ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10KSB
March 28, 2007

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U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-KSB

(Mark One)

þ	**ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** **For the fiscal year ended December 31, 2006**
o	**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** **For the transition period from to**

Commission File Number: 000-23-661

ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Name of small business issuer 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
(Issuer s telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:
Common Shares, no par value

Name of each exchange on which registered:
Nasdaq Stock Market

Securities registered under Section 12 (g) of the Exchange Act:
None

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES þ NO o

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. o

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

State issuer s revenues for its most recent fiscal year: $28,638,859

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which our common shares were last sold on March 1, 2007 was $74,635,151. In making this calculation, we have excluded common shares held by our executive officers, directors and other common shareholders with 5% or more of the common shares outstanding at December 31, 2006. Such determination should not be deemed an admission that such officers, directors and beneficial owners are, in fact, affiliates. Determination of common share holdings was determined by reference to public filings, information provided to us by our transfer agent and discussions with certain shareholders.

State the number of shares outstanding of each of the issuer s classes of common equity as of the latest practicable date: 11,500,349 common shares outstanding as of March 1, 2007.

Documents incorporated by reference: Portions of the Registrant s definitive Proxy Statement pertaining to the 2007 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-KSB.

Transitional Small Business Disclosure Format (check one). Yes o No þ

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PART I

Item 1. *Description of Business.*

General

Rockwell Medical Technologies, Inc., incorporated in the state of Michigan in 1996 (the Company, we, us and our) 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.

Dialysis patients also routinely receive pharmaceutical drugs treating several different indications. Among these therapeutic areas, we believe that our dialysis concentrate products can deliver drugs and vitamins for certain of these indications.

We have entered into several licensing agreements covering patents for certain drugs and vitamins to be delivered by our dialysis concentrate products. One such therapeutic area is anemia. Iron supplementation is routinely administered to approximately 90% of patients receiving treatment for anemia. One licensing agreement is for the delivery of iron supplementation for anemic dialysis patients which we refer to as dialysate iron and more specifically as Soluble Ferric Pyrophosphate (SFP). To realize a commercial benefit from this therapy, and pursuant to the licensing agreement, we must complete clinical trials and obtain U.S. Food and Drug Administration (FDA) approval to market iron supplemented dialysate. We also plan to seek foreign market approval for this product. We believe this product will substantially improve iron maintenance therapy and, if approved, will compete for the global market for iron maintenance therapy. Based on reports from manufacturers of intravenous (IV) iron products, the market size in the United States for this iron therapy is over $400,000,000 per year. We estimate the global market is in excess of $750,000,000. 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.

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.

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Dialysis Industry Trends

Hemodialysis providers are generally either independent clinics or hospitals. According to the latest statistics published by the Centers for Medicare and Medicaid Services (CMS), 321,539 patients in the United States were receiving dialysis treatments at the end of 2004 in more than 4,500 clinics. The domestic dialysis industry has experienced steady patient population growth with the patient population increasing between 3-10% each year over the last ten years with a compound annual growth rate of 6%. ESRD is an irreversible deterioration of kidney function. 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. During 2004, more than 82% of new ESRD cases were primarily attributed to either diabetes (42.2%), hypertension (28.1%) or glomerulonephritis (11.7%).

ESRD incidence rates vary by country with some higher and some lower than the United States. Based on industry reports, the global ESRD population undergoing dialysis treatments is estimated to be over 1.5 million and to be growing approximately 5-6% annually. The three major dialysis markets are the United States, the European Union and Japan representing approximately 60% of the 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 and SteriLyte® Liquid Bicarbonate,

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,

increasing our revenues by expanding our ancillary product line,

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 more than 35 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.

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.

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Dri-Sate® Dry Acid Concentrate

In June of 1998, we obtained 510(k) clearance from the FDA to manufacture and market Dri-Sate Dry Acid Concentrate. 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 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 the clinic in liquid form. By using Dri-Sate Dry Acid Concentrate numerous advantages are realized by the clinics 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.

Bicarbonate

Bicarbonate is generally sold in powder form and each clinic generally mixes bicarbonate on site as required. We offer approximately 20 bicarbonate products covering all three series of generally used bicarbonate dilution ratios.

SteriLyte® Liquid Bicarbonate

In June of 1997, we obtained 510(k) clearance from the FDA to manufacture and market SteriLyte Liquid Bicarbonate. Our SteriLyte Liquid Bicarbonate is used in both acute care and chronic care settings. Our SteriLyte Liquid Bicarbonate offers the dialysis community a high-quality product and provides the clinic a safe supply of bicarbonate.

Ancillary Products

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

Iron Supplemented Dialysate

We have licensed the exclusive right to manufacture and sell 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 erythropoetin (Epoetin alfa or EPO). EPO is a 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 EPO 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. EPO 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 EPO 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 EPO therapy also receive iron supplement therapy in order to maintain sufficient iron stores and to achieve the full benefit of EPO treatments.

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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 EPO 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 to achieve superior therapeutic response from EPO 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 are currently in the process of preparing to seek FDA approval of iron supplemented dialysate. A Phase II clinical trial on one of our licensed iron supplemented dialysate products under an Investigational New Drug (IND) exemption was completed by one of our licensors. We plan to conduct the testing required to obtain FDA approval to market SFP in the United States. We began safety and pharmacology testing in accordance with international standards and FDA guidelines in the fourth quarter of 2005 and expect to complete the final two studies in the first half of 2007. In 2007, we intend to perform a dose ranging study. The objectives of a dose ranging study include determination of a maximum tolerated dose, the lowest dose with a measurable therapeutic effect as well as other important safety and efficacy data. We plan to submit a Phase III protocol for FDA review following completion of the results of the dose ranging study. We intend to commence Phase III clinical trials after the FDA approves our Phase III protocol and conditioned upon successful completion of safety and pharmacology testing and dose ranging study.

We estimate the cost to obtain FDA approval from the beginning of 2007 through approval to be between $10-12 million. However, this estimate may be modified as the approval process progresses. We will be 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 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.

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 over 45 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

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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.

Our trucking operations are and will continue to be subject to various state and federal regulations, which if changed or modified, could adversely affect our business, financial condition and results of operations.

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 110,000 dialysis patients in North America and operates in approximately 1,560 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., our largest customer. Gambro operated one manufacturing facility in Florida and additionally used other manufacturers, including a private label manufacturer in the eastern United States to manufacture concentrate. Gambro also imported products from its European manufacturing facilities. Gambro engaged a third party trucking company to deliver its products throughout the United States directly from the point of manufacture and regional public and private warehouse locations. Gambro served the independent clinic market with liquid acid and powder bicarbonate concentrate products used by its brand of dialysis machines as well as those machines manufactured by its competitors in that segment. Gambro does not manufacture a liquid bicarbonate product line.

In October 2005, Gambro completed the sale of its U.S. clinic business to DaVita, Inc. (DaVita), our largest customer, resulting in DaVita having approximately 103,000 patients and 1,450 clinics. Gambro entered into a supply agreement with DaVita for certain dialysis products and supplies. Gambro subsequently supplied all Davita clinics with dialysis concentrates with the exception of those supplied by us. 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.

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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 is presently serviced by two companies. We believe the market leader is Watson Pharmaceutical, Inc. (Watson). Watson markets a product called Ferrlecit® which is an injectable iron supplement made of sodium ferric gluconate complex in sucrose, and also markets a product called IN-FeD® which is an injectable iron supplement made of dextran and ferric hydroxide. Watson is a large manufacturer of both generic and branded drugs. A second competitor in the IV iron market is American Regent Laboratories, Inc which markets Venofer®, an injectable iron sucrose product. Both Watson and American Regent Laboratories, Inc. have substantially greater resources than us. American Regent Laboratories, is a subsidiary of Luitpold, Inc. who has the U.S. marketing rights for Venofer which was developed and is owned by the Galenica Group through its subsidiary, Vifor International, Ltd.

The markets for drug products are highly competitive. New products we are developing will face competition from both conventional forms of iron delivery (i.e., oral and parenteral). In addition we believe that several companies including Galenica are attempting to develop new IV iron drugs. Galenica has commenced clinical studies on another parenteral iron product VIT-45. Advanced Magnetics, Inc. is also developing an IV iron product. Both of these products are undergoing clinical trials. We believe that both of these products are primarily intended to target the pre-ESRD markets and other indications such as oncology but they may compete against our products in the ESRD market as well.

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 has already implemented a change in its reimbursement practices to reclassify the administration portion of drug payments to the composite rate. Currently it reimburses separately for the drug cost and has included the amount paid for drug administration into the composite rate.

We believe that CMS s payment practices may eventually result in a single composite rate per treatment, thereby eliminating reimbursement for individual drugs to providers. We believe that if and when a single reimbursement rate per treatment is implemented by CMS that the provider market may find the potential economic advantages of our iron supplemented dialysate an attractive alternative to IV iron drugs. Providers may be attracted to SFP over IV iron products due to lower cost of administration and due to the potential of improved therapeutic response from EPO 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 FDA Act), and FDA regulations, the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and promotion 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 regulatory review and 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 FDA 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 by the FDA as posing less risk than class III devices are categorized as class I devices (general controls) or class II devices (general and specific controls) and 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 class I or II device already legally on the market or to a pre-amendment class III device (i.e., one that has been in commercial distribution since before May 28,

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1976) for which the FDA has not called for pre-market approval (PMA) applications. 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 now usually takes from three to six months from the date of submission to obtain 510(k) clearance, but it may take substantially longer. Our hemodialysis concentrates, liquid bicarbonate and other ancillary products are categorized as class II devices.

A device requiring prior marketing authorization that does not qualify for 510(k) clearance is categorized as class III, which is reserved for devices classified by the FDA as posing the greatest risk (e.g., life-sustaining, life-supporting or implantable devices), or devices that are not substantially equivalent to a legally marketed class I or class II device. A class III device generally must receive approval of 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 after filing the request, but it may take 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), human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-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 (MDR) 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 FDA 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 licensing agreements for iron supplemented dialysate to be included in our dialysate products. Water soluble iron supplements when coupled with our dialysate are intended to be used as an iron maintenance therapy for dialysis patients, and we have been advised that this dialysate iron product will be considered a drug/device combination by

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the FDA. As a result, our iron maintenance therapy product will be subject to the FDA regulations for pharmaceutical products, as well.

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 Exemption (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. These costs can be reduced, however, for delivery systems which utilize approved drugs.

An ANDA involves an abbreviated approval process that may be 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 clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product. Under FDA ANDA 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. 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 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. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at different test sites. A clinical plan, or protocol, accompanied by the approval of the institution participating in the trials, must be reviewed by the FDA prior to commencement of each phase 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 clinical testing. Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA or an ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the

product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

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. Even after foreign

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approvals are obtained, further delays may be encountered before products may be marketed. For example, many countries require additional governmental approval for price reimbursement under national health insurance systems.

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 insure full technical compliance. 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 involve additional testing for products that have received 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.

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.

In 2006, we entered into 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.

Two license agreements for iron supplemented dialysate were entered into during 2001 and 2002, respectively. These license agreements cover both issued and pending patents in the United States. These agreements also cover issued and pending patents in a number of foreign jurisdictions. The license agreements continue for the duration of the underlying patents in each country, or approximately 13 years 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.

The product license agreements require us to obtain FDA approval of iron supplemented dialysate. A Phase II clinical trial on one such iron supplemented dialysate under an Investigational New Drug (IND) exemption was completed by one of our licensors. We plan to conduct product testing and clinical trials in order to obtain FDA approval to market this product. We will be required to pay the cost of obtaining approval from the FDA to market the product in order to realize any benefit from commercialization of the product which we estimate will take several years and cost between $10 million and $12 million. In addition to funding clinical trials and patent

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maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product as previously described.

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 a U.S. patent for our Dri-Sate Dry Acid Concentrate method and apparatus for preparing liquid dialysate on May 28, 2002 which expires on September 17, 2019. We have applied for a corresponding patent in Canada which is pending at this time. In addition, we have a pending patent application for packaging of soluble ferric pyrophosphate for dialysis.

Suppliers

We believe the raw 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., Cargill, Inc., and Morton Salt Company.

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 year ended December 31, 2006, one customer accounted for more than 10% of our total sales, representing 33% of total sales. For the year ended December 31, 2005, two customers each accounted for more than 10% of our total sales, representing 55% of total sales. Our accounts receivable from these customers were $925,000 and $840,000 as of December 31, 2006 and 2005, respectively. We are dependent on these customers and the loss of any of them could have a material adverse effect on our business, financial condition and results of operations. Our international sales including products sold to domestic distributors that are delivered internationally aggregated 18% and 28% of overall sales in 2006 and 2005, respectively.

Employees

As of December 31, 2006, we had approximately 200 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 iron supplemented dialysate. We incurred expenses during 2006 and 2005 for product development, to obtain regulatory approval and for regulatory maintenance of the intellectual property underlying our licensing agreements. We engaged outside consultants and legal counsel to assist us with 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 2006 and 2005, we incurred expenses related to the commercial development of our iron supplemented dialysate product aggregating approximately $4,778,000 and $347,000, respectively.

We must undertake substantial testing to obtain FDA approval for our new iron supplemented dialysate product. The cost of this testing including clinical trials (which we estimate to be between $10 million and $12 million for the period from January 2007 until approval is obtained) will have a material impact on us and we expect that we are likely 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 to obtain FDA approval of our new iron maintenance therapy product. If we are unable to obtain FDA approval of our new iron maintenance therapy product or to make certain milestone payments we may forfeit our rights under our license agreements.

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Statements in this annual report concerning the timing of regulatory filings and approvals are forward looking statements which are subject to risks and uncertainties. The length of time necessary to complete product testing and clinical trials, and from submission of an application for market approval to a final decision by a regulatory authority, varies significantly. We might not have the financial resources necessary to complete all of the testing and the clinical trials for this product, and even if we do, they might not be successfully completed. We might not be able to obtain regulatory approval for any such product, and even if we do, any approved product might not be successfully marketed. Similarly, our competitors, most of whom have greater resources than us, might develop and introduce products that will adversely affect our business and results of operations.

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 450 Fifth Street, N.W., Washington, D.C. 20549. 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.

We also maintain a website at http://www.rockwellmed.com. We make our annual reports on Form 10-KSB available free of charge on or through our website.

Risk Factors and 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. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, continue , predict , forecast , pr expressions, or make statements regarding the intent, belief, or current expectations of us or our officers, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the potential for the CMS to change its reimbursement policies and the effect on our business if such change is made, and statements regarding the timing and costs of obtaining FDA approval of our new iron product.

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 and from time to time in our other reports filed with the Securities and Exchange Commission. Other factors not currently anticipated by management may also materially and adversely affect our financial condition, liquidity or results of operations. Except as required by applicable law, we do not undertake, and expressly disclaim, any obligation to publicly update or alter our statements whether as a result of new information, events or circumstances occurring after the date of this report or otherwise.

The dialysis provider market is highly concentrated in national and regional dialysis chains that account for the majority of our domestic revenue.

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. If we were to lose a significant portion of our business with major national and regional dialysis chains, it could have a substantial negative impact on our cash flow and operating results. If we were to lose a substantial portion of our business, it may 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

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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 most of 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.

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.

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 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 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 funding to be viable businesses. If Medicare 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 operate the business.

We have experienced rapid revenue growth and have incurred substantial costs to increase our inventory and our infrastructure to service new business. Our research and development costs are expected to be significant cash outlays. In 2006, we anticipated that we would spend between $6-8 million to complete the approval process for

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SFP. However, it was subsequently determined that additional testing was necessary and we now estimate that we will require $10-12 million, in addition to expenses incurred through December 31, 2006, to complete testing. The FDA may require additional work or testing that may further increase the anticipated costs.

We believe that we will have to raise additional capital through equity sources or debt instruments in order to execute our business strategy. If we are unable to obtain sources of capital, we may have to alter our strategy or we could fail and go out of business.

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 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. 9,807,510 of the Company s common shares are freely tradable as of March 1, 2007, and an additional 1,692,839 shares are tradable subject to the resale limitations contained in Rule 144 under the Securities Act. In addition, as of March 1, 2007, 3,709,091 shares were available for future issuance under our 1997 Stock Option Plan, including 3,219,235 shares issuable upon the exercise of outstanding stock options, all of which were exercisable. In the future, we may issue additional shares 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.

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.

We may not be successful in improving our gross profit margins and 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. As we increase our business in certain markets and regions, which are further 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 raw materials.

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

We depend on key personnel.

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for managing our sales and marketing efforts, which has driven our growth. We maintain key man life insurance on

Mr. Chioini in the amount of $1 million. Neither Mr. Chioini nor Mr. Klema are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini or Mr. Klema, our business, financial condition and results of operations could be adversely affected.

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Our business is highly regulated.

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

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

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 the business or operating results of the Company.

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

As of December 31, 2006, our officers and directors beneficially owned approximately 26.8% 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, takeovers and control share acquisitions 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

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effect on the market price of the Company s securities and can limit shareholders ability to receive a premium on their shares by discouraging takeover and tender offer offers.

Our directors serve staggered three-year terms, and directors may not be removed without cause. The Company s 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 the Company s voting shares to amend these provisions. These provisions could have an anti-takeover effect by making it more difficult to acquire the Company by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

We 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.

Item 2. ***Description of Property.***

We occupy a 51,000 square foot facility in Wixom, Michigan under a lease expiring in July 2008. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in August 2010. In addition, during 2006, we occupied a 61,000 square foot facility in Hodges, South Carolina under a month to month lease. The lease was terminated on February 25, 2007, and we moved this operation to a 57,000 square foot facility in Greer, South Carolina. The lease provides for a minimum lease term through July 15, 2007 with an option to continue on a month to month basis thereafter.

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. We believe these facilities are suitable and adequate to meet our current production and distribution requirements. However, should our business continue to expand, we expect that we will require additional office space, manufacturing capacity and distribution facilities to meet our requirements.

Item 3. ***Legal Proceedings***

There are no material legal proceedings to which we are a party.

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 2006.

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PART II

Item 5. ***Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities.***

Until January 2007, our common shares were traded on The Nasdaq Capital Market under the symbol RMTI. In January 2007, our shares began trading on the Nasdaq Global Market under the same symbol.

The prices below are the high and low sale prices as reported by The Nasdaq Capital Market in each quarter during 2005 and 2006

	Sale Price	
Quarter Ended	**High**	**Low**
March 31, 2005	3.94	2.95
June 30, 2005	3.50	2.70
September 30, 2005	4.33	2.82
December 31, 2005	5.30	3.40
March 31, 2006	9.39	3.91
June 30, 2006	8.60	5.94
September 30, 2006	8.02	6.31
December 31, 2006	7.74	6.86

As of March 1, 2007, there were 46 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. Our credit line agreement does not permit the payment of cash dividends.

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, 2006:

Number of securities to be issued upon exercise of outstanding options, warrants	**Weighted average exercise price of**	**Number of securities remaining available for future issuance under**

Plan Category	and rights (a)	outstanding options, warrants and rights (b)	equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,219,235	$ 2.68	489,856
Equity compensation plans not approved by security holders			
Total	3,219,235	$ 2.68	489,856

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Item 6. ***Management s Discussions and Analysis of Financial Condition and Plan of Operation.***

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included elsewhere in this report. The discussion that follows contains certain forward-looking statements relating to our anticipated future financial condition, operating results, cash flows and our current business plans. When we use words such as may, might, will, should, believe, expect, anticipate, estimate, conti forecast , projected or similar expressions, or make statements regarding the intent, belief, or current expectations of us or our officers, we are making forward-looking statements. These forward-looking statements represent our outlook only as of the date of this report. 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. 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 under Item 1 Description of Business Risk Factors and Forward Looking Statements, and from time to time in our other reports filed with the Securities and Exchange Commission. The cross-referenced information is incorporated herein by reference. Other factors not currently anticipated by management may also materially and adversely affect our financial condition, liquidity or results of operations. Except as required by applicable law, we do not undertake, and expressly disclaim, any obligation to publicly update or alter our statements whether as a result of new information, events or circumstances occurring after the date of this report or otherwise.

Overview

We operate in a single business segment the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process. We have gained market share each year since our inception in 1996. We have increased our sales by approximately 60% over the last two years.

The dialysis supply market is very competitive and is characterized by having a few dialysis providers treating the majority of patients in the United States. We compete against companies which have substantially greater resources than we have. Our revenue is highly concentrated in a few customers and the loss of any of those customers would adversely affect our results. However, we expect to continue to grow our business while executing our strategic plan to expand our product lines, to expand our geographic reach and to develop our proprietary technology which may include adding facilities and personnel to support our growth.

Concurrent with the exit from the concentrate business of one of our competitors in late 2006, we began to service many DaVita clinics previously serviced by this competitor. As a result, we anticipate gaining market share in 2007. We also expect that we will be able to raise prices in some circumstances in 2007 and, if we are successful in doing so, we expect our gross profit margins to improve later in the year.

As we increase our business in certain markets and regions, we may incur additional costs that are greater than the additional revenue generated from these initiatives. While the majority of our business is 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 are seeking to gain FDA approval for our iron supplemented dialysate product. We believe our iron supplemented dialysate product 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 $10-12 million to complete testing and the regulatory approval process in the United States from the beginning of 2007 until approval is obtained. This amount is substantially higher than our previous estimate due to additional

testing that we have determined will be required in order to complete the approval process. These expenditures may more than offset our profits from sales of existing products and result in reported losses during the approval process.

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Results of Operations

For the year ended December 31, 2006 compared to the year ended December 31, 2005

Sales

For the year ended December 31, 2006, our sales were $28.6 million as compared to sales of $27.7 million for 2005, representing an increase of 3.4%. Sales of our core concentrate products, which represented 94% of our sales in 2006 increased $6.0 million or 28% due to the factors discussed below. This increase was partially offset by a decrease in sales of our ancillary products of $5.2 million or 88% due to an equal reduction in ancillary product sales to a single international distributor. Our domestic business realized overall sales growth of $3.6 million or 18.4% while our sales to distributors of our products internationally decreased $2.7 million or 35%.

The domestic hemodialysis service provider market has experienced substantial consolidation in the last year with the four largest dialysis service provider chains consolidating into two during the last year. DaVita, Inc., our largest customer, completed its acquisition of Gambro s clinic division, the third largest dialysis provider, in November 2005 and in March 2006, Fresenius Medical Care completed its acquisition of Renal Care Group, Inc., the fourth largest dialysis provider in the United States. Together, DaVita and Fresenius are estimated to provide treatments to over 60% of the chronic hemodialysis patient population in the United States.

Renal Care Group, Inc., a customer of ours until it was acquired by Fresenius, breached several supply contracts with us. We entered into a settlement with Renal Care Group, Inc. in 2006 pursuant to which we received $755,000. In the first quarter of 2006, approximately 12% of our revenue was related to this settlement. Future revenue from the former RCG clinics is anticipated to be immaterial. Sales growth to our other domestic customers in 2006 compared to 2005 was 25.0%.

We competed against both Fresenius and Gambro, which remained in the dialysis products business following the sale of its clinic business to DaVita. However, Gambro began to exit the dialysis concentrate business in the last half of 2006 and completed its exit in the first quarter of 2007. As a result of Gambro s exit, we have realized increased sales during the second half of 2006 and anticipate further growth in 2007.

In 2006, 53% of our sales were to customers other than the two major dialysis chains and the major international distributors discussed above. This portion of our business consists primarily of other national and regional chains along with other independent accounts and grew by 43.7% compared to 2005, with a majority of this growth attributable to the withdrawal of certain competitors from the concentrate market. While we expect to continue to realize growth in this portion of our customer base in 2007, it is not clear to what extent this trend will continue.

Our sales to distributors who distribute our products internationally represented 18% of sales in 2006 and 28% of sales in 2005. We experienced a reduction in sales to our largest international distributors of $3.2 million in 2006 compared to 2005. In 2005, one of these large international distributors placed a large purchase order with us aggregating $6.5 million in the first quarter of 2005 which was fulfilled throughout 2005. Although, we had minimal orders from our large major international distributors in the first half of 2006, our largest international distributors increased their order requirements in the third quarter of 2006. We anticipate that we will continue to realize substantial orders from time to time from our largest international distributors but expect the size of these orders to fluctuate from period to period.

Gross Profit

Gross profit margins decreased from 10.9% in 2005 to 9.8% in 2006 or 1.1% of sales. There were substantial changes to customer mix, as well as our product mix and our overall costs of operation that resulted in an overall decrease to our gross profit margins in 2006. Ancillary product sales to an international distributor in 2005 that did not recur in 2006 had a negative impact on margins of 1.6 percentage points compared to 2005.

Several other factors impacted our gross profit margins in 2006. We realized higher pricing on new and maturing contracts. Due to consolidation in the provider market, we lost certain customers that had purchased higher margin products. We made investments to increase our production capacity in the last two years for which we have just recently begun to realize benefits from those investments. We incurred raw material inventory write-offs

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and recorded reserves for certain ancillary products aggregating 0.7% of sales in 2006. We have incurred higher costs for material and distribution of our products. Fuel costs increased 0.5% of sales in 2006 compared to 2005.

We anticipate that we will experience changes in our customer and product mix in future periods that may also impact our gross profit. We anticipate that as our business grows our margins should benefit from increased plant utilization. We may also add manufacturing and distribution resources to support our business growth and these resources may reduce our gross profit margins until sufficient new volume is realized. Since we sell a wide range of products with varying profit margins and to customers with varying order patterns, we expect that the gross profit we generate and our gross profit margins may vary from period to period.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses were $2,661,000 and were 9.3% of sales compared to 9.1% of sales in 2005. Selling, General & Administrative expense increased $141,000 or 5.6% in 2006 compared to 2005 due to additional costs to support our business growth and development including human resources and information technology.

Research and Development

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 $4,778,000 and $347,000 in 2006 and 2005, respectively. This substantial increase in cost was for completion of pre-clinical studies and preparation for human clinical trials. Spending is expected to be at the same or higher level in 2007.

Operating Income(Loss)

Operating loss in 2006 was $4,637,830 compared to operating income of $137,000 in 2005 due to increased spending on research and development of approximately $4,778,000.

Interest Income, net

In the first quarter of 2006, we raised approximately $8.3 million of equity capital after offering expenses. We repaid all of our borrowings under our line of credit totaling $1,800,000 and invested the balance of the proceeds in short term investments which yielded interest income of $189,167 in 2006. Our net interest income was $62,851 in 2006 compared to a net interest expense of $198,095 in 2005.

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.

Net Income (Loss)

Our net loss in 2006 was $4,574,979 or $.41 per share compared to a net profit of $76,808 or $.01 per share in 2005. The change was primarily attributable to research and product development with the remainder attributable to reduced international orders partially offset by domestic sales growth.

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

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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 and 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 and allowance for doubtful accounts

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. We also recognize revenue for delivery of freight for third parties upon completion of the delivery service.

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

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.

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.

Liquidity and Capital Resources

We have two major areas of strategic focus in our business. First, we plan to develop our dialysis concentrate solutions and ancillary supply business. Second, we plan to expand our product offering to include drugs and

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vitamins administered to dialysis patients. Both of these initiatives require investments of substantial amounts of capital in the year ahead.

Growth in our core concentrate business will require additional investment. During the last two years our sales have increased approximately 60%. With the consolidation of suppliers in our industry we anticipate substantial domestic growth in 2007 which we anticipate may require capital expenditures above normal replacement capital requirements and additional working capital. If sales and margins improve as expected in 2007, cash flow from operations would increase and partially fund our additional cash requirements.

We anticipate that we will continue to invest in SFP, our proprietary iron therapy drug, and we estimate that total SFP spending in 2007 will be approximately $4.5 to $5.0 million depending on the timing of certain expenditures.

Our cash resources include cash generated from our business operations and as of December 31, 2006, we had $2.6 million in cash. We also had unused borrowing capacity of $2.75 million under our credit line. The terms of our credit line and the related borrowing limitations are discussed in Note 8 of our Consolidated Financial Statements. In addition, we anticipate that we will enter into an equipment leasing arrangement to fund the majority of capital expenditures associated with facility expansions or additions. We believe these sources of liquidity and capital resources will be adequate to fund our cash requirements for 2007.

However, if these cash resources are not adequate or if our results do not generate the cash from operations that we anticipate, we may have to seek alternative sources of cash resources. If we do not have adequate cash to fund our development efforts, we will evaluate both debt and equity financing as potential sources of funds. Should we not be able to obtain additional financing, we may alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources.

Our longer term pharmaceutical product development initiatives and regulatory approval work will require additional sources of funding other than cash flows from our operations. We estimate that from 2007 until the approval process is complete we will spend between $10-$12 million on SFP approval although actual clinical trial costs and changes in FDA requirements for testing may result in higher levels of spending than we estimate. We will evaluate alternative sources of business development funding which may include seeking equity financing, international marketing partners, sub-licensing of certain products for certain markets as well as other potential funding sources.

Item 7. ***Financial Statements***

The Consolidated Financial Statements of the Registrant required by this item are set forth on pages F-1 through F-16.

Item 8. ***Changes In and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 8A. ***Controls and Procedures***

(a) 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.

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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 our disclosure controls and procedures as of December 31, 2006. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of December 31, 2006 in ensuring that information required to be disclosed by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the Exchange Act rules and forms.

(b) 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 followed. There was no change in our internal control over financial reporting identified in connection with such evaluation that occurred during our fiscal quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 8B. ***Other Information***

The following information is included in this report in lieu of filing such information under Items 1.01 and 2.03 of Form 8-K:

On March 23, 2007, LaSalle Bank Midwest National Association, formerly known as Standard Federal Bank National Association (the Lender), approved a renewal of its Loan and Security Agreement (the Loan Agreement) with the Company. The Lender s commitment to make revolving borrowings under the Loan Agreement now expires on April 1, 2008. The letter furnished to the Company by the Lender in connection with such renewal is filed as Exhibit 10.17 to this Annual Report on Form 10-KSB.

The Loan Agreement provides for revolving borrowings by the Company up to $2,750,000. Borrowings under the Loan Agreement are secured by accounts receivable, inventory and certain other assets, and are guaranteed by the Company s subsidiary, Rockwell Transportation, Inc. The Loan Agreement, and the related Revolving Note, Unconditional Guaranty and 2006 letter amending the Loan Agreement, are filed as Exhibits 10.9, 10.10, 10.11 and 10.14 to this Annual Report on Form 10-KSB.

PART III

Item 9. ***Directors, Executive Officers, Promoters and Control Persons; Compliance With Section 16(a) of the Exchange Act.***

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 10. ***Executive Compensation.***

The required information will be contained in the Proxy Statement under the caption Compensation of Executive Officers and Directors and is incorporated herein by reference.

Item 11. ***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. In addition, the information contained under Item 5. Market for Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities Securities Authorized for Issuance Under Equity Compensation Plans of this Annual Report on Form 10-KSB is incorporated herein by reference.

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Item 12. ***Certain Relationships and Related Transactions.***

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

Items 13. ***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(i).1	Articles of Incorporation of the Company, incorporated by reference to Exhibit 3(i).1 to the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(i).2	Certificate of Amendment to Articles of Incorporation of the Company, incorporated by reference to Exhibit 3(i).2 to the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(i).3	Certificate of Correction to Articles of Incorporation of the Company, incorporated by reference to Exhibit 3(i).3 to the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(i).4	Certificate of Amendment to Articles of Incorporation of the Company, incorporated by reference to Exhibit 3(i).4 to the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(ii)	Bylaws of the Company, incorporated by reference to Exhibit 3(ii) to the Company s Registration Statement on Form SB-2, File No. 333-31991.
*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 quarterly report on Form 10-QSB filed November 14, 2000.
10.4	Licensing Agreement between the Company and Ash Medical Systems, Inc. dated October 3, 2001 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	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.
10.6	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.
10.8	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.
10.9	

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.

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10.10	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.
10.11	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.
10.12	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.
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17	Letter dated March 23, 2007 from LaSalle Bank Midwest National Association to Rockwell Medical Technologies, Inc.
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	Certifications of Chief Executive Officer Pursuant to Rule 13a-14(a).
31.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a).
32.1	Certifications 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.

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.

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant 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 27, 2007

In accordance with 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.

Signature	Title	Date
/s/ ROBERT L. CHIOINI Robert L. Chioini	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2007
/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 27, 2007
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 27, 2007
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 27, 2007
/s/ PATRICK J. BAGLEY Patrick J. Bagley	Director	March 27, 2007

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PLANTE & MORAN, PLLC LETTERHEAD

REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

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

We have audited the consolidated balance sheet of Rockwell Medical Technologies, Inc. and Subsidiary as of December 31, 2006 and 2005 and the related consolidated statements of income, 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Rockwell Medical Technologies, Inc. and Subsidiary is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Accordingly, we express no such opinion. 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 consolidated financial statements referred to above, present fairly, in all material respects, the financial position of Rockwell Medical Technologies, Inc. and Subsidiary as of December 31, 2006 and 2005, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Plante & Moran, PLLC

Auburn Hills, Michigan
March 23, 2007

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2006 and 2005
(Whole Dollars)

	December 31, 2006	December 31, 2005
ASSETS		
Cash and Cash Equivalents	$ 2,662,873	$ 299,031
Accounts Receivable, net of a reserve of $72,500 in 2006 and $70,000 in 2005	3,474,402	2,836,072
Inventory	2,660,098	2,051,819
Other Current Assets	261,473	193,158
Total Current Assets	9,058,846	5,380,080
Property and Equipment, net	2,587,771	2,430,222
Intangible Assets	457,846	394,819
Goodwill	920,745	920,745
Other Non-current Assets	127,625	134,794
Total Assets	$ 13,152,833	$ 9,260,660
LIABILITIES AND SHAREHOLDERS EQUITY		
Short Term Borrowings	$	$ 1,800,000
Notes Payable & Capitalized Lease Obligations	369,551	522,439
Accounts Payable	2,920,258	1,795,393
Accrued Liabilities	1,114,592	530,749
Customer Deposits	48,274	33,558
Total Current Liabilities	4,452,675	4,682,139
Long Term Notes Payable & Capitalized Lease Obligations	326,045	733,723
Shareholders Equity:		
Common Shares, no par value, 11,500,349 and 8,886,948 shares issued and outstanding	23,147,709	12,628,539
Common Share Purchase Warrants, -0- and 3,591,385 shares issued and outstanding		1,414,876
Accumulated Deficit	(14,773,596)	(10,198,617)
Total Shareholders Equity	8,374,113	3,844,798
Total Liabilities And Shareholders Equity	$ 13,152,833	$ 9,260,660

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

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the Years Ended December 31, 2006 and 2005
(Whole Dollars)

	2006	2005
Sales	$ 28,638,859	$ 27,694,955
Cost of Sales	25,837,294	24,689,912
Gross Profit	2,801,565	3,005,043
Selling, General and Administrative	2,661,419	2,520,670
Research and Product Development	4,777,976	346,938
Operating Income (Loss)	(4,637,830)	137,435
Other Income		137,468
Interest (Income) Expense, net	(62,851)	198,095
Income (Loss) Before Income Taxes	(4,574,979)	76,808
Income Tax Expense		
Net Income (Loss)	$ (4,574,979)	$ 76,808
Basic And Diluted Earnings (Loss) Per Share	$ (.41)	$ .01

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, 2006 and 2005
(Whole Dollars)

	Common Shares		Purchase Warrants		Accumulated	Total Shareholders
	Shares	Amount	Warrants	Amount	Deficit	Equity
Balance as of December 31, 2004	8,556,531	$ 11,870,909	3,761,071	$ 320,150	$ (8,768,740)	$ 3,422,319
Issuance of Common Shares	167,881	336,849				336,849
Exercise of Purchase Warrants	162,536	420,781	(162,536)	(80,630)		340,151
Expiration of Warrants			(7,150)			
Warrant Exchange				1,175,356	(1,506,685)	(331,329)
Net Income					76,808	76,808
Balance as of December 31, 2005	8,886,948	$ 12,628,539	3,591,385	$ 1,414,876	$ (10,198,617)	$ 3,844,798
Issuance of Common Shares	245,995	836,601				836,601
Exercise of Purchase Warrants	2,367,406	9,523,210	(2,367,406)	(1,255,517)		8,267,693
Expiration of Warrants		159,359	(1,223,979)	(159,359)		
Net Loss					(4,574,979)	(4,574,979)
Balance as of December 31, 2006	11,500,349	$ 23,147,709	-0-	$ -0-	$ (14,773,596)	$ 8,374,113

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 CASH FLOWS

For The Years Ended December 31, 2006 and 2005
(Whole Dollars)

	2006	2005
Cash Flows From Operating Activities:		
Net Income (Loss)	$ (4,574,979)	$ 76,808
Adjustments To Reconcile Net Income To Net Cash Used In Operating Activities:		
Depreciation and Amortization	756,868	716,312
Gain on Asset Disposal	(4,539)	
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(638,330)	(533,979)
(Increase) in Inventory	(608,279)	(399,362)
(Increase) in Other Assets	(61,146)	(95,725)
Increase (Decrease) in Accounts Payable	1,124,865	(329,286)
Increase (Decrease) in Other Liabilities	598,559	71,715
Changes in Assets and Liabilities	415,669	(1,286,637)
Cash Provided (Used) By Operating Activities	(3,406,981)	(493,517)
Cash Flows From Investing Activities:		
Purchase of Equipment	(907,554)	(576,450)
(Increase) Decrease in Restricted Cash Equivalents		8,662
Purchase of Intangible Assets	(105,730)	(59,924)
Cash Provided (Used) By Investing Activities	(1,013,284)	(627,712)
Cash Flows From Financing Activities:		
Proceeds From Borrowings on Line of Credit		5,937,395
Payments on Line of Credit	(1,800,000)	(4,590,077)
Issuance of Common Shares and Purchase Warrants	9,104,294	345,671
Payments on Notes Payable	(520,187)	(438,924)
Cash Provided (Used) By Financing Activities	6,784,107	1,254,065
Increase In Cash	2,363,842	132,836
Cash At Beginning Of Period	299,031	166,195
Cash At End Of Period	$ 2,662,873	$ 299,031

Supplemental Cash Flow disclosure:

	2006	2005

Interest Paid		$ 126,316	$ 198,192
Non-Cash Investing and Financing Activity	Equipment Acquired Under Capital Lease Obligations	$ 133,120	$ 486,806

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 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 for which we are developing and seeking FDA approval to market.

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, 2006 and 2005 we had customer deposits of $48,274 and $33,557, respectively. .

For the quarter ended March 31, 2006, we reached a settlement with a customer related to its breach of several purchase contracts. Under the terms of the settlement, we were paid $755,000 in exchange for release of the customer s future obligations under these contracts. All of this settlement was recognized as a component of revenue in 2006.

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. Our trucks which deliver our products to our customers sometimes generate backhaul revenue from hauling freight for other third parties. Revenue from backhaul activity is recognized upon completion of the delivery service.

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.

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 account receivable balances and based on our assessment of expected collections, we estimate the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily based on historical experience. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for doubtful accounts.

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.

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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 have reclassified research and product development costs incurred in 2005 to this statement line from selling, general and administrative expense in 2005 to conform with the current year presentation for research and product development expense.

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 $4,778,000 and $347,000 in 2006 and 2005, respectively.

During 2006, we entered into a number of research and development related contracts for safety, pharmacology and toxicology testing of our iron dialysate drug product under which we made commitments to spend $3.4 million. Services under the contracts were to be performed over periods ranging from 3 to 15 months. We are recognizing the cost of these contracts as research and development expense over the periods in which the testing is being performed and on a basis reflective of the level of activity under those contracts in each period. During, 2006, we expensed approximately $2.9 million under these contracts.

Other Income

We were the plaintiff in certain litigation that was settled in the first quarter of 2005. We realized the full proceeds of the settlement which totaled $241,000 and we recognized $137,468 of other income from this settlement in the first quarter of 2005. A portion of the cash received was from the exercise of stock options by the defendant during the first quarter of 2005 which totaled $103,750.

Stock Options

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement No. 123R (SFAS 123R), a revision to Statement No. 123, Accounting for Stock-Based Compensation. This standard requires us to 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. The cost will be recognized as compensation expense over the vesting period of the awards. The Company has adopted SFAS 123R as of January 1, 2006 using the modified prospective method, and therefore has not restated results for prior periods. Under this method, the Company will begin recognizing compensation cost for equity based compensation for all new or modified grants after the date of adoption. In addition, the standard requires the Company to recognize compensation cost for the remaining unvested portion of prior option grants over the remaining service period. All of the Company s options granted in 2005 and prior years were fully vested as of December 31, 2005, and therefore, the Company has not recorded any expense for options granted prior to 2006 upon adoption of SFAS 123R. The Company did not grant any stock options in 2006.

The following table shows the effect on net income (loss) and the earnings (loss) per share if the Company had applied the fair values recognition provisions of SFAS 123 for the years ended December 31:

	2006	2005

As reported net income (loss) available to common shareholders	$ (4,574,979)	$ 76,808
Less: Stock based compensation expense determined under the fair market value method, net of tax	-0-	2,427,257
Pro forma net income (loss)	$ (4,574,979)	$ (2,350,449)
As reported basic earnings per share and diluted earnings per share	$ (.41)	$ .01
Pro forma earnings (loss) per share and diluted earnings (loss) per share	$ (.41)	$ (.27)

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	2006	2005
Basic Weighted Average Shares Outstanding	11,189,001	8,674,651
Effect of Dilutive Securities	-0-	682,239
Diluted Weighted Average Shares Outstanding	11,189,001	9,356,990

For 2006, the dilutive effect of the stock options 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 2006.

At December 31, 2006 potentially dilutive securities comprised 3,219,235 stock options exercisable at prices from $.55 to $4.55 per share.

At December 31, 2005 potentially dilutive securities comprised 3,359,335 stock options exercisable at prices from $.55 to $4.55 per share, 3,211,688 common share purchase warrants exercisable at $3.90 per common share, 354,697 common share purchase warrants exercisable at $4.50 per common share and 25,000 common share purchase warrants exercisable at $2.50 per common share.

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 Operation

We have two major areas of strategic focus in our business. First, we plan to develop our dialysis concentrate solutions and ancillary supply business. Second, we plan to expand our product offering to include drugs and vitamins administered to dialysis patients. Both of these initiatives require investments of substantial amounts of capital in the year ahead.

Growth in our core concentrate business will require additional investment. During the last two years our sales have increased approximately 60%. With the consolidation of suppliers in our industry we anticipate substantial domestic

growth in 2007 which we anticipate may require capital expenditures above normal replacement capital requirements and additional working capital. If sales and margins improve as expected in 2007, cash flow from operations would increase and partially fund our additional cash requirements.

We anticipate that we will continue to invest in SFP, our proprietary iron therapy drug, and we estimate that total SFP spending in 2007 will be approximately $4.5 to $5.0 million depending on the timing of certain expenditures.

Our cash resources include cash generated from our business operations and as of December 31, 2006, we had $2.6 million in cash. We also had unused borrowing capacity of $2.75 million under our credit line. The terms of our credit line and the related borrowing limitations are discussed in Note 8 of our Consolidated Financial Statements. In addition, we anticipate that we will enter into an equipment leasing arrangement to fund the majority of capital

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

expenditures associated with facility expansions or additions. We believe these sources of liquidity and capital resources will be adequate to fund our cash requirements for 2007.

However, if these cash resources are not adequate or if our results do not generate the cash from operations that we anticipate, we may have to seek alternative sources of cash resources. If we do not have adequate cash to fund our development efforts, we will evaluate both debt and equity financing as potential sources of funds. Should we not be able to obtain additional financing, we may alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources.

Our longer term pharmaceutical product development initiatives and regulatory approval work will require additional sources of funding other than cash flows from our operations. We estimate that from 2007 until the approval process is complete we will spend between $10-$12 million on SFP approval although actual clinical trial costs and changes in FDA requirements for testing may result in higher levels of spending than we estimate. We will evaluate alternative sources of business development funding which may include seeking equity financing, international marketing partners, sub-licensing of certain products for certain markets as well as 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 year ended December 31, 2006, one customer accounted for more than 10% of our total sales, representing 33% of total sales. For the year ended December 31, 2005, two customers each accounted for more than 10% of our total sales, representing 55% of total sales. Our accounts receivable from these customers were $925,000 and $840,000 as of December 31, 2006 and 2005, respectively. We are dependent on these customers and the loss of any of them would have a material adverse effect on our business, financial condition and results of operations. Our international sales including products sold to domestic distributors that are delivered internationally aggregated 18% and 28% of overall sales in 2006 and 2005, respectively.

5. Inventory

Components of inventory as of December 31, 2006 and 2005 are as follows:

	2006	2005
Raw Materials	$ 717,876	$ 509,248
Finished Goods	1,942,222	1,542,571
Total	$ 2,660,098	$ 2,051,819

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. Property and Equipment

Major classes of Property and Equipment, stated at cost, as of December 31, 2006 and 2005 are as follows:

	2006	2005
Leasehold Improvements	$ 446,150	$ 447,207
Machinery and Equipment	3,891,890	3,326,552
Office Equipment and Furniture	479,427	308,992
Laboratory Equipment	304,992	298,510
Transportation Equipment	637,634	904,862
	5,760,093	5,286,123
Accumulated Depreciation	(3,172,322)	(2,855,901)
Net Property and Equipment	$ 2,587,771	$ 2,430,222

Included in the table above are assets under capital lease obligations with a cost of $1,041,372 and $1,256,186 and a net book value of $697,519 and $901,698, as of December 31, 2006 and 2005, respectively.

Depreciation expense was $714,165 for 2006 and $681,699 for 2005.

7. Goodwill and Intangible Assets

Total goodwill was $920,745 at December 31, 2006 and 2005. We completed our annual impairment tests as of November 30, 2006 and 2005 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, 2006, we have capitalized licensing fees of $615,868, net of accumulated amortization of $158,022. As of December 31, 2005, we have capitalized licensing fees of $510,138, net of accumulated amortization of $115,319.

Our policy is to amortize licensing fees over the life of the patents pertaining to the licensing agreements. We recognized amortization expense of $42,703 in 2006 and $34,614 in 2005. Estimated amortization expense for licensing fees for 2007 through 2011 is approximately $50,000 per year. One of the licensing agreements requires additional payments upon achievement of certain milestones.

8. Line of Credit

On March 29, 2006 and March 23, 2007, we renewed our line of credit with a financial institution. The loan agreement provides for revolving borrowings by us of up to $2,750,000. We are 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 are secured by accounts receivable, inventory and certain other assets. The annual interest rate payable on revolving borrowings under the loan agreement is the lender s prime rate plus 75 basis points. The lender s commitment to make revolving borrowings under the loan agreement now expires on April 1, 2008. As of December 31, 2006, we had no outstanding borrowings under this line of credit.

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 requires monthly payments of principal and interest aggregating $20,884 through June 2007. The note had a balance of $122,206 and $351,739 at December 31, 2006 and 2005, respectively. The note bears interest at a fixed rate of 8.65% and is collateralized by the equipment acquired by the Company.

Future principal payments on notes payable are:

Year ending December 31, 2007	$ 122,206
Total Notes Payable	$ 122,206

Capital Lease Obligations

We entered into capital lease obligations primarily related to equipment with a fair market value aggregating $133,120 and $486,806 for the years ended December 31, 2006 and 2005, respectively. In addition, we have other capital lease obligations related to financing other equipment. These capital lease obligations require even monthly installments over periods ranging from through 2010 and interest rates on the leases range from 5% to 17.0%. These obligations under capital leases had outstanding balances of $573,390 and $904,783 at December 31, 2006 and 2005, respectively.

Future minimum lease payments under capital lease obligations are:

Year ending December 31, 2007	$ 299,286
Year ending December 31, 2008	199,488
Year ending December 31, 2009	155,615
Year ending December 31, 2010	8,819
Total minimum payments on capital lease obligations	663,208
Interest	(89,817)
Present value of minimum lease payments	573,391
Current portion of capital lease obligations	(247,345)
Long-term capital lease obligations	$ 326,046

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 $1,597,127 and $1,058,004 for the years ended December 31, 2006 and 2005, respectively.

We have long term leases on two buildings that are approximately 51,000 square feet each and that expire in July 2008 and August 2010, respectively. As of December 31, 2006, we also have a short term lease on a building that is approximately 60,000 square feet.

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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, 2007	1,295,289
Year ending December 31, 2008	835,250
Year ending December 31, 2009	655,964
Year ending December 31, 2010	477,109
Year ending December 31, 2011	243,600
Thereafter	171,450
Total	$ 3,678,662

11. Income Taxes

We recognized no income tax expense or benefit for the years ended December 31, 2006 and 2005. We incurred a net loss in 2006 related to research and development spending for drug approval. Our business without this drug approval related spending has been profitable in both 2006 and 2005. However, 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 two years.

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

	2006	2005
Tax Expense Computed at 34% of Pretax Income	$ (1,555,000)	$ 26,000
Effect of Permanent Differences Principally Related to Non-deductible expenses		
Effect of Change in Valuation Allowance	(1,555,000)	(26,000)
Total Income Tax Benefit	$ -0-	$ -0-

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

	2006	2005
Total Deferred Tax Assets	$ 4,244,000	$ 2,908,000
Total Deferred Tax Liabilities	(173,000)	(257,600)
Valuation Allowance Recognized for Deferred Tax Assets	(4,071,000)	(2,650,400)

Net Deferred Tax Asset	$ -0-	$ -0-

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 $12,950,000 that expire between 2012 and 2025.

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, 2006 and 2005.

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Capital Stock

Our authorized capital stock consists of 20,000,000 common shares, no par value per share, of which 11,500,349 shares were outstanding at December 31, 2006 and 8,886,948 shares were outstanding at December 31, 2005; 2,000,000 preferred shares, none of which were issued or outstanding at either December 31, 2006 or December 31, 2005 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, 2006 or December 31, 2005.

During 2006, we issued 2,613,401 common shares and realized net cash proceeds of approximately $9,100,000. This total includes 2,342,406 of freely trading common shares we issued upon the exercise of publicly traded warrants (Public Warrants, as defined below). During 2006, we realized $9,135,000 or $3.90 per share in gross proceeds from these exercises and net proceeds of $8,205,194 after the expenses of the offering described below.

In 2006, we also issued 134,100 common shares as a result of the exercise of stock options by employees and realized proceeds of $451,744 or $3.36 per share on average. We also issued 111,895 common shares pursuant to a private placement of our common shares and realized net proceeds of $384,857 after expenses of the offering. These shares were subsequently registered and were reissued as free trading common shares.

We also issued 25,000 common shares upon the exercise of warrants to an investor from an earlier private placement (Private Warrants, as defined below). We realized proceeds of $62,500 or $2.50 per share on average. The investor exercising these private placement warrants received unregistered common shares.

During 2005, we issued 167,881 common shares as a result of the exercise of stock options by employees and realized proceeds of $336,849 or $2.01 per share on average. We also issued 103,921 common shares upon the exercise of our Private Warrants . We realized proceeds of $111,554 or $1.07 per share on average. Investors exercising these Private Warrants received unregistered common shares. We also issued 58,615 freely trading common shares upon the exercise of our Public Warrants . We realized $228,599 or $3.90 per share in gross proceeds from these exercises.

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

As of December 31, 2006, there were no outstanding warrants. However, at the beginning of 2006, we had both publicly traded common share purchase warrants (Public Warrants) issued in 1998 and common share purchase warrants (Private Warrants) issued in conjunction with a private placement of our common shares in 2002 and other investment banking activities.

Holders of the Public Warrants, were entitled to purchase one common share at the exercise price of $4.50 per share until January 26, 2006. There were 3,625,000 Public Warrants originally issued and all were outstanding until November 28, 2005.

In late 2005, we offered to exchange new common share purchase warrants expiring January 26, 2006 with an exercise price of $3.90 (New Warrants) for each of the 3,625,000 then-outstanding Public Warrants expiring January 26, 2006 with an exercise price of $4.50 (Old Warrants)

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On November 28, 2005, we completed this exchange. All other terms and conditions, including expiration, remained the same. There were 354,697 Old Warrants that were not tendered for exchange and expired unexercised at January 26, 2006.

We issued 3,270,303 New Warrants in the warrant exchange. During 2005, 58,615 New Warrants were exercised and we realized $228,599 in gross proceeds from these warrant exercises. As of December 31, 2005, 3,211,688 of the New Warrants remained outstanding.

In 2006, we issued 2,342,406 Common Shares upon New Warrant exercises, for which we received gross proceeds of $9,135,383. All remaining unexercised Public Warrants expired on January 26, 2006.

Holders of the Private Warrants issued in conjunction with subscriptions to private placement offerings of common shares in 2002 were entitled to purchase one common share at a stated price. The Private Warrants had a three year term expiring between May 2005 and October 2005. The common shares underlying these Private Warrants were not registered. Investors that exercised these Private Warrants received unregistered common shares.

13. Stock Options

Employee Stock Options

The Board of Directors approved the Rockwell Medical Technologies, Inc., 1997 Stock Option Plan on July 15, 1997 (the Plan). The Stock Option Committee as appointed by the Board of Directors administers the Plan, which provides for grants of nonqualified or incentive stock options to key employees, officers, directors, consultants and advisors to the Company. Currently, the Stock Option Committee consists of our entire Board of Directors. The plan terminates on July 15, 2007 and no options may be granted after July 15, 2007 unless the plan is further extended by approval of the Board of Directors and approval by a vote of the shareholders.

On May 25, 2006, our shareholders adopted an amendment to the stock option plan to increase the number of options available to be granted to 4,750,000 from 4,500,000. Exercise prices, subject to certain plan limitations, are at the discretion of the Stock Option Committee of the Board of Directors. Option awards are generally granted with an exercise price equal to the market price of the Company s stock on the date of the grant. Options granted normally expire 10 years from the date of grant or upon termination of employment. The Stock Option Committee of the Board of Directors determines vesting rights on the date of grant. Employee options typically vest over a three year period from the date of grant. In 2005, the Board of Directors accelerated the vesting rights to all unvested current and prior option grants such that they all became vested effective as of December 31, 2005.

A summary of the status of the Company s Employee Stock Option Plan excluding options granted to consultants is as follows:

	Weighted Average Exercise	Aggregate Intrinsic

	Shares	Price	Value
Outstanding at December 31, 2004	2,707,717	2.12	
Granted	853,000	4.46	
Exercised	(167,881)	2.01	$ 184,257
Cancelled	(33,501)	2.42	
Outstanding at December 31, 2005	3,359,335	2.12	$ 6,087,407
Granted	-0-		
Exercised	(134,100)	3.37	$ 363,124
Cancelled	(6,000)	4.17	
Outstanding at December 31, 2006	3,219,235	2.68	$ 14,368,196

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The intrinsic value of options exercised during the years ended December 31, 2006 and 2005 were $363,124 and $184,257, respectively. The intrinsic value of in-the money options as of December 31, 2006 and 2005, was $14,368,196 and $6,087,407, respectively.

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Options	Remaining Contractual Life	Weighted Exercise Price	Number of Options	Weighted Average Exercise Price
$.55 to $1.50	653,100	.6-6.0 yrs.	$ .77	653,100	$ .77
$1.81 to $2.79	1,348,635	1.5-8.5 yrs.	$ 2.26	1,348,635	$ 2.26
$3.00 to $4.55	1,217,500	1.6-10.0 yrs.	$ 4.18	1,217,500	$ 4.18
Total	3,219,235	6.5 yrs.	$ 2.68	3,219,235	$ 2.68

The Company did not grant any employees stock options during the year ended December 31, 2006. The per share weighted average fair values at the date of grant for the options granted to employees during the year ended December 31, 2005 was $4.46. For the period ended December 31, 2005, the fair value was determined using the Black Scholes option pricing model using the following assumptions: dividend yield of 0.0 percent, risk free interest rates of 3.8-4.33%, volatility of 70% and expected lives of .5-3.0 years

As of December 31, 2006, the remaining number of stock options available for future grants was 489,856.

14. Related Party Transactions

During the year ended December 31, 2005, we had revenue from companies in which one of our outside directors held an equity interest. Mr. Kenneth L. Holt, a director of the Company, previously held an equity interest in certain customers of ours which he divested during 2005. Revenue from these entities was $42,000 in 2005.

15. Supplemental Cash Flow Information

We entered into non-cash transactions described below during the years ended December 31, 2006 and 2005 which have not been included in the Consolidated Statement of Cash Flows.

We entered into capital leases on equipment with a cost of $133,120 and $486,806 for the years ended December 31, 2006 and 2005, respectively, and financed those with capital lease obligations.

16. Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, Inventory Costs (SFAS 151). SFAS 151 requires that abnormal amounts of idle facility expense, freight, handling costs, and spoilage, be charged to expense in the period they are incurred rather than capitalized as a component of inventory costs. SFAS 151 was adopted as of January 1, 2006.

There was no material impact from this statement on our financial statements.

Financial Accounting Standard Number 157 Fair Value Measurements (SFAS 157). In September 2006, the FASB issued SFAS 157, Fair Value Measurements. This statement clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosure on fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The Company has not determined the impact that the adoption of SFAS 157 will have on its consolidated financial statements

In June 2006, the Financial Accounting Standards Board issued Financial Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48). FIN 48, which is an interpretation of Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes, provides guidance on the manner in which tax positions taken or to be taken on tax returns should be reflected in an entity s financial statements prior to their resolution with taxing authorities. The Company is required to adopt FIN 48 during the first quarter of fiscal 2007. The Company is currently evaluating the requirements of FIN 48 and has not yet determined the impact this interpretation may have on its consolidated financial statements.