ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10KSB
March 22, 2005

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

FORM 10-KSB

(Mark One)
[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

OR

[ ] 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	38-3317208
(State or other jurisdiction of incorporation or organization)	(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 PURSUANT TO SECTION 12 (b) OF THE EXCHANGE ACT:
NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12 (g) OF THE EXCHANGE ACT:

COMMON SHARES, NO PAR VALUE
(Title of class)

COMMON SHARE PURCHASE WARRANTS

(Title of class)

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 [X] No [ ]

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. [ ]

State issuer's revenues for its most recent fiscal year: $17,944,710

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 7, 2005 was $26,783,000. In making this calculation, we have excluded common shares held by our executive officers and directors. 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: 8,596,531 common shares outstanding as of March 7, 2005.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement pertaining to the 2004 Annual Meeting of Shareholders (the "Proxy Statement") filed pursuant to Regulation 14A are herein incorporated by reference to Parts II and III.

PART I

ITEM 1. DESCRIPTION OF BUSINESS.

GENERAL

We are a Michigan corporation, incorporated on October 25, 1996. We manufacture hemodialysis concentrates and dialysis kits, and we sell, distribute and deliver these and other ancillary hemodialysis products to hemodialysis providers in the United States, the Far East, eastern Europe and Latin America. Hemodialysis duplicates kidney function in patients with failing kidneys. Without properly functioning kidneys, a patient's body cannot get rid of excess water and waste products and cannot regulate electrolytes in their blood. Without frequent and ongoing hemodialysis treatments these patients would die.

We have also entered into two licensing agreements covering three U.S. patents, two issued and one pending, as well as several foreign patents for iron supplemented dialysate for treatment of iron deficiency in dialysis patients. We are planning to conduct clinical trials of iron supplemented dialysate also known as dialysate iron. To realize a commercial benefit from this therapy, and pursuant to the agreements, we must complete clinical trials and obtain U.S. Food and Drug Administration ("FDA") approval to market iron supplemented dialysate. We will also 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. We estimate that the global market size for intravenous iron maintenance therapy to exceed $500,000,000 per year, with the market size in the United States for such therapy to be $300,000,000 per year. We cannot, however, give any assurance that

this product will be approved by the FDA or, if approved, that it will be successfully marketed.

INDUSTRY BACKGROUND

We provide products used in the treatment of patients with end stage renal disease ("ESRD"). We estimate there are over 360,000 ESRD patients in the United States and 1.2 million ESRD patients globally, who as a result of permanent kidney failure require long-term dialysis for survival. The incidence of kidney failure in the United States is increasing as a result of an aging population, an increasing occurrence of diabetes and hypertension and increased use of prescription drugs. ESRD patients are treated with recurring dialysis treatments replacing the functions of their nonfunctioning kidneys. The most common form of dialysis treatment is hemodialysis; representing approximately 90% of dialysis patients in the United States. Most ESRD patients undergoing hemodialysis treatments generally receive three treatments per week, or 156 treatments per year, although the number of weekly treatments may vary.

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, calcium, potassium, magnesium, chloride 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 dialysis on-off kits, sterile subclavian dressing change trays, arterial and venous blood tubing lines, fistula needles, intravenous administration sets, transducer protectors, dialyzers, specialized kits and various other ancillary products, many of which we sell.

DIALYSIS INDUSTRY TRENDS

According to statistics compiled by the Centers for Medicare and Medicaid Services ("CMS"), the dialysis industry has experienced steady patient population growth with the patient population increasing between 4-9% each year over the last ten years. ESRD is an irreversible deterioration of kidney function. Population segments with the highest incidence of ESRD are also the fastest growing within the U.S. population including the elderly, Hispanic and African-American population segments. More than 73% of new ESRD cases are attributed to either diabetes, (45%) or hypertension (28%), while glomerulonephritis is the primary factor behind nearly (8%) of treated cases.

Hemodialysis providers are generally either independent clinics or hospitals. According to the CMS, since 1973 the total number of hemodialysis providers in the United States increased from 606 in 1973 to 4,433 in December

2002. The number of patients receiving hemodialysis has also grown substantially in the last decade with annual patient growth averaging about 14,000 patients or between 4-9%. According to the CMS, in 2002, more than 298,000 patients were treated in Medicare-approved renal facilities as compared to 157,525 patients in 1993 and, from 1993 to 2002, the number of hemodialysis stations, which are areas equipped to provide adequate and safe dialysis therapy, grew from 35,240 stations to 72,115 stations or 104%. In addition, according to CMS, the number of Medicare-approved dialysis machines increased by approximately 4,000 stations or 5.8% between 2001 and 2002.

According to reports by major companies in our industry there are believed to be 1.3 million kidney dialysis patients globally.

STRATEGY

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 Sales Through Sales of New Innovative Products. We have signed global licensing agreements for delivery of iron supplemented dialysate. The FDA considers this product to be a combination pharmaceutical drug (iron) and device (dialysate). We believe iron supplemented dialysate will substantially improve iron maintenance therapy. See PRODUCTS -- "Iron Supplemented Dialysate" on page 5 below. This product requires FDA approval before it can be included in our product line. In addition, to be commercially successful, the drug portion of the product will need to be reimbursed by Medicare (CMS). If it is not reimbursed it may not be adopted by dialysis providers. If it is not adopted by dialysis providers, our entire investment may be worthless or of limited commercial value. We believe that if FDA approval is obtained for this drug and providers are reimbursed by insurers and CMS for using this drug, the superiority of this drug will enable us to capture market share in the market for iron maintenance therapy. The process of obtaining FDA approval for a new drug may take several years and many drugs that undergo clinical trials are never approved for patient use. It is possible that our new proprietary product may never be approved to be marketed.

  We introduced two new product lines in 1999; Dri-Sate(R) Dry Acid Concentrate and SteriLyte(R) Liquid Bicarbonate which we believe are superior to competitors' product offerings and have acted as a catalyst to attract new customers and to expand our existing business relationships with dialysis providers. See PRODUCTS -- "Dri-Sate Dry Acid Concentrate" and "SteriLyte Liquid Bicarbonate" on page 4 below.

- Acting as a Single Source Supplier. We have positioned Rockwell as an independent "one-stop-shop" to our customers for the concentrates, chemicals and supplies necessary to support a hemodialysis provider's operation. Some of our competitors do not offer a full line of hemodialysis products requiring customers to do business with a number of suppliers in order to purchase necessary supplies.

- Increasing Sales Through Ancillary Product Line Expansion. We believe the market potential for ancillary products and supplies used by hemodialysis providers is equivalent to or greater than the market for dialysis concentrates. Our strategy is to offer cost effective ancillary products that include ancillary products such as specialized kits, fistula needles, chemicals, sterile dressings and blood tubing.

Customers purchase many of these ancillary items based on price from various suppliers. We believe that as we continue to gain market share, we will increasingly be able to procure these ancillary items on a cost-effective basis and will provide our customers with the convenience of a single supply source and a highly competitive price level.

- Offering a Higher Level of Delivery/Customer Service. By using our own delivery vehicles and drivers, we believe we can offer a higher level of customer service to hemodialysis providers than we could if we relied primarily on the use of common carriers to distribute our products. Our drivers perform services for customers that are generally not available from common carriers, such as stock rotation, non-loading-dock delivery and drum pump-offs. A drum pump-off requires the driver to pump hemodialysis concentrates from a 55 gallon drum into larger holding tanks within the hemodialysis clinic. Certain of our competitors generally use common carriers for delivery of their products. We believe we offer a higher distribution service level to our customers through the use of our own delivery vehicles and drivers.

- Expanding Market Share in Target Regions. Because of the costs associated with transporting and delivering hemodialysis concentrates, we believe we have a cost advantage with respect to certain customers located near our manufacturing facilities. Our long range strategy is to add additional manufacturing facilities or distribution centers in locations which will provide us with a competitive cost advantage and allow us to provide customers with superior customer service levels due to our proximity to them. We would expect to execute this strategy by leveraging off of our existing customer relationships by serving those customers in areas where we currently only have a minor or negligible presence. We expect to add additional manufacturing or distribution capabilities.

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 33 states as well as several foreign countries, primarily in the Far East, eastern Europe and Latin America. 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.

"DRI-SATE(R) 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 in 1999, our dry acid concentrate product line has grown to represent over 50% of our acid concentrate sales.

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 generate back-haul revenue because our trucks are available to haul freight on the return trip rather than being used to return empty 55 gallon drums to our facilities.

"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(R) 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 mostly used in acute care settings. Our SteriLyte Liquid Bicarbonate offers the dialysis community a high-quality product and provides the clinic a safe and uninterrupted 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. Iron deficiency is pervasive in the dialysis patient population. Blood has several components including plasma which contains electrolytes, proteins, nutrients, hormones and other substances, and white blood cells, red blood cells and platelets. Red blood cells carry oxygen throughout the body to nourish tissues and sustain life. The most important constituent of red blood cells is hemoglobin, a complex molecule composed of protein and iron, which is responsible for carrying oxygen to body tissues. Red blood cells are produced in bone marrow. The body regulates the production of red blood cells so that enough red blood cells are produced to carry oxygen, but not so many that the blood becomes viscous or thick. A healthy kidney triggers the release of a hormone, erythropoietin which acts in the bone marrow to increase the production of red blood cells. The kidneys of patients with ESRD are often deficient in the production of this hormone.

Anemia is characterized by an abnormally low number of red blood cells in the circulatory system. Severe anemia associated with ESRD is mainly due to a deficiency in erythropoietin, a hormone produced by healthy kidneys that stimulates red blood cell production. Most dialysis patients receive replacement therapy of recombinant human erythropoietin (Epoetin alfa). Treatment with this drug therapy requires adequate amounts of iron for new hemoglobin synthesis and new red blood cell formation. Dialysis patients being treated with Epoetin alfa therapy require rapid mobilization of iron reserves in order to meet the demands of new red blood cell growth. The demands of this therapy can outstrip the

body's ability to mobilize iron stores and iron deficiency can result. Iron supplementation is required, not only to maintain proper iron balance, but to ensure good therapeutic response.

The majority of dialysis patients also suffer from iron deficiency. Blood loss from dialysis treatments and reduced dietary intake of iron are the key reason for this deficiency in iron stores. The liver is the site of most stored iron. Depletion of iron stores precedes impaired production of iron-containing proteins, the most prominent of which is hemoglobin, a primary component of red blood cells. Most dialysis patients receiving Epoetin alfa therapy also receive iron supplement therapy in order to maintain sufficient iron stores and to achieve the full benefit of Epoetin alfa treatments.

Current intravenous ("IV") parenteral iron compounds do not pass their iron load directly to blood plasma to be carried to the bone marrow. Instead these IV compounds deposit their iron load into the liver. The liver slowly processes this iron deposit into a useable form. As a result of the time between a dosage of IV iron and its availability to the body in useable form there can be volatility in iron stores which can reduce the effectiveness of Epoetin alfa treatments. Epoetin alfa is commonly administered as a large intravenous 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.

Our iron supplemented dialysate has a distinct difference from IV iron compounds in that our product transfers iron in a useable form directly from dialysate into the blood plasma and 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 Epoetin alfa 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 liver damage. 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 seeking 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 further product testing and clinical trials in order to obtain FDA approval for iron supplemented dialysate. We currently expect that the scope, duration and cost of this testing is likely to be greater than we initially anticipated. We now estimate the cost to obtain FDA approval to be between $5-7 million. However, this estimate may be modified as the approval process progresses. We plan to conduct safety pharmacology testing and to conduct clinical trials. 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 products are delivered by our subsidiary, Rockwell Transportation, Inc. Rockwell Transportation, Inc. operates a fleet of 22 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.

Rockwell Transportation, Inc. currently employs 22 drivers to operate its truck fleet and a fleet operations manager to manage its distribution operations. 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.

As we continue to grow our Dri-Sate Dry Acid Concentrate sales and migrate our product mix from liquid acid dialysate in drums to Dri-Sate Dry Acid Concentrate, we anticipate we will achieve improved distribution efficiencies from our truck fleet as a result of reduced frequency of deliveries and increased sales volume per truckload. As an example, a pallet containing four drums of liquid acid concentrate contains 220 gallons of liquid acid concentrate. On a pallet containing our Dri-Sate Dry Acid Concentrate, we can ship the equivalent of 1,200 gallons of acid concentrate in powder form.

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 three independent sales representation companies and three direct salespeople employed by us. 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.

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 than ours. We compete against three major competitors, of which our two largest competitors are primarily in the business of operating

hemodialysis clinics. The two largest manufacturers of hemodialysis concentrates are Fresenius Medical Care, Inc. ("Fresenius") and Gambro Healthcare, Inc. ("Gambro") who we believe also have, respectively, the first and third largest ESRD patient base in the United States. Gambro recently announced its intention to sell its clinic business to DaVita, Inc. These companies produce and sell a more comprehensive line of dialysis equipment, supplies and services than we sell.

Fresenius treats over 80,000 dialysis patients in North America and operates in over 1,100 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. We believe 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 treats an estimated 42,500 dialysis patients in the United States and operates approximately 580 clinics. Gambro manufactures and sells hemodialysis machines, dialyzers and other ancillary supplies. Gambro sells its concentrate solutions both to its own captive clinic base and to other clinic chains and independent clinics. We believe Gambro operates one manufacturing facility in Florida and additionally uses other manufacturers, including Fresenius and a private label manufacturer in the eastern United States to manufacture concentrate. Gambro also imports products from its European manufacturing facilities. Gambro engages 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 serves 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 nor does it manufacture a powder acidified concentrate product line in the United States.

In December 2004, Gambro announced that it was going to sell its U.S. clinic business to DaVita, Inc., our largest customer. This transaction is pending government approval. Once completed it is not clear whether Gambro will remain in the concentrate business or seek to alter its strategy in some way. How this sale may impact our market or our results is not clear at this time. We believe these events may prove beneficial in our business development efforts.

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. We believe Minntech has one domestic manufacturing facility located in Minnesota, a distribution center in Camp Hill, Pennsylvania and a distribution center in Mississippi. We believe Minntech uses a private label manufacturer to supply certain products in the northeastern United States to its warehouse locations. We believe Minntech largely uses its own vehicles to deliver its products to its customers.

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 is serviced by two manufacturers and three products. We believe the market

leader is Watson Pharmaceutical, Inc. ("Watson"). Watson markets a product called Ferrlecit(R) which is an injectable iron supplement made of sodium ferric gluconate complex in sucrose, and also markets a product called IN-FeD(R) 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(R), an injectable iron sucrose product. Both Watson and American Regent Laboratories, Inc. have substantially greater resources than us.

The markets for our products are highly competitive. New products we are developing will face competition from both conventional forms of iron delivery (i.e., oral and parenteral).

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.

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 within Rockwell. These quality systems involve control procedures that result in rigid specifications. Rockwell's 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, to assess the effectiveness of our quality systems and to 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 package 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 Federal Food, Drug and Cosmetic 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, 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 can 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 can 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 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 water soluble iron supplements to be included in our dialysate products. Water soluble iron supplements when coupled with our dialysate will be used as an iron maintenance therapy for dialysis patients, and we have been advised that these water soluble iron supplements will be considered a drug/device combination by the FDA. As a result, our iron maintenance therapy product will be subject to the FDA regulations for 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 is likely to involve 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 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.

PRODUCT LICENSE AGREEMENTS

We entered into two license agreements for iron supplemented dialysate 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.

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 are currently evaluating the cost, duration and scope of this product testing and clinical trials is under evaluation. 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 $5 million and $7 million. In addition to funding clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product as previously described.

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 registrations have now been issued.

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 18, 2018. We have applied for corresponding international patents in selected countries and these are pending at this time. We have no other patents.

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, Cargill, Inc., Roquette, Inc., Church & Dwight Co. Inc., Morton Salt Company and Nipro Medical Corporation.

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, 2004, two customers each accounted for more than 10% of our total sales, representing 52% of total sales. For the year ended December 31, 2003, three customers each accounted for more than 10% of our total sales, representing 42% of total sales. Our accounts receivable from these customers were $1,362,000 and $1,032,000 as of December 31, 2004 and 2003, 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 aggregated slightly over 4% and 3% of overall sales in 2004 and 2003, respectively.

EMPLOYEES

As of December 31, 2004, we had approximately 120 employees, all but one of whom are full-time employees.

If our sales volumes continue to increase, we expect to add additional production, distribution, sales and administrative personnel. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an "at-will" basis.

Our employment agreements with Mr. Robert L. Chioini, our Chairman, President and Chief Executive Officer and Mr. Thomas E. Klema, our Vice President, Chief Financial Officer and Secretary have expired. Mr. Chioini and Mr. Klema are continuing their employment without an employment agreement under the same compensation terms.

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 2004 and 2003 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 2004 and 2003, we incurred expenses related to the commercial development of our iron supplemented dialysate product aggregating approximately $200,000 and $250,000, 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 $5 million and $7 million) will have a material impact on us, and we will be required to seek additional sources of financing to fund these costs. Should we be unable to fund new product development efforts, we may have to abandon or postpone our efforts 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.

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 produced in commercial quantities, at reasonable costs, or 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.

OTHER

We do not expect any significant cost or impact from compliance with environmental laws.

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 available free of charge on or through our website, our annual reports on form 10-KSB.

ITEM 2. DESCRIPTION OF PROPERTY.

We entered into a lease agreement in October 2000 to lease a new 51,000 square foot facility in Wixom, Michigan. We occupied the new facility in July 2001 under a seven year lease. Base rent for the facility is $31,786 per month. In addition, we are responsible for all property taxes, insurance premiums and maintenance costs.

On March 12, 2000 we entered into an agreement to lease a 51,000 square foot facility in Grapevine, Texas through August 2005. Base monthly rent for the facility is $17,521, and we are responsible for all property taxes, insurance premiums and maintenance costs.

On February 23, 2005, we entered into short term lease agreement for a 61,000 square foot facility in Hodges, South Carolina. Monthly rent for the facility is $17,500. We expect to commence operations from this facility by April 2005.

We intend to use all of our facilities to manufacture and warehouse our products. 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 may require additional office space, manufacturing capacity and distribution facilities to meet our requirements.

ITEM 3. LEGAL PROCEEDINGS.

We filed a civil action on September 20, 2000 in the Circuit Court of Wayne County Michigan against Mr. Gary D. Lewis, individually and Wall Street Partners, Inc., a Michigan corporation, jointly and severally. We agreed to settle this action in the first quarter of 2005. We expect to receive gross proceeds from this settlement of approximately $241,000. We received cash of $130,000 during 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. The balance of the settlement is due by April 29, 2005. As of December 31, 2004, we have not recognized income for any portion of this settlement.

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 2004.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS.

Our common shares are traded on The Nasdaq SmallCap Market under the symbol RMTI.

It is a requirement for continued listing of our common shares on The Nasdaq SmallCap Market that we either maintain a minimum of $2,500,000 in shareholders' equity, have a $35,000,000 market capitalization or have earned $500,000 in net income for two of our three most recently completed fiscal years. We have relied on having shareholders' equity in excess of $2,500,000 to meet this requirement. As of December 31, 2004, Rockwell had shareholders'

equity of $3,422,319. If the cost of our clinical trials exceeds the income generated by our operations or if we otherwise incur losses and if we are unable to raise sufficient equity to keep shareholders' equity at or above $2,500,000, we may be subject to delisting from The Nasdaq SmallCap Market.

If our common shares and common share purchase warrants are delisted from The Nasdaq SmallCap Market, they would likely be quoted on the OTC Bulletin Board. Any delisting could cause the market price of the common shares and common share purchase warrants to decline and could make it more difficult to buy or sell common shares or common share purchase warrants on the open market.

The prices below are the high and low bid prices as reported by The Nasdaq SmallCap Market in each quarter during 2003 and 2004. The prices are inter-dealer prices, without retail mark-up, mark down or commission and may not represent actual transactions.

	BID PRICE INFORMATION	
QUARTER ENDED	HIGH	LOW
March 31, 2003	1.56	0.41
June 30, 2003	2.05	1.00
September 30, 2003	3.49	1.95
December 31, 2003	3.99	2.70
March 31, 2004	4.50	3.45
June 30, 2004	4.25	2.52
September 30, 2004	3.41	2.28
December 31, 2004	3.75	2.67

As of March 9, 2005, there were 56 record holders of our common shares.

DIVIDENDS

Our Board of Directors has discretion whether or not to pay dividends. Among the factors our Board of Directors considers when determining whether or not to pay dividends are our earnings, capital requirements, financial condition, future business prospects and business conditions. We have never paid any cash dividends on our common shares and do not anticipate paying dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our operations.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2004:

PLAN CATEGORIES	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (A)	WEIGHTED AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (B)	NUMBER OF FOR FU COMPENSATI RE

Equity compensation plans approved by security holders.....	2,707,717	$2.12
Equity compensation plans not approved by security holders.....	--	--
Total.....	2,707,717	$2.12

ITEM 6. MANAGEMENT'S DISCUSSIONS AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Some of the statements in this report are forward-looking statements. These forward-looking statements include statements relating to our performance in this Management's Discussion and Analysis of Financial Condition and Results of Operations. In addition, we may make forward-looking statements in future filings with the Securities and Exchange Commission and in written material, press releases and oral statements issued by us or on our behalf. Forward-looking statements include statements regarding the intent, belief, or current expectations of us or our officers, including statements preceded by, followed by or including forward-looking terminology such as "may", "might", "will", "should", "believe", "expect", "anticipate", "estimate", "continue", "predict", "forecast", "projected" or similar expressions, with respect to various matters.

Our actual results might differ materially from those projected in the forward-looking statements depending on various important factors. The important factors include our history of losses, the cost of obtaining FDA approval to market our new iron supplemented dialysate product, the challenges associated with developing new products, the uncertainty of the acceptance of our products by the hemodialysis community, competition in our markets, and other factors discussed in this report and other filings, all of which constitute cautionary statements identifying important factors with respect to forward-looking statements, including certain risks and uncertainties, that could cause actual results to differ materially from those in such forward-looking statements.

All forward-looking statements in this report are based on information available to us on the date of this report. We do not undertake to update any forward-looking statements that may be made by us or on our behalf in 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 increased sales of our concentrate product lines by over 30% this year, allowing us to more fully utilize our facilities, equipment and staff, and increasing our profitability. We believe that our core concentrate and supply business can continue to be profitable.

The dialysis industry is highly concentrated with several large clinic chains representing the majority of the industry. We expect that the consolidation of large and regional dialysis service providers will continue in the future. Our largest customer, DaVita, Inc., the second largest dialysis treatment provider in the United States has announced its pending acquisition of the dialysis clinic business of Gambro, the third largest dialysis treatment provider in the United States. How this acquisition by DaVita may impact our

market or our results is not clear at this time. We believe these events may prove beneficial in our business development efforts.

As a result of this industry concentration, the dialysis supply market is very competitive. 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. 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.

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. If we are successful in introducing our dialysate iron product, we believe it is possible that we may also increase our market share for the other products we sell. The cost to obtain regulatory approval for a drug in the United States is expensive and we expect that the development costs of our iron supplemented dialysate product will require us to raise additional funds or collaborate with a strategic partner. We expect to incur substantial costs to conduct required clinical trials and to obtain marketing approval which may offset some or all of any profits generated from sales of our existing products during the approval process. We expect this process to take several years and we might not be successful.

RESULTS OF OPERATIONS

FOR THE YEAR ENDED DECEMBER 31, 2004 COMPARED TO THE YEAR ENDED DECEMBER 31, 2003

Sales

For the year ended December 31, 2004, our sales were $17.95 million as compared to sales of $15 million for 2003, representing an increase of 19.9%. We increased our sales to our key national and regional chain customers. Sales of our concentrate product lines increased by over 30% while sales in our ancillary product

lines decreased by $600,000. The decrease in our ancillary product sales was due to a reduction in blood tubing sales to a single customer of $860,000 in 2004 as compared to 2003.

Our core concentrate product lines which represent approximately 85% of our total sales increased by over 30% in 2004 over 2003. Sales of our concentrate product lines were up $3.6 million in 2004 over 2003. Demand increased for all of our concentrate product lines with substantial growth in both powder and liquid product lines. Both clinic chains and independent providers are attracted to our Dri-Sate product line and its patented Dri-Sate (R)Dry Acid Concentrate Mixing System. Our Dri-Sate Dry Acid Concentrate unit volumes increased 38% over 2003. Similarly, our gallon volume of liquid acid concentrate grew by 40%. Our SteriLyte(R) Liquid Bicarbonate unit volume increased 52% in 2004 as compared to 2003. Powder bicarbonate unit volumes increased by 32%.

While our overall ancillary sales declined in 2004 as compared to 2003 due to the reduction in blood tubing purchases by a single customer of $860,000, the remainder of our ancillary products realized increases in sales volumes. We

realized additional blood tubing sales aggregating $150,000 and we experienced an increase of $110,000 in specialty kit sales.

We also experienced a reduction in backhaul revenue from our transportation fleet. Our backhaul revenue declined $67,000 in 2004 as compared to 2003 as a result of a combination of factors including new driver regulations that reduced the amount of driving time available and due to the significant business growth we realized that resulted in greater utilization of our fleet to deliver our own products. We do not expect backhaul revenue to be a material source of revenue in the future.

Gross Profit

Gross profit was $2,805,000 and increased by $250,000 in 2004 as compared to 2003. In 2004, we made a change to the relative allocation of certain costs for facility, depreciation and other costs that increased the portion of those costs included in cost of goods sold. As a result, we increased cost of sales by $136,800 in 2004 as compared to 2003 or .8% of sales for this change in allocations. Overall, our comparable gross profit margins between 2004 and 2003 decreased by .5 percentage points after adjusting for this change in allocations. Despite higher sales volumes, our gross profit margins of 15.6% decreased largely due to increased delivery costs for our products which more than offset productivity improvements from higher production volumes.

We experienced substantially higher delivery costs throughout 2004 due to several contributing factors including additional fleet resources added to support new business growth, higher fuel costs to operate our fleet, increased frequency of deliveries for certain customers and in the second half of 2004 a higher growth rate in customers in territories beyond our traditional distribution footprint. As a result of a combination of these factors, our distribution costs were up approximately 3 percentage points to sales as compared to 2003. We anticipate that the negative impact from some of these factors may be mitigated in the future as we gain efficiencies from our fleet additions, reduce delivery frequency for certain customers and optimize our distribution efforts in certain markets. We have added a new facility in the Southeast to address, on an interim basis, distribution of our products in that region. We would expect that if the cost of fuel continues to increase that it may offset any future distribution improvements and other productivity improvements from higher sales volumes.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses were $2,396,000 and were 13.4% of sales, an improvement of 2.4 percentage points compared to 2003. However, we reduced the allocation of facility, depreciation and other costs charged to selling, general and administrative expense by $136,800. Without this allocation change, selling, general and administrative costs increased by $165,000, or 7% compared to the 2003. The majority of the cost increase was due to additional resources and expenses, including additional personnel costs, to handle increased transaction activity associated with our 30% increase in concentrate sales.

We made a considerable investment for research and product development of dialysate iron in 2004 with aggregate spending of $200,000. We spent over $250,000 for development of our iron supplemented dialysate product in 2003. We expense these investments in the year they are incurred.

Operating Income

Our Operating Income in 2004 increased over our operating income in 2003 by $221,000 or 118% to $409,000 or 2.3% of sales. This improvement resulted primarily from our increased sales volumes.

Interest Expense

Interest expense increased by $14,600 in 2004 over 2003 due to higher interest expense on new capitalized leases obligations. This increase was partially offset by lower average borrowings under our line of credit.

Net Income

Net income in 2004 was $211,522, an improvement of $206,700 over 2003. Net income to sales improved by 1.2 percentage points to sales compared to 2003. We have substantial tax loss carryforwards from our earlier losses and the impact of those carryforward losses offset the statutory tax liability for 2004. We have not recorded a federal income tax benefit from our prior losses because we might not realize the carryforward benefit of the remaining losses.

Basic earnings per share was $.02 which was a $.02 improvement in net income per share in 2004 over 2003. Similarly, fully diluted earnings per share of $.02 improved $.02 as compared to 2003.

FOR THE YEAR ENDED DECEMBER 31, 2003 COMPARED TO THE YEAR ENDED DECEMBER 31, 2002

Sales

For the year ended December 31, 2003, sales were $15 million as compared to sales of $11.5 million for 2002 representing an increase of 30.2%. Our sales increased largely because of unit volume growth across our key product lines with the addition of new customers and increase in sales to existing customers. Sales of our concentrate product lines which represented 79% of our sales in 2003 increased 24%. In addition, in 2002 we added blood tubing to the line of ancillary products we sell, resulting in ancillary product line sales increasing 89% in 2003.

Sales of our concentrate product lines increased by $2.2 million or 24% over 2002. We experienced increased demand across all of our concentrate product lines. We added several significant regional dialysis providers as customers in 2003 and signed a large supply contract with a major provider during 2003. As a result of the new business, we achieved significant growth in all of our product lines. Both clinic chains and independent providers are attracted to our Dri-Sate product line and its patented Dri-Sate (R)Dry Acid Concentrate Mixing System. Our Dri-Sate Dry Acid Concentrate unit volumes increased 35% over 2002. Similarly, our liquid acid concentrate unit volume grew by 15%. Our SteriLyte(R) Liquid Bicarbonate unit volume increased 50% in 2003 as compared to 2002. Our addition of a manufacturing facility in Texas has also allowed us to steadily increase our sales in the southern United States.

We also increased our sales of ancillary products significantly during 2003. Our total ancillary product sales increased by $1.3 million or 89% in 2003 driven by a 180% increase in sales of blood tubing as compared to 2002. Sales in our kit products grew by over $200,000, however our sales of fistula needles declined by $275,000 due to one of our suppliers withdrawing its fistula needles from the market during 2002.

Gross Profit

Our gross profit margins continued to improve throughout 2003 resulting from substantially higher production volumes and greater capacity utilization in both of our manufacturing facilities. Our gross profit margins improved each

quarter in 2003 with fourth quarter gross profit margins of 19.2%. Overall, 2003 gross

profit margins were 17.1% and were 4.4 percentage points higher than in 2002. Our gross profit in 2003 was $2,555,600 which represents an increase of $1,102,000 or 76% over 2002 with the improvement largely driven by higher sales volume.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses were $2,368,000 and were 15.8% of sales, an improvement of 4.4 percentage points compared to 2002. Overall, Selling, General and Administrative costs increased $49,000 or 2.1% over 2002. We were able to control our costs and add additional sales volume with limited increases in expenses. In addition, we spent substantially more on research and product development in 2003 with spending up $130,000 from the level in 2002. Overall, we spent over $250,000 for development of our iron supplemented dialysate product in 2003.

Interest Expense

Interest expense increased by $67,500 in 2003 over 2002 due to increased borrowings under our line of credit and interest expense under a note payable related to equipment we added to our new facilities in 2001 and 2002 coupled with interest expense on capital lease obligations.

Net Income and Earnings Per Share

Net Income for 2003 was $4,853 as compared to a net loss of ($980,711) representing over a 100% reduction in the 2002 net loss with a $985,000 net profit improvement in 2003 over 2002. During the second half of 2003, we had a net profit of $185,000. We have substantial tax loss carryforwards from our earlier losses and the impact of those carryforward losses offset the statutory tax liability for 2003. The Company has not recorded a federal income tax benefit from its prior losses because it might not realize the carryforward benefit of those losses.

Net Income per share was negligible in 2003 as compared to a net loss of ($.12) per share in 2002. The $.12 improvement in earnings per share in 2003 was the result of higher sales, improved gross profit margins and tight expense control.

CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America.

These accounting principles require us to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and contingencies.

All significant estimates, judgments and assumptions are developed based on the best information available to us at the time made and are regularly reviewed and updated when necessary. Actual results will generally differ from these estimates. Changes in estimates are reflected in our financial statements in the period of change based upon on-going actual experience, trends, or subsequent realization depending on the nature and predictability of the estimates and contingencies.

Interim changes in estimates are generally applied prospectively within annual periods. Certain accounting estimates, including those concerning revenue recognition and allowance for doubtful accounts, impairments and valuation adjustments, 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.

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 generally transfer title to the buyer when the container leaves our facility and therefore we recognize revenue upon shipment to foreign customers. 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.

We adopted Statement of Financial Accounting Standards (SFAS) No. 142, Goodwill and Other Intangible Assets. Under SFAS No. 142, goodwill is no longer amortized; however, it must be tested for impairment at least annually. Goodwill impairment 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 for the current year 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 or future events unpredictable.

LIQUIDITY AND CAPITAL RESOURCES

Our strategy is to expand our operations to serve dialysis providers throughout the United States. We anticipate that, as a result of our existing supply agreements, our customer relationships and our changing market dynamics, we have the opportunity to capture substantial market share that will lead to sustaining and increasing our profitable operations. We expect that we will continue to realize substantial growth during 2005 and that we will require additional working capital and capital expenditures to fund this growth. In addition, over the next several years, we expect to make substantial investments in our dialysate iron product in order to gain FDA approval to market dialysate iron.

In 2004, we generated cash from our business operations and reinvested those funds into the development and expansion of our business. Cash flow generated from our business operations aggregated $840,000 in 2004 after adjusting our earnings for non-cash charges against earnings for depreciation and amortization. We realized substantial growth of over 30% in our core concentrate business in 2004 and as a result we increased our accounts receivable and inventory by over $430,000 to support this growth. Based on current and prospective developments that we anticipate in our business in 2005, we will require additional working capital

and capital expenditures to support our development plans. Positive cash flow from operations is anticipated to provide a portion of the funding that we anticipate that we may need to support future growth.

In addition to funding provided by operations, we intend to raise additional capital. We continue to engage in discussions with potential financing sources including potential lenders, strategic partners and investors.

We have a line of credit with GE Healthcare Finance with a $2.5 million credit limit. We are permitted to borrow up to 80% of our eligible accounts receivable and we are required to maintain a net worth of at least $750,000. Borrowings under this line were $452,700 at December 31, 2004 and were $200,000 less than at the start of 2004. This credit line expires March 25, 2005.

In addressing our need for expanded working capital requirements, we have received a commitment letter for a new line of credit with a financial institution which expands our borrowing capacity. This credit line has a $2.75 million credit limit. We are permitted to borrow up to 80% of our eligible accounts receivable and 40% of eligible inventory up to $600,000. This line of credit is dependent upon certain conditions including satisfactory completion of due diligence by the lender and completion of legal documentation.

We reached a financial settlement with the defendant in a legal action we brought against the defendant. As a result, we expect to realize cash proceeds in the first half of 2005 of approximately $225,000 after expenses.

We are seeking FDA approval for our dialysate iron drug product. The

development and approval of drugs can be expensive and take a long time. The development and approval costs may offset some or all of our earnings during the approval process. During 2004, we made cash investments of $250,000 in dialysate iron which included $75,000 for licensing fees related to a patent issuance which we capitalized. We estimate the cash required to fund approval of our new iron supplemented dialysate product will be between $5,000,000 -- $7,000,000 over the next several years. We may raise these funds ourselves or if we do not raise the capital to fund this project ourselves, we may decide to seek a partner with greater technical and financial resources to facilitate approval of this product.

We believe that we will be able to raise the capital required to expand our operations and fund our new product development strategy through a combination of cash flow from operations and licensing, debt or equity financing arrangements; however we may not be successful.

If we are not successful in raising additional funds, we may be required to alter our growth strategy, defer spending on business development, curtail production expansion plans or take other measures to conserve our cash resources.

In addition, the dialysis provider industry that we serve is becoming increasingly concentrated. As a result, our business is predominantly with national and regional dialysis chains. 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 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 would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

ITEM 7. FINANCIAL STATEMENTS

The Consolidated Financial Statements of the Registrant required by this item are set forth on pages F-1 through F-15.

ITEM 8. CHANGES AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

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, 2004. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of December 31, 2004 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. 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, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

(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. For the quarter ended December 31, 2004, there were no significant changes to the Company's internal controls or in factors that could significantly affect the Company's internal controls.

ITEM 8B. OTHER INFORMATION

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

Incorporated herein by reference to Rockwell Medical Technologies, Inc. definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the year covered by this Form 10-KSB with respect to its Annual Meeting of Shareholders to be held on May 26, 2005.

ITEM 10. EXECUTIVE COMPENSATION.

Incorporated herein by reference to Rockwell Medical Technologies, Inc. definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the year covered by this Form 10-KSB with respect to its Annual Meeting of Shareholders to be held on May 26, 2005.

ITEM 11. SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

Incorporated herein by reference to Rockwell Medical Technologies, Inc. definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the year covered by this Form 10-KSB with respect to its Annual Meeting of Shareholders to be held on May 26, 2005.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Incorporated herein by reference to Rockwell Medical Technologies, Inc. definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the year covered by this Form 10-KSB with respect to its Annual Meeting of Shareholders to be held on May 26, 2005.

ITEMS 13. EXHIBITS.

(a) Exhibits

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.
4.1	Form of Warrant Agreement, incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.2	Form of Underwriters Warrant Agreement, incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.3	Registration Rights Agreement among the Company and the holders of certain of the Company's Common Share Purchase Warrants, incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.4	Form of Lock-up Agreement, incorporated by reference to Exhibit 4.7 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 Exhibit 10.1 to the Company's Registration Statement on Form SB-2, File No. 333-31991.

10.2	Employment Agreement dated as of February 19, 1997 between the Company and Robert L. Chioini, incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.3	Consulting and Financial Advisory Services Agreement dated as of February 19, 1997 between the Company and Wall Street Partners, Inc., incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.4	Asset Purchase Agreement dated as of November 1, 1996 by and among the Predecessor Company, the Family Partnerships (as defined therein), the Members (as defined therein) and the Company (formerly known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.5	First Amendment to Asset Purchase Agreement dated as of January 31, 1997 by and among the Predecessor Company, the Family Partnerships, the Members and the Company (formerly

	known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.6	Second Amendment to Asset Purchase Agreement dated as of February 19, 1997 by and among the Predecessor Company, the Family Partnerships, the Members and the Company (formerly known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.7	Letter Agreement dated April 4, 1997 among the parties to the Asset Purchase Agreement concerning the conversion of the promissory note payable to the Supply Company, incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.8	Lease Agreement dated as of September 5, 1995 between the Supply Company, as tenant, and Oakland Oaks, L.L.C., as landlord, incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.9	Assignment and First Amendment to Wixom Building Lease dated as of February 19, 1997 among the Supply Company, as assignor, the Company, as assignee, and Oakland Oaks, L.L.C., as landlord, incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.10	Letter Agreement dated November 21, 1997 among the parties to the Asset Purchase Agreement to confirm the reduction of the purchase price of the Asset Purchase Agreement, incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.11	Employment Agreement dated as of January 12, 1999 between the Company and Thomas E. Klema incorporated by reference to the annual report on Form 10-KSB filed March 30, 1999.
10.12	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.
10.13	Employment Agreement dated as of March 20, 2000 between the Company and Robert L. Chioini incorporated by reference to the quarterly report on Form 10-QSB filed August 11, 2000.
10.14	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.
10.15	Loan and Security Agreement dated March 28, 2001 between the Company and Heller Healthcare Finance, Inc. incorporated by reference to the annual report on Form 10-KSB filed April 2, 2001.
10.16	Promissory Note between GE Healthcare Financial Services and Rockwell Medical Technologies, Inc. dated August 15, 2001 incorporated by reference to the quarterly report on Form 10-QSB filed November 14, 2001.
10.17	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed April 1, 2002.

10.18	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed April 1, 2002.
10.19	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed March 28, 2003.
10.20	Amendment No. 1 to the Loan and Security Agreement dated March 25, 2003 between the Company and Heller Healthcare Finance, Inc. incorporated by reference to the annual report on form 10-KSB filed March 28, 2003.
10.21	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.
14.1	Rockwell Medical Technologies, Inc. Code of Ethics incorporated by reference to the Definitive Proxy Statement for our 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), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Incorporated herein by reference to Rockwell Medical Technologies, Inc. definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the year covered by this Form 10-KSB with respect to its Annual Meeting of Shareholders to be held on May 26, 2005.

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, thereto duly authorized.

ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Registrant)

By: /s/ ROBERT L. CHIOINI

Robert L. Chioini
President and Chief Executive Officer

In accordance with Section 13 or 15(d) of the Exchange Act, this report has been signed by the following persons 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 22, 2005
/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 22, 2005
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 22, 2005
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 22, 2005

INDEX TO FINANCIAL STATEMENTS

PLANT2

INDEPENDENT AUDITOR'S REPORT

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, 2004 and 2003 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. 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, 2004 and 2003, 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.

Plante & Moran, PLLC

Auburn Hills, Michigan
March 21, 2005

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2004 AND 2003
(WHOLE DOLLARS)

	DECEMBER 31, 2004	DECEMBER 31, 2003
ASSETS		
Cash and Cash Equivalents	$ 166,195	$ 106,639
Restricted Cash Equivalents	8,662	8,662
Accounts Receivable, net of a reserve of $44,500 in 2004 and $34,500 in 2003	2,302,093	2,169,564
Inventory	1,652,457	1,350,291

Other Current Assets	111,630	103,971
Total Current Assets	4,241,037	3,739,127
Property and Equipment, net	2,048,665	1,943,376
Intangible Assets	369,508	314,071
Goodwill	920,745	920,745
Other Non-current Assets	120,597	127,467
Total Assets	$ 7,700,552	$ 7,044,786
LIABILITIES AND SHAREHOLDERS' EQUITY		
Short Term Borrowings	$ 452,682	$ 642,018
Notes Payable & Capitalized Lease Obligations	389,602	307,959
Accounts Payable	2,124,679	1,666,952
Accrued Liabilities	492,592	329,519
Total Current Liabilities	3,459,555	2,946,448
Long Term Notes Payable & Capitalized Lease Obligations	818,678	926,230
Shareholders' Equity:		
Common Share, no par value, 8,556,531 and 8,519,405 shares issued and outstanding	11,870,909	11,832,220
Common Share Purchase Warrants, 3,761,071 and 3,766,071 shares issued and outstanding	320,150	320,150
Accumulated Deficit	(8,768,740)	(8,980,262)
Total Shareholders' Equity	3,422,319	3,172,108
Total Liabilities And Shareholders' Equity	$ 7,700,552	$ 7,044,786

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

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
(WHOLE DOLLARS)

	2004	2003
Sales	$17,944,710	$14,970,144
Cost of Sales	15,139,215	12,414,462
Gross Profit	2,805,495	2,555,682
Selling, General and Administrative	2,396,315	2,367,773
Operating Income	409,180	187,909
Interest Expense, net	197,658	183,056
Income Before Income Taxes	211,522	4,853
Income Tax Expense	--	--
Net Income	$ 211,522	$ 4,853

Basic And Diluted Earnings Per Share.....	$ .02	$ -0-

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, 2004 AND 2003
(WHOLE DOLLARS)

	COMMON SHARES		PURCHASE WARRANTS			
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	SHAR E
Balance as of December 31, 2002.....	8,488,283	$11,724,507	3,753,460	$306,108	$(8,985,115)	$3,
Issuance of Common Shares...	18,733	24,914	--	--	--	
Exercise of Purchase Warrants.....	12,389	12,799	(12,389)	--	--	
Compensation Expense related to Stock Options and Purchase Warrants.....	--	70,000	25,000	14,042	--	
Net Income.....					4,853	
Balance as of December 31, 2003.....	8,519,405	$11,832,220	3,766,071	$320,150	$(8,980,262)	$3,
Issuance of Common Shares...	32,126	34,989	--	--	--	
Exercise of Purchase Warrants.....	5,000	3,700	(5,000)	--	--	
Net Income.....					211,522	
Balance as of December 31, 2004.....	8,556,531	$11,870,909	3,761,071	$320,150	$(8,768,740)	$3,

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, 2004 AND 2003
(WHOLE DOLLARS)

	2004	2003

Cash Flows From Operating Activities:		
Net Income	$ 211,522	$ 4,853
Adjustments To Reconcile Net Income To Net Cash Used In Operating Activities:		
Depreciation and Amortization	629,697	453,926
Compensation Recognized For Stock Options & Purchase Warrants	--	84,042
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(132,529)	(447,109)
(Increase) Decrease in Inventory	(302,166)	126,215
(Increase) Decrease in Other Assets	(789)	21,654
Increase (Decrease) in Accounts Payable	457,727	(13,890)
Increase (Decrease) in Other Liabilities	163,073	(4,273)
Changes in Assets and Liabilities	185,316	(317,403)
Cash Provided By Operating Activities	1,026,535	225,418
Cash Flows From Investing Activities:		
Purchase of Equipment	(392,046)	(164,626)
(Increase) Decrease in Restricted Cash Equivalents	--	5,303
Purchase of Intangible Assets	(83,095)	(2,419)
Cash Provided By (Used In) Investing Activities	(475,141)	(161,742)
Cash Flows From Financing Activities:		
Proceeds from Borrowings on Line of Credit	16,794,439	14,122,113
Payments on Line of Credit	(16,983,775)	(13,897,349)
Issuance of Common Shares and Purchase Warrants	38,689	37,713
Payments on Notes Payable	(341,191)	(219,647)
Cash Provided (Used) By Financing Activities	(491,838)	42,830
Increase In Cash	59,556	106,506
Cash At Beginning Of Period	106,639	133
Cash At End Of Period	$ 166,195	$ 106,639

Supplemental Cash Flow disclosure:

	2004	2003
Interest Paid	$197,818	$183,616

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

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 patient's 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.

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. In most instances title for goods shipped internationally transfers to the buyer once it leaves our facility and therefore, we recognize revenue upon shipment to foreign customers.

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 AND RESTRICTED CASH EQUIVALENTS

We consider cash on hand, unrestricted certificates of deposit and short term marketable securities as cash and cash equivalents.

At December 31, 2004 and 2003, restricted cash equivalents consisted of a certificate of deposit of $8,662 and $8,662, respectively, securing a letter of credit.

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

We adopted Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets". Under SFAS No. 142, 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 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. We assess goodwill for impairment annually. 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.

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

PRODUCT DEVELOPMENT AND RESEARCH

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 $200,000 and $250,000 in 2004 and 2003, respectively.

STOCK OPTIONS

Stock options granted to employees are accounted for using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25 Accounting for Stock Issued to Employees, as allowed under SFAS No. 123 Accounting for Stock-Based Compensation. Stock option grants to employees do not result in an expense if the exercise price is at least equal to the market price at the date of grant. Exercise prices on all options granted equal or exceed the fair market value of the underlying stock at the applicable grant dates and, accordingly, no compensation cost is recorded in the accompanying financial statements as a result of stock options awarded under the plan to employees. Stock options granted to non-employees are recorded at the fair value of the awards at the date of the grant using the Black-Scholes model.

Our reported and pro forma information for the years ended December 31:

	2004	2003
As reported net income (loss) available to common shareholders	$ 211,522	$ 4,853
Less: Stock based compensation expense determined under the fair market value method, net of tax	879,457	481,292
Pro forma net income (loss)	$(667,935)	$(476,439)
As reported basic earnings per share and diluted earnings per share	$ .02	$ 0.00
Pro forma earnings (loss) per share and diluted earnings (loss) per share	$ (0.08)	$ (0.06)

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:

	2004	2003

Basic Weighted Average Shares Outstanding.....	8,546,302	8,495,134
Effect of Dilutive Securities.....	758,821	734,620
Diluted Weighted Average Shares Outstanding.....	9,305,123	9,229,754

At December 31, 2004 potentially dilutive securities comprised 2,707,717 stock options exercisable at prices from $.55 to $4.05 per share, 3,625,000 common share purchase warrants exercisable at $4.50 per common share and 136,071 common share purchase warrants exercisable at various prices ranging from $.50 to $4.05.

At December 31, 2003 potentially dilutive securities comprised 1,918,927 stock options exercisable at prices from $.55 to $3.06 per share, 3,625,000 common share purchase warrants exercisable at $4.50 per common share and 141,071 common share purchase warrants exercisable at various prices ranging from $.50 to $2.70.

ACCOUNTING CHANGE

In 2004, we made a change to the relative allocation of certain costs for facility, depreciation and other costs that increased the portion of those costs included in cost of sales. As a result, we increased cost of sales and decreased selling, general and administrative expenses by $136,800 in 2004 as compared to 2003 for this change in allocations.

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 followed a strategy of developing market share through a differentiated value proposition to our customers including new products, superior delivery and customer service, and tailoring product line offerings to match customer requirements, including offering a full range of formulations and supplies. In 2004, our revenue increased by $2,974,566 or 19.9% over 2003. In 2003, our revenue increased by $3,474,000 or 30.2% over 2002.

Our strategy is to expand our operations to serve dialysis providers throughout the United States and internationally on an export basis. We anticipate that, as a result of our existing supply agreements, our customer relationships and our changing market dynamics, we have the opportunity to capture substantial market share that will lead to sustaining and increasing our profitable operations. We expect that we will continue to realize substantial growth during 2005 and that we will require additional working capital and capital expenditures to fund this growth. In addition, over the next several years, we expect to make substantial investments in our dialysate iron product in order to gain FDA approval to market dialysate iron.

In 2004, we generated cash from our business operations and reinvested those funds into the development and expansion of our business. Cash flow generated from our business operations aggregated $840,000 in 2004 after adjusting our earnings for non-cash charges against earnings for depreciation and amortization. We realized substantial growth of over 30% in our core concentrate business in 2004 and as a result we increased our accounts receivable and inventory by over $430,000 to support this growth. Based on current and prospective developments that we anticipate in our business in 2005, we will require additional working capital and capital expenditures to support our development plans. Positive cash flow from operations is anticipated to provide a portion of the funding that we anticipate that we may need to support future growth.

In addressing our need for expanded working capital requirements, we have received a commitment letter for a new line of credit with a financial institution which expands our borrowing capacity. This credit line has a $2.75 million credit limit. We are permitted to borrow up to 80% of our eligible accounts receivable and 40% of eligible inventory up to $600,000. This line of credit is dependent upon certain conditions including satisfactory completion of due diligence by the lender and completion of legal documentation.

We are seeking FDA approval for our dialysate iron drug product. The development and approval of drugs can be expensive and take a long time. The development and approval costs may offset some or all of our earnings during the approval process. We estimate the cash required to fund approval of our new iron supplemented dialysate product will be between $5,000,000 -- $7,000,000 over the next several years. We may raise these funds ourselves or if we do not raise the capital to fund this project ourselves, we may decide to seek a partner with greater technical and financial resources to facilitate approval of this product.

We believe that we will be able to raise the capital required to expand our operations and fund our new product development strategy through a combination of cash flow from operations and licensing, debt or equity financing arrangements; however we may not be successful.

If we are not successful in raising additional funds, we may be required to alter our growth strategy, defer spending on business development, curtail production expansion plans or take other measures to conserve our cash resources.

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, 2004, two customers each accounted for more than 10% of our total sales, representing 52% of total sales. For the year ended December 31, 2003, three customers each accounted for more than 10% of our total sales, representing 42% of total sales. Our accounts receivable from these customers were $1,362,000 and $1,032,000 as of December 31, 2004 and 2003, 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 aggregated slightly over 4% and 3% of overall sales in 2004 and 2003, respectively.

5. INVENTORY

Components of inventory as of December 31, 2004 and 2003 are as follows:

	2004	2003
Raw Materials	$ 399,455	$ 241,317
Finished Goods	1,253,002	1,108,974
Total	$1,652,457	$1,350,291

6. PROPERTY AND EQUIPMENT

Major classes of Property and Equipment, stated at cost, as of December 31, 2004 and 2003 are as follows:

	2004	2003
Leasehold Improvements	$ 380,319	$ 379,244
Machinery and Equipment	2,652,899	2,337,726
Office Equipment and Furniture	247,582	208,692
Laboratory Equipment	236,747	236,747
Transportation Equipment	705,320	533,717
	4,222,867	3,696,126
Accumulated Depreciation	(2,174,202)	(1,752,750)
Net Property and Equipment	$ 2,048,665	$ 1,943,376

Included in the table above are assets under capital lease obligations with a cost of $873,628 and $523,345 and a net book value of $669,514 and $477,612, as of December 31, 2004 and 2003, respectively.

Depreciation expense was $602,039 for 2004 and $429,377 for 2003.

7. GOODWILL AND INTANGIBLE ASSETS

Total goodwill was $920,745 at December 31, 2004 and 2003. We completed our annual impairment tests as of November 30, 2004 and 2003 and determined that no adjustment for impairment of goodwill was required.

We entered into a global licensing agreement in 2001 covering patents for a method for iron delivery to a patient by transfer from dialysate. The invention relates to methods and compositions for delivering iron to an iron-deficient patient using an iron complex in an aqueous solution. We entered into a second

licensing agreement in 2002 covering patents for a more specific form of iron which may be delivered via dialysate. We intend to obtain FDA approval for this product as a drug additive to our dialysate product line which upon approval will be marketed as an iron maintenance therapy for dialysis patients.

We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset. As of December 31, 2004, we have capitalized licensing fees of $450,214, net of accumulated amortization of $80,705. As of December 31, 2003, we have capitalized licensing fees of $314,071, net of accumulated amortization of $53,047. Our policy is to amortize licensing fees over the life of the patents pertaining to the licensing agreements. We recognized amortization expense of $27,658 in 2004 and $24,549 in 2003. Estimated amortization expense for licensing fees for 2005 through 2009 is approximately $31,000 per year. One of the licensing agreements requires the additional payments upon achievement of certain milestones.

8. LINE OF CREDIT

As of March 28, 2003, we renewed and expanded our credit facility under a $2,500,000 revolving line of credit facility with a financial institution. The two year loan facility is secured by our accounts receivable and other assets. Borrowings under the facility are limited to 80% of eligible accounts receivable. We are required to maintain a net worth of $750,000. We are obligated to pay interest at the rate of two percentage points over the prime rate, plus other fees aggregating .25% of the loan balance. Our outstanding borrowings under this loan facility were $452,700 and $642,018 as of December 31, 2004 and 2003, respectively.

Subsequent to the end of the year, we received a commitment letter for a new line of credit with a financial institution which expands our borrowing capacity. This credit line has a $2.75 million credit limit with interest at .75% over the prime rate. We are permitted to borrow up to 80% of our eligible accounts receivable and 40% of eligible inventory up to $600,000. This line of credit is dependent upon certain conditions including satisfactory completion of due diligence by the lender and completion of legal documentation.

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 $561,637 and $754,541 at December 31, 2004 and 2003, 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, 2005	$210,258
Year ending December 31, 2006	229,173
Year ending December 31, 2007	122,206

Total Notes Payable	$561,637

CAPITAL LEASE OBLIGATIONS

During 2004, we entered into capital lease obligations primarily related to equipment with an initial fair market value aggregating $315,282. 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 2005-2010 and interest rates on the leases range from 5%-17.0%. These obligations under capital leases had outstanding balances of $646,643 and $479,648 at December 31, 2004 and 2003, respectively.

Future minimum lease payments under capital lease obligations are:

Year ending December 31, 2005	$ 237,231
Year ending December 31, 2006	214,304
Year ending December 31, 2007	163,400
Year ending December 31, 2008	95,992
Year ending December 31, 2009	67,755
Thereafter	5,159
Total minimum payments on capital lease obligations	784,441
Interest	(137,798)
Present value of minimum lease payments	646,643
Current portion of capital lease obligations	(179,344)
Long-term capital lease obligations	$ 467,299

11. OPERATING LEASES

We lease our production facilities and administrative offices as well as certain equipment used in our operations. The lease terms are three to seven years. Lease payments under all operating leases were $651,642 and $810,105 for the years ended December 31, 2004 and 2003, respectively.

We have leases on two buildings that approximate 51,000 square feet each and that expire in August 2005 and July 2008, respectively.

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

Year ending December 31, 2005	$ 597,681
Year ending December 31, 2006	444,139
Year ending December 31, 2007	417,596
Year ending December 31, 2008	216,294
Year ending December 31, 2009	11,501
Total	$1,687,211

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

12. INCOME TAXES

We recognized no income tax expense or benefit for the years ended December 31, 2004 and 2003. We earned a profit in both years and retained a valuation allowance against our net deferred tax assets due to our limited history of taxable income.

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

	2004	2003
Tax Expense Computed at 34% of Pretax Income	$ 72,000	$ 1,600
Effect of Permanent Differences Principally Related to Non-deductible expenses	--	--
Effect of Change in Valuation Allowance	(72,000)	(1,600)
Total Income Tax Benefit	$ -0-	$ -0-

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

	2004	2003
Total Deferred Tax Assets	$ 2,721,400	$ 2,793,400
Total Deferred Tax Liabilities	(45,000)	(45,000)
Valuation Allowance Recognized for Deferred Tax Assets	(2,676,400)	(2,748,400)
Net Deferred Tax Asset	$ -0-	$ -0-

Deferred income tax liabilities result primarily from the use of accelerated depreciation for tax reporting purposes. Deferred income tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $7,700,000 that expire between 2012 and 2024.

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 our history of operating losses, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2004 and 2003.

13. CAPITAL STOCK

Our authorized capital stock consists of 20,000,000 common shares, no par value per share, of which 8,556,531 shares were outstanding at December 31, 2004 and 8,519,405 shares were outstanding at December 31, 2003; 2,000,000 preferred shares, none issued or outstanding, and 1,416,664 of 8.5% non-voting cumulative redeemable Series A Preferred Shares, $1.00 par value, of which none were

outstanding at either December 31, 2004 or December 31, 2003.

During 2004, we issued 32,126 common shares as a result of the exercise of stock options by employees and realized proceeds of $34,989 or $1.09 per share on average. We also issued 5,000 common shares upon the exercise of warrants to investors in our private placement. We realized proceeds of $3,700 or $.74 per share on average. Investors exercising these private placement warrants received unregistered common shares which may not be resold for a period of one year following the date they were acquired.

During 2003, we issued 18,733 common shares as a result of the exercise of stock options by employees and realized proceeds of $24,914 or $1.33 per share on average. We also issued 12,389 common shares upon the exercise of warrants to investors in our private placement. We realized proceeds of $12,800 or $1.03 per

share on average. Investors exercising these private placement warrants received unregistered common shares which may not be resold for a period of one year following the date they were acquired.

COMMON SHARES

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

WARRANTS

We have 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 for a period of three years commencing January 26, 1999 and expiring January 26, 2002. The Board of Directors approved extending the expiration date of these warrants until January 26, 2006 under the same terms and conditions. The exercise price and the number of common shares to be issued upon the exercise of each warrant are subject to adjustment in the event of share split, share dividend, recapitalization, merger, consolidation or certain other events. There were 3,625,000 Public Warrants issued and outstanding at both December 31, 2004 and 2003.

Under certain conditions, the Public Warrants may be redeemed by the Company at a redemption price of $.10 per Public Warrant upon not less than 30 days prior written notice to the holders of such Public Warrants; provided the closing bid price of the common shares has been at least $7.00 per common share for 20 consecutive trading days ending on the third day prior to the date the notice of redemption is given.

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

Warrants would receive unregistered common shares which may not be resold for a period of one year following the date they are acquired. In 2003, we issued 25,000 Private Warrants to an investment banker with an exercise price of $2.50 per common share. In 2002, we issued 128,460 Private Warrants to investors and investment bankers with exercise prices ranging from $.50 per common share to $2.70 per common share.

14. 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. On May 27, 2004, our shareholders adopted an amendment to the stock option plan to increase the number of options available to be granted to 3,900,000 from 2,900,000. Under the amendment to the stock option plan, we may grant up to 3,900,000 options to purchase common shares. Exercise prices, subject to certain plan limitations, are at the discretion of the Stock Option Committee of the Board of Directors. 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.

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

	SHARES	PRICE
Outstanding at December 31, 2002	1,215,160	$1.38
Granted	728,000	1.99
Exercised	(18,733)	1.33
Cancelled	(6,000)	1.10
Outstanding at December 31, 2003	1,918,927	1.51
Granted	858,000	3.17
Exercised	(32,126)	1.09
Cancelled	(37,084)	1.56
Outstanding at December 31, 2004	2,707,717	2.12

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	700,467	2.6-8.0 yrs.	$0.76	641,300	$ .78
$1.81 to $2.79	1,487,250	4.1-10 yrs.	$2.25	811,750	$2.10
$3.00 to $4.05.....	520,000	2.6-9.0 yrs.	$3.56	297,500	$3.27
Total	2,707,717	7.7 yrs.....	$2.12	1,750,550	$1.81

The per share weighted average fair values at the date of grant for the options granted to employees during the years ended December 31, 2004 and 2003 were $3.17 and $1.43 respectively. For the period ended December 31, 2004, 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 1.6-3.2 percent, volatility of 94% and expected lives of 2.0-3.0 years. For the period ended December 31, 2003 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 rate of 1.6-2.1 percent, volatility of 123% and expected lives of 3.0 years.

As of December 31, 2004, the remaining number of stock options available for future grants was 453,355.

NON-EMPLOYEE STOCK OPTIONS AND PURCHASE WARRANTS

In 2003, we issued warrants to purchase 25,000 common shares at an exercise price of $2.50 to an investment banker in consideration for investment banking services. These warrants had a fair market value of $14,025 on the date of grant. Upon exercise of these warrants, the investment banker would receive unregistered common shares which may not be resold for a period of one year following the date they were acquired.

Our policy is to amortize the fair market value of options and warrants granted to non-employees to expense over the term of the related consulting agreement. There was no expense recognized for the year ended December 31, 2004. We recognized $84,042 of amortization expense for the year ended December 31, 2003.

15. RELATED PARTY TRANSACTIONS

During the years ended December 31, 2004 and 2003, we had revenue from companies in which our outside directors held an equity interest. Mr. Ronald D. Boyd, a director of the Company as of March 14, 2000 , held an equity interest in certain customers of our products. Revenue from these entities was $15,000 and $101,000 in 2004 and 2003, respectively. Mr. Kenneth L. Holt, a director of the Company as of March 14, 2000, holds an equity interest in certain other customers of ours. Revenue from these entities was $119,000 and $156,000 in 2004 and 2003, respectively.

16. SUPPLEMENTAL CASH FLOW INFORMATION

We entered into non-cash transactions described below during the years ended December 31, 2004 and 2003 which have not been included in the Consolidated Statement of Cash Flows.

We entered into capital leases on equipment with a cost of $315,282 and $477,533 for the years ended December 31, 2004 and 2003, respectively, and financed those with capital lease obligations.

17. SUBSEQUENT EVENT -- LITIGATION SETTLEMENT

We were the plaintiff in certain litigation that was settled in the first quarter of 2005. We expect to receive gross proceeds from this settlement of approximately $241,000. We received cash of $130,000 during 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. The balance of the settlement is due by April 29, 2005. As of December 31, 2004, we have not recognized income for any portion of this settlement.

18. RECENT ACCOUNTING PRONOUNCEMENTS

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 the Company 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 is required to adopt SFAS 123R beginning January 1, 2006. The standard provides for a prospective application. 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 Company will recognize the unvested portion of the grant date fair value of awards issued prior to adoption based on the fair values previously calculated for disclosure purposes. At December 31, 2004, the aggregate value of unvested options, as determined using a Black-Scholes option valuation model, was $1,413,000. Upon adoption of SFAS 123R, approximately $750,000 of this amount will be recognized over the remaining vesting period of these options.

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. Statement 151 is effective for inventory costs incurred after January 1, 2006. The Company is currently evaluating the impact this new standard will have on its financial statements.

EXHIBIT INDEX

EXHIBIT	DESCRIPTION
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.
4.1	Form of Warrant Agreement, incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.2	Form of Underwriters Warrant Agreement, incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.3	Registration Rights Agreement among the Company and the holders of certain of the Company's Common Share Purchase Warrants, incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
4.4	Form of Lock-up Agreement, incorporated by reference to Exhibit 4.7 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 Exhibit 10.1 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.2	Employment Agreement dated as of February 19, 1997 between the Company and Robert L. Chioini, incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.3	Consulting and Financial Advisory Services Agreement dated as of February 19, 1997 between the Company and Wall Street Partners, Inc., incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.4	Asset Purchase Agreement dated as of November 1, 1996 by and among the Predecessor Company, the Family Partnerships (as defined therein), the Members (as defined therein) and the Company (formerly known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.5	First Amendment to Asset Purchase Agreement dated as of January 31, 1997 by and among the Predecessor Company, the Family Partnerships, the Members and the Company (formerly known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.6	Second Amendment to Asset Purchase Agreement dated as of February 19, 1997 by and among the Predecessor Company, the Family Partnerships, the Members and the Company (formerly known as Acquisition Partners, Inc.), incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.7	Letter Agreement dated April 4, 1997 among the parties to the Asset Purchase Agreement concerning the conversion of the promissory note payable to the Supply Company, incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.8	Lease Agreement dated as of September 5, 1995 between the Supply Company, as tenant, and Oakland Oaks, L.L.C., as landlord, incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form SB-2, File No. 333-31991.

EXHIBIT	DESCRIPTION
10.9	Assignment and First Amendment to Wixom Building Lease dated as of February 19, 1997 among the Supply Company, as assignor, the Company, as assignee, and Oakland Oaks, L.L.C., as landlord, incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.10	Letter Agreement dated November 21, 1997 among the parties to the Asset Purchase Agreement to confirm the reduction of the purchase price of the Asset Purchase Agreement, incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form SB-2, File No. 333-31991.
10.11	Employment Agreement dated as of January 12, 1999 between the Company and Thomas E. Klema incorporated by reference to the annual report on Form 10-KSB filed March 30, 1999.
10.12	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.
10.13	Employment Agreement dated as of March 20, 2000 between the Company and Robert L. Chioini incorporated by reference to the quarterly report on Form 10-QSB filed August 11, 2000.
10.14	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.
10.15	Loan and Security Agreement dated March 28, 2001 between the Company and Heller Healthcare Finance, Inc. incorporated by reference to the annual report on Form 10-KSB filed April 2, 2001.
10.16	Promissory Note between GE Healthcare Financial Services and Rockwell Medical Technologies, Inc. dated August 15, 2001 incorporated by reference to the quarterly report on Form 10-QSB filed November 14, 2001.
10.17	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed April 1, 2002.
10.18	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed April 1, 2002.
10.19	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 Act of 1934 incorporated by reference to the annual report on form 10-KSB filed March 28, 2003.
10.20	Amendment No. 1 to the Loan and Security Agreement dated March 25, 2003 between the Company and Heller Healthcare Finance, Inc. incorporated by reference to the annual report on form 10-KSB filed March 28, 2003.
10.21	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.
14.1	Rockwell Medical Technologies, Inc. Code of Ethics incorporated by reference to the Definitive Proxy Statement for our 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), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

EXHIBIT	DESCRIPTION
31.2	Certifications of Chief Financial Officer Pursuant to Rule 13a-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.