

ROCKWELL MEDICAL TECHNOLOGIES INC  
Form 10KSB  
March 19, 2004

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

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FORM 10-KSB

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934.

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

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  
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ROCKWELL MEDICAL TECHNOLOGIES, INC.  
(Name of small business issuer in its charter)

MICHIGAN  
(State or other jurisdiction of  
incorporation or organization)

38-3317208  
(I.R.S. employer  
identification no.)

30142 WIXOM ROAD  
WIXOM, MICHIGAN  
(Address of principal executive offices)

48393  
(Zip code)

(248) 960-9009  
(Issuer's telephone number, including area code)

SECURITIES REGISTERED 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

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(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: \$14,970,144

State the aggregate market value of the voting and non voting common equity held by non-affiliates: \$23,754,016 as of February 27, 2004.

Indicate the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date: 8,537,172 common shares outstanding and 3,761,071 common share purchase warrants outstanding as of February 27, 2004.

Documents incorporated by reference: Portions of the Registrant's definitive Proxy Statement pertaining to the 2003 Annual Meeting of Shareholders (the "Proxy Statement") filed pursuant to Regulation 14A are herein incorporated by reference.

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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 revenues generated from intravenous iron maintenance therapy may be as much as \$500,000,000 per year, with the revenues in the United States generated by such therapy being as much as \$270,000,000 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.

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### 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.

1

### 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 5-10% 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 69% of new ESRD cases are attributed to either diabetes or hypertension, 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 4,163 in December 2001. According to the CMS, at the end of 2001, independent clinics comprised 3,278 of such providers, hospitals comprised 532 of such providers and kidney

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transplant centers comprised 240 of such providers. The number of patients receiving hemodialysis has also grown substantially in recent years. According to the CMS, in 2001, more than 258,000 patients were treated in Medicare-approved renal facilities as compared to 68,390 patients in 1985, and from 1990 to 2001, the number of hemodialysis stations, which are areas equipped to provide adequate and safe dialysis therapy, grew from 25,052 stations to 67,479 stations. In addition, according to CMS, the number of Medicare-approved dialysis machines increased by 4,866 stations or 7.7% between 2000 and 2001.

### 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 4 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. Thus 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.

- 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

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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. While we do not have any immediate plans to add additional manufacturing or distribution 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.

### 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

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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.

3

### "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, which is mostly used in acute care settings, is currently the only liquid bicarbonate on the market manufactured utilizing a process called gamma irradiation. Historically, other manufacturers have been required to recall product due to excess levels of molds or bacteria. Gamma irradiation is a process that minimizes the presence of mold and bacteria in the product thereby providing a higher quality product to our customers. 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. We added blood tubing to our product line in 2002.

### " 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

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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.

4

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 clinical trials in order to obtain FDA approval for iron supplemented dialysate. We are preparing a clinical trial protocol for iron supplemented dialysate. Once it is completed we plan to submit the clinical trial protocol to the FDA for review. 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 clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties

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upon successful introduction of the product. The milestone payments include a payment of \$75,000 which became due upon the issuance of a patent on the product, 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 15 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 15 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.

5

### 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



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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. 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 an estimated 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 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. We believe 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 offer a liquid bicarbonate product line nor does it offer a powder acidified concentrate product line.

We also compete against Cantel Medical Corp.'s subsidiary, Minntech ("Minntech"). Minntech's Renal Systems division primarily sells acid dialysate concentrates and Renalin, a specialty reuse agent for dialyzers. We believe Minntech has one domestic manufacturing facility located in Minnesota and a distribution center in Camp Hill, Pennsylvania. 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

6

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

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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

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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"),

7

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.

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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

8

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

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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 dialysate supplemented iron 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

9

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

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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.

10

### 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 14 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

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of our licensors. We plan to conduct further clinical trials in order to obtain FDA approval to market this product. The duration and scope of these 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 expect will take one to two years and cost between \$3 million and \$4 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.

### 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 while one other remains pending.

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 Archer Daniels Midland Co., Ashland Inc., Cargill 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, 2003, three customers each accounted for more than 10% of our total sales, representing 42% of total sales. For the year ended December 31, 2002, one customer accounted for more than 10% of our total sales, representing approximately 19% of total sales. We are dependent on these customers and the loss of any of them could have a material adverse effect on our business, financial condition and results of operations.

### EMPLOYEES

As of December 31, 2003, we had approximately 80 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. We are negotiating with both Mr. Chioini and Mr. Klema with respect to new employment agreements.

### RESEARCH & DEVELOPMENT

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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 2003 and 2002 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 in our 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 2003 and 2002, we incurred expenses related to the commercial development of our iron supplemented dialysate product aggregating approximately \$250,000 and \$120,000, respectively.

We must undertake clinical trials to obtain FDA approval for our new iron supplemented dialysate product. The cost of these clinical trials (which we estimate to be between \$3 million and \$4 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 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 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.

### 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.

We use both of our facilities to manufacture our products and to stage deliveries to our customers. 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 manufacturing capacity and distribution facilities to meet our requirements.

### ITEM 3. LEGAL PROCEEDINGS.



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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 filed a breach of contract suit against Wall Street Partners, Inc. for breach of contract pertaining to consulting services provided us by Wall Street Partners, Inc. Also named in the suit was Mr. Gary D. Lewis, the principal of the consulting firm. Mr. Lewis is our former Chairman, a former director and in 2001 was the

12

beneficial owner of record of more than 5% of our common shares. We requested recovery of amounts paid to Wall Street Partners, Inc. and Mr. Lewis.

On November 21, 2001 a jury found in our favor and awarded us \$350,000 plus interest. On December 13, 2001, an official judgment in the amount of \$175,000 with interest was entered for us against Mr. Lewis personally and a judgment in the amount of \$175,000 with interest was entered for us against Wall Street Partners. A motion by Mr. Lewis for re-trial was denied February 15, 2002. Mr. Lewis subsequently filed an appeal to the judgment.

As a condition of the appeal process, Mr. Lewis was required by the court to post an irrevocable letter of credit in the amount of \$238,750 with us as the beneficiary. We will receive the proceeds from this irrevocable letter of credit if Mr. Lewis is unsuccessful in his appeal. The Appeals Court has heard oral arguments and a decision is pending. If the Appeals Court rules against Mr. Lewis, we can then seek to enforce the judgment. If the Appeals Court rules in favor of Mr. Lewis then we might have to retry the suit.

#### 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 2003.

### PART II

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

Our common shares and common share purchase warrants are traded on The Nasdaq SmallCap Market under the symbols RMTI and RMTIW, respectively. The common shares and the common share purchase warrants began trading on The Nasdaq SmallCap Market on January 26, 1998 at an initial public offering price of \$4.00 per common share and \$0.10 per common share purchase warrant.

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, 2003, Rockwell had shareholders' equity of \$3,172,108. 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.

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13

The prices below are the high and low bid prices as reported by The Nasdaq SmallCap Market in each quarter during 2002 and 2003. The prices are inter-dealer prices, without retail mark-up, mark down or commission and may not represent actual transactions.

QUARTER ENDED -----	BID PRICE INFORMATION -----	
	HIGH ----	LOW ----
March 31, 2002.....	3.15	1.30
June 30, 2002.....	2.68	1.04
September 30, 2002.....	1.20	.59
December 31, 2002.....	.88	.42
March 31, 2003.....	1.56	.41
June 30, 2003.....	2.05	1.00
September 30, 2003.....	3.49	1.95
December 31, 2003.....	3.99	2.70

As of February 27, 2004, there were 72 record holders of our common shares and 57 record holders of our common share purchase warrants.

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, 2003:

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 S FOR FUT COMPENSATIO REF
Equity compensation plans approved by security holders...	1,918,927	\$1.51	
Equity compensation plans not approved by security holders.....	--	--	
Total.....	1,918,927	\$1.51	

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.

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### 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.

14

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. Our business has gained market share each year since our inception in 1996. Our sales have grown each year since we started. We incurred losses each year since we started until this year when the volume of our sales exceeded the cost of operating our business. We increased our sales by over 30% this year, allowing us to more fully utilize our facilities, equipment and staff, and causing our gross profit margins to increase.

We believe that our core concentrate and supply business can continue to be profitable. The dialysis supply market is very competitive and we compete against companies with substantially greater resources than us. 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.

We are seeking to gain FDA approval for our iron supplemented dialysate product. We believe our iron supplemented dialysate product has 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

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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 between one and three years and we might not be successful.

### RESULTS OF OPERATIONS

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 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

15

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 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. We believe that our gross profit margins may be negatively impacted in 2004 by increases in the price of oil which may result in higher packaging costs and higher delivery costs for our products.

#### Selling, General and Administrative Expenses

Selling, General and Administrative expenses were \$2,368,000 and were 15.8%

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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 expenses 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.

FOR THE YEAR ENDED DECEMBER 31, 2002 COMPARED TO THE YEAR ENDED DECEMBER 31, 2001

### Sales

For the year ended December 31, 2002, our sales were \$11.5 million as compared to sales of \$9.0 million for 2001, representing an increase of 27.5%. Our revenue increased largely from unit volume growth across all of our key product lines as a result of the addition of new clinics with existing customers and the addition of new customers. We realized substantial sales growth in our concentrate product lines with sales up 20%. In addition, we expanded our ancillary product line offering to include blood tubing resulting in our ancillary product line sales more than doubling during 2002.

16

Our overall concentrate sales represented 80% of our total sales and increased by 20% over 2001. We experienced increased demand across all of our concentrate product lines. We believe that both clinic chains and independent providers are attracted to our Dri-Sate product line and our patented Dri-Sate(R) Dry Acid Concentrate Mixing System. Dri-Sate Dry Acid Concentrate unit volumes increased 20% over 2001. Similarly, liquid acid concentrate volume grew by 19%. SteriLyte(R) Liquid Bicarbonate product line unit volume increased 58% in 2002 as compared to 2001. Our growth benefited from the breadth of our product offering as well as the addition of a second manufacturing facility in the second half of 2001, which positioned us to capture market share in the southern United States.

Our sales of ancillary products increased by 135% in 2002 over 2001, with the increase due to the introduction of blood tubing and a new line of fistula

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needles. Ancillary product revenue grew to 13% of revenue in 2002 from 8% of revenue in 2001. Freight and backhaul revenue increased 9% during 2002 over 2001 in part reflecting a larger and more efficient fleet operation that benefited from the proximity to customers from the new manufacturing facility in the southern United States.

### Gross Profit

We continued to improve our gross profit margins in 2002 as a result of lower per unit costs from new manufacturing equipment added in 2002 and late 2001 coupled with the addition of increased production volumes. In the second half of 2002, we realized improved gross profit margins, with gross profit margins aggregating 15.1% for the last six months of 2002. For the entire year, we generated gross profit of \$1,454,000 as compared to \$912,000 in 2001 or a 59.4% improvement. Gross profit margins increased to 12.6% for 2002 as compared to 10.1% in 2001.

### Selling, General and Administrative Expenses

Selling, General and Administrative costs decreased \$33,600, or 1.4% in 2002 as compared to 2001. Selling, General and Administrative costs decreased as a percentage of sales to 20.2% of sales from 26.1% of sales in 2001, representing a 5.9 percentage point reduction as a percentage of sales. We incurred additional selling and marketing costs to support our growth and introduction of new product lines. In addition, we incurred approximately \$120,000 in expenses for product development and licensing costs related to our iron therapy product; however, these increased costs were offset by the reduction of other costs. As a result of the adoption of Statement of Financial Accounting Standards No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets", we ceased recording goodwill amortization in the first quarter of 2002. In 2001, we recorded goodwill amortization expense of \$165,000.

### Interest Expense

Interest expense totaled \$115,500 net of interest income in 2002 as compared to \$90,000 in 2001. The increase in interest expense was due to borrowings used to finance new equipment, partially offset by a reduction in interest expense resulting from principal payments on other borrowings.

### Net Income (Loss) and Earnings (Loss) Per Share

Net loss was (\$980,711) in 2002 as compared to a net loss of (\$1,579,103) in 2001, representing a 38% reduction in our net loss. We have not recorded a federal income tax benefit from our current or prior losses given a lack of assurance of realization of the carryforward benefit of those losses.

Net loss per share for 2002 was (\$.12) as compared to a loss of (\$.26) in 2001 with the 2002 loss per share reduced by (\$.04) due to an increase in the average number of common shares outstanding.

### 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.

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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 of our products to our customers consistent with generally accepted accounting principles. Accounts receivable are stated at the invoice amount. 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 an assessment of the trade accounts receivable our estimates the portion, if any, of the balance that will not be collected as well as a general valuation allowance for other accounts 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," effective January 1, 2002. 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

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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.

18

### LIQUIDITY AND CAPITAL RESOURCES

We have utilized cash since we started business, and expect that we will require additional cash to fund our business development and operating requirements. Until 2003, we had incurred operating losses each year since inception. While we had net profits of \$4,853 for 2003 as a whole, we reported profits in the second half of 2003 of \$185,000. We have substantially grown our business and recently achieved a modest level of profitability and, therefore, have reduced our operating cash requirements. In 2003, our net cash position improved by \$106,500. We required cash to fund our development and operating activities in 2003 including capital expenditures and working capital which was primarily provided by increasing the borrowings under our line of credit and through capital lease arrangements for equipment.

Our long term strategy is to expand our operations to serve dialysis providers. We anticipate that, as a result of our existing supply agreements and our customer relationships, we have the capability to capture substantial market share that will lead to sustaining profitable operations. We expect that we will continue to realize substantial growth during 2004 and that we will require additional working capital and capital expenditures to fund this growth.

We renewed our line of credit with GE Healthcare Finance as of March 25, 2003 under a two year agreement. Under the new loan agreement, there is 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. We anticipate that this credit line may be sufficient to fund much of our working capital requirements for our concentrate business operations in 2004. Borrowings under this line were \$642,000 at December 31, 2003.

In order for us to fund our working capital and capital expenditure requirements and to continue to execute our new product development strategy, we will require additional financing. We estimate the cost to fund developing our new iron supplemented dialysate product will be between \$3,000,000-\$4,000,000 over the next one to two years. We believe that we will be able to raise the capital required to expand our operations and fund our new product development strategy through either debt or equity financing arrangements. We have identified possible sources of financing, and we are currently in negotiations with potential lenders, strategic partners and investors; however, we might not be successful in raising additional funds. 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.

While we have raised our sales level each year and have customer commitments for additional business we might not be able to continue to increase our sales levels and market share and to sustain profitable operations. There can be no assurance that we will have or be able to raise sufficient funds to carry out our business plans and continue a profitable level of operations. These factors, among others, raise doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount or classification of liabilities that might be necessary should we be unable to continue as a going concern.



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## ITEM 7. FINANCIAL STATEMENTS

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

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

None.

19

## 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 27, 2004.

## 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 27, 2004.

## 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 27, 2004.

## 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 27, 2004.

## ITEMS 13. EXHIBITS AND REPORTS ON FORM 8-K.

### (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.

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- 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.

20

- 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.

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- 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.

21

- 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

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- Finance, Inc. incorporated by reference to the annual report on form 10-KSB filed March 28, 2003.
- 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.

### (b) Reports on Form 8-K

No reports on Form 8-K were filed by us during the fourth quarter of the year ended December 31, 2003. We furnished a Current Report on Form 8-K on November 7, 2003, reporting under Item 9 and Item 12 the information required by Item 12 -- Results of Operations and Financial Condition in connection with our press release regarding third quarter 2003 results. No financial statements were filed, although we furnished the financial information included in the press release furnished with the Form 8-K Current Report.

## ITEM 14. 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, 2003. 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, 2003 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, 2003 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.

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(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, 2003, there were no significant changes to the Company's internal controls or in factors that could significantly affect the Company's internal controls.

ITEM 15. 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 27, 2004.

23

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
<p>/s/ ROBERT L. CHIOINI ----- Robert L. Chioini</p>	<p>President, Chief Executive Officer and Director (Principal Executive Officer)</p>	<p>March</p>
<p>/s/ THOMAS E. KLEMA ----- Thomas E. Klema</p>	<p>Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)</p>	<p>March</p>
<p>/s/ KENNETH L. HOLT ----- Kenneth L. Holt</p>	<p>Director</p>	<p>March</p>
<p>/s/ RONALD D. BOYD</p>	<p>Director</p>	<p>March</p>

-----  
Ronald D. Boyd

INDEX TO FINANCIAL STATEMENTS

	PAGE
	-----
I Consolidated Financial Statements for Rockwell Medical Technologies, Inc. and Subsidiary	
Report of Independent Accountants for the years ended December 31, 2003 and 2002.....	F-1
Consolidated Balance Sheets at December 31, 2003 and December 31, 2002.....	F-2
Consolidated Income Statement for the years ended December 31, 2003 and 2002.....	F-3
Consolidated Statement of Changes in Shareholders' Equity for the years ended December 31, 2003 and 2002.....	F-4
Consolidated Statements of Cash Flow for the years ended December 31, 2003 and 2002.....	F-5
Notes to the Consolidated Financial Statements.....	F-6 - F-17

PLANTE & MORAN, PLLC LETTERHEAD

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, 2003 and 2002 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 auditing standards generally accepted in the United States of America. 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, 2003 and 2002, 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.

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The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has incurred substantial losses from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

PLANTE & MORAN, PLLC

Auburn Hills, Michigan  
February 20, 2004

F-1

## ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

### CONSOLIDATED BALANCE SHEETS

AS OF DECEMBER 31, 2003 AND 2002  
(WHOLE DOLLARS)

	DECEMBER 31, 2003	DECEMBER 31, 2002
	-----	-----
<b>ASSETS</b>		
Cash and Cash Equivalents.....	\$ 106,639	\$ 133
Restricted Cash and Cash Equivalents.....	8,662	13,965
Accounts Receivable, net of a reserve of \$34,500 in 2003 and \$51,500 in 2002.....	2,169,564	1,722,455
Inventory.....	1,350,291	1,476,506
Other Current Assets.....	103,971	118,316
	-----	-----
Total Current Assets.....	3,739,127	3,331,375
Property and Equipment, net.....	1,943,376	1,730,594
Intangible Assets.....	314,071	336,201
Goodwill.....	920,745	920,745
Other Non-current Assets.....	127,467	134,776
	-----	-----
Total Assets.....	\$ 7,044,786	\$ 6,453,691
	=====	=====
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Short Term Borrowings.....	\$ 642,018	\$ 417,254
Notes Payable & Capitalized Lease Obligations.....	307,959	194,799
Accounts Payable.....	1,666,952	1,680,842
Accrued Liabilities.....	329,519	333,792
	-----	-----
Total Current Liabilities.....	2,946,448	2,626,687
Long Term Notes Payable & Capitalized Lease Obligations.....	926,230	781,504
Shareholders' Equity:		
Common Share, no par value, 8,519,405 and 8,488,283 shares issued and outstanding.....	11,832,220	11,724,507
Common Share Purchase Warrants, 3,766,071 and 3,753,460 shares issued and outstanding.....	320,150	306,108
Accumulated Deficit.....	(8,980,262)	(8,985,115)
	-----	-----

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Total Shareholders' Equity.....	3,172,108	3,045,500
	-----	-----
Total Liabilities And Shareholders' Equity.....	\$ 7,044,786	\$ 6,453,691
	=====	=====

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

F-2

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002  
(WHOLE DOLLARS)

	2003	2002
	-----	-----
Sales.....	\$14,970,144	\$11,495,764
Cost of Sales.....	12,414,462	10,042,000
	-----	-----
Gross Profit.....	2,555,682	1,453,764
Selling, General and Administrative.....	2,367,773	2,318,945
	-----	-----
Operating Income (Loss).....	187,909	(865,181)
Interest Expense, net.....	183,056	115,530
	-----	-----
Income (Loss) Before Income Taxes.....	4,853	(980,711)
Income Tax Expense.....	--	--
	-----	-----
Net Income (Loss).....	\$ 4,853	\$ (980,711)
	=====	=====
Basic And Diluted Earnings ( Loss) Per Share.....	\$ -0-	\$ (.12)

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

F-3

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002  
(WHOLE DOLLARS)

COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED DEFICIT	T SHARE EQ
SHARES	AMOUNT	WARRANTS	AMOUNT		
-----	-----	-----	-----	-----	-----

Balance as of December 31,



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2001.....	7,197,390	\$10,349,865	3,625,000	\$251,150	\$ (8,004,404)	\$ 2,
Issuance of Common Shares.....	1,290,893	1,289,642	128,460	54,958		1,
Compensation Expense related to Stock Options.....		85,000				(
Net Loss.....					(980,711)	(
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,
	=====	=====	=====	=====	=====	=====

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

F-4

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2003 AND 2002  
(WHOLE DOLLARS)

	2003	2002
	-----	-----
Cash Flows From Operating Activities:		
Net Income (Loss).....	\$ 4,853	\$ (980,711)
Adjustments To Reconcile Net Income (Loss) To Net Cash Used In Operating Activities:		
Depreciation and Amortization.....	453,926	391,838
Compensation Recognized For Stock Options & Purchase Warrants.....	84,042	85,000
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable.....	(447,109)	(607,090)
(Increase) Decrease in Inventory.....	126,215	(409,978)
(Increase) Decrease in Other Assets.....	21,654	100,453
Increase (Decrease) in Accounts Payable.....	(13,890)	557,509
Increase (Decrease) in Other Liabilities.....	(4,273)	(252,304)
	-----	-----
Changes in Assets and Liabilities.....	(317,403)	(611,410)
	-----	-----
Cash Provided By (Used In) Operating Activities...	225,418	(1,115,283)
Cash Flows From Investing Activities:		
Purchase of Equipment.....	(164,626)	(381,901)
(Increase) Decrease in Restricted Cash Equivalents.....	5,303	542,936

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Purchase of Intangible Assets.....	(2,419)	(64,698)
	-----	-----
Cash Provided By (Used In) Investing Activities...	(161,742)	96,337
Cash Flows From Financing Activities:		
Proceeds From Borrowings on Line of Credit.....	14,122,113	10,429,177
Payments on Line of Credit.....	(13,897,349)	(10,558,483)
Issuance of Common Shares and Purchase Warrants.....	37,713	1,258,550
Payments on Notes Payable.....	(219,647)	(193,206)
	-----	-----
Cash Provided By Financing Activities.....	42,830	936,038
Increase (Decrease) In Cash.....	106,506	(82,908)
Cash At Beginning Of Period.....	133	83,041
	-----	-----
Cash At End Of Period.....	\$ 106,639	\$ 133
	=====	=====

Supplemental Cash Flow disclosure:

	2003	2002
	-----	-----
Interest Paid.....	\$183,616	\$118,395

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

F-5

### 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

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We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles.

### CASH AND CASH EQUIVALENTS AND RESTRICTED CASH

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

At December 31, 2003 and December 31, 2002, restricted cash consisted of a certificate of deposit of \$8,662 and \$13,965, respectively, securing a letter of credit.

### ACCOUNTS RECEIVABLE

Accounts receivable are stated at the invoice amount. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts that reflects management's best estimate of accounts that may not be collected. Management reviews outstanding trade account receivable balances and based on an assessment of collectibility of its trade accounts receivable it estimates the portion, if any, of the balance that will not be collected as well as a general valuation allowance for other accounts 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

F-6

## ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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.

### GOODWILL AND INTANGIBLE ASSETS

We adopted Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets," effective January 1, 2002. Under SFAS No. 142, goodwill is no longer 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.

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. Annually, we assess goodwill for impairment. The useful lives of other intangible assets are based on management's best estimates of the period over which the assets are

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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.

### 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 \$250,000 and \$120,000 in 2003 and 2002, 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.

F-7

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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

	2003 -----	2002 -----
As reported net income (loss) available to common shareholders.....	\$ 4,853	\$ (980,711)
Less: Stock based compensation expense determined under the fair market value method, net of tax.....	481,292	201,258
	-----	-----
Pro forma net income (loss).....	\$ (476,439)	\$ (1,181,969)
	=====	=====
As reported earnings (loss) per share and diluted earnings (loss) per share.....	\$ -0-	\$ (0.12)
Pro forma earnings (loss) per share and diluted earnings (loss) per share.....	\$ (0.06)	\$ (0.14)

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### NET EARNINGS (LOSS) PER SHARE

Basic net loss per share for the years ended December 31, 2003 and December 31, 2002 were calculated based on the weighted average shares outstanding of 8,495,134 and 7,867,464, respectively. As Rockwell had negligible earnings per share in 2003, basic and diluted earnings per share were similarly negligible. For 2002, the dilutive effect of stock options have not been included in the average shares outstanding for the calculation of diluted loss per share as the effect would be anti-dilutive as a result of our net loss in 2002.

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.

At December 31, 2002 potentially dilutive securities comprised 1,215,660 stock options exercisable at prices from \$.55 to \$3.00 per share, 3,625,000 common share purchase warrants exercisable at \$ 4.50 per common share; 128,460 common share purchase warrants exercisable at various prices ranging from \$.50 to \$2.70 and Underwriter's Warrants which were comprised of an option to purchase 95,000 common shares at a price of \$ 6.60 per share and 142,500 warrants to purchase shares at \$7.43 per share.

### ESTIMATES IN PREPARATION OF FINANCIAL STATEMENTS

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

### 3. MANAGEMENT'S PLAN OF OPERATION

We are engaged in the manufacture, sale and distribution of hemodialysis concentrates and kits to various clinics primarily in the United States. We provide hemodialysis solutions and supplies to leading national hemodialysis provider chains along with a number of independently operated regional and local clinics. We have established relationships with a number of the leading hemodialysis treatment providers to supply our hemodialysis solutions and other hemodialysis supplies. We manufacture hemodialysis solutions and deliver those directly to our customers through our distribution subsidiary, Rockwell Transportation, Inc.

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 2003, our

F-8

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

revenue increased by \$3,474,000 or 30.2% over 2002. In 2002, our revenue increased by \$2,480,000 or 27.5% over 2001.

### STRATEGY

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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. 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. Thus 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.

- 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

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associated with transporting and delivering hemodialysis concentrates, we believe we have a cost advantage with respect to certain

F-9

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

customers located near our manufacturing facilities. While we do not have any immediate plans to add additional manufacturing or distribution 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.

#### LIQUIDITY AND CAPITAL RESOURCES

We have utilized cash since we started business, and expect that we will require additional cash to fund our business development and operating requirements. Until 2003, we had incurred operating losses each year since inception. While we had net profits of \$4,853 for 2003 as a whole, we reported profits in the second half of 2003 of \$185,000. We have substantially grown our business and recently achieved a modest level of profitability and, therefore, have reduced our operating cash requirements. In 2003, our net cash position improved by \$106,500. We required cash to fund our development and operating activities in 2003 including capital expenditures and working capital which was primarily provided by increasing the borrowings under our line of credit and through capital lease arrangements for equipment.

Our long term strategy is to expand our operations to serve dialysis providers. We anticipate that, as a result of our existing supply agreements and our customer relationships, we have the capability to capture substantial market share that will lead to sustaining profitable operations. We expect that we will continue to realize substantial growth during 2004 and that we will require additional working capital and capital expenditures to fund this growth.

We renewed our line of credit with GE Healthcare Finance as of March 25, 2003 under a two year agreement. Under the new loan agreement, there is 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. We anticipate that this credit line may be sufficient to fund much of our working capital requirements for our concentrate business operations in 2004. Borrowings under this line were \$642,000 at December 31, 2003.

In order for us to fund our working capital and capital expenditure requirements and to continue to execute our new product development strategy, we will require additional financing. We estimate the cost to fund developing our new iron supplemented dialysate product will be between \$3,000,000-\$4,000,000 over the next one to two years. We believe that we will be able to raise the capital required to expand our operations and fund our new product development strategy through either debt or equity financing arrangements. We have identified possible sources of financing, and we are currently in negotiations with potential lenders, strategic partners and investors; however, we might not be successful in raising additional funds. 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.

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While we have raised our sales level each year and have customer commitments for additional business we might not be able to continue to increase our sales levels and market share and to sustain profitable operations. There can be no assurance that we will have or be able to raise sufficient funds to carry out our business plans and continue a profitable level of operations. These factors, among others, raise doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount or classification of liabilities that might be necessary should we be unable to continue as a going concern.

F-10

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### 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, 2003, three customers each accounted for more than 10% of our total sales, representing 42% of total sales. For the year ended December 31, 2002, one customer accounted for more than 10% of our total sales, representing approximately 19% of total sales. We are dependent on these customers and the loss of any of them could have a material adverse effect on our business, financial condition and results of operations.

#### 5. INVENTORY

Components of inventory as of December 31, 2003 and 2002 are as follows:

	2003	2002
	-----	-----
Raw Materials.....	\$ 241,317	\$ 322,908
Finished Goods.....	1,108,974	1,153,598
	-----	-----
Total.....	\$1,350,291	\$1,476,506
	=====	=====

#### 6. PROPERTY AND EQUIPMENT

Major classes of Property and Equipment, stated at cost, as of December 31, 2003 and 2002 are as follows:

	2003	2002
	-----	-----
Leasehold Improvements.....	\$ 379,244	\$ 379,244
Machinery and Equipment.....	2,337,726	2,172,929
Office Furniture and Equipment.....	208,692	202,498
Laboratory Equipment.....	236,747	182,118
Transportation Equipment.....	533,717	117,179
	-----	-----
	3,696,126	3,053,968



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Accumulated Depreciation.....	(1,752,750)	(1,323,374)
	-----	-----
Net Property and Equipment.....	\$ 1,943,376	\$ 1,730,594
	=====	=====

Included in the table above are assets under capital lease obligations with a cost of \$523,345 and \$45,813 and a net book value of \$477,612 and \$39,953, as of December 31, 2003 and 2002, respectively.

Depreciation expense was \$429,377 for 2003 and \$367,531 for 2002.

### 7. INTANGIBLE ASSETS

In 2001, we entered into a global licensing agreement 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. In 2002, we entered into a second licensing agreement 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 an additive to our dialysate product line which upon approval will be marketed as an iron maintenance therapy for dialysis patients.

As of December 31, 2003, we recorded licensing fees of \$314,071, net of accumulated amortization of \$53,047. As of December 31, 2002, we had recorded licensing fees of \$336,201, net of accumulated

F-11

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

amortization of \$28,498. Our policy is to amortize licensing fees over the life of the patents pertaining to the licensing agreements. We recognized amortization expense of \$24,549 in 2003 and \$24,308 in 2002. Estimated amortization expense for licensing fees for 2004 through 2008 is approximately \$24,660 per year. One of the licensing agreements requires additional payments upon achievement of certain milestones.

### 8. GOODWILL

We adopted SFAS 142 effective January 1, 2002. SFAS 142 no longer requires amortization of goodwill but it requires goodwill to be tested for impairment at adoption of SFAS 142 and annually thereafter by using a fair-value based approach. In accordance with the transition provisions of SFAS 142, we ceased amortizing goodwill in the first quarter of 2002. No impairment loss was recorded upon the adoption of SFAS 142. Total goodwill, net of accumulated amortization of \$771,091, was \$920,745 at December 31, 2003 and December 31, 2002. We completed our annual impairment test as of November 30, 2003 and determined that no adjustment for impairment of goodwill was required.

### 9. 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

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borrowings under this loan facility were \$642,018 and \$417,254 as of December 31, 2003 and 2002, respectively.

### 10. 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 \$754,541 and \$931,525 at December 31, 2003 and 2002, 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, 2004.....	\$192,904
Year ending December 31, 2005.....	210,258
Year ending December 31, 2006.....	229,173
Year ending December 31, 2007.....	122,206
	-----
Total Notes Payable.....	\$754,541
	=====

#### CAPITAL LEASE OBLIGATIONS

During 2003, we entered into capital lease obligations primarily related to equipment with a fair market value aggregating \$477,533. 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 2004-2010 and interest rates on the leases range from 5%-12.3%. These obligations under capital leases had outstanding balances of \$479,648 and \$44,778 at December 31, 2003 and 2002, respectively.

F-12

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Future minimum lease payments under capital lease obligations are:

Year ending December 31, 2004.....	\$ 198,180
Year ending December 31, 2005.....	195,462
Year ending December 31, 2006.....	168,217
Year ending December 31, 2007.....	124,597
Year ending December 31, 2008.....	82,742
Thereafter.....	63,627
	-----
Total minimum payments on capital lease obligations....	832,825
Interest.....	(353,177)
	-----
Present value of minimum lease payments.....	479,648
Current portion of capital lease obligations.....	(115,055)
	-----
Long-term capital lease obligations.....	\$ 364,593

=====

11. OPERATING LEASES

We lease our production facilities and administrative offices as well as certain transportation equipment used by our subsidiary, Rockwell Transportation, Inc. under operating lease agreements. The lease terms are three to seven years. Lease payments under all operating leases were \$810,105 and \$841,505 for the years ended December 31, 2003 and 2002, respectively.

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

In the instance of early termination, the transportation equipment leases require the Company to pay the excess of the purchase price for such vehicles (determined in accordance with the terms of the lease) over the equipment's fair market value.

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

Year ending December 31, 2004.....	\$ 625,300
Year ending December 31, 2005.....	549,755
Year ending December 31, 2006.....	388,012
Year ending December 31, 2007.....	381,435
Year ending December 31, 2008.....	190,717
Thereafter.....	-0-
	-----
Total.....	\$2,135,219
	=====

12. INCOME TAXES

We recorded no income tax expense or benefit for the years ended December 31, 2003 and 2002 due to our earning a negligible profit in 2003 and incurring a net operating loss in 2002 and recording a valuation allowance against its net deferred tax assets.

F-13

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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

	2003	2002
	-----	-----
Tax Expense (Recovery) Computed at 34% of Pretax Income (Loss).....	\$ 1,600	\$(333,000)
Effect of Permanent Differences Principally Related to Non-deductible expenses.....	--	--
Effect of Change in Valuation Allowance.....	(1,600)	333,000
	-----	-----
Total Income Tax Benefit.....	\$ -0-	\$ -0-

=====

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

	2003	2002
	-----	-----
Total Deferred Tax Assets.....	\$ 2,793,400	\$ 2,795,000
Total Deferred Tax Liabilities.....	(45,000)	(45,000)
Valuation Allowance Recognized for Deferred Tax Assets.....	(2,748,400)	(2,750,000)
	-----	-----
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 \$8,100,000 that expire between 2012 and 2023.

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 is dependent 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, 2003 and 2002.

### 13. CAPITAL STOCK

Our authorized capital stock consists of 20,000,000 common shares, no par value per share, of which 8,519,405 shares were outstanding at December 31, 2003 and 8,488,283 shares were outstanding at December 31, 2002; 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, 2003 or December 31, 2002.

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.

In 2002, we issued common shares pursuant to private placement offerings of our common shares. Investors in these offerings received unregistered common shares which may not be resold for a period of one year following the date they were acquired. We engaged placement agents on a best efforts basis for which the agent was entitled to 10% of gross proceeds raised by the placement agent. During 2002, we issued 982,095 common shares at prices between \$.54-\$2.10 realizing gross proceeds of \$1,320,500 under these offerings and net proceeds of \$1,205,350 after expenses.

In addition, during 2002, we issued 308,798 common shares as a result of the exercise of stock options by both employees and non-employees. We issued 64,000 common shares to employees and realized proceeds of

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ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

\$53,200 or \$.83 per share on average. We also issued 244,798 common shares to consultants and other service providers from the exercise of options with a fair market value of \$241,050 on the date of grant, issued in exchange for services rendered.

## 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, 2005 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, 2003 and 2002.

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.

## UNDERWRITERS' WARRANTS

In conjunction with the Company's Initial Public Offering in January 1998, the Underwriters' of the offering were entitled to warrants ("the Underwriters' Warrants") which provided them options to purchase 180,000 common shares for a purchase price of \$6.60 per share and 270,000 warrants for a purchase price of \$.165 per warrant. Each underlying warrant entitled the Underwriter to purchase a common share at a purchase price of \$7.43 per share, exercisable at any time

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from January 26, 1999 to January 26, 2003. At December 31, 2002, Underwriters' warrants with options to purchase 95,000 common shares and 142,500 underlying warrants remained outstanding. As of January 26, 2003, these warrants expired without exercise.

F-15

### ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### 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, 2003, our shareholders adopted an amendment to the stock option plan to increase the number of options available to be granted to 2,900,000 from 1,900,000. Under the amendment to the stock option plan, we may grant up to 2,900,000 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, 2001.....	1,036,193	\$1.59
Granted.....	318,200	.60
Exercised.....	(64,000)	.83
Cancelled.....	(74,733)	1.57
	-----	
Outstanding at December 31, 2002.....	1,215,660	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
	=====	

OPTIONS OUTSTANDING				OPTIONS EXERCISABLE	
				-----	
RANGE OF EXERCISE PRICES	NUMBER OF OPTIONS	REMAINING CONTRACTUAL LIFE	WEIGHTED EXERCISE PRICE	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
-----	-----	-----	-----	-----	-----

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		6.9-9.0			
\$ .55 to \$1.00	629,034	yrs.....	\$0.64	423,295	\$ .65
		3.5-9.5			
\$1.44 to \$2.00	806,143	yrs.....	\$1.78	335,643	\$1.75
		3.5-9.7			
\$2.18 to \$3.06	483,750	yrs.....	\$2.62	421,250	\$2.55
	-----			-----	
Total	1,918,927	7.8 yrs.....	\$1.62	1,180,188	\$1.64

The per share weighted average fair values at the date of grant for the options granted to employees during the years ended December 31, 2003 and 2002 were \$1.43 and \$.40 respectively. 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 rates of between 1.6-2.1 percent, volatility of 123% and expected lives of 3.0 years. For the period ended December 31, 2002 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 2.3 percent, volatility of 126% and expected lives of 3.0 years.

As of December 31, 2003, the remaining number of stock options available for future grants was 274,271.

F-16

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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.

In 2002, we granted 246,313 options to several business consultants and to legal counsel in payment for services rendered or for future services. These options were immediately exercised by the consultants and legal counsel resulting in the issuance of 244,798 common shares. These options had a fair market value of \$241,050 on the date of their respective grants.

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. We recognized \$84,042 and \$85,000 of amortization expense for the years ended December 31, 2003 and 2002.

15. RELATED PARTY TRANSACTIONS

During the years ended December 31, 2003 and 2002, 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, holds an equity interest in certain customers of our products. Revenue from these entities was \$101,000 and \$103,000 in 2003 and 2002, 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 \$156,000 and \$143,000 in 2003 and 2002, respectively.

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### 16. SUPPLEMENTAL CASH FLOW INFORMATION

We entered into non-cash transactions described below during the years ended December 31, 2003 and 2002 which have not been included in the Consolidated Statement of Cash Flows.

In 2003, we entered into capital leases on equipment with a cost of \$477,533 and financed those with capital lease obligations.

In 2002, we issued 244,798 common shares upon exercise of options granted to consultants and legal counsel in consideration for services rendered. The fair market value of the shares issued in exchange for services aggregated \$241,050 of which \$36,050 was issued in satisfaction of an outstanding payable and \$205,000 is being amortized over the term of the related consulting agreements.

F-17

#### 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



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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.
- 10.16 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.

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- 10.17 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.
- 10.18 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.
- 10.19 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-2of 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 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-2of the Securities Act of 1934 incorporated by reference to the annual report on form 10-KSB filed April 1, 2002.
- 21.2 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.

