the delivery mechanism. Iron supplementation is routinely

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

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

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

### **Our Business Strategy**

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

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

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

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

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

#### ***Identify Novel Drug Targets to Address Unmet Market Opportunities.***

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

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

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

#### ***Acquire Rights to Complementary Drug Candidates and Technologies.***

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

#### ***Continue Development of our Commercial Business and Market Position.***

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

## **Our Markets**

### **How Hemodialysis Works**

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

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

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

## **Dialysis Industry Trends**

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

ESRD incidence rates vary by country with some higher and most lower than the United States. Based on industry reports, the global ESRD population is estimated to be over 2 million and to be growing at a rate of approximately 6% annually. The three major dialysis markets are the United States, the European Union and Japan, which together represent between approximately 55-60% of the total global treatments based on industry estimates.

## **Our Products**

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

### ***Renal Pure Liquid Acid Concentrate***

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

### ***Dri-Sate® Dry Acid Concentrate & Mixing System***

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



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

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### ***RenalPure Powder Bicarbonate Concentrate***

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

### ***SteriLyte® Liquid Bicarbonate Concentrate***

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

### ***Ancillary Products***

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

### ***Iron Supplemented Dialysate***

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

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

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

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

response from ESA treatments.

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

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

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

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

## **Distribution and Delivery Operations**

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

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

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

## **Sales and Marketing**

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

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

## **Competition**

***Dialysis Concentrate and Supplies Competition***

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

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

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

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

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

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

***Iron Maintenance Therapy Market Competition***

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

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

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

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

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

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

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

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

## **Quality Assurance and Control**

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

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

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

## **Government Regulation**



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

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

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

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

### ***Medical Device Approval and Regulation***

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

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

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

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

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

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

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

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

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

***Drug Approval and Regulation***

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

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

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

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

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

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

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

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

### ***Other government regulations***

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results. Recent health reform proposals, if enacted, are likely to result in material changes to the Medicare and Medicaid programs and levels of reimbursement and possibly the imposition of fees or excise taxes on pharmaceutical and device manufacturers based on revenues. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries which typically do not require additional testing for products that have received FDA approval.

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

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

### **Product License Agreements**

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

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

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

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

### **Trademarks & Patents**

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

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

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

### **Suppliers**

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



**Customers**

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

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

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

## **Employees**

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

## **Research & Development**

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

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

## **Where You Can Get Information We File with the SEC**

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

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

## **Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are*

*not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.*

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**RISKS RELATED TO OUR BUSINESS**

**The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue. Our business is substantially dependent on one of our customers that accounts for a substantial portion of our sales. The loss of this customer would have a material adverse 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 a majority of our total sales during each of the last three years. If we were to lose this customer or our relationship with any of our other major national and regional dialysis chain customers, it would have a substantial negative impact on our cash flow and operating results and could have a detrimental impact on our ability to continue our operations in their current form or to continue to execute our business strategy. If we lost a substantial portion of our business, we would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

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

There is intense competition in the hemodialysis product market and our competitors are large diversified companies which have substantially greater financial, technical, manufacturing, marketing, research and development and management resources than we do. We may not be able to successfully compete with these other companies. Our national competitors have historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell and as we do not manufacture or sell the same breadth of products as our competitors, we may be at a disadvantage in competing against their marketing strategies.

**Our new drug product requires FDA approval and expensive clinical trials before it can be marketed.**

We are seeking FDA approval for SFP, a drug used in the treatment of anemia. Obtaining FDA approval for any drug is expensive and can take a long time. We may not be successful in obtaining FDA approval for SFP. The FDA may change, expand or alter its requirements for testing, which may increase the scope, duration and cost of our clinical development plan. Clinical trials are expensive and time consuming to complete, and we may not have sufficient funds to complete the clinical trials to obtain marketing approval. Our clinical trials might not prove successful. In addition, the FDA may order the temporary or permanent discontinuation of a clinical trial at any time. Many products that undergo clinical trials are never approved for patient use. Thus, it is possible that our new proprietary products may never be approved to be marketed. If we are unable to obtain marketing approval, our entire investment in new products may be worthless and our licensing rights could be forfeited.

**Even if our new drug product is approved by the FDA, we may not be able to market it successfully.**

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

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

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

A significant portion of our costs are for chemicals and fuel which are subject to pricing volatility based on demand and are highly influenced by the overall level of economic activity. While our gross profit margins improved substantially in 2009 due to a variety of factors including product mix shifts to less expensive products,

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

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

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

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

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

### **We depend on government funding of healthcare.**

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare and Medicaid funding to be viable businesses. A variety of changes to health insurance and reimbursement have been proposed in Congress, some of which, if enacted into law, could have a negative impact on Medicare and Medicaid funding 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 2011, the government will implement a change to reimbursement practices by shifting to a fully bundled rate per dialysis session compared to the current practice of separately billed services and medications. 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 costs. As a result, we may see increased pressure to reduce the cost of our products, which would have a negative impact on our revenue and gross profit margins.

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

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

### **We depend on key personnel.**

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, Dr. Richard Yocum MD, our Vice President of Drug Development & Medical Affairs, Dr. Ajay Gupta MD, our Chief Scientific 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. Yocum is primarily responsible for managing

our product development efforts. Dr. Gupta is primarily responsible for discovery and development of new technologies. None of our executive management are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini, Dr. Yocum, Dr. Gupta or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

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### **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 as a pharmaceutical drug 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 and consultants 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 causing us to delay our development plans or have to do more testing than planned.**

We utilize a contract research organization to conduct our clinical trials in accordance with a specified protocol. 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.

### **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 has debated bills that, if adopted, would make significant changes to the health care payment and delivery system. It is difficult to determine at this time whether a health care reform bill will be passed and if passed, what the provisions of such a bill would be. Any health care reform that impacts the level of

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health care benefits, the insurers responsible for payment or the providers responsible for performing services, particularly changes in the Medicare and Medicaid programs, could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations. In addition, the current health reform bills would impose fees or excise taxes on pharmaceutical and device manufacturers based on their revenues, which could also have a material adverse effect on the Company.

### **We may not have sufficient products liability insurance.**

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

### **Our Board of Directors is subject to potential deadlock.**

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

## **RISKS RELATED TO OUR COMMON STOCK**

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

We are unable to predict the effect, if any, that future sales of common shares, or the availability of our common shares for future sales, will have on the market price of our common shares from time to time. Sales of substantial amounts of our common shares (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. As of December 31, 2009 an additional 1,694,169 shares may be issued upon exercise of outstanding warrants. In addition, as of December 31, 2009, there were an additional 1,624,400 warrants that become exercisable in 2010. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares.

In addition, as of December 31, 2009, there were 3,136,500 shares issuable upon the exercise of outstanding and exercisable stock options, 1,305,000 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 473,333 additional shares available for grant under our 2007 Long Term Incentive Plan. Additional grants have been made in 2010. 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.

### **The market price of our securities may be volatile.**

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

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

As of December 31, 2009, our officers and directors beneficially owned approximately 20.8% of our voting shares (assuming the exercise of exercisable options granted to such officers and directors). Accordingly, they may

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be able to effectively control our affairs. Our shareholders do not have the right to cumulative voting in the election of directors. In addition, the Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we are subject to Michigan statutes regulating business combinations 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 2010. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in August 2010. We expect to extend or renew these leases on terms acceptable to us or find comparable facilities. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a three year lease expiring February 28, 2011. We have an option to renew thereafter for one or two years.

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 not currently subject to any litigation that we expect to have a material effect on our financial condition and results of operations.

**Table of Contents****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 2008 through 2009.

| <b>Quarter Ended</b> | <b>Sale Price</b> |            |
|----------------------|-------------------|------------|
|                      | <b>High</b>       | <b>Low</b> |
| March 31, 2008       | \$ 7.26           | \$ 5.72    |
| June 30, 2008        | \$ 7.49           | \$ 4.65    |
| September 30, 2008   | \$ 7.20           | \$ 3.40    |
| December 31, 2008    | \$ 4.79           | \$ 1.06    |
| March 31, 2009       | \$ 4.85           | \$ 2.56    |
| June 30, 2009        | \$ 8.79           | \$ 3.82    |
| September 30, 2009   | \$ 9.39           | \$ 7.20    |
| December 31, 2009    | \$ 8.14           | \$ 6.00    |

As of February 28, 2010, there were 33 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.

**Table of Contents****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, 2004 with relative performance tracked through December 31, 2009. 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 12/31/04 in stock or index, including reinvestment of dividends.  
Fiscal year ending December 31.

|                             | <b>12/31/2004</b> | <b>12/31/2005</b> | <b>12/31/2006</b> | <b>12/31/2007</b> | <b>12/31/2008</b> | <b>12/31/2009</b> |
|-----------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| <b>Rockwell Medical</b>     | <b>\$ 100.00</b>  | <b>\$ 141.90</b>  | <b>\$ 226.35</b>  | <b>\$ 227.94</b>  | <b>\$ 133.02</b>  | <b>\$ 244.13</b>  |
| <b>Russell 2000</b>         | <b>\$ 100.00</b>  | <b>\$ 104.55</b>  | <b>\$ 123.76</b>  | <b>\$ 121.82</b>  | <b>\$ 80.66</b>   | <b>\$ 102.58</b>  |
| <b>NASDAQ Biotechnology</b> | <b>\$ 100.00</b>  | <b>\$ 117.54</b>  | <b>\$ 117.37</b>  | <b>\$ 121.37</b>  | <b>\$ 113.41</b>  | <b>\$ 124.58</b>  |

*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.*

**Table of Contents****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.

|  | <b>For the Year Ended December 31,</b> |               |               |               |               |
|--|--|---------------|---------------|---------------|---------------|
|  | <b>2009</b>                            | <b>2008</b>   | <b>2007</b>   | <b>2006</b>   | <b>2005</b>   |
| Net sales  | \$ 54,729,505                          | \$ 51,666,033 | \$ 43,045,304 | \$ 28,638,859 | \$ 27,694,955 |
| Cost of sales(2)   | 46,842,334                             | 49,159,478    | 40,156,041    | 25,837,294    | 24,689,912    |
| Gross profit(2)  | 7,887,171                              | 2,506,555     | 2,889,263     | 2,801,565     | 3,005,043     |
| Income from continuing operations before interest expense and income taxes | (5,481,379)                            | (8,085,196)   | (3,608,353)   | (4,637,830)   | 274,903       |
| Interest expense, net  | 19,859                                 | (221,139)     | 110,542       | (62,851)      | 198,095       |
| Income from continuing operations before income taxes                      | (5,501,238)                            | (7,864,057)   | (3,718,895)   | (4,574,979)   | 76,808        |
| Income taxes   |  |               |               |               |               |
| Net income   | (5,501,238)                            | (7,864,057)   | (3,718,895)   | (4,574,979)   | 76,808        |
| Earnings per common share:   |  |               |               |               |               |
| Basic  | \$ (0.37)                              | \$ (0.57)     | \$ (0.32)     | \$ (0.41)     | \$ 0.01       |
| Diluted  | \$ (0.37)                              | \$ (0.57)     | \$ (0.32)     | \$ (0.41)     | \$ 0.01       |
| Weighted average number of common shares and common share equivalents      |  |               |               |               |               |
| Basic  | 14,709,016                             | 13,836,435    | 11,771,381    | 11,189,001    | 8,674,651     |
| Diluted  | 14,709,016                             | 13,836,435    | 11,771,381    | 11,189,001    | 9,356,990     |

|  | <b>As of December 31,</b> |               |               |               |              |
|--|---------------------------|---------------|---------------|---------------|--------------|
|  | <b>2009</b>               | <b>2008</b>   | <b>2007</b>   | <b>2006</b>   | <b>2005</b>  |
| Total assets                                     | \$ 34,879,221             | \$ 18,959,982 | \$ 22,803,134 | \$ 13,152,833 | \$ 9,260,660 |
| Current assets                                   | 29,948,945                | 14,428,691    | 18,645,945    | 9,058,846     | 5,380,080    |
| Current liabilities                              | 5,536,957                 | 7,097,836     | 4,637,271     | 4,452,675     | 4,682,139    |
| Working capital                                  | 24,411,988                | 7,330,855     | 14,008,674    | 4,606,171     | 697,941      |
| Long-term debt and capitalized lease obligations | 19,062                    | 41,203        | 204,837       | 326,045       | 733,723      |
| Stockholders' equity(1)                          | 29,323,202                | 11,820,943    | 17,961,026    | 8,374,113     | 3,844,798    |
| Book value per outstanding common share          | \$ 1.70                   | \$ 0.84       | \$ 1.30       | \$ 0.37       | \$ 0.43      |



|                              |            |            |            |            |           |
|------------------------------|------------|------------|------------|------------|-----------|
| Common shares<br>outstanding | 17,200,442 | 14,104,690 | 13,815,186 | 11,500,349 | 8,886,948 |
|------------------------------|------------|------------|------------|------------|-----------|

- (1) There were no cash dividends paid during the periods presented.
- (2) The Company has reclassified certain expenses from Selling, General and Administrative Expense to Cost of Sales in the 2008 and 2007 consolidated income statements to conform with the current year presentation. The impact of the change was not material. Earlier periods were not adjusted as the amounts were immaterial.

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

**Overview and Recent Developments**

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

We are currently developing unique, proprietary renal drug therapies. These exclusive 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 \$54.7 million in 2009. Our dialysis products business was cash flow positive in 2009, which partially offset the cash requirements for our product development efforts, which totaled \$6.5 million in 2009.

Our product development costs were primarily for the Phase IIb clinical trial of SFP, our lead drug candidate. We believe our SFP product has unique and substantive benefits compared to current treatment options and has the potential to compete in the iron maintenance therapy market. The cost to obtain regulatory approval for a drug in the United States is expensive and can take several years. We anticipate that costs to complete the expected clinical trials and obtain FDA approval to market SFP will total approximately \$15 million. 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. We raised \$20.4 million, net of expenses, in the fourth quarter of 2009 primarily to fund these activities and believe these cash resources will be sufficient to complete the SFP testing and FDA approval process and our other planned research and development activities.

In 2009, our business operating results improved significantly, largely as a result of actions taken in late 2008 coupled with improved pricing conditions on many of the specialty chemicals and other raw materials that constitute a majority of our product costs. Following two years of high inflation in our key costs during 2007 and 2008, we realized a substantial reduction in the cost of specialty chemicals, packaging and diesel fuel during 2009. We also benefitted from a significant shift to lower cost products by our customers which further improved our gross profit margins. Conversion to our Dri-sate Dry Acid product line typically results in lower sales and cost per treatment for the provider while the lower associated distribution costs helps to increase our gross profit margins.

While our gross profit margins achieved historical highs of approximately 17% in the second half of 2009, we anticipate a moderate amount of downward pressure on gross profit margins in 2010. We anticipate a continued increase in fuel and other costs in 2010 along with competitive pricing pressures in the renal market, both of which may inhibit our ability to maintain gross profit margins at the level realized in the second half of 2009.

We could also 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. As we add business in certain markets and regions in order to increase the scale of our business operations, we may incur additional costs that are greater than the additional revenue generated from these initiatives until we have achieved a scale of operations that is profitable.

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

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### **Results of Operations**

#### ***For the year ended December 31, 2009 compared to the year ended December 31, 2008***

##### *Sales*

In 2009, our sales were \$54.7 million, an increase of \$3.1 million or 5.9% over 2008. This increase was due to growth in both our domestic sales of \$1.6 million or 3.3% and in our international sales of \$1.5 million or 30%. Our international sales were 12% of total sales in 2009 compared to 10% of sales in 2008. The majority of our sales growth in 2009 came from unit volume growth primarily in our Dri-Sate Dry Acid product line as customers continued to migrate from liquid to dry acid concentrate, and to a lesser extent from conversion from higher cost formulations to lower cost formulations. In addition, our average selling prices increased approximately 2.3% in 2009.

##### *Gross Profit*

Our gross profit in 2009 was \$7.9 million, an increase of \$5.4 million or 215% over 2008. Our gross profit margins increased to 14.4% in 2009 compared to 4.9% in 2008. The improvement in our gross profit was primarily due to significant changes to our product mix coupled with lower operating and procurement costs and higher sales prices. Our product mix was favorably impacted by the continued conversion of customers to our Dri-Sate product line and to lower cost formulations of our dialysis concentrates. Dri-Sate case volume increased by 35% in 2009 compared to 2008. We also benefitted from lower diesel fuel costs and chemical procurement costs.

##### *Selling, General and Administrative Expenses*

Selling, general and administrative, or SG&A, expenses were \$6.9 million or 12.6% of sales in 2009 compared to 13.1% of sales in 2008. SG&A costs increased \$0.15 million compared to 2008, primarily due to an increase in non-cash charges for equity compensation, which aggregated \$2.35 million in 2009 compared to \$1.45 million in 2008, and minor increases in compensation and other operating expense. The increase was offset by the effect of legal and settlement costs of \$925,000 related to the settlement of certain litigation in 2008.

##### *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 \$6.5 million and \$3.8 million in 2009 and 2008, respectively. Costs incurred in both 2009 and 2008 were primarily for conducting human clinical trials of SFP.

##### *Interest Expense, Net*

Net interest expense in 2009 increased by \$241,000 compared to 2008 primarily due to a \$268,000 reduction in interest income from our cash investments as a result of lower investable funds and a substantially lower interest rate environment in 2009 compared to 2008. The investment of the proceeds of the October 2009 equity offering in short term investments had an immaterial effect on interest income in 2009 and is not expected to cause interest income to increase significantly due to the very low short term interest rate environment.

##### *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, 2008 compared to the year ended December 31, 2007***

*Sales*

For the year ended December 31, 2008, our sales were \$51.6 million, an increase of \$8.6 million or 20.0% over sales for the year ended December 31, 2007. This increase was due to growth in both our domestic sales of \$5.5 million or 13.4% and in our international sales of \$3.1 million or 160%. Our domestic sales growth was largely due to the

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impact of business acquired following the exit of Gambro from the dialysis concentrate market in early 2007. Our international sales growth included expansion to new markets and our total international business increased to 10% of total sales in 2008 from 5% of sales in 2007. We realized unit volume sales growth of approximately 15% in our concentrate product lines which accounted for the majority of our sales growth in 2008 compared to 2007 with the remainder of our sales growth primarily due to increased prices. Our unit volume sales growth was due to higher international demand for our concentrate product lines and domestically, an increase in the number of clinics we service.

### *Gross Profit*

Our gross profit in 2008 was \$2.5 million compared to \$2.9 million in 2007 which included the reclassification of certain expenses to cost of sales from SG&A expense for both periods to conform with the current year presentation. While we realized higher sales in 2008, the impact of cost increases for chemicals, packaging and fuel more than offset the beneficial impact of higher selling prices and increased sales volumes. We experienced unprecedented increases in our key cost drivers in 2008 continuing the trends experienced in 2007. We also incurred cost increases in the second half of 2008 relating to our operational improvements discussed above that adversely affected our gross profit in 2008, some of which increases, such as the costs relating to additional human resources and information technology, will continue to affect our operating expenses in future periods. As a result, our gross profit margins decreased to 4.8% in 2008 from 6.7%. We experienced substantially higher costs in our key chemical ingredients in 2008 and our fuel costs increased 1.6% as a percent of domestic sales in 2008 compared to 2007. The weighted average market price of domestic diesel fuel increased approximately 32% in 2008 compared to 2007 based on Department of Energy diesel fuel statistics.

Prices for several of our key raw material ingredients decreased substantially at the end of 2008. Beginning in 2009, we negotiated new annual contracts for certain key chemicals at substantially lower prices than paid in the fourth quarter of 2008.

### *Selling, General and Administrative Expenses*

Selling, general and administrative, or SG&A, expenses were \$6.8 million or 13.1% of sales in 2008 compared to 7.5% of sales in 2007, including the reclassification for both periods of certain expenses to cost of sales adjusted to conform to the current year presentation. SG&A costs increased \$3.5 million in 2008 compared to 2007. In 2008, SG&A included non-cash charges for equity related compensation of \$1.45 million, an increase of \$1.2 million in 2008 compared to 2007. In addition, we settled a legal dispute with a former landlord for \$750,000 and incurred overall costs of \$925,000 related to this litigation in 2008. Approximately half of the remaining increase in SG&A of \$1.4 million was due to increased costs for human resources. We made a substantial investment in information technology and the associated costs increased approximately \$0.2 million compared to 2007. We also began to increase our public relations and investor relations activities pertaining to SFP and increased our related spending by approximately \$0.2 million compared to 2007. In addition, we incurred approximately \$0.1 million in additional costs associated with the audit of our internal controls by our independent accounting firm for the first time in 2008.

### *Research and Development*

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including SFP, aggregating approximately \$3.8 million and \$3.3 million in 2008 and 2007, respectively. Costs incurred in 2008 were primarily for conducting human clinical trials of SFP. Expenditures in 2007 included expenditures for non-clinical testing and costs related to preparation for human clinical testing of SFP.

*Interest Expense, Net*

Net interest income in 2008 increased by \$332,000 compared to 2007 primarily due to investment income from our cash investments following our equity offering in late 2007 and, to a lesser extent, to a decrease in interest expense because of lower overall borrowings.

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### *Income Tax Expense*

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

### **Critical Accounting Estimates and Judgments**

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

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

#### *Revenue recognition*

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

#### *Allowance for doubtful accounts*

Accounts receivable are stated at invoice amounts. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts that reflects our best estimate of accounts that may not be collected. We review outstanding trade account receivable balances and based on our assessment of expected collections, we estimate the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily based 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 and 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 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.

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### *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.

### **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. These initiatives will require the expenditure of substantial cash resources.

In October 2009, we raised \$20.4 million in equity capital, net of related expenses, primarily for the purpose of funding the clinical development and FDA approval of SFP. We estimate that we will spend \$18 million on our SFP Phase III clinical development program and FDA approval activities and other development initiatives over the next two years. Positive cash flows from operations should reduce our overall use of cash going forward.

We recently completed our Phase IIb clinical trial for SFP and plan to seek FDA approval to conduct Phase III clinical trials for SFP. We anticipate that costs to complete the remaining planned clinical trials for SFP and obtain FDA approval to market SFP will total approximately \$15 million.

Our cash resources include cash generated from our business operations and the proceeds from our equity offerings in 2007 and 2009. Our current assets exceeded our current liabilities by over \$24.4 million as of December 31, 2009 and included \$23 million in cash and cash equivalents. In 2009, we realized \$20.5 million in cash from financing activities while using \$1.6 million in investing activities, primarily on capital spending, and also using \$1.4 million in operating activities. Cash used in operations of \$1.4 million was net of \$6.5 million in research and development expenditures. Impacting the cash generated from business operations was a \$1.7 million reduction in accounts receivable from 2008 with approximately \$1 million of the increase in cash due to earlier than expected cash receipts from a customer at year end.

We believe our cash resources are sufficient to fund our anticipated research and development activities as well as our ordinary course operating cash requirements in 2010 and 2011. We expect to generate positive cash flow from operations in 2010, excluding the effect of our research and development expenses assuming stable operating results and relative stability in the markets for our key raw materials. However, if we use more cash than anticipated for SFP development, or are required to do more testing than expected or if the assumptions underlying our cash flow projections for 2010 and 2011 prove to be incorrect, we may need to obtain additional cash, such as through equity financing, debt financing of capital expenditures or a line of credit, to supplement our working capital. Alternatively, we may seek to enter into development arrangements with an international partner in order to fully execute our strategic plan. We may also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets and other potential funding sources.

**Contractual Obligations**

The following table details our contractual obligations as of December 31, 2009:

| <b>Contractual Obligations</b> | <b>Total</b>        | <b>Payments due by period</b> |                     |                   | <b>More than 5 years</b> |
|--------------------------------|---------------------|-------------------------------|---------------------|-------------------|--------------------------|
|                                |                     | <b>Less than 1 year</b>       | <b>1-3 years</b>    | <b>3-5 years</b>  |                          |
| Capital leases                 | \$ 65,789           | \$ 45,806                     | \$ 19,983           |                   |                          |
| Operating leases               | \$ 3,510,840        | \$ 1,655,687                  | \$ 1,648,141        | \$ 207,012        |                          |
| Purchase obligations           | \$ 4,500            | \$ 4,500                      |                     |                   |                          |
| <b>Total</b>                   | <b>\$ 3,581,129</b> | <b>\$ 1,705,993</b>           | <b>\$ 1,668,124</b> | <b>\$ 207,012</b> |                          |

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**Off-Balance Sheet Arrangements**

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

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

**Interest Rate Risk**

Our current exposure to interest rate risk is limited to changes in interest rates on short term investments of cash. As of December 31, 2009, we had \$20.5 million in short term investments in a money market fund.

A hypothetical 100 basis point increase in market interest rates for short term liquid investments would increase our annualized interest income by approximately \$0.2 million, assuming we invested \$20.5 million in cash and that level remained constant for the year. We did not perform an analysis of a 100 basis point decrease in market interest rates as such an analysis would be meaningless.

**Foreign Currency Exchange Rate Risk**

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

**Item 8. *Financial Statements.***

The Consolidated Financial Statements of the Registrant required by this item are set forth on pages F-1 through F-19 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 assurance, not absolute,

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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, 2009. 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, 2009.

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, 2009. 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, 2009 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.***

The required information will be contained in the Proxy Statement under the captions “Election of Directors” and “Section 16(a) Beneficial Ownership Reporting Compliance” and (excluding the Report of the Audit Committee) is incorporated herein by reference.

## **Item 11. *Executive Compensation.***

The required information will be contained in the Proxy Statement under the captions “Compensation of Executive Officers and Directors,” “Other Information Relating to Directors” and “Compensation Committee” and is incorporated herein by reference.

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

The required information will be contained in the Proxy Statement under the caption "Voting Securities and Principal Holders" and is incorporated herein by reference.

**Table of Contents****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, 2009:

| <b>Plan Category</b>                                       | <b>Number of securities to be</b> | <b>Weighted-average</b>  | <b>Number of securities</b>           |
|--|-----------------------------------|--------------------------|---------------------------------------|
|  | <b>issued upon exercise of</b>    |                          | <b>remaining</b>                      |
|  | <b>outstanding options,</b>       | <b>exercise price of</b> | <b>available for future issuance</b>  |
|  | <b>warrants</b>                   | <b>outstanding</b>       | <b>under</b>                          |
|  | <b>and rights</b>                 | <b>options,</b>          | <b>equity compensation plans</b>      |
|  | <b>(a)</b>                        | <b>warrants and</b>      | <b>(excluding</b>                     |
|  |                                   | <b>rights</b>            | <b>securities reflected in column</b> |
|  |                                   | <b>(b)</b>               | <b>(a)</b>                            |
|  |                                   |                          | <b>(c)</b>                            |
| Equity compensation plans approved by security holders     | 4,441,500                         | \$ 3.95                  | 473,333                               |
| Equity compensation plans not approved by security holders | 1,160,200                         | \$ 5.84                  | - 0 -                                 |
| Total  | 5,601,700                         | \$ 4.32                  | 473,333                               |

In 2007, 2008 and 2009, we issued warrants to purchase common shares pursuant to compensation arrangements with four 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.

As of October 3, 2007, we entered into a consulting agreement pursuant to which we have issued warrants to acquire 135,000 Common Shares. The warrants were earned at the rate of 15,000 warrants per month of service. The first 90,000 warrants that were earned have an exercise price of \$7.00 per share and the remaining 45,000 warrants have an exercise price of \$7.50 per share and in each case are exercisable for cash. The warrants expire at the close of business on October 3, 2011. These warrants become exercisable on the first anniversary of the date on which they are earned and may be exercised in whole or in part at any time until their expiration. The Common Shares underlying these warrants have been registered for resale by the holder under the Securities Act of 1933.

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. 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 will become exercisable on May 28, 2009. The warrants will expire on the earlier of (i) May 28, 2012, or (ii) the termination of the agreement prior to May 28, 2009 (A) by us due to a material breach of the agreement by the consultant or (B) by the consultant. The warrants have 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.

On September 30, 2008, we entered into an advisory agreement pursuant to which we issued warrants to acquire 60,000 Common Shares. The warrants were earned in 20,000 share increments on September 30, 2008, January 1, 2009 and July 1, 2009. The warrants became exercisable on January 1, 2010 and will expire on September 30, 2012. Upon a termination of the agreement (A) by us due to a material breach of the agreement by the consultant or (B) by the consultant, any unearned warrants at the time of such termination would have expired. The warrants have an exercise price of \$6.50 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.

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In November 2008, the Company entered into an advisory agreement, as amended, pursuant to which we issued warrants to acquire a total of 700,000 Common Shares. All of the warrants were immediately earned. Warrants to purchase 300,000 Common Shares at an exercise price of \$1.99 per share became exercisable on November 5, 2009, and will expire on November 5, 2011. The warrants would have expired upon an earlier termination of the agreement prior to November 5, 2009 (A) by us due to a material breach of the agreement by the consultant or (B) by the consultant. Warrants to purchase 400,000 Common Shares will become exercisable on November 5, 2010, and will expire on the earlier of (i) November 5, 2011, or (ii) the termination of the agreement prior to November 5, 2010 (A) by us due to a material breach of the agreement by the consultant or (B) by the consultant. One-half of these warrants have an exercise price of \$4.54, and the remainder have an exercise price of \$7.00 per share. The warrants are exercisable only for cash. The Common Shares underlying these warrants have been registered for resale by the holder under the Securities Act of 1933.

On September 29, 2009, the Company entered into a placement agency agreement with two co-placement agents related to the registered direct offering by the Company of Common Shares and warrants to purchase Common Shares that closed on October 5, 2009. At the closing, the Company issued to the placement agents warrants to purchase 85,200 Common Shares, which is 3.0% of the Common Shares sold in the offering, at an exercise price of \$9.55 per share. These warrants are exercisable commencing six months from the date of issuance thereof and expire on the third anniversary of the date of issuance thereof. These warrants and the underlying shares were issued pursuant to registration statement on Form S-3 (File No. 333-160791) filed with the SEC.

### **Item 13. *Certain Relationships and Related Transactions, and Director Independence.***

The required information will be contained in the Proxy Statement under the caption **Other Information Relating to Directors** and is incorporated herein by reference.

### **Item 14. *Principal Accountant Fees and Services.***

The required information will be contained in the Proxy Statement under the caption **Independent Accountants** and is incorporated herein by reference.

### **Item 15. *Exhibits, 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 000-23-661.

- 3.1 Amended and Restated Articles of Incorporation, dated as of June 4, 2008 (Company's Form 10-Q filed August 12, 2008).
- 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)).
- 4.6 Warrant issued to Lions Gate Capital as of October 3, 2007 (Company's Form S-3 (file no. 333-160710)).

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- 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)).
- \*10.1 Rockwell Medical Technologies, 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).
- 10.6 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-QSB filed May 17, 2004).
- 10.10 Second Amendment of Industrial Lease Agreement between Rockwell Medical Technologies, 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 Technologies, Inc. (Company's Form 10-KSB filed March 31, 2006).
- \*10.16 Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan (Company's Proxy Statement filed April 18, 2007).
- 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).
- \*10.23 Amendment No. 1 to Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan (Company's Form 8-K filed May 30, 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).



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- 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).
- \*10.32 Amendment No. 2 to Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan (Company's Form 10-Q filed August 10, 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).
- 14.1 Rockwell Medical Technologies, 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.

\* Current management contracts or compensatory plans or arrangements.

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**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 TECHNOLOGIES, INC. (Registrant)

By: /s/ ROBERT L. CHIOINI

Robert L. Chioini  
President and Chief Executive Officer

Date: March 12, 2010

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.

| <b>Signature</b>                               | <b>Title</b>  | <b>Date</b>    |
|--|---|----------------|
| /s/ ROBERT L. CHIOINI<br><br>Robert L. Chioini | President, Chief Executive Officer and<br>Director (Principal Executive Officer)  | March 12, 2010 |
| /s/ THOMAS E. KLEMA<br><br>Thomas E. Klema     | Vice President of Finance, Chief Financial<br>Officer, Treasurer and Secretary (Principal<br>Financial Officer and Principal Accounting<br>Officer) | March 12, 2010 |
| /s/ KENNETH L. HOLT<br><br>Kenneth L. Holt     | Director  | March 12, 2010 |
| /s/ RONALD D. BOYD<br><br>Ronald D. Boyd       | Director  | March 12, 2010 |
| /s/ PATRICK J. BAGLEY<br><br>Patrick J. Bagley | Director  | March 12, 2010 |

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Rockwell Medical Technologies, Inc. and Subsidiary (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2009. 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 presents fairly, in all material respects, the consolidated financial position of Rockwell Medical Technologies, Inc. and Subsidiary at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2009, 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, present fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Rockwell Medical Technologies, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2009, 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 11, 2010 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Plante & Moran, PLLC

Auburn Hills, Michigan  
March 11, 2010

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited Rockwell Medical Technologies, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2009, 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 Technologies, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, 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 Technologies, Inc. and Subsidiary (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2009 and related financial statement schedule and our report dated March 11, 2010 expressed an unqualified opinion thereon.

/s/ Plante & Moran, PLLC

Auburn Hills, Michigan  
March 11, 2010

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS**

As of December 31, 2009 and 2008

|   | <b>December 31,<br/>2009</b> | <b>December 31,<br/>2008</b> |
|---|------------------------------|------------------------------|
| <b>ASSETS</b>   |                              |                              |
| Cash and Cash Equivalents   | \$ 23,038,095                | \$ 5,596,645                 |
| Accounts Receivable, net of a reserve of \$31,000 in 2009 and \$97,000 in 2008          | 3,492,622                    | 5,229,656                    |
| Inventory   | 3,088,352                    | 3,161,625                    |
| Other Current Assets  | 329,876                      | 440,765                      |
| <b>Total Current Assets</b>   | <b>29,948,945</b>            | <b>14,428,691</b>            |
| Property and Equipment, net   | 3,631,549                    | 3,249,003                    |
| Intangible Assets   | 214,337                      | 240,656                      |
| Goodwill  | 920,745                      | 920,745                      |
| Other Non-current Assets  | 163,645                      | 120,887                      |
| <b>Total Assets</b>   | <b>\$ 34,879,221</b>         | <b>\$ 18,959,982</b>         |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |                              |                              |
| Capitalized Lease Obligations   | \$ 42,938                    | \$ 176,850                   |
| Accounts Payable  | 3,388,757                    | 5,210,972                    |
| Accrued Liabilities   | 1,854,347                    | 1,464,828                    |
| Customer Deposits   | 250,915                      | 245,186                      |
| <b>Total Current Liabilities</b>  | <b>5,536,957</b>             | <b>7,097,836</b>             |
| Capitalized Lease Obligations   | 19,062                       | 41,203                       |
| Shareholders Equity:  |                              |                              |
| Common Shares, no par value, 17,200,442 and 14,104,690 shares issued and outstanding    | 53,545,394                   | 34,799,093                   |
| Common Share Purchase Warrants, 3,318,569 and 2,114,169 warrants issued and outstanding | 7,635,594                    | 3,378,398                    |
| Accumulated Deficit   | (31,857,786)                 | (26,356,548)                 |
| <b>Total Shareholders Equity</b>  | <b>29,323,202</b>            | <b>11,820,943</b>            |
| <b>Total Liabilities And Shareholders Equity</b>  | <b>\$ 34,879,221</b>         | <b>\$ 18,959,982</b>         |

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

**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED INCOME STATEMENTS****For The Years Ended December 31, 2009, 2008 and 2007**

|   | <b>2009</b>    | <b>2008</b>    | <b>2007</b>    |
|---|----------------|----------------|----------------|
| Sales                                       | \$ 54,729,505  | \$ 51,666,033  | \$ 43,045,304  |
| Cost of Sales                               | 46,842,334     | 49,159,478     | 40,156,041     |
| Gross Profit                                | 7,887,171      | 2,506,555      | 2,889,263      |
| Selling, General and Administrative         | 6,914,198      | 6,761,617      | 3,233,883      |
| Research and Product Development            | 6,454,352      | 3,830,134      | 3,263,733      |
| Operating Income (Loss)                     | (5,481,379)    | (8,085,196)    | (3,608,353)    |
| Interest (Income) Expense, net              | 19,859         | (221,139)      | 110,542        |
| Income (Loss) Before Income Taxes           | (5,501,238)    | (7,864,057)    | (3,718,895)    |
| Income Tax Expense                          |                |                |                |
| Net Income (Loss)                           | \$ (5,501,238) | \$ (7,864,057) | \$ (3,718,895) |
| Basic And Diluted Earnings (Loss) Per Share | \$ (.37)       | \$ (.57)       | \$ (.32)       |

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

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY****For The Years Ended December 31, 2009, 2008 and 2007**

|                                 | Common Shares |               | Purchase Warrants |           | Accumulated     | Total               |
|---------------------------------|---------------|---------------|-------------------|-----------|-----------------|---------------------|
|                                 | Shares        | Amount        | Warrants          | Amount    | Deficit         | Shareholders Equity |
| Balance as of December 31, 2006 | 11,500,349    | \$ 23,147,709 | -0-               | -0-       | \$ (14,773,596) | \$ 8,374,113        |
| Issuance of Common Shares       | 2,314,837     | 10,209,459    |                   |           |                 | 10,209,459          |
| Issuance of Purchase Warrants   |               |               | 1,204,169         | 3,038,411 |                 | 3,038,411           |
| Stock Option Based Expense      |               | 57,938        |                   |           |                 | 57,938              |
| Net Loss                        |               |               |                   |           | (3,718,895)     | (3,718,895)         |
| Balance as of December 31, 2007 | 13,815,186    | \$ 33,415,106 | 1,204,169         | 3,038,411 | \$ (18,492,491) | \$ 17,961,026       |
| Issuance of Common Shares       | 289,504       | 268,757       |                   |           |                 | 268,757             |
| Issuance of Purchase Warrants   |               |               | 910,000           | 339,987   |                 | 339,987             |
| Stock Option Based Expense      |               | 1,097,432     |                   |           |                 | 1,097,432           |
| Restricted Stock Amortization   |               | 17,798        |                   |           |                 | 17,798              |
| Net Loss                        |               |               |                   |           | (7,864,057)     | (7,864,057)         |
| Balance as of December 31, 2008 | 14,104,690    | \$ 34,799,093 | 2,114,169         | 3,378,398 | \$ (26,356,548) | \$ 11,820,943       |
| Issuance of Common Shares       | 3,095,752     | 16,796,617    |                   |           |                 | 16,796,617          |
| Issuance of Purchase Warrants   |               |               | 1,204,400         | 4,257,196 |                 | 4,257,196           |
| Stock Option Based Expense      |               | 1,795,246     |                   |           |                 | 1,795,246           |
| Restricted Stock Amortization   |               | 154,438       |                   |           |                 | 154,438             |

|                                       |            |               |           |              |                 |               |
|---------------------------------------|------------|---------------|-----------|--------------|-----------------|---------------|
| Net Loss                              |            |               |           |              | (5,501,238)     | (5,501,238)   |
| Balance as of<br>December 31,<br>2009 | 17,200,442 | \$ 53,545,394 | 3,318,569 | \$ 7,635,594 | \$ (31,857,786) | \$ 29,323,202 |

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

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED STATEMENTS OF CASH FLOWS****For The Years Ended December 31, 2009, 2008 and 2007**

|   | <b>2009</b>    | <b>2008</b>    | <b>2007</b>    |
|---|----------------|----------------|----------------|
| Cash Flows From Operating Activities:                                       |                |                |                |
| Net (Loss)  | \$ (5,501,238) | \$ (7,864,057) | \$ (3,718,895) |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: |                |                |                |
| Depreciation and Amortization   | 1,233,706      | 911,718        | 949,739        |
| Share Based Compensation Non-employee warrants                              | 403,203        | 339,987        | 85,911         |
| Share Based Compensation- Employees   | 1,949,684      | 1,115,231      | 57,938         |
| Loss (Gain) on Disposal of Assets   | 36,415         | (7,534)        | 17,710         |
| Changes in Assets and Liabilities:  |                |                |                |
| (Increase) Decrease in Accounts Receivable                                  | 1,737,034      | (542,427)      | (1,212,827)    |
| (Increase) Decrease in Inventory  | 73,273         | (602,574)      | 101,047        |
| (Increase) Decrease in Other Assets   | 68,131         | (133,412)      | (39,142)       |
| Increase (Decrease)in Accounts Payable                                      | (1,822,215)    | 2,228,073      | 62,641         |
| Increase in Other Liabilities   | 395,248        | 286,497        | 297,267        |
| Changes in Assets and Liabilities   | 451,471        | 1,236,157      | (791,014)      |
| Cash (Used) In Operating Activities   | (1,426,759)    | (4,268,498)    | (3,398,611)    |
| Cash Flows From Investing Activities:                                       |                |                |                |
| Purchase of Equipment   | (1,595,999)    | (1,268,498)    | (924,608)      |
| Proceeds on Sale of Assets  |                | 9,555          |                |
| Purchase of Intangible Assets   | (4,949)        | (903)          | (8,189)        |
| Cash (Used ) In Investing Activities  | (1,600,948)    | (1,259,846)    | (932,797)      |
| Cash Flows From Financing Activities:                                       |                |                |                |
| Proceeds From Borrowings on Line of Credit                                  |                |                | 1,800,000      |
| Payments on Line of Credit  |                |                | (1,800,000)    |
| Proceeds from Issuance of Common Shares and Purchase Warrants               | 20,650,610     | 232,140        | 13,161,959     |
| Payments on Notes Payable and Capital Lease Obligations                     | (181,453)      | (204,243)      | (396,332)      |
| Cash Provided By Financing Activities                                       | 20,469,157     | 27,897         | 12,765,627     |
| Increase (Decrease) In Cash   | 17,441,450     | (5,500,447)    | 8,434,219      |
| Cash At Beginning Of Period   | 5,596,645      | 11,097,092     | 2,662,873      |
| Cash At End Of Period   | \$ 23,038,095  | \$ 5,596,645   | \$ 11,097,092  |

Supplemental Cash Flow disclosure



|  | <b>2009</b> | <b>2008</b> | <b>2007</b> |
|--|-------------|-------------|-------------|
| Interest Paid                                      | \$ 25,179   | \$ 52,361   | \$ 159,444  |
| Non-Cash Investing and Financing Activity          |             |             |             |
| Equipment Acquired Under Capital Lease Obligations | \$ 25,400   | \$ 23,220   | \$ 99,812   |

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

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**ROCKWELL MEDICAL TECHNOLOGIES, 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 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, 2009 and 2008 we had customer deposits of \$250,915 and \$245,186, 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, unrestricted certificates of deposit and short term marketable securities with an original maturity of 90 days or less as cash and cash equivalents.

***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

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**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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, 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. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****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 \$6,454,000, \$3,830,000 and \$3,264,000 in 2009, 2008 and 2007, 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 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 antidilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

|   | <b>2009</b> | <b>2008</b> | <b>2007</b> |
|---|-------------|-------------|-------------|
| Basic Weighted Average Shares Outstanding   | 14,709,016  | 13,836,435  | 11,771,381  |
| Effect of Dilutive Securities               | -0-         | -0-         | -0-         |
| Diluted Weighted Average Shares Outstanding | 14,709,016  | 13,836,435  | 11,771,381  |

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For 2009, 2008 and 2007, 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.

At December 31, 2009, potentially dilutive securities comprised 4,441,500 stock options exercisable at prices from \$.55 to \$8.35 , 3,318,569 common share purchase warrants exercisable at prices ranging from \$1.99 to \$10.00 and 150,000 restricted common shares.

At December, 31, 2008, potentially dilutive securities comprised 4,063,031 stock options exercisable at prices from \$.55 to \$6.50 , 2,114,169 common share purchase warrants exercisable at prices ranging from \$1.99 to \$10.00 and 150,000 restricted common shares.

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**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December, 31, 2007, potentially dilutive securities comprised 3,807,035 stock options exercisable at prices from \$.55 to \$6.50 and 1,204,169 common share purchase warrants exercisable at prices ranging from \$7.00 to \$10.00.

***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***

On January 1, 2008, we adopted the methods of fair value as described in ASC 820-10, *Fair Value Measurements and Disclosures* to value our financial assets and liabilities. In order to increase consistency and comparability in fair value measurements, ASC 820-10 establishes a fair value 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 cash and cash equivalents using Level 1 inputs in the fair value hierarchy as these short term investments are immediately available at our direction and without market risk to principal. We do not have other financial assets that would be characterized as Level 2 or Level 3 assets.

ASC 820-10 was effective for non-financial assets and liabilities for the year beginning January 1, 2009. There was no impact on our consolidated financial statements as a result of adopting fair value measurements for non-financial assets and liabilities for the year ended December 31, 2009.

We chose not to elect the fair value option as prescribed by ASC 820-10 for our financial assets and liabilities that had not been previously carried at fair value. Therefore, material financial assets and liabilities not carried at fair value, such as our trade accounts receivable and payable are still reported at their face values.

***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.



***Reclassifications***

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

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. 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, 2009, 2008 and 2007, one customer, DaVita, Inc., accounted for 50%, 51% and 52% of our sales, respectively. Our accounts receivable from this customer were \$1,267,500 and \$2,620,000 as of December 31, 2009 and 2008, respectively. We are dependent on this key customer and the loss of its business would have a material adverse effect on our business, financial condition and results of operations. No other customers accounted for more than 10% of our sales.

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

**4. Inventory**

Components of inventory as of December 31, 2009 and 2008 are as follows:

|                 | <b>2009</b>  | <b>2008</b>  |
|-----------------|--------------|--------------|
| Raw Materials   | \$ 1,051,781 | \$ 1,316,875 |
| Work in Process | 196,603      | 291,937      |
| Finished Goods  | 1,839,968    | 1,552,813    |
| Total           | \$ 3,088,352 | \$ 3,161,625 |

**5. Property and Equipment**

Major classes of property and equipment, stated at cost, as of December 31, 2009 and 2008 are as follows:

|   | <b>2009</b> | <b>2008</b> |
|---|-------------|-------------|
| Leasehold Improvements                    | \$ 380,497  | \$ 279,382  |
| Machinery and Equipment                   | 5,283,703   | 4,605,251   |
| Information Technology & Office Equipment | 1,750,485   | 1,433,830   |
| Laboratory Equipment                      | 522,270     | 365,515     |
| Transportation Equipment                  | 425,020     | 407,802     |

|                            |                          |                          |
|----------------------------|--------------------------|--------------------------|
| Accumulated Depreciation   | 8,361,975<br>(4,730,426) | 7,091,780<br>(3,842,777) |
| Net Property and Equipment | \$ 3,631,549             | \$ 3,249,003             |

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

|  | <b>2009</b> | <b>2008</b> |
|--|-------------|-------------|
| Assets under Capital Lease Obligations                   | \$ 658,028  | \$ 665,454  |
| Net Book Value of Assets under Capital Lease Obligations | 318,350     | 373,013     |

Depreciation expense was \$1,202,438 for 2009, \$881,025 for 2008 and \$754,150 for 2007.

**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Goodwill and Intangible Assets**

Total goodwill was \$920,745 at December 31, 2009 and 2008. We completed our annual impairment tests as of November 30, 2009 and 2008, and determined that no adjustment for impairment of goodwill was required.

We have entered into several global licensing agreements for certain patents covering therapeutic drug compounds and vitamins to be delivered using our dialysate product lines. We intend to seek FDA approval for these products. We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset.

As of December 31, 2009 we had capitalized licensing fees of \$375,387, net of accumulated amortization of \$161,050.

As of December 31, 2008 we had capitalized licensing fees of \$370,438, net of accumulated amortization of \$129,782.

During 2007, we terminated a licensing agreement related to a patent which we determined we would not benefit from. As a result, we determined that the remaining unamortized costs of that licensing agreement of \$146,355 were impaired and expensed this amount which is included in research and product development expenses for 2007 in the consolidated income statement.

Our policy is to amortize licensing fees over the life of the patents pertaining to the licensing agreements. We recognized amortization expense of \$31,268 in 2009, \$30,693 in 2008, and \$49,223 in 2007. Estimated amortization expense for licensing fees for 2010 through 2016 is approximately \$32,000 per year. One of the licensing agreements requires additional payments upon achievement of certain milestones.

**7. Capital Lease Obligations**

We entered into capital lease obligations primarily related to equipment with a fair market value aggregating \$25,400 and \$23,220 for the years ended December 31, 2009 and 2008, respectively. In addition, we have other capital lease obligations related to financing other equipment. These capital lease obligations require even monthly installments through 2012 and interest rates on the leases range from 4% to 10.5%. These obligations under capital leases had outstanding balances of \$62,000 and \$218,053 at December 31, 2009 and 2008, respectively.

Future minimum lease payments under capital lease obligations are:

|   |           |
|---|-----------|
| Year Ending December 31, 2010                       | \$ 45,806 |
| Year Ending December 31, 2011                       | 16,447    |
| Year Ending December 31, 2012                       | 3,536     |
| Total minimum payments on capital lease obligations | 65,789    |
| Interest  | (3,789)   |

|  |           |
|--|-----------|
| Present value of minimum lease payments      | 62,000    |
| Current portion of capital lease obligations | (42,938)  |
| Long-term capital lease obligations          | \$ 19,062 |

## 8. 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 seven years. Lease payments under all operating leases were \$2,191,884, \$2,132,731 and \$1,833,670 for the years ended December 31, 2009, 2008 and 2007, respectively.

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We have long term leases on two buildings that are each approximately 51,000 square feet. Those leases expire in August 2010. We also have a lease on a building that is approximately 57,000 square feet that expires on February 28, 2011.

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

|                               |                     |
|-------------------------------|---------------------|
| Year ending December 31, 2010 | \$ 1,655,687        |
| Year ending December 31, 2011 | 893,133             |
| Year ending December 31, 2012 | 755,008             |
| Year ending December 31, 2013 | 193,410             |
| Year ending December 31, 2014 | 13,602              |
| <b>Total</b>                  | <b>\$ 3,510,840</b> |

**9. Income Taxes**

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

|  | <b>2009</b>    | <b>2008</b>    | <b>2007</b>    |
|--|----------------|----------------|----------------|
| Tax Expense Computed at 34% of Pretax Income                                   | \$ (1,870,000) | \$ (2,674,000) | \$ (1,264,000) |
| Effect of Permanent Differences Principally Related to Non-deductible expenses |                |                |                |
| Effect of Change in Valuation Allowance  | (1,870,000)    | (2,674,000)    | (1,264,000)    |
| <b>Total Income Tax Benefit</b>  | <b>\$ -0-</b>  | <b>\$ -0-</b>  | <b>\$ -0-</b>  |

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

|                                 | <b>December 31,</b> |              |
|---------------------------------|---------------------|--------------|
|                                 | <b>2009</b>         | <b>2008</b>  |
| Deferred tax assets:            |                     |              |
| Net Operating Loss Carryforward | \$ 10,181,000       | \$ 8,542,000 |
| Stock Based Compensation        | 610,000             | 379,000      |
| Accrued Expenses                | 66,000              | 27,000       |
| Inventories                     | 74,000              | 110,000      |
| Accounts Receivable             | 11,000              | 33,000       |

|                              |              |             |
|------------------------------|--------------|-------------|
| Subtotal                     | 10,942,000   | 9,091,000   |
| Deferred Tax Liabilities :   |              |             |
| Tax over Book Depreciation   | 217,000      | 219,000     |
| Goodwill & Intangible Assets | 224,000      | 188,000     |
| Prepaid Expenses             | 20,000       | 26,000      |
| Subtotal                     | 461,000      | 433,000     |
| Subtotal                     | 10,481,000   | 8,658,000   |
| Valuation Allowance          | (10,481,000) | (8,658,000) |
| Net Deferred Tax Asset       | \$ -0-       | \$ -0-      |

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**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately \$29,944,000 that expire between 2012 and 2029 with approximately \$975,000 expiring in 2012 and the remainder expiring between 2018 through 2029.

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, 2009, 2008 and 2007. 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 2009, 2008 and 2007, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2009 and 2008.

Since January 1, 2007, the Company has accounted 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, 2009 and 2008.

**10. Capital Stock**

Our authorized capital stock consists of 40,000,000 common shares, no par value per share, of which 17,200,442 shares were outstanding as of December 31, 2009, 14,104,690 shares were outstanding at December 31, 2008 and 13,815,186 shares were outstanding at December 31, 2007; 2,000,000 preferred shares, none of which were issued or outstanding at December 31, 2009, 2008 or 2007 and 1,416,664 shares of 8.5% non-voting cumulative redeemable Series A Preferred Shares, \$1.00 par value, of which none were outstanding at December 31, 2009, 2008 or 2007.

During 2009, we also issued 3,095,752 common shares and 1,204,400 common share purchase warrants and realized net cash proceeds of \$20,651,000. This total includes 2,840,000 common shares issued pursuant to a registered direct offering in October 2009 to institutional investors for which we received gross proceeds of \$22,000,000 and net proceeds of \$20,388,000 after deducting investment banking fees, legal, registration, accounting and other expenses related to this offering. This registered direct offering consisted of a unit priced at \$7.75, which included one common share and a warrant to purchase .38 common shares per unit at an exercise price of \$9.55 per share. For financial reporting purposes, the net proceeds were allocated between common stock and warrants on a relative fair value basis.

During 2009, we issued 255,752 common shares from the exercise of 333,198 stock options by employees and realized proceeds of \$262,654. The weighted average exercise price of options exercised was \$2.14.

During 2008, we issued 139,504 common shares as a result of the exercise of stock options by employees and realized proceeds of \$232,140 or \$1.66 per share on average. The Board of Directors approved restricted stock grants totaling 150,000 common shares in 2008.

During 2007, we issued 2,314,837 common shares and 1,079,169 common share purchase warrants and realized net cash proceeds of approximately \$13,200,000. This total includes 2,158,337 common shares issued pursuant to a private offering of our common shares with institutional investors for which we received gross proceeds of \$12,950,000. The private offering consisted of a unit priced at \$6.00, which included one common share and a warrant



to purchase one-half of a common share at an exercise price of \$7.18 per share. We realized net proceeds of \$12,743,000 after deducting legal, registration, accounting and other expenses related to this offering. The shares issued under this stock purchase agreement were later registered for resale and such registration statement was declared effective by the Securities and Exchange Commission on January 29, 2008. We were required to maintain the registration statement effective until either all registered shares were sold or January 29, 2010.

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**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During 2007, we also issued 156,500 common shares as a result of the exercise of stock options by employees and realized proceeds of \$474,828 or \$3.03 per share on average.

***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 3,318,569 common share purchase warrants outstanding at December 31, 2009 of which 1,694,169 were exercisable as of December 31, 2009. During 2009, we issued 1,164,400 warrants pertaining to our registered direct offering, consisting of 1,079,200 warrants exercisable at \$9.55 with a five year term and 85,200 warrants exercisable at \$9.55 with a three year term. In addition, pursuant to an agreement executed in September 2008, 40,000 warrants issued in exchange for services were earned. These warrants have an exercise price of \$6.50 and expire on September 30, 2012.

We had 2,114,169 common share purchase warrants outstanding at December 31, 2008 of which 1,204,169 were exercisable as of December 31, 2008. During 2008, we issued 910,000 warrants, in exchange for services, that will be exercisable after time periods ranging from 1 to 2 years. Exercise prices for these warrants ranged from \$1.99 to \$9.00. Warrants issued in 2008 expire between October 3, 2011 and September 30, 2012.

As of December 31, 2007, we had 1,204,169 common share purchase warrants outstanding all of which were issued in 2007. Pursuant to a Securities Purchase Agreement dated November 28, 2007, we issued 1,079,169 warrants with an exercise price of \$7.18 and a five year term. The warrants are exercisable at any time during the period November 28, 2008 to November 28, 2012. Also, in conjunction with that offering, we issued 80,000 warrants to a placement agent with an exercise price of \$10.00 and that are exercisable until November 28, 2012.

In 2007, we also issued 135,000 warrants in exchange for services which were vested on a monthly basis over a one year period with 90,000 of such warrants exercisable at \$7.00 and 45,000 of such warrants exercisable at \$7.50. The warrants have a four year term expiring October 3, 2011. As of December 31, 2008, 90,000 of the warrants with an exercise price of \$7.00 and 45,000 of the warrants with an exercise price of \$7.50 were earned and vested. As of December 31, 2007, 45,000 of the warrants with an exercise price of \$7.00 were earned and vested.

Warrants were valued using the Black Scholes model. The net proceeds from our 2009 registered direct offering and the private placement of our common shares and common share purchase warrants in 2007 described above were prorated between the fair market value of our common shares issued and the Black Scholes valuation of the warrants. In 2009, 2008 and 2007 we recognized \$403,000, \$340,000 and \$86,000 in expense related to services provided in exchange for warrants. At December 31, 2009, the amount of unrecorded expense for services in exchange for warrants attributable to future periods was approximately \$487,000 which is expected to be amortized to expense on a straight line basis over the remaining service period in 2010.



**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Outstanding warrants by exercise price consisted of the following as of December 31, 2009, 2008 and 2007:

| <b>Exercise Price</b> | <b>Expiration Date</b> | <b>2009</b> | <b>2008</b> | <b>2007</b> |
|-----------------------|------------------------|-------------|-------------|-------------|
| \$9.55                | 10/5/2014              | 1,079,200   |             |             |
| \$7.18                | 11/28/2012             | 1,079,169   | 1,079,169   | 1,079,169   |
| \$1.99                | 11/5/2011              | 300,000     | 300,000     |             |
| \$4.54                | 11/5/2011              | 200,000     | 200,000     |             |
| \$7.00                | 11/5/2011              | 200,000     | 200,000     |             |
| \$9.00                | 5/28/2012              | 100,000     | 100,000     |             |
| \$7.00                | 10/3/2011              | 90,000      | 90,000      | 45,000      |
| \$9.55                | 10/5/2012              | 85,200      |             |             |
| \$10.00               | 11/28/2012             | 80,000      | 80,000      | 80,000      |
| \$7.50                | 10/3/2011              | 45,000      | 45,000      |             |
| \$6.50                | 9/30/2012              | 60,000      | 20,000      |             |
| Total                 |                        | 3,318,569   | 2,114,169   | 1,204,169   |

**11. Long Term Incentive Plan & Stock Options*****Long Term Incentive Plan & Stock Options***

The Board of Directors adopted the Rockwell Medical Technologies, 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 and May 21, 2009. There are 2,500,000 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 2009, 2008 and 2007 and restricted stock grants during 2008 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.

We granted 150,000 restricted shares under the LTIP in 2008. Restricted stock was granted with half of the shares vesting after 18 months from the grant date and the remainder vesting after 36 months from the grant date with vesting conditioned upon continued employment with the Company. These restricted stock grants were valued at the market

price on the date of grant. For the years ended December 31, 2009 and 2008, we recognized \$154,438 and \$17,800 in compensation expense for restricted stock awards. The amount of unrecorded stock-based compensation expense for restricted stock awards attributable to future periods was approximately \$291,263 as of December 31, 2009.

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.

**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In 2009, 2008 and 2007, the Company received cash proceeds of \$262,654, \$232,140 and \$474,828, respectively, in exchange for shares issued upon the exercise of options during the year. No income tax benefits were recognized during 2009, 2008 and 2007 related to stock option activity as the Company has a full valuation allowance recorded against its deferred tax assets.

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

|                                  | Shares    | Weighted<br>Average<br>Exercise<br>Price | Aggregate<br>Intrinsic<br>Value |
|----------------------------------|-----------|--|---------------------------------|
| Outstanding at December 31, 2006 | 3,219,235 | 2.68                                     | \$ 14,313,218                   |
| Granted                          | 785,000   | 6.43                                     |                                 |
| Exercised                        | (156,500) | 3.03                                     | \$ 342,853                      |
| Forfeited                        | (40,700)  | 5.26                                     |                                 |
| Outstanding at December 31, 2007 | 3,807,035 | 3.42                                     | \$ 14,034,941                   |
| Granted                          | 495,000   | 3.75                                     |                                 |
| Exercised                        | (139,504) | 1.66                                     | \$ 308,740                      |
| Forfeited                        | (99,500)  | 6.16                                     |                                 |
| Outstanding at December 31, 2008 | 4,063,031 | 3.44                                     | \$ 4,557,158                    |
| Granted                          | 805,000   | 6.22                                     |                                 |
| Exercised                        | (333,198) | 2.14                                     | \$ 1,037,689                    |
| Forfeited                        | (93,333)  | 5.13                                     |                                 |
| Outstanding at December 31, 2009 | 4,441,500 | 3.95                                     | \$ 16,604,310                   |

| Range of<br>Exercise Prices | Options Outstanding  |                                  | Weighted<br>Exercise<br>Price | Options Exercisable     |  |
|-----------------------------|----------------------|----------------------------------|-------------------------------|-------------------------|--|
|                             | Number of<br>Options | Remaining<br>Contractual<br>Life |                               | Number<br>of<br>Options | Weighted<br>Average<br>Exercise<br>Price |
| \$ .55 to \$1.50            | 508,000              | 1.0-3.0 yrs.                     | \$ 0.64                       | 508,000                 | \$ 0.64                                  |
| \$1.81to \$2.79             | 1,011,500            | 1.0-5.5 yrs.                     | \$ 2.30                       | 1,011,500               | \$ 2.30                                  |
| \$2.98 to \$4.55            | 1,512,000            | 3.8-9.2 yrs.                     | \$ 3.91                       | 1,168,667               | \$ 4.15                                  |
| \$4.93 to \$8.35            | 1,410,000            | 7.8-9.7 yrs.                     | \$ 6.38                       | 448,333                 | \$ 6.46                                  |
| Total                       | 4,441,500            | 6.2 yrs.                         | \$ 3.95                       | 3,136,500               | \$ 3.32                                  |

|                 |               |               |
|-----------------|---------------|---------------|
| Intrinsic Value | \$ 16,604,310 | \$ 13,717,093 |
|-----------------|---------------|---------------|

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

|                         | <b>Number of<br/>Unvested<br/>Options</b> | <b>Weighted<br/>Average<br/>Fair Market<br/>Value at<br/>Grant Date</b> |
|-------------------------|---|---|
| As of December 31, 2006 |   |   |
| Granted                 | 785,000                                   | \$ 4.37   |
| Forfeited               | (30,000)                                  |   |
| Vested                  |   |   |
| As of December 31, 2007 | 755,000                                   |   |
| Granted                 | 495,000                                   | \$ 2.33   |
| Forfeited               | (85,000)                                  |   |
| Vested                  | (223,333)                                 |   |
| As of December 31, 2008 | 941,667                                   |   |
| Granted                 | 805,000                                   | \$ 6.22   |
| Forfeited               | (93,333)                                  |   |
| Vested                  | (348,334)                                 |   |
| As of December 31, 2009 | 1,305,000                                 |   |

The per share weighted average fair market values at the date of grant for options granted to employees during the year ended December 31, 2009 was \$6.22. The fair market values of stock options granted during the year ended December 31, 2009 was determined using the Black Scholes option pricing model using the following assumptions: dividend yield of 0.0%, risk free interest rates of 2.1-3.2%, volatility of 65-66% and expected lives of 6 years. The per share weighted average fair market values at the date of grant for options granted to employees during the year ended December 31, 2008 was \$2.33. The fair market values of stock options granted during the year ended December 31, 2008 was determined using the Black Scholes option pricing model using the following assumptions: dividend yield of 0.0%, risk free interest rates of 2.4-3.4%, volatility of 67-73% and expected lives of 6 years. The per share weighted average fair market values at the date of grant for options granted to employees during the year ended December 31, 2007 was \$4.37. The fair market values of stock options granted during the year ended December 31, 2007 was determined using the Black Scholes option pricing model using the following assumptions: dividend yield of 0.0%, risk free interest rates of 3.7-4.3%, volatility of 75% and expected lives of 6 years.

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 year ended December 31, 2009, we recognized compensation expense of \$1,795,246 related to options granted to employees under the LTIP with a corresponding credit to common stock. At December 31, 2009, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately \$3,955,000 which is expected to be amortized to expense on a straight line basis over the remaining three year vesting period of the options.

For the year ended December 31, 2008, we recognized compensation expense of \$1,097,431 related to options granted to employees under the LTIP with a corresponding credit to common stock. At December 31, 2008, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately \$2,935,000.

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For the year ended December 31, 2007, we recognized compensation expense of \$57,938 related to options granted to employees in 2007 with a corresponding credit to common stock. At December 31, 2007, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately \$3,253,000.

As of December 31, 2009, the remaining number of common shares available for equity awards under the LTIP was 473,333.

**12. Quarterly Results of Operations**

The following is a summary of the quarterly results of operations for the years ended December 31, 2009 and 2008.

|   | <b>First Quarter</b> | <b>Second Quarter</b> | <b>Third Quarter</b> | <b>Fourth Quarter</b> |
|---|----------------------|-----------------------|----------------------|-----------------------|
| <b>2009</b>                                 |                      |                       |                      |                       |
| Sales                                       | \$ 12,796,772        | \$ 13,013,012         | \$ 14,158,234        | \$ 14,761,487         |
| Cost of Sales                               | 11,603,825           | 11,153,086            | 11,751,499           | 12,333,924            |
| Gross Profit                                | 1,192,947            | 1,859,926             | 2,406,735            | 2,427,563             |
| Selling, General and Administrative         | 1,560,815            | 1,570,688             | 1,946,570            | 1,836,125             |
| Research and Product Development            | 1,338,310            | 1,996,571             | 1,977,618            | 1,141,853             |
| Operating Income (Loss)                     | (1,706,178)          | (1,707,333)           | (1,517,453)          | (550,415)             |
| Interest (Income) Expense, net              | 9,265                | 7,238                 | 3,990                | (634)                 |
| Income (Loss) Before Income Taxes           | (1,715,443)          | (1,714,571)           | (1,521,443)          | (549,781)             |
| Income Tax Expense                          |                      |                       |                      |                       |
| Net Income (Loss)                           | \$ (1,715,443)       | \$ (1,714,571)        | \$ (1,521,443)       | \$ (549,781)          |
| Basic And Diluted Earnings (Loss) Per Share | \$ (.12)             | \$ (.12)              | \$ (.11)             | \$ (.03)              |
|   | <b>First Quarter</b> | <b>Second Quarter</b> | <b>Third Quarter</b> | <b>Fourth Quarter</b> |
| <b>2008</b>                                 |                      |                       |                      |                       |
| Sales                                       | \$ 12,412,037        | \$ 12,182,336         | \$ 13,533,986        | \$ 13,537,674         |
| Cost of Sales*                              | 11,694,736           | 11,210,558            | 12,893,377           | 13,360,807            |
| Gross Profit*                               | 717,301              | 971,778               | 640,609              | 176,867               |
| Selling, General and Administrative         | 1,289,752            | 1,319,735             | 2,176,188            | 1,975,942             |

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|   |                |                |                |                |
|---|----------------|----------------|----------------|----------------|
| Research and Product Development            | 782,713        | 781,743        | 993,262        | 1,272,416      |
| Operating Income (Loss)                     | (1,355,164)    | (1,129,700)    | (2,528,841)    | (3,071,491)    |
| Interest (Income) Expense, net              | (144,991)      | (19,696)       | (17,795)       | (38,657)       |
| Income (Loss) Before Income Taxes           | (1,210,173)    | (1,110,004)    | (2,511,046)    | (3,032,834)    |
| Income Tax Expense                          |                |                |                |                |
| Net Income (Loss)                           | \$ (1,210,173) | \$ (1,110,004) | \$ (2,511,046) | \$ (3,032,834) |
| Basic And Diluted Earnings (Loss) Per Share | \$ (.09)       | \$ (.08)       | \$ (.18)       | \$ (.22)       |

\* The Company has reclassified certain expenses from Selling, General and Administrative Expense to Cost of Sales in the 2008 consolidated income statement to conform with the current year presentation. The amounts reclassified by quarter were \$140,000, \$120,000, \$138,000 and \$112,000 in the first through fourth quarter, respectively.

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**Table of Contents****SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

|   | <b>Balance at<br/>Beginning<br/>of Period</b> | <b>Additions</b> | <b>(Deductions)</b> | <b>Balance<br/>at End<br/>of Period</b> |
|---|---|------------------|---------------------|---|
| Allowance for Doubtful Accounts:        |   |                  |                     |   |
| Year ended December 31, 2009            | \$ 96,751                                     | \$ 9,840         | \$ (75,120)         | \$ 31,472                               |
| Year ended December 31, 2008            | \$ 69,073                                     | \$ 28,213        | \$ (535)            | \$ 96,751                               |
| Year ended December 31, 2007            | \$ 72,502                                     | \$ 36,664        | \$ (40,093)         | \$ 69,073                               |
| Inventory Reserve:                      |   |                  |                     |   |
| Year ended December 31, 2009            | \$ 98,345                                     | \$ 27,169        | \$ (93,059)         | \$ 32,455                               |
| Year ended December 31, 2008            | \$ 132,209                                    | \$ 93,497        | \$ (127,361)        | \$ 98,345                               |
| Year ended December 31, 2007            | \$ 78,698                                     | \$ 74,126        | \$ (20,615)         | \$ 132,209                              |
| Deferred Tax Asset Valuation Allowance: |   |                  |                     |   |
| Year ended December 31, 2009            | \$ 8,658,000                                  | \$ 1,823,000     |                     | \$ 10,481,000                           |
| Year ended December 31, 2008            | \$ 5,713,000                                  | \$ 2,945,000     |                     | \$ 8,658,000                            |
| Year ended December 31, 2007            | \$ 4,071,000                                  | \$ 1,642,000     |                     | \$ 5,713,000                            |

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

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