

ROCKWELL MEDICAL TECHNOLOGIES INC

Form 10-K

March 16, 2009

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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, 2008**
- 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

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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 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 voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2008 was \$90,884,500. 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.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 14,132,712 common shares outstanding as of February 28, 2009.

### Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2009 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 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

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intravenous (IV) iron products, the market size in the United States for IV iron therapy for all indications is approximately \$500,000,000 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.

## **How Hemodialysis Works**

Hemodialysis patients generally receive their treatments at independent hemodialysis clinics or at hospitals. A hemodialysis provider such as a hospital or a free standing clinic uses a dialysis station to treat patients. A dialysis station contains a dialysis machine that takes concentrate solutions primarily consisting of nutrients and minerals, such as our liquid concentrate solutions or our concentrate powders mixed with purified water, and accurately dilutes those solutions with purified water. The resulting solution, known as dialysate, is then pumped through a device known as a dialyzer (artificial kidney), while at the same time the patient's blood is pumped through a semi-permeable membrane within the dialyzer. Excess water and chemicals from the patient's blood pass through the membrane and are carried away in the dialysate while certain nutrients and minerals in the dialysate penetrate the membrane and enter the patient's blood to maintain proper blood chemistry. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and acetic acid. 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 regional and national for profit dialysis chains. We estimate that there are approximately 5,000 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 the U.S. Renal Data Systems (USRDS), 345,000 patients in the United States were receiving dialysis treatments at the end of 2006. The domestic dialysis industry has experienced steady patient population growth over the last two decades. In the last five years, the patient growth rate has averaged 4% per year. Population segments with the highest incidence of ESRD are also among the fastest growing within the U.S. population including the elderly, Hispanic and African-American population segments. Recent U.S. demographic projections indicate that the incidence of ESRD is expected to increase in the years ahead and is expected to exceed current incidence levels.

ESRD incidence rates vary by country with some higher and some 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 Strategy**

Our strategy is to develop our dialysis concentrate and supply business and to develop drugs, nutrients and vitamins to be delivered by our dialysis concentrate products. Our long term objectives are to increase our market share, expand our product line, expand our geographical selling territory and improve our profitability by implementing the following strategies:

increasing our revenues through new innovative products, such as our Dri-Sate® Dry Acid Concentrate Mixing System and SteriLyte® Liquid Bicarbonate Concentrate,

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gaining FDA approval to market innovative products such as iron supplemented dialysate,

acting as a single source supplier to our customers for the concentrates, chemicals and supplies necessary to support a hemodialysis provider's operation,

offering our customers a higher level of delivery and customer service by using our own delivery vehicles and drivers, and

expanding our market share in target regions, including regions where our proximity to customers will provide us with a competitive cost advantage and allow us to provide superior customer service levels.

## **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 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***

In June of 1998, we obtained 510(k) clearance from the FDA to market Dri-Sate Dry Acid Concentrate & Mixing System. This product line enhanced our previous liquid acid concentrate product offerings. Since its introduction, our dry acid concentrate product line has been a significant catalyst behind our growth. See [Government Regulation](#) for a discussion of 510(k) clearance and other applicable governmental regulation.

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, the freight costs to us are lower for Dri-Sate Dry Acid Concentrate than for acid concentrate in the liquid form. We can also realize greater productivity from our truck fleet resources delivering dry products.

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

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

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



In June of 1997, we obtained 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.

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### ***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 a product that we believe 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. The most commonly used ESA is Epogen, or EPO. 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 onto 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 administration savings due to decreased nursing time for administration and elimination of supplies necessary to administer IV iron compounds.

We plan to conduct the testing required to obtain FDA approval to market SFP in the United States. We are currently conducting human clinical trials of SFP. A Phase II 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 are currently conducting a second Phase II study with the primary objective to determine the optimal dosage to test in our pivotal studies. It is our intention to commence Phase III clinical trials after the FDA approves our Phase III protocol and following successful completion of our dose ranging study.

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### **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 Fresenius Medical Care, Inc. ( Fresenius ) which is primarily in the business of operating dialysis clinics. Fresenius is also vertically integrated and manufactures a broad range of dialysis products. They produce and sell a more comprehensive line of dialysis equipment, supplies and services than we sell.

Fresenius treats over 125,000 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. 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 110,000 patients in 1,400 clinics.

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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's primary concentrate marketing strategy is to sell its liquid concentrate products to domestic customers within a 300 mile radius of its facility. We believe Minntech largely uses its own vehicles to deliver its products to its customers.

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 two competitors and is dominated by two second generation IV iron drugs, Venofer<sup>®</sup> and Ferrlecit<sup>®</sup>. Venofer<sup>®</sup> is the global market leader for IV iron therapy. Venofer<sup>®</sup> is owned by Switzerland-based Galenica. Galenica has also developed a new product, Ferinject<sup>®</sup>, for which it is seeking FDA approval. In the U.S. and Canada, Galenica exclusively licenses Venofer<sup>®</sup> and Injectafer<sup>®</sup> (US brand name for Ferinject<sup>®</sup>) to Luitpold Pharmaceuticals, Inc., which has entered into a corresponding sublicense agreement with Fresenius Medical Care to manufacture and distribute Venofer<sup>®</sup> and Injectafer<sup>®</sup> for dialysis to dialysis clinics in the US and Canada. Luitpold continues to sell Venofer<sup>®</sup> in the US and Canada outside the field of dialysis for use in treating chronic kidney disease patients who are not yet on dialysis and patients with acute renal failure in hospitals. Ferinject<sup>®</sup> is a new IV iron product being marketed by Galenica for new parenteral indications beyond hemodialysis.

The other major supplier in the IV iron market is Watson Pharmaceutical, Inc. (Watson). Watson markets a product called Ferrlecit<sup>®</sup> which is an injectable iron supplement made of sodium ferric gluconate complex in sucrose, and also markets a product called IN-FeD<sup>®</sup> which is an injectable iron supplement made of dextran and ferric hydroxide. Watson is a large manufacturer of both generic and branded drugs.

Advanced Magnetics, Inc. is also seeking FDA approval for Ferumoxytol, a parenteral iron product. The New Drug Application for Ferumoxytol is currently under FDA review. We believe that both Ferumoxytol and Ferinject<sup>®</sup> are primarily intended to target the pre-ESRD markets and other indications such as oncology but if approved by the FDA 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 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 agencies. Drugs approved by the FDA might not receive reimbursement from private insurers or government agencies. Even if approved by the FDA, providers of dialysate iron maintenance therapy might not obtain reimbursement from insurers or government agencies. 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 in two parts: the composite rate and separately reimbursed drugs and services. CMS reimbursement practices are changing, which we think may benefit our marketing efforts. CMS will begin implementation of a fully bundled reimbursement rate in 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 to providers. While the precise terms and structure of the reimbursement

procedures under this capitated rate program are not expected to be known until 2010, 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 ESA treatments.

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### **Quality Assurance and Control**

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

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

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

### **Government Regulation**

The testing, manufacture and sale of our hemodialysis concentrates and the ancillary products we distribute are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Under the Federal Food, Drug and Cosmetic Act (the FD&C Act), and FDA regulations, the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and marketing of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution.

We plan to develop and commercialize selected drug candidates by ourselves such as 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. Such clearance generally is granted when submitted information establishes that a proposed device is substantially equivalent in intended use 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 and which has not been significantly changed or modified and for which the

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FDA has not called for pre-market approval ( PMA ) applications, or a device found to be substantially equivalent through the 510(k) process or a device which has been reclassified from Class III to Class II or Class I. 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 PMA application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We have been advised that it usually takes from one to three years to obtain approval after filing the request, and may take substantially longer.

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

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

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

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

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

would be prohibited during the period we do not have such clearances.

In addition to the regulations for medical devices covering our current dialysate products, our new product development efforts will be subject to the regulations pertaining to pharmaceutical products. We have signed a licensing agreement for iron supplemented dialysate to be included in our dialysate products. Water soluble iron supplements when coupled with our dialysate are intended to be used as an iron maintenance therapy for dialysis

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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 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 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 product's efficacy and safety in animal or in vitro models. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may begin 30 days after receipt of the IND by the FDA unless the FDA objects to the commencement of clinical trials.

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

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or an ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or an ANDA in a timely manner. The FDA may deny an NDA or an ANDA if applicable regulatory criteria are not satisfied or it may require additional testing, including pre-clinical, clinical and or product manufacturing tests.

Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA or an ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing

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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.

### ***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. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries which typically do not require additional testing for products that have received FDA approval. However, since medical practice and governmental regulations differ across regions, further testing may be needed to support market introduction in some foreign countries. Some foreign regulatory agencies may require additional studies involving patients located in their countries. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Issues related to import and export can delay product introduction. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

### **Product License Agreements**

We entered into two license agreements with an entity covering drugs and vitamin additives to dialysate. These license agreements cover both issued and pending patents in the United States and abroad. We entered into these license agreements in 2002 and 2006. Both 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 for a combination drug and vitamin supplement to be delivered by dialysate. This product license includes a complex of carnitine and vitamins. In addition to a U.S. patent, patents are pending internationally. 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 iron supplemented dialysate that covers issued patents in the United States, the European Union and Japan and other jurisdictions as well as pending patents in a number of 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. A European patent was issued in 2005.

Our iron supplemented dialysate product license agreement requires us to obtain FDA approval of iron supplemented dialysate. Under the applicable license agreement, we are required to pay the cost of obtaining marketing 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

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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, our iron drug, 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, 2008 and 2007, one customer, DaVita, Inc., accounted for 51% and 52% of our sales, respectively. Our accounts receivable from this customer were \$2,620,000 and \$1,268,000 as of December 31, 2008 and 2007, 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. Our international sales, including products sold to domestic distributors that are delivered internationally, aggregated 10% and 5% of overall sales in 2008 and 2007, respectively.

## **Employees**

As of December 31, 2008, we had approximately 250 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 have licensed an iron maintenance therapy product for the treatment of iron deficiency in anemic dialysis patients which we refer to as SFP. We are required to pay the cost of obtaining FDA approval to market the product 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 commenced a Phase IIb, dose ranging study in late 2007. In 2008, we continued to conduct a Phase IIb clinical trial with the primary objective to determine the drug dosage for our pivotal studies. 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 2008 and 2007, we incurred aggregate expenses related to the commercial development of SFP of approximately \$3.8 million and \$3.3 million, respectively. We expect to complete the Phase IIb study in 2009 and to commence preparation for Phase III clinical studies. We estimate that we will spend approximately \$3.5-\$4.0 million in 2009 on research and development for SFP.

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Upon successful completion of our dose ranging study and subsequent approval by the FDA to commence Phase III studies, we estimate that from 2010 until approval it will cost as much as \$15 million or more to obtain FDA approval to market SFP. In addition to funding 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 as previously described. These costs will have a material impact on us and we expect to incur losses for the duration of the clinical trials. Should our testing and clinical trial expenses exceed our capital resources, we may need to seek additional sources of financing or seek to enter into global development partnerships to obtain FDA approval of our new iron maintenance therapy product. If we are unable to obtain FDA approval of SFP or to make certain milestone payments we may forfeit our rights under our license agreements.

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

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 am to 3 pm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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>. These reports are also available on our website at <http://www.rockwellmed.com>.

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

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.*

## **RISKS RELATED TO OUR BUSINESS**

**The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue. Our business is substantially dependent on one of our customers that accounts for a substantial portion of our sales. The loss of this customer would have a material adverse affect on our results of operations and cash flow.**

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. One customer in particular accounted for 51% of our total sales during 2008. 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.

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**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 be able to raise or obtain 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 it may not be successfully marketed.**

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 improving our gross profit margins and our business may remain unprofitable.**

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. Since 2007, we have experienced dramatic increases in our costs which we have not yet been able to fully recover from our customers through price increases. While we have recently changed certain vendors and realized cost decreases in several of our key cost inputs, we may be subject to future cost increases which may negatively impact our results if we are unable to recover those cost increases. If we are unable to improve our gross profit margins by reducing our costs and increasing our prices, our business may remain unprofitable.

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.

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**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. If Medicare and Medicaid funding were to be materially decreased, our customers would be severely impacted and could be unable to pay us.

**We may not have sufficient cash to fund future growth or SFP development.**

Our research and development plan for SFP is expected to result in significant cash outlays beyond 2009. We expect to spend between \$3.5-\$4.0 million in 2009 on SFP product development and approval. We believe we have adequate cash resources to fund the testing and regulatory approval for SFP in 2009. However, for us to complete our Phase III clinical development plan we will need to obtain additional funding. SFP development costs for Phase III and to obtain FDA approval are projected from 2010 until approval to be \$15 million or more. Also, if our current clinical trial efforts do not achieve acceptable results, we may have to do more testing and, depending on the scope and duration of any additional testing, our available cash resources may not be sufficient to fund that additional testing.

We are likely to require additional capital in 2010. If conditions in the credit and equity markets do not improve during 2009, we may be unable to obtain the financing we will need in future years on terms we deem acceptable or in the best interests of our Company and our shareholders, or such financing may not be available to us at all. If such financing is not available, we may have to take action to conserve capital, such as alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources.

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

Our revenue from international distributors may not recur consistently or may not recur at all. Such revenue is often dependent upon government funding in those nations and there may be local, regional or geopolitical changes that may 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, 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. 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 or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

**Our business is highly regulated.**

The testing, manufacture and sale of the products we manufacture and distribute are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before medical devices can be commercially marketed in the United States, the FDA must give either 510(k) clearance or pre-market approval for the devices. If we do not comply with these requirements, we may be subject to a variety of sanctions, including fines, injunctions, seizure of products, suspension of production, denial of future regulatory approvals, withdrawal of existing regulatory approvals and criminal prosecution. Our business could be adversely affected by any of these actions.

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding

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manufacturing quality. In addition, our new products will be subject to review as a pharmaceutical drug by the FDA. 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. 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.

**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.

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**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, 2008 an additional 1,204,169 shares may be issued upon exercise of outstanding warrants. In addition, as of December 31, 2008, there were an additional 955,000 warrants that become exercisable over the next two years. In the future, we may issue additional shares or warrants in connection with investments, repayment of our debt 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, 2008, there were 3,121,364 shares issuable upon the exercise of outstanding and exercisable stock options, 941,667 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 435,000 additional shares available for grant under our 2007 Long Term Incentive Plan. Additional grants were made in 2009. 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. Further, while the options are outstanding, we may be unable to obtain additional financing on favorable terms.

**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, 2008, our officers and directors beneficially owned approximately 23.2% of our voting shares (assuming the exercise of exercisable options granted to such officers and directors). Accordingly, they may 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, takeovers and control share acquisitions 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.

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**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 cash resources, if any, 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 which we have an option to renew. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in August 2010. 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 adverse effect on our financial condition and results of operations.

**Item 4. *Submission of Matters to a Vote of Security Holders.***

We did not submit any matter to a vote of security holders during the fourth quarter of 2008.

**PART II**

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

In January 2007, our shares began trading on the Nasdaq Global Market under the trading symbol **RMTI** and previously traded on the Nasdaq Capital Market.

The prices below are the high and low sale prices as reported by the Nasdaq Global Market in each quarter during 2007 and 2008.

<b>Quarter Ended</b>	<b>Sale Price</b>	
	<b>High</b>	<b>Low</b>

March 31, 2007	8.10	5.46
June 30, 2007	7.20	5.07
September 30, 2007	6.30	4.33
December 31, 2007	7.99	5.54
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

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As of February 28, 2009, there were 39 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.

### **Recent Sales of Unregistered Securities**

On November 21, 2008, we entered into an amendment to the advisory agreement dated November 5, 2008 with Emerald Asset Advisors, LLC, or Emerald, pursuant to which we issued warrants to purchase an additional 400,000 shares of our common stock in a private placement exempt from registration under Section 4(2) of the Securities Act. The amendment extended the term of the original agreement and the additional warrants were issued as compensation for additional services to be rendered over a 24 month period under the agreement, as amended, including introducing the Company to potential licensing partners and acquisition candidates and acting as a liaison to the equity investment community. Emerald is a financially sophisticated accredited investor who had access to information relating to the investment, the warrants were sold in a manner not involving general solicitation or advertising and the warrants and underlying shares are subject to customary restrictions on transfer.

All of the warrants were immediately earned. The original warrants to purchase 300,000 shares of our common stock, or the Tranche A Warrants, will become exercisable on November 5, 2009. The Tranche A warrants will expire on the earlier of (i) November 5, 2011, or (ii) the termination of the agreement prior to November 5, 2009 (A) by us due to a material breach of the agreement by Emerald or (B) by Emerald. The Tranche A Warrants have an exercise price of \$1.99 per share. The additional warrants to purchase 200,000 shares of our common stock, or the Tranche B Warrants, 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 Emerald or (B) by Emerald. The Tranche B Warrants have an exercise price of \$4.54 per share. The additional warrants to purchase 200,000 shares of our common stock, or the Tranche C Warrants, will also 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 Emerald or (B) by Emerald. The Tranche C Warrants have an exercise price of \$7.00 per share.

Warrants may be exercised in whole or in part at any time until their expiration by the submission of an exercise notice accompanied by payment of the exercise price in cash or certified check. We have agreed to use reasonable commercial efforts to register, under the Securities Act of 1933, the shares to be issued upon exercise of the warrants. To the extent the shares issuable upon exercise of the warrants are not registered prior to issuance, they will bear a legend restricting transfer.

The terms and conditions of the warrants will be set forth in a separate agreement containing terms and conditions set forth above and such other terms and conditions as are mutually acceptable to us and Emerald.



**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 Operation included in this Form 10-K.

	<b>For the Year Ended December 31,</b>				
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
Net sales	\$ 51,666,033	\$ 43,045,304	\$ 28,638,859	\$ 27,694,955	\$ 17,944,710
Cost of sales	48,649,478	40,015,466	25,837,294	24,689,912	15,139,215
Gross profit	3,016,555	3,029,838	2,801,565	3,005,043	2,805,495
Income from continuing operations before interest expense and income taxes	(8,085,196)	(3,608,353)	(4,637,830)	274,903	409,180
Interest expense, net	(221,139)	110,542	(62,851)	198,095	197,658
Income from continuing operations before income taxes	(7,864,057)	(3,718,895)	(4,574,979)	76,808	211,522
Income taxes					
Net income	(7,864,057)	(3,718,895)	(4,574,979)	76,808	211,522
Earnings per common share:					
Basic	\$ (0.57)	\$ (0.32)	\$ (0.41)	\$ 0.01	\$ 0.02
Diluted	\$ (0.57)	\$ (0.32)	\$ (0.41)	\$ 0.01	\$ 0.02
Weighted average number of common shares and common share equivalents					
Basic	13,836,435	11,771,381	11,189,001	8,674,651	8,546,302
Diluted	13,836,435	11,771,381	11,189,001	9,356,990	9,305,123

	<b>For the Year Ended December 31,</b>				
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
Total assets	\$ 18,959,982	\$ 22,803,134	\$ 13,152,833	\$ 9,260,660	\$ 7,700,552
Current assets	14,428,691	18,645,945	9,058,846	5,380,080	4,241,037
Current liabilities	7,097,836	4,637,271	4,452,675	4,682,139	3,459,555
Working capital	7,330,855	14,008,674	4,606,171	697,941	781,482
Long-term debt	41,203	204,837	326,045	733,723	818,678
Stockholders' equity(1)	11,820,943	17,961,026	8,374,113	3,844,798	3,422,319
Book value per outstanding common share	\$ 0.84	\$ 1.30	\$ 0.37	\$ 0.43	\$ 0.40
Common shares outstanding	14,104,690	13,815,186	11,500,349	8,886,948	8,556,531

(1) There were no cash dividends paid during the periods presented.





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

**Overview and Recent Developments**

We operate in a single business segment, the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the kidney dialysis process. We have gained domestic market share each year since our inception in 1996. In 2008 our sales increased 20% compared to 2007 and our sales in 2007 increased by 50.3% compared to 2006. Our strategy is to continue to develop and expand our dialysis products business while at the same time developing new products, including pharmaceutical products for the renal market.

Our strategy is also to expand the geographic footprint of our business in North America. We realized a unique business opportunity to do so in the last quarter of 2006 and the first quarter of 2007 due to the exit of one of our competitors, Gambro, from the market. Concurrent with Gambro's withdrawal from the concentrate business, we began to service many of the chain and independent clinics previously serviced by Gambro, including many clinics owned by DaVita, the second largest dialysis provider in the United States. As a result, the number of clinics we service increased by over 50% during 2007 and to a lesser extent in 2008.

Largely as a result of these changes, our sales have increased approximately 80% in the last two years with a majority of the growth coming from the increase in the number of clinics we service. At the same time our primary costs for chemicals, packaging materials and fuel increased at unprecedented rates. As a result our gross profit margins decreased significantly as the price increases we implemented were not sufficient to recover ongoing cost increases we incurred throughout 2007 and 2008. While our sales increased significantly, we did not increase our gross profit as the cost of our products and the cost to deliver our products both increased faster than our prices. We plan to continue to increase prices to improve our gross profit. However, it may be difficult to raise prices adequately due to price competition. We typically enter into supply contracts that have a term similar to our contracts with customers to mitigate our exposure to raw material and other cost increases.

The dramatic growth in our business over the past two years has led us to take actions in the second half of 2008 to make necessary investments and improvements in our operations, including an increase in management resources for operations, a substantial investment to improve our quality control systems, the addition of a new enterprise resource planning (ERP) software platform and an upgrade of production operations to add more efficient equipment and processes. Improvements to our operations were necessary to accommodate the substantial demands from the sales increases realized over the past two years.

In late 2008, we began to realize substantial reductions in the costs of key chemicals and packaging supplies and expect the downward trend in fuel costs seen in the fourth quarter of 2008 to continue into 2009. We expect to continue to take actions to improve our gross profit margins, including raising prices. However, while we have supply contracts in place for 2009 for our major raw materials, these costs could rise in 2010 if the economy improves.

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.

While the majority of our business is with domestic clinics who order routinely, certain major distributors of our products internationally have not ordered consistently 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.

We are continuing the FDA approval process for our iron supplemented dialysate product, SFP. We believe our SFP product, which has a unique method of action and other substantive benefits compared to current treatment options, 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 currently expect to spend approximately

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\$3.5-\$4 million in 2009 to complete our Phase IIb clinical trials and other related development costs. Once we complete the Phase II clinical study, we will seek FDA approval to commence a Phase III clinical trial. We anticipate that costs to complete clinical trials and to obtain FDA approval to market SFP from 2010 until such approval may total approximately \$15 million. This amount is substantially higher than our previous estimates due to higher than anticipated study costs and the possibility of additional testing in order to complete the approval process.

## **Results of Operations**

### ***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 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 \$3.0 million, unchanged from 2007. While we realized higher sales in 2008, the impact of cost increases for chemicals, packaging and fuel 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 5.8% in 2008 from 7.0% in 2007. 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.

We expect improvement in our gross profit margins in 2009 as a result of recent cost reductions due to reduced demand for chemicals and fuel. Commodity 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. As a result, we anticipate we may recover at least a portion of the decrease in our gross profit margins.

We have also taken action to raise prices on maturing contracts and pricing arrangements. We anticipate that price increases implemented in late 2008 along with prospective price increases in 2009 will also help to improve our gross profit margins in 2009.

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

Selling, general and administrative, or SG&A, expenses were \$7.3 million or 14.1% of sales in 2008 compared to 7.8% of sales in 2007. SG&A costs increased \$3.9 million in 2008 compared to 2007 and included non-cash charges for equity related compensation of \$1.45 million. 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 \$1.5 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 were obligated

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to comply with the full requirements of Section 404(c) of the Sarbanes-Oxley Act of 2002 for the first time in 2008 and incurred approximately \$0.1 million in additional costs related to compliance with this law.

### *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. Interest income is anticipated to be lower in 2009 due to a lower level of investments as these funds are used in operations, and lower rates of return on invested assets due to the current 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.

## **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

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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 the provisions of SFAS No. 144 *Accounting for the Impairment or Disposal of Long-Lived Assets* or SFAS No. 142 *Goodwill and Other Intangible Assets*, as applicable. An impairment review is performed annually or whenever a change in condition occurs which indicates that the carrying amounts of assets may not be recoverable. Such changes may include changes in our business strategies and plans, changes to our customer contracts, changes to our product lines and changes in our operating practices. We use a variety of factors to assess the realizable value of long-lived assets depending on their nature and use.

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

### *Accounting for income taxes*

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

## **Liquidity and Capital Resources**

We have two major areas of strategic focus in our business. We plan to develop our dialysis products business and to expand our product offering to include drugs and vitamins administered to dialysis patients. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions. Each of these initiatives require investments of substantial amounts of capital.

In November 2007, we raised approximately \$12.75 million in equity capital (net of related expenses) primarily for the purpose of funding the clinical development and FDA approval of SFP. We expect to spend approximately \$3.5-\$4.0 million on SFP development and testing in 2009.

Upon completion of our Phase IIb clinical trial we will seek FDA approval to conduct Phase III clinical trials for SFP. We anticipate that the cost to fund our Phase III clinical trials and to obtain FDA approval to market SFP will cost as much as \$15 million from 2010 until approval. We will evaluate various alternative sources of funding in order to raise additional capital or enter into development arrangements with an international development partner in order to fully execute our strategic plan. In our efforts to obtain additional capital resources, we will evaluate both debt and



equity financing as potential sources of funds. We will also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets as well as other potential funding sources.

Our cash resources include cash generated from our business operations and the remaining proceeds from our November 2007 equity offering. Our current assets exceed our current liabilities by over \$7.3 million as of December 31, 2008 and include \$5.6 million in cash. In 2008, we used \$5.5 million in cash including \$4.3 million in

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operating activities and \$1.3 million in investing activities, primarily capital expenditures. Our cash used in operations was primarily used to fund our research and development expenditures of \$3.8 million, and the remainder was used to fund our core business operations and a litigation settlement.

We project that in 2009 that we will generate positive cash flow from operations, excluding our research and development expenses. We base our projections upon the reductions in material costs that commenced in January 2009 from new supply contracts we have entered into, increased prices to our customers, reduced diesel fuel expenses and actions taken to reduce certain other operating expenses.

We believe our cash resources are sufficient to fund the completion of our Phase IIb clinical trial and prepare for our Phase III clinical trial as well as fund our ordinary course operating cash requirements in 2009. However, if we use more cash than anticipated for SFP development or to fund business operations, or if the assumptions underlying our cash flow projections for 2009 prove to be incorrect, we may need to obtain additional cash sources such as equity financing, debt financing of capital expenditures or a line of credit to supplement our working capital requirements in 2009. Should we not be able to obtain additional financing, we may be forced to alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources. 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.

## **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 December 31, 2008, 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 not effective at the reasonable assurance level as of December 31, 2008 in ensuring that information required to be disclosed by us

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under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the Exchange Act rules and forms due to the material weaknesses described below. As a result, we performed additional analysis and post-closing procedures to ensure that there was not a material misstatement in our consolidated financial statements. Accordingly, management believes the consolidated financial statements included in this Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

### **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 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 assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. 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. Management identified two material weaknesses in the Company's internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. As a result of these material weaknesses, we concluded that the Company's internal control over financial reporting was not effective as of December 31, 2008 based on the criteria in Internal Control – Integrated Framework. These weaknesses did not result in a material misstatement of our financial statements but rather pose the risk that they could result in a material misstatement that may not be prevented or detected on a timely basis.

During 2008, we implemented a new inventory control and enterprise resource planning information system. The two weaknesses we identified pertain to the changes we made in 2008 related to this new information technology platform and operating environment. We determined that we do not have adequate segregation of duties pertaining to access to information technology applications used in our business operations. Management has taken certain steps to reduce this risk and is considering other appropriate changes to reduce this risk in the future balanced against the cost and practicality of those changes.

Management also identified significant deficiencies related to its inventory valuation and reporting procedures which when taken as a whole were considered to be a material weakness. Inventory transaction processing and inventory valuation procedures were not executed as intended and failure to do so was not identified on a timely basis. Failure to follow inventory transaction processing procedures and inventory control procedures could result in a material misstatement of the financial statements. Remedial efforts taken by management were directed at improving controls for more timely monitoring of transaction processing, addition of routine inventory control procedures and increased training on transaction processing procedures.

**This Annual Report on Form 10-K includes an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting.**

### **Changes in Internal Controls**

The Company maintains a system of internal controls that are designed to provide reasonable assurance that its books and records accurately reflect the Company's transactions and that its established policies and procedures are

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followed. 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, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other Information.***

On November 18, 2008, we entered into an amendment with respect to our supply agreement with DaVita, Inc. dated May 5, 2004, pursuant to which we, among other matters, extended the term of the agreement to December 31, 2010 and modified certain pricing and delivery terms. This description of the amendment does not purport to be a complete statement of the provisions thereof. Such description is qualified in its entirety by reference to the amendment, which is attached to this periodic report on Form 10-K as Exhibit 10.31 and is incorporated herein by reference.

**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.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2008:

Plan Category	Number of securities to be	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	issued upon exercise of outstanding options, warrants and rights (a)		(c)

Equity compensation plans approved by security holders	4,063,031	\$	3.44	435,000
Equity compensation plans not approved by security holders				
Total	4,063,031	\$	3.44	435,000

**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.

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**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.***

*(a) Exhibits*

The following documents are filed as part of this report. Those exhibits previously filed and incorporated herein by reference are identified below. 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 incorporated herein by reference to the quarterly report on Form 10-Q filed August 12, 2008.
- 3.2 Amended and Restated Bylaws of the Company, filed as an exhibit to the Company's Current Report on Form 8-K on November 25, 2008 and incorporated herein by reference.
- 4.1 Form of Warrant, filed as an exhibit to the Company's Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
- 4.2 RJ Aubrey Warrant Agreement, dated November 28, 2007, filed as an exhibit to the Company's Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
- \*10.1 Rockwell Medical Technologies, Inc. 1997 Stock Option Plan, incorporated by reference to Rockwell's Proxy Statement for the Annual Meeting of Shareholders filed with the Securities and Exchange Commission on April 17, 2006.
- 10.2 Lease Agreement dated March 12, 2000 between the Company and DFW Trade Center III Limited Partnership, incorporated by reference to the annual report on Form 10-KSB filed March 30, 2000.
- 10.3 Lease Agreement dated October 23, 2000 between the Company and International-Wixom, LLC, incorporated by reference to the annual report on 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), incorporated by reference to the annual report on Form 10-KSB filed April 1, 2002.
- 10.5 Supply Agreement between the Company and DaVita, Inc. dated March 7, 2003 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934), incorporated by reference to the annual report on Form 10-KSB filed March 28, 2003.
- 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), incorporated by reference to the quarterly report on Form 10-QSB filed on May 17, 2004.
- 10.7 Loan and Security Agreement dated as of March 29, 2005 between the Company and Standard Federal Bank National Association, incorporated by reference to the annual report on Form 10-KSB filed March 31, 2005.
- 10.8 Revolving Note dated as of March 29, 2005 executed by the Company for the benefit of Standard Federal Bank National Association, incorporated by reference to the annual report on Form 10-KSB filed March 31, 2005.
- 10.9 Unconditional Guaranty dated as of March 29, 2005 executed by Rockwell Transportation, Inc. for the benefit of Standard Federal Bank National Association, incorporated by reference to the annual report



on Form 10-KSB filed March 31, 2005.

- 10.10 Second Amendment of Industrial Lease Agreement between Rockwell Medical Technologies, Inc. and DCT DFW, LP dated August 17, 2005, incorporated by reference to Exhibit 99.1 on Form 8-K filed on August 19, 2005.

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- 10.11 Amending Agreement made the 16th day of January, 2006, by and between Dr. Ajay Gupta, Charak LLC and Rockwell Medical Technologies, Inc., incorporated by reference to the annual report on Form 10-KSB filed March 31, 2006.
- 10.12 Letter dated March 29, 2006 from LaSalle Bank Midwest National Association to Rockwell Medical Technologies, Inc., incorporated by reference to Exhibit 99.1 to Form 8-K filed with the Securities and Exchange Commission on April 11, 2006.
- 10.13 Securities Purchase Agreement between Rockwell Medical Technologies, Inc. and Emerald Asset Advisors, LLC dated June 22, 2006 incorporated by reference to Exhibit 10.1 on Form 8-K filed with the Securities and Exchange Commission on June 23, 2006.
- 10.14 Registration Rights Agreement between Rockwell Medical Technologies, Inc. and Emerald Asset Advisors, LLC dated June 22, 2006, incorporated by reference to Exhibit 10.2 on Form 8-K filed with the Securities and Exchange Commission on June 23, 2006.
- 10.15 Letter dated March 23, 2007 from LaSalle Bank Midwest National Association to Rockwell Medical Technologies, Inc., incorporated by reference to the Annual Report on Form 10-KSB filed on March 27, 2007.
- \*10.16 Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan, incorporated by reference to the Proxy Statement for the Annual Meeting of Shareholders filed on April 18, 2007.
- 10.17 Consulting Agreement, dated as of October 3, 2007, filed as an exhibit to the Company's Current Report on Form 8-K on October 9, 2007 and incorporated herein by reference.
- 10.18 Common Stock Purchase Agreement dated November 28, 2007, between the Company and certain Purchasers, filed as an exhibit to the Company's Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
- 10.19 Registration Rights Agreement, dated November 28, 2007, between the Company and certain Purchasers, filed as an exhibit to the Company's Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
- \*10.20 Form of Nonqualified Stock Option Agreement (Director Version), filed as an exhibit to the Company's Current Report on Form 8-K on December 20, 2007 and incorporated herein by reference.
- \*10.21 Form of Nonqualified Stock Option Agreement (Employee Version), filed as an exhibit to the Company's Current Report on Form 8-K on December 20, 2007 and incorporated herein by reference.
- 10.22 Lease Agreement dated March 19, 2008 between the Company and EZE Management Properties Limited Partners filed as an exhibit to the Company's Annual Report on Form 10-K filed on March 24, 2008 and incorporated herein by reference.
- \*10.23 Amendment No. 1 to Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan, filed as an exhibit to the Company's Current Report on Form 8-K on May 30, 2008 and incorporated herein by reference.
- 10.24 Advisory Agreement dated May 28, 2008 between the Company and Capitol Securities Management, Inc. filed as an exhibit to the quarterly report on Form 10-Q filed on August 12, 2008 and incorporated herein by reference.
- 10.25 Mutual Release and Settlement Agreement dated September 24, 2008 by and among the Company, FWLL, LLC and ST Holdings, Inc filed as an exhibit to the quarterly report on Form 10-Q filed on November 13, 2008 and incorporated herein by reference.
- 10.26 Advisory Agreement dated September 30, 2008 between the Company and RJ Aubrey IR Services LLC filed as an exhibit to the quarterly report on Form 10-Q filed on November 13, 2008 and incorporated herein by reference.
- 10.27 Advisory Agreement dated November 5, 2008 between the Company and Emerald Asset Advisors, LLC filed as an exhibit to the quarterly report on Form 10-Q filed on November 13, 2008 and incorporated herein by reference.
- \*10.28

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Form of Restricted Stock Award Agreement (Executive Version), filed as an exhibit to the Company's  
Current Report on Form 8-K on November 25, 2008 and incorporated herein by reference.

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- 10.29 Amendment to Advisory Agreement dated November 21, 2008 between the Company and Emerald Asset Advisors, LLC.
- 10.30 Lease Renewal dated August 21, 2008 between the Company and International-Wixom, LLC with respect to the Lease Agreement dated March 12, 2000.
- 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).
- 14.1 Rockwell Medical Technologies, Inc. Code of Ethics, incorporated by reference to the Definitive Proxy Statement for the 2004 Annual Meeting of Shareholders filed April 23, 2004.
- 21.1 List of Subsidiaries, incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on 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 Exchange Act, 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 16, 2009

Pursuant to Section 13 or 15(d) of the Exchange Act, 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  Robert L. Chioini	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2009
/s/ THOMAS E. KLEMA  Thomas E. Klema	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 16, 2009
/s/ KENNETH L. HOLT  Kenneth L. Holt	Director	March 16, 2009
/s/ RONALD D. BOYD  Ronald D. Boyd	Director	March 16, 2009
/s/ PATRICK J. BAGLEY  Patrick J. Bagley	Director	March 16, 2009

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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, 2008 and 2007, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Rockwell Medical Technologies, Inc. and Subsidiary at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

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, 2008, 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 12, 2009 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the effect of two material weaknesses.

/s/ Plante & Moran, PLLC

Auburn Hill, Michigan  
March 12, 2009

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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, 2008, 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 audits 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified material weaknesses in controls related to access rights to its information technology system and inventory tracking and valuation. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2008 financial statements, and this report does not affect our report dated March 12, 2009 on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Rockwell Medical Technologies, Inc. and Subsidiary has not maintained effective internal



control over financial reporting as of December 31, 2008, based on the COSO criteria.

/s/ Plante & Moran, PLLC

Auburn Hill, Michigan

March 12, 2009

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****CONSOLIDATED BALANCE SHEETS****As of December 31, 2008 and December 31, 2007**

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 5,596,645	\$ 11,097,092
Accounts Receivable, net of a reserve of \$97,000 in 2008 and \$69,000 in 2007	5,229,656	4,687,229
Inventory	3,161,625	2,559,051
Other Current Assets	440,765	302,573
<b>Total Current Assets</b>	<b>14,428,691</b>	<b>18,645,945</b>
Property and Equipment, net	3,249,003	2,840,331
Intangible Assets	240,656	270,446
Goodwill	920,745	920,745
Other Non-current Assets	120,887	125,667
<b>Total Assets</b>	<b>\$ 18,959,982</b>	<b>\$ 22,803,134</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Notes Payable & Capitalized Lease Obligations	\$ 176,850	\$ 194,239
Accounts Payable	5,210,972	2,982,899
Accrued Liabilities	1,464,828	1,122,737
Customer Deposits	245,186	337,396
<b>Total Current Liabilities</b>	<b>7,097,836</b>	<b>4,637,271</b>
Long Term Notes Payable & Capitalized Lease Obligations	41,203	204,837
Shareholders' Equity:		
Common Shares, no par value, 14,104,690 and 13,815,186 shares issued and outstanding	34,799,093	33,415,106
Common Share Purchase Warrants, 2,114,169 and 1,204,169 warrants issued and outstanding	3,378,398	3,038,411
Accumulated Deficit	(26,356,548)	(18,492,491)
<b>Total Shareholders' Equity</b>	<b>11,820,943</b>	<b>17,961,026</b>
<b>Total Liabilities And Shareholders' Equity</b>	<b>\$ 18,959,982</b>	<b>\$ 22,803,134</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, 2008 and 2007****(Whole Dollars)**

	<b>2008</b>	<b>2007</b>
Sales	\$ 51,666,033	\$ 43,045,304
Cost of Sales	48,649,478	40,015,466
Gross Profit	3,016,555	3,029,838
Selling, General and Administrative	7,271,617	3,374,458
Research and Product Development	3,830,134	3,263,733
Operating Income (Loss)	(8,085,196)	(3,608,353)
Interest (Income) Expense, net	(221,139)	110,542
Income (Loss) Before Income Taxes	(7,864,057)	(3,718,895)
Income Tax Expense		
Net Income (Loss)	\$ (7,864,057)	\$ (3,718,895)
Basic And Diluted Earnings (Loss) Per Share	\$ (.57)	\$ (.32)

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

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**ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY**

**For The Years Ended December 31, 2008 and 2007**  
**(Whole Dollars)**

	<b>Common Shares</b>		<b>Purchase Warrants</b>		<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Warrants</b>	<b>Amount</b>	<b>Deficit</b>	<b>Shareholders</b>
						<b>Equity</b>
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

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

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

	<b>2008</b>	<b>2007</b>
Cash Flows From Operating Activities:		
Net (Loss)	\$ (7,864,057)	\$ (3,718,895)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	911,718	949,739
Share Based Compensation Non-employee warrants	339,987	85,911
Share Based Compensation Employees	1,115,231	57,938
Loss (Gain) on Disposal of Assets	(7,534)	17,710
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(542,427)	(1,212,827)
(Increase) Decrease in Inventory	(602,574)	101,047
(Increase) in Other Assets	(133,412)	(39,142)
Increase in Accounts Payable	2,228,073	62,641
Increase in Other Liabilities	286,497	297,267
Changes in Assets and Liabilities	1,236,157	(791,014)
Cash (Used) In Operating Activities	(4,268,498)	(3,398,611)
Cash Flows From Investing Activities:		
Purchase of Equipment	(1,268,498)	(924,608)
Proceeds on Sale of Assets	9,555	
Purchase of Intangible Assets	(903)	(8,189)
Cash (Used ) In Investing Activities	(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)
Issuance of Common Shares and Purchase Warrants	232,140	13,161,959
Payments on Notes Payable	(204,243)	(396,332)
Cash Provided By Financing Activities	27,897	12,765,627
Increase (Decrease) In Cash	(5,500,447)	8,434,219
Cash At Beginning Of Period	11,097,092	2,662,873
Cash At End Of Period	\$ 5,596,645	\$ 11,097,092

Supplemental Cash Flow disclosure

**2008****2007**

Interest Paid	\$ 52,361	\$ 159,444
Non-Cash Investing and Financing Activity	Equipment Acquired Under	
Capital Lease Obligations	\$ 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.

***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, 2008 and 2007 we had customer deposits of \$245,186 and \$337,396, 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, unrestricted certificates of deposit and short term marketable securities 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***

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 \$3,830,000 and \$3,264,000 in 2008 and 2007, respectively.

We are conducting human clinical trials on iron supplemented dialysate and we recognize the costs of the human clinical trial 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 Statement of Financial Accounting Standards No. 123R ( SFAS 123R ), a revision to Statement No. 123, Accounting for Stock-Based Compensation. . The cost of equity based compensation is recognized as compensation expense over the vesting period of the awards. We adopted SFAS 123R as of January 1, 2006 using the modified prospective method. Under this method, we began recognizing compensation cost for equity based compensation for all new or modified grants after the date of adoption. All of the Company's options granted in 2005 and prior years were fully vested as of December 31, 2005, and therefore, the Company did not record any expense for options granted prior to 2006 upon adoption of SFAS 123R.

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 SFAS 123R requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, the issuance of new options.

***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:

	2008	2007
Basic Weighted Average Shares Outstanding	13,836,435	11,771,381
Effect of Dilutive Securities	-0-	-0-

Diluted Weighted Average Shares Outstanding	13,836,435	11,771,381
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For 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 both periods.

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.

***Fair Market Value Measurements***

On January 1, 2008, we adopted the methods of fair value as described in SFAS No. 157, Fair Value Measurements ( SFAS 157 ) to value our financial assets and liabilities. In order to increase consistency and comparability in fair value measurements, SFAS 157 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 on 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.

SFAS 157 is effective for non-financial assets and liabilities for the year beginning January 1, 2009. We are currently assessing the impact of this pronouncement as it relates to non-financial assets and liabilities.

We chose not to elect the fair value option as prescribed by SFAS No. 159, The Fair Value Option for Financial Assets and Liabilities Including an Amendment of Financial Accounting Standards Board, or FASB , Statement No. 115 ( SFAS 159 ) 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.

Although we have not elected the fair value option for financial assets and liabilities existing at January 1, 2008 or transacted in 2008, any future transacted financial asset or liability will be evaluated for the fair value election as prescribed by SFAS 159 and valued under the provisions of SFAS 157.

***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.

### **3. Management's Plan of Action**

We have two major areas of strategic focus in our business. We plan to develop our dialysis products business and to expand our product offering to include drugs and vitamins administered to dialysis patients. We expect to expend substantial amounts in support of our clinical development plan and regulatory approval of SFP and its extensions. Each of these initiatives require investments of substantial amounts of capital.

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

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

In November 2007, we raised approximately \$12.75 million in equity capital (net of related expenses) primarily for the purpose of funding the clinical development and FDA approval of SFP. We expect to spend approximately \$3.5-4.0 million on SFP development and testing in 2009.

Upon completion of our Phase IIb clinical trial we will seek FDA approval to conduct Phase III clinical trials for SFP. We anticipate that the cost to fund our Phase III clinical trials and to obtain FDA approval to market SFP will cost as much as \$15 million from 2010 until approval. We will evaluate various alternative sources of funding in order to raise additional capital or enter into development arrangements with an international development partner in order to fully execute our strategic plan. In our efforts to obtain additional capital resources, we will evaluate both debt and equity financing as potential sources of funds. We will also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets as well as other potential funding sources.

Our cash resources include cash generated from our business operations and the remaining proceeds from our November 2007 equity offering. Our current assets exceed our current liabilities by over \$7.3 million as of December 31, 2008 and include \$5.6 million in cash. In 2008, we used \$5.5 million in cash including \$4.3 million in operating activities and \$1.3 million in investing activities, primarily capital expenditures. Our cash used in operations was primarily used to fund our research and development expenditures of \$3.8 million, and the remainder was used to fund our core business operations and a litigation settlement.

We project that in 2009 that we will generate positive cash flow from operations, excluding our research and development expenses. We base our projections upon the reductions in material costs that commenced in January 2009 from new supply contracts we have entered into, increased prices to our customers, reduced diesel fuel expenses and actions taken to reduce certain other operating expenses.

We believe our cash resources are sufficient to fund the completion of our Phase IIb clinical trial and prepare for our Phase III clinical trial as well as fund our ordinary course operating cash requirements in 2009. However, if we use more cash than anticipated for SFP development or to fund business operations, or if the assumptions underlying our cash flow projections for 2009 prove to be incorrect, we may need to obtain additional cash sources such as equity financing, debt financing of capital expenditures or a line of credit to supplement our working capital requirements in 2009. Should we not be able to obtain additional financing, we may be forced to alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources. 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.

**4. Significant Market Segments**

We operate in one market segment which involves the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process to hemodialysis clinics. For the years ended December 31, 2008 and 2007, one customer, DaVita, Inc., accounted for 51% and 52% of our sales, respectively. Our accounts receivable from this customer were \$2,620,000 and \$1,268,000 as of December 31, 2008 and 2007, 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. Our international sales, including products sold to domestic distributors that are delivered internationally, aggregated 10% and 5% of overall sales in 2008 and 2007, respectively.

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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. Inventory**

Components of inventory as of December 31, 2008 and 2007 are as follows:

	<b>2008</b>	<b>2007</b>
Raw Materials	\$ 1,316,875	\$ 1,096,191
Work in Process	291,937	75,167
Finished Goods	1,552,813	1,387,693
Total	\$ 3,161,625	\$ 2,559,051

**6. Property and Equipment**

Major classes of Property and Equipment, stated at cost, as of December 31, 2008 and 2007 are as follows:

	<b>2008</b>	<b>2007</b>
Leasehold Improvements	\$ 279,382	\$ 229,941
Machinery and Equipment	4,605,251	4,333,693
Information Technology & Office Equipment	1,433,830	519,278
Laboratory Equipment	365,515	339,380
Transportation Equipment	407,802	389,477
	7,091,780	5,811,770
Accumulated Depreciation	(3,842,777)	(2,971,439)
Net Property and Equipment	\$ 3,249,003	\$ 2,840,331

Included in the table above are assets under capital lease obligations with a cost of \$655,454 and \$791,276 and a net book value of \$373,013 and \$520,905, as of December 31, 2008 and 2007, respectively.

Depreciation expense was \$881,025 for 2008 and \$754,150 for 2007.

**7. Goodwill and Intangible Assets**

Total goodwill was \$920,745 at December 31, 2008 and 2007. We completed our annual impairment tests as of November 30, 2008 and 2007 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, 2008 we had capitalized licensing fees of \$370,438, net of accumulated amortization of \$129,782.

As of December 31, 2007 we had capitalized licensing fees of \$369,536, net of accumulated amortization of \$99,090. 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 was impaired and expensed this amount which is included in research and product development expenses 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 \$30,693 in 2008, and \$49,223 in 2007. Estimated amortization expense for

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

licensing fees for 2008 through 2016 is approximately \$30,000 per year. One of the licensing agreements requires additional payments upon achievement of certain milestones.

**8. Line of Credit**

The Company's line of credit expired April 1, 2008. The loan agreement provided for revolving borrowings by us of up to \$2,750,000. We were permitted to borrow up to 80% of our eligible accounts receivable and up to 40% of our eligible inventory up to \$600,000. Borrowings under the loan agreement were secured by accounts receivable, inventory and certain other assets. The annual interest rate payable on revolving borrowings under the loan agreement was the lender's prime rate plus 75 basis points. The lender's commitment to make revolving borrowings under the loan agreement expired on April 1, 2008. As of December 31, 2007, we had no outstanding borrowings under this line of credit.

**9. Notes Payable & Capital Lease Obligations*****Notes Payable***

In August 2001, we entered into a financing agreement with a financial institution to fund \$1,000,000 of equipment capital expenditures for our manufacturing facilities. The note payable required monthly payments of principal and interest aggregating \$20,884 through June 2007. The note was paid off in 2007.

***Capital Lease Obligations***

We entered into capital lease obligations primarily related to equipment with a fair market value aggregating \$23,220 and \$99,812 for the years ended December 31, 2008 and 2007, respectively. In addition, we have other capital lease obligations related to financing other equipment. These capital lease obligations require even monthly installments through 2011 and interest rates on the leases range from 5% to 15.0%. These obligations under capital leases had outstanding balances of \$218,053 and \$399,076 at December 31, 2008 and 2007, respectively.

Future minimum lease payments under capital lease obligations are:

Year ending December 31, 2009	\$ 188,783
Year ending December 31, 2010	35,868
Year ending December 31, 2011	6,782
Total minimum payments on capital lease obligations	231,433
Interest	(13,380)
Present value of minimum lease payments	218,053
Current portion of capital lease obligations	(176,850)
Long-term capital lease obligations	\$ 41,203

## **10. 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 \$2,132,731 and \$1,833,670 for the years ended December 31, 2008 and 2007, respectively.

We have long term leases on two buildings that are each approximately 51,000 square feet. Those leases expire in August 2010. As of December 31, 2007, we also had a month to month lease on a building that is approximately 57,000 square feet and for which in 2008 we entered into a long term lease for this space that expires February 28, 2011.

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

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

Year ending December 31, 2009	\$ 1,864,864
Year ending December 31, 2010	1,540,904
Year ending December 31, 2011	786,236
Year ending December 31, 2012	649,737
Year ending December 31, 2013	100,897
Thereafter	4,392
<b>Total</b>	<b>\$ 4,947,030</b>

**11. Income Taxes**

We recognized no income tax expense or benefit for the years ended December 31, 2008 and 2007. We incurred net losses in 2008 and 2007. We have retained a valuation allowance against our net deferred tax assets due to our limited history of taxable income coupled with anticipated future spending on our product development plans which may offset some or all of our income in the next several years.

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

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

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

	<b>2008</b>	<b>2007</b>
Total Deferred Tax Assets	\$ 9,090,000	\$ 6,092,000
Total Deferred Tax Liabilities	(432,000)	(379,000)
Valuation Allowance Recognized for Deferred Tax Assets	(8,658,000)	(5,713,000)
<b>Net Deferred Tax Asset</b>	<b>\$ -0-</b>	<b>\$ -0-</b>

Deferred tax liabilities result primarily from the use of accelerated depreciation for tax reporting purposes. Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately \$25,125,000 that expire between 2012 and 2028.

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. Due to anticipated spending on research and development over the next several years, coupled with our limited history of operating income, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2008 and 2007.

The Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), as of January 1, 2007. FIN 48 clarifies the guidance for the recognition and measurement of income tax benefits related to uncertain tax positions in accordance with SFAS No. 109, Accounting for Income Taxes. The

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

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

impact of this change in accounting was immaterial, and the amount of unrecognized tax benefits related to uncertain tax positions is not significant at December 31, 2008 or December 31, 2007.

**12. Capital Stock**

Our authorized capital stock consists of 40,000,000 common shares, no par value per share, of which 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 either December 31, 2008 or December 31, 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 either December 31, 2008 or December 31, 2007.

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, as noted below, 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 are required to maintain the registration statement effective until all registered shares have been sold or January 29, 2010, whichever occurs first.

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.

***Warrants***

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 at any time during the period November 28, 2008 to November 28, 2012.

We also issued 135,000 warrants in exchange for services which are 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

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

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 issued in 2008 and 2007 were valued using the Black Scholes model. The net proceeds from our 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 2008, we recognized \$340,000 in expense related to services in exchange for warrants. Future expenses related to warrants issued in exchange for services total \$890,000.

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

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

**13. 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 an amendment to the LTIP on May 23, 2008. There are 1,750,000 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 in 2007.

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 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 year ended December 31, 2008, we recognized \$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 \$445,700 as of December 31, 2008.

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

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. In 2008, the Company received cash proceeds of \$232,140 in exchange for shares issued upon exercise of options during the year. In 2007, the Company received cash proceeds of \$474,828 in exchange for shares issued upon exercise of options during the year. No income tax benefits were recognized during 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 excluding options granted to consultants is as follows:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic 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
Cancelled	(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
Cancelled	(99,500)	6.16	
Outstanding at December 31, 2008	4,063,031	3.44	\$ 4,557,158

Range of Exercise Prices	Options Outstanding		Weighted Exercise Price	Options Exercisable	
	Number of Options	Remaining Contractual Life		Number of Options	Weighted Average Exercise Price
\$ .55 to \$1.50	529,763	2.0-4.0 yrs.	\$ .64	529,763	\$ .64
\$1.81 to \$2.79	1,308,268	.1-6.5 yrs.	\$ 2.26	1,308,268	\$ 2.26
\$3.00 to \$4.55	1,455,000	4.7-9.9 yrs.	\$ 3.96	1,060,000	\$ 4.28
\$5.87 to \$6.50	770,000	8.8-9.6 yrs.	\$ 6.40	223,333	\$ 6.45
Total	4,063,031	6.1 yrs.	\$ 3.44	3,121,364	\$ 2.97

Intrinsic Value	\$ 4,991,658	\$ 4,557,158
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**Table of Contents****ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>Number of Unvested Options</b>	<b>Weighted Average Fair Market Value At 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	

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 between 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 SFAS 123R 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 its expected 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, 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 which is expected to be amortized to expense on a straight line basis over the remaining three year vesting period of the options. This estimate is subject to change based upon future events which include, but are not limited to,

changes in estimated forfeiture rates, and the issuance of new options.

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, 2008, the remaining number of common shares available for equity awards under the LTIP was 435,000.

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

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

**14. Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141R (revised 2007), *Business Combinations* ( SFAS141R ). SFAS141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for fiscal years beginning after December 15, 2008, and will be adopted by us in the first quarter of 2009. We do not expect the adoption of SFAS 141R to have a material effect on our consolidated results of operations and financial condition.

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