ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10-K
March 24, 2008

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2007

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File Number 000-23661

ROCKWELL MEDICAL TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Michigan	**38-3317208**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
30142 Wixom Road Wixom, Michigan	**48393**
(Address of principal executive offices)	*(Zip Code)*

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, no par value	Nasdaq Global Market

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2007 is $59,439,199. For purposes of this computation, shares of common stock held by our executive officers, directors and common shareholders with 10% or more of the outstanding shares of common stock were excluded. Such determination should not be deemed an admission that such officers, directors and beneficial owners are, in fact, affiliates.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date. 13,817,453 common shares outstanding as of February 29, 2008.

Documents Incorporated by Reference

Portions of the Registrant s definitive Proxy Statement pertaining to the 2008 Annual Meeting of Shareholders (the Proxy Statement) to be filed pursuant to Regulation 14A are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

Table of Contents

PART I

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

Forward Looking Statements

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

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

Item 1. *Description of Business.*

General

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

Our dialysis solutions (also known as dialysate) are used to maintain life, removing toxins and replacing nutrients in the dialysis patient s bloodstream. We have licensed and are currently developing proprietary renal drug therapies for both iron-delivery and carnitine/vitamin-delivery, utilizing dialysate as the delivery mechanism. Iron supplementation is routinely administered to approximately 90% of patients receiving treatment for anemia. We have licensed a drug therapy for the delivery of iron supplementation for anemic dialysis patients which we refer to as dialysate iron and

more specifically as soluble ferric pyrophosphate (SFP). To realize a commercial benefit from this therapy, and pursuant to the licensing agreement, we must complete clinical trials and obtain U.S. Food and Drug Administration (FDA) approval to market iron supplemented dialysate. We also plan to seek foreign market approval for this product. We believe this product will substantially improve iron maintenance therapy and, if approved, will compete for the global market for iron maintenance therapy. Based on reports from manufacturers of intravenous (IV) iron products, the market size in the United States for this iron therapy is over $400,000,000 per

Table of Contents

year. We estimate the global market is in excess of $750,000,000. We cannot, however, give any assurance that this product will be approved by the FDA or, if approved, that it will be successfully marketed.

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

How Hemodialysis Works

Hemodialysis patients generally receive their treatments at independent hemodialysis clinics or at hospitals. A hemodialysis provider such as a hospital or a free standing clinic uses a dialysis station to treat patients. A dialysis station contains a dialysis machine that takes concentrate solutions primarily consisting of nutrients and minerals, such as our liquid concentrate solutions or our concentrate powders mixed with purified water, and accurately dilutes those solutions with purified water. The resulting solution, known as dialysate, is then pumped through a device known as a dialyzer (artificial kidney), while at the same time the patient s blood is pumped through a semi-permeable membrane within the dialyzer. Excess water and chemicals from the patient s blood pass through the membrane and are carried away in the dialysate while certain nutrients and minerals in the dialysate penetrate the membrane and enter the patient s blood to maintain proper blood chemistry. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and acetic acid. The patient s physician chooses the formula required for each patient based on each particular patient s needs, although most patients receive one of eight common formulations.

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

Dialysis Industry Trends

Hemodialysis treatments are generally performed in independent clinics or hospitals with the majority of dialysis services performed by regional and national for profit dialysis chains. The two largest national for-profit dialysis chains service approximately 60% of the domestic hemodialysis market. According to the latest industry statistics published by the U.S. Renal Data Systems (USRDS), 341,000 patients in the United States were receiving dialysis treatments at the end of 2005. The domestic dialysis industry has experienced steady patient population growth over the last two decades. In the last five years, the patient growth rate has increased between 3% and 5% per year. Population segments with the highest incidence of ESRD are also among the fastest growing within the U.S. population including the elderly, Hispanic and African-American population segments. Recent U.S. demographic projections indicate that the incidence of ESRD is expected to increase in the years ahead and will exceed current incidence levels.

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

Our Strategy

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

following strategies:

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

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

Table of Contents

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

increasing our revenues by expanding our ancillary product line,

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

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

Products

We manufacture, sell, distribute and deliver hemodialysis concentrates as well as a full line of ancillary hemodialysis products to hemodialysis providers and distributors located in approximately 40 states as well as a number of foreign countries, primarily in Latin America, Asia and Europe. Hemodialysis concentrates are comprised of two primary product types, which are generally described as acidified dialysate concentrate, also known as acid concentrate, and bicarbonate.

Renal Pure Liquid Acid Concentrate

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

Dri-Sate® Dry Acid Concentrate & Mixing System

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

Our Dri-Sate Dry Acid Concentrate & Mixing System allows a clinic to mix its acid concentrate on-site. The clinical technician, using a specially designed mixer, adds pre-measured packets of the necessary ingredients to 50 or 100 gallons of purified water (AMII standard). Once mixed, the product is equivalent to the acid concentrate provided to our customers in liquid form. Clinics using Dri-Sate Dry Acid Concentrate realize numerous advantages, including lower cost per treatment, reduced storage space requirements, reduced number of deliveries and more flexibility in scheduling deliveries. In addition to the advantages to our customers, the freight costs to us are lower for Dri-Sate Dry Acid Concentrate than for acid concentrate in the liquid form. We can also realize greater productivity from our truck fleet resources delivering dry products.

RenalPure Powder Bicarbonate Concentrate

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

SteriLyte® Liquid Bicarbonate Concentrate

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

Table of Contents

Ancillary Products

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

Iron Supplemented Dialysate

We have licensed the exclusive right to manufacture and sell a product that we believe will substantially improve the treatment of dialysis patients with iron deficiency, which is pervasive in the dialysis patient population. Iron deficiency in dialysis patients typically results from the demands placed upon the body by current dialysis drug therapies. Most dialysis patients receive replacement therapy of recombinant human erythropoetin (Epoetin alfa or EPO). EPO is a hormone that acts in the bone marrow to increase the production of red blood cells, which carry oxygen throughout the body to nourish tissues and sustain life. Hemoglobin, an important constituent of red blood cells, is composed largely of iron and protein.

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

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

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

Iron supplemented dialysate has other benefits that we believe are important. Iron administered by our product bypasses the liver altogether and thereby avoids causing oxidative stress to the liver, which we believe is a significant risk of current iron supplement therapies. In addition, we believe that clinics may realize significant drug administration savings due to decreased nursing time for administration and elimination of supplies necessary to administer IV iron compounds.

We are currently in the process of preparing to seek FDA approval of iron supplemented dialysate. A Phase II clinical trial on one of our licensed iron supplemented dialysate products under an Investigational New Drug (IND) exemption was completed by one of our licensors primary to us licensing the product. We plan to conduct the testing required to obtain FDA approval to market SFP in the United States. We commenced a second Phase II clinical trial, our dose

ranging study, in the fourth quarter of 2007. It is our intention to commence Phase III clinical trials after the FDA approves our Phase III protocol and following successful completion of our dose ranging study.

Table of Contents

Distribution and Delivery Operations

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

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

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

Sales and Marketing

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

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

Competition

Dialysis Concentrate and Supplies Competition

We compete against larger more established competitors with substantially greater financial, technical, manufacturing, marketing, research and development and management resources. We had three major competitors until one of our major competitors, Gambro Healthcare, Inc. (Gambro), exited the hemodialysis concentrate market at the end of 2006. Our largest competitor is Fresenius Medical Care, Inc. (Fresenius) which is primarily in the business of operating dialysis clinics. Fresenius is also vertically integrated and manufactures a broad range of dialysis products. They produce and sell a more comprehensive line of dialysis equipment, supplies and services than we sell.

Fresenius treats over 121,000 dialysis patients in North America and operates approximately 1,600 clinics. It also has a renal products business that manufactures a broad array of equipment and supplies, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. In addition to its captive customer base in its own clinics, Fresenius also serves other clinic chains and independent clinics with its broad array of products. Fresenius manufactures its concentrate in its own regional manufacturing facilities. Fresenius operates an extensive warehouse network in the United States serving its captive customer base and other independent clinics.

Gambro manufactures and sells hemodialysis machines, dialyzers and other ancillary supplies. Until the end of 2006, Gambro marketed its concentrate solutions to dialysis chains and independent clinics. Gambro sold products to its own clinics until October 2005 when it sold those clinics to DaVita, Inc. (DaVita), our largest customer. The sale resulted in DaVita having approximately 107,000 patients and 1,350 clinics. Concurrent with Gambro s exit from the concentrate business in late 2006, we began to service many of the DaVita clinics previously serviced by Gambro.

Table of Contents

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

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

Iron Maintenance Therapy Market Competition

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

The markets for drug products are highly competitive. New products we are developing will face competition from both conventional forms of iron delivery (i.e., oral and parenteral). In addition we believe that several companies including Galenica are attempting to develop new IV iron drugs. Galenica is seeking FDA approval of an additional parenteral iron product, Ferrinject. Advanced Magnetics, Inc. is also seeking FDA approval for Ferumoxytol, a parenteral iron product. Both of these products are under FDA review. We believe that both of these products are primarily intended to target the pre-ESRD markets and other indications such as oncology but if approved by the FDA they may compete against us in the ESRD market as well.

Competition in drug delivery systems is generally based on marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by dialysis providers and nephrologists is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share. In a highly competitive marketplace and with evolving technology, additional product introductions or developments by others might render our products or technologies noncompetitive or obsolete. In addition, pharmaceutical and medical device companies are largely dependent upon health care providers being reimbursed by private insurers and government agencies. Drugs approved by the FDA might not receive reimbursement from private insurers or government agencies. Even if approved by the FDA, providers of dialysate iron maintenance therapy might not obtain reimbursement from insurers or government agencies. If providers do not receive reimbursement for dialysate iron maintenance therapy, the commercial prospects and marketability of the product would be severely diminished.

CMS has historically paid providers for dialysis treatments in two parts: the composite rate and separately reimbursed drugs and services. CMS reimbursement practices are changing, which we think may benefit our marketing efforts. CMS has already implemented a change in its reimbursement practices to reclassify the administration portion of drug payments to the composite rate. Currently, it reimburses separately for the drug cost and has included the amount paid for drug administration into the composite rate.

We believe that CMS s payment practices may eventually result in a single composite rate per treatment, thereby eliminating reimbursement for individual drugs to providers. We believe that if and when a single reimbursement rate per treatment is implemented by CMS that the provider market may find the potential economic advantages of our iron supplemented dialysate an attractive alternative to IV iron drugs. Providers may be attracted to SFP over IV iron products due to lower cost of administration and due to the potential of improved therapeutic response from EPO treatments.

Table of Contents

Quality Assurance and Control

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

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

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

Government Regulation

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

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

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

Medical Device Approval and Regulation

A medical device may be marketed in the United States only with prior authorization from the FDA unless it is subject to a specific exemption. Devices classified 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 and which has not been significantly changed or modified) for

Table of Contents

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 usually takes from three to six months from the date of submission to obtain 510(k) clearance, and may take substantially longer. Our hemodialysis concentrates, liquid bicarbonate and other ancillary products are categorized as Class II devices.

A device which sustains or supports life, prevents impairment of human health or which presents a potential unreasonable risk of illness or injury is categorized as a Class III device. Class III devices and devices that are not substantially equivalent to a legally marketed Class I or Class II device. A Class III device generally must receive approval through a PMA application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We have been advised that it usually takes from one to three years to obtain approval after filing the request, and may take substantially longer.

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

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

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

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

We must comply with the 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 a licensing agreement for iron supplemented dialysate to be included in our dialysate products. Water soluble iron supplements when coupled with our dialysate are intended to be used as an iron maintenance therapy for dialysis

Table of Contents

patients, and we have been advised that this dialysate iron product will be considered a drug/device combination by the FDA. As a result, our iron maintenance therapy product will be subject to the FDA regulations for pharmaceutical products, as well.

Drug Approval and Regulation

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

An ANDA involves an abbreviated approval process that may be available for products that have the same active ingredient(s), indication, route of administration, dosage form and dosage strength as an existing FDAd-approved product, if clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product. Under applicable regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on the approved product s patent or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent, and the FDA may not finally approve the ANDA until a court finally determines that the applicable patent is invalid or would not be infringed by the applicant s product.

Pre-clinical studies are conducted to obtain preliminary information on a product s efficacy and safety. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may begin 30 days after receipt of the IND by the FDA unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase I trials consist of testing the product primarily for safety in a small number of patients at one or more doses. In Phase II trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase I trials. Phase III trials typically involve additional testing for safety and clinical efficacy in an expanded population at different test sites. A clinical plan, or protocol, accompanied by the approval of the institution participating in the trials, must be reviewed by the FDA prior to commencement of each phase of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or an ANDA for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA or an ANDA in a timely manner. The FDA may deny an NDA or an ANDA if applicable regulatory criteria are not satisfied or it may require additional clinical testing. Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA or an ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if

compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

Table of Contents

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.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries which typically do not involve additional testing for products that have received FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional governmental approval for price reimbursement under national health insurance systems. Additional studies may be required to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

Product License Agreements

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

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

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

Our iron supplemented dialysate product license agreement requires us to obtain FDA approval of iron supplemented dialysate. Under the applicable license agreement, we are required to pay the cost of obtaining marketing approval of the product in order to realize any benefit from commercialization of the product. In addition to funding, safety pharmacology testing, clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product. The milestone

Table of Contents

payments include a payment of $50,000 which will become due upon completion of Phase III clinical trials, a payment of $100,000 which will become due upon FDA approval of the product and a payment of $175,000 which will become due upon issuance of a reimbursement code covering the product.

Trademarks & Patents

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

We were issued a U.S. patent for our Dri-Sate Dry Acid Concentrate method and apparatus for preparing liquid dialysate on May 28, 2002 which expires on September 17, 2019. We have applied for a corresponding patent in Canada that is pending at this time.

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

Suppliers

We believe the raw materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products distributed by us are generally available from several potential suppliers. Our principal suppliers include Roquette, Inc., Church & Dwight Co. Inc. and Morton Salt Company.

Customers

We operate in one market segment which involves the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process to hemodialysis clinics. One customer, DaVita, accounted for 52% and 33% of our total sales during 2007 and 2006, respectively. Our accounts receivable from this customer was $1,268,000 and $925,000 as of December 31, 2007 and 2006, respectively. We are dependent on this key customer and the loss of its business would have a material adverse effect on our business, financial condition and results of operations. Our international sales, including products sold to domestic distributors that were delivered internationally, accounted for 5% and 18% of overall sales in 2007 and 2006, respectively.

Employees

As of December 31, 2007, we had approximately 210 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an at-will basis.

Research & Development

We have licensed an iron maintenance therapy product for the treatment of iron deficiency in anemic dialysis patients which we refer to as iron supplemented dialysate. We incurred expenses during 2007 and 2006 for product development and testing to obtain regulatory approval and for regulatory maintenance of the intellectual property underlying our licensing agreements. In 2007, we also completed our pre-clinical testing plan and initiated human clinical trials. We engaged outside consultants and legal counsel to assist us with product development and obtaining regulatory approval. In addition, we incurred ongoing expenses related to obtaining additional protection of the intellectual property underlying our licensing agreements. In 2007 and 2006, we incurred aggregate expenses related to the commercial development of our iron supplemented dialysate product of approximately $3,264,000 and

$4,778,000, respectively.

We must undertake substantial testing to obtain FDA approval for our new iron supplemented dialysate product. A Phase II clinical trial under an Investigational New Drug exemption was completed by our licensors. We completed our pre-clinical testing in 2007 and commenced a Phase IIb, dose ranging study in late 2007. We plan to conduct product testing and clinical trials in order to obtain FDA approval to market this product. We are 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 several years and be costly to us. We estimate the

Table of Contents

remaining cost from 2008 until approval is received to be between $12 million and $13 million. In addition to funding clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product as previously described. These costs will have a material impact on us and we expect to incur losses for the duration of the clinical trials. Should our testing and clinical trial expenses exceed our capital resources, we may need to seek additional sources of financing to obtain FDA approval of our new iron maintenance therapy product. If we are unable to obtain FDA approval of SFP or to make certain milestone payments we may forfeit our rights under our license agreements.

Where You Can Get Information We File with the SEC

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website on the internet that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. The address of the SEC s Web site is http://www.sec.gov.

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

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

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

RISKS RELATED TO OUR BUSINESS

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

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. One customer in particular accounted for 52% of our total sales during 2007 and 33% in 2006. If we were to lose this customer or our relationship with any of our other major national and regional dialysis chain customers, it would have a substantial negative impact on our cash flow and operating results and could have a detrimental impact on our ability to continue our operations in their current form or to continue to execute our business strategy. If we lost a substantial portion of our business, we would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

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

There is intense competition in the hemodialysis product market and most of our competitors are large diversified companies which have substantially greater financial, technical, manufacturing, marketing, research and development and management resources than we do. We may not be able to successfully compete with these other companies. Our

national competitors have historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell and as we do not manufacture or sell the same breadth of products as our competitors, we may be at a disadvantage in competing against their marketing strategies.

Table of Contents

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

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

Even if our new drug product is approved by the FDA it may not be successfully marketed.

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

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

We depend on government funding of healthcare.

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare funding to be viable businesses. If Medicare funding were to be materially decreased, our customers would be severely impacted and could be unable to pay us.

We may not be successful in improving our gross profit margins and our business may remain unprofitable.

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

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

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

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

Table of Contents

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

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

We depend on key personnel.

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for managing our sales and marketing efforts, which has driven our growth. We maintain key man life insurance on Mr. Chioini in the amount of $1 million. Neither Mr. Chioini nor Mr. Klema are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini or Mr. Klema, our business, financial condition and results of operations could be adversely affected.

Our business is highly regulated.

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

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding manufacturing quality. In addition, our new products will be subject to review as a pharmaceutical drug by the FDA. Changes in applicable regulatory requirements could significantly increase the costs of our operations and may reduce our profitability if we are unable to recover any such cost increases through higher prices.

Foreign approvals to market our new drug products may be difficult to obtain.

The approval procedures for the marketing of our new drug products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Additional studies may be required to obtain foreign regulatory approval. Further, some foreign regulatory agencies may require additional studies involving patients located in their countries.

Health care reform could adversely affect our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform

proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results.

Table of Contents

We may not have sufficient cash to fund SFP development in future years.

Our research and development plan for SFP is expected to result in significant cash outlays in 2008 and 2009. We expect to spend between $4-$5 million in 2008 on SFP product development and approval. We expect that our cash resources are adequate to fund our cash requirements in 2008. We believe we have adequate sources of liquidity to fund the testing and regulatory approval for SFP. However, if additional testing is required that is beyond that which we have planned for, we may not have adequate cash resources to fund our product development and approval efforts. If our clinical trial efforts do not achieve acceptable results, we may have to do more testing and, depending on the scope and duration of any additional testing, our available cash resources may not be sufficient to fund that additional testing.

We may not have sufficient products liability insurance.

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

Our Board of Directors is subject to potential deadlock.

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

RISKS RELATED TO OUR COMMON STOCK

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

We are unable to predict the effect, if any, that future sales of common shares, or the availability of our common shares for future sales, will have on the market price of our common shares from time to time. Sales of substantial amounts of our common shares (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. 9,807,510 of our common shares are freely tradable as of December 31, 2007, and an additional 1,159,169 shares which may be issued upon exercise of outstanding warrants will be freely tradable upon issuance. In the future, we may issue additional shares or warrants in connection with investments, repayment of our debt or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares.

In addition, as of December 31, 2007, there were 3,052,035 shares issuable upon the exercise of outstanding and exercisable stock options, 755,000 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 245,000 additional shares available for grant under our 2007 Long Term Incentive Plan. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than

those provided by the options. Further, while the options are outstanding, we may be unable to obtain additional financing on favorable terms.

The market price of our securities may be volatile.

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

Table of Contents

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

As of December 31, 2007, our officers and directors beneficially owned approximately 21.6% of our voting shares (assuming the exercise of exercisable options granted to such officers and directors). Accordingly, they may be able to effectively control our affairs. Our shareholders do not have the right to cumulative voting in the election of directors. In addition, the Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we are subject to Michigan statutes regulating business combinations, takeovers and control share acquisitions which might also hinder or delay a change in control. Anti-takeover provisions that could be included in the preferred stock when issued and the Michigan statutes regulating business combinations, takeovers and control share acquisitions can have a depressive effect on the market price of our common shares and can limit shareholders ability to receive a premium on their shares by discouraging takeover and tender offer offers.

Our directors serve staggered three-year terms, and directors may not be removed without cause. Our Articles of Incorporation also set the minimum and maximum number of directors constituting the entire Board at three and fifteen, respectively, and require approval of holders of a majority of our voting shares to amend these provisions. These provisions could have an anti-takeover effect by making it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common shares and do not anticipate paying such dividends in the foreseeable future. Our line of credit agreement prohibits the payment of dividends without the consent of the lender. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and cash resources, if any, to finance our operations.

Item 1B. ***Unresolved Staff Comments.***

Not applicable.

Item 2. ***Properties.***

We occupy a 51,000 square foot facility in Wixom, Michigan under a lease expiring in July 2008 which we have an option to renew. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in August 2010. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a three year lease expiring February 28, 2011. We have an option to renew thereafter for one or two years.

We intend to use each of our facilities to manufacture and warehouse our products. All such facilities and their contents are covered under various insurance policies which management believes provide adequate coverage. We also use the office space in Wixom, Michigan as our principal administrative office. With our continued growth we expect that we will require additional office space, manufacturing capacity and distribution facilities to meet our

business requirements.

Table of Contents

Item 3. ***Legal Proceedings***

We are not currently subject to any litigation that we expect to have a material adverse effect on our financial condition and results of operations. For more information on outstanding litigation, see Note 13 of the Notes to Consolidated Financial Statements.

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 2007.

PART II

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

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

The prices below are the high and low sale prices as reported by the Nasdaq Global Market in each quarter during 2006 and 2007.

	Sale Price	
Quarter Ended	**High**	**Low**
March 31, 2006	9.39	3.91
June 30, 2006	8.60	5.94
September 30, 2006	8.02	6.31
December 31, 2006	7.74	6.86
March 31, 2007	8.10	5.46
June 30, 2007	7.20	5.07
September 30, 2007	6.30	4.33
December 31, 2007	7.99	5.54

As of February 28, 2008, there were 47 holders of record of our common shares.

Dividends

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

Securities Authorized for Issuance Under Equity Compensation Plans

The information contained under Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters of this Annual Report on Form 10-K under the heading Securities Authorized for

Issuance Under Equity Compensation Plans is incorporated herein by reference.

Table of Contents

Item 6. ***Selected Financial Data***

The financial data in the following tables should be read in conjunction with the consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operation included in this Form 10-K.

	For the Year Ended December 31,				
	2007	2006	2005	2004	2003
Net sales	$ 43,045,304	$ 28,638,859	$ 27,694,955	$ 17,944,710	$ 14,970,144
Cost of sales	40,015,466	25,837,294	24,689,912	15,139,215	12,414,462
Gross profit	3,029,838	2,801,565	3,005,043	2,805,495	2,555,682
Income from continuing operations before interest expense and income taxes	(3,608,353)	(4,637,830)	274,903	409,180	187,909
Interest expense, net	110,542	(62,851)	198,095	197,658	183,056
Income from continuing operations before income taxes	(3,718,895)	(4,574,979)	76,808	211,522	4,853
Income taxes					
Net income	$ (3,718,895)	$ (4,574,979)	$ 76,808	$ 211,522	$ 4,853
Earnings per common share:					
Basic	$ (0.32)	$ (0.41)	$ 0.01	$ 0.02	$ 0.00
Diluted	$ (0.32)	$ (0.41)	$ 0.01	$ 0.02	$ 0.00
Weighted average number of common and common equivalent shares:					
Basic	11,771,381	11,189,001	8,674,651	8,546,302	8,495,134
Diluted	11,771,381	11,189,001	9,356,990	9,305,123	9,229,754

	As of December 31,				
	2007	2006	2005	2004	2003
Total assets	$ 22,803,134	$ 13,152,833	$ 9,260,660	$ 7,700,552	$ 7,044,786
Current assets	18,645,945	9,058,846	5,380,080	4,241,037	3,739,127
Current liabilities	4,637,271	4,452,675	4,682,139	3,459,555	2,946,448
Working capital	14,008,674	4,606,171	697,941	781,482	792,679
Long-term debt	204,837	326,045	733,723	818,678	926,230
Stockholders equity(1)	17,961,026	8,374,113	3,844,798	3,422,319	3,172,108
Book value per outstanding common share	$ 1.30	$ 0.73	$ 0.43	$ 0.40	$ 0.37
Common shares outstanding	13,815,186	11,500,349	8,886,948	8,556,531	8,519,405

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

Table of Contents

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

Overview and Recent Developments

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

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

We intend to continue to increase the size of our customer portfolio in order to expand our production and distribution operations into regions where we previously had business but no production facility. We believe this strategic initiative will ultimately lead to efficiencies and economies of scale, and will position us for an adequate and sustainable return on investment. We anticipate that we will continue to gain domestic market share though not as dramatically as in 2007.

As a result of the increase in sales volume and the increased geographic diversity of the clinics we serve, we took actions during 2007 to ensure adequacy of product supply and uninterrupted order fulfillment for the new business we added. We relocated one of our production facilities in a region where the additional business we acquired had outstripped our ability to properly supply, distribute and service the business. As a result of this relocation, we incurred costs aggregating approximately $500,000 for physical relocation, extra labor, plant start-up expenses, distribution start-up expenses, inventory write-offs and dual facility operating costs during the start-up period. Although these costs are not expected to recur at this location, we expect to incur similar types of costs in other regions as we continue to adjust our production and distribution facilities to meet new or changing demand. Our intention is to open two additional manufacturing facilities during 2008.

Increased operating costs that are subject to inflation, such as fuel and material costs, may not be recoverable through price increases to our customers if our competitors do not also raise prices. Unexpected further increases in our costs could further negatively impact gross profit. If we are not able to recover cost increases, it could materially adversely affect our business, financial condition and results of operations. We generally enter into short and medium term contracts of one to two years for our major raw materials and we generally enter into customer contracts of similar duration to mitigate our exposure to raw material and other cost increases.

Also, since we sell a wide range of products with varying profit margins and to customers with varying order patterns, our gross profit and our gross profit margins could vary from period to period due to these changes in our customer and product mix. As we increase our business in certain markets and regions, we may incur additional costs that are greater than the additional revenue generated from these initiatives until we have achieved a scale of operations that is profitable. In 2007, we raised our average selling prices in part to offset these additional costs and the higher costs of raw materials and fuel. We implemented price increases on maturing contracts during 2007 and expect to continue implementing price increases in 2008. Our price increases during 2007 were not able to keep pace with rising costs, however, resulting in a decrease in margins. We anticipate that our margins will improve in 2008 if we are successful

at increasing our prices in advance of prospective cost increases in our key operating costs.

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

Table of Contents

We are seeking to gain FDA approval for our iron supplemented dialysate product, SFP. We believe our SFP product, which has a unique method of action and other substantive benefits compared to current treatment options, has the potential to compete in the iron maintenance therapy market. The cost to obtain regulatory approval for a drug in the United States is expensive and can take several years. We currently expect to spend approximately $12 to $13 million to complete testing and the regulatory approval process in the United States from the beginning of 2008 until approval is obtained. This amount is substantially higher than our previous estimates due to additional testing and study costs that we have determined will be required in order to complete the approval process. Due to these additional expenditures, we expect to incur losses during the approval process.

Results of Operations

For the year ended December 31, 2007 compared to the year ended December 31, 2006

Sales

For the year ended December 31, 2007, our sales were $43.0 million, an increase of $14.4 million or 50.3% over sales for the year ended December 31, 2006. This increase was largely due to the domestic sales growth and market share gains resulting from the exit of Gambro from the dialysis concentrate market. The increase in 2007 was partially offset by the effect of a breach of contract settlement that increased sales in 2006 by $755,000. Domestic sales in 2007 increased by $17.0 million or 70.7% over 2006. Unit volume increases in our business accounted for the majority of the domestic sales increase in 2007 compared to 2006.

Sales to DaVita clinics represented approximately 75% of the total increase in domestic sales, while growth in sales to other national chains, regional chains and other independent clinics increased by over 29% and represented 25% of the growth in domestic business in 2007 compared to 2006. Our sales to both foreign and domestic based international distributors of our products were approximately 5% of total sales in 2007 compared to 18% of total sales in 2006. The $2.6 million decrease in international sales in 2007 compared to 2006 was attributable to $2.9 million in orders from major distributors for certain business in Latin America in 2006 that was not renewed in 2007. Our other international business increased by $250,000 compared to 2006.

Sales of our dialysis concentrate product lines, which represented 93.5% of our sales in 2007, increased 49.3% in 2007 over 2006. Sales of our acid concentrate product lines, which represented 66% of our sales in 2007, increased 78% in 2007 over 2006 while sales of our liquid bicarbonate decreased by $2.4 million in 2007 due to the aforementioned reduction in sales to certain Latin American markets.

Gross Profit

Gross profit in 2007 increased by $0.2 million or 7.1% to $3.0 million compared to $2.8 million in 2006. This increase in gross profit was due to a combination of higher prices and higher volumes of products sold. We have increased prices on maturing contractual arrangements in response to rising raw material, fuel and other operating costs incurred over the last year.

Gross profit margins decreased to 7.0% of sales from 9.8% in 2006. This decrease was primarily due to the impact on sales of the aforementioned $755,000 breach of contract settlement received in 2006, and higher costs due to the $500,000 of facility relocation costs incurred in the first quarter of 2007. To a lesser extent, the decrease was due to higher raw material and fuel costs, offset in part by price increases implemented during 2007. Some of the new business we added was in geographic areas that were distant from our facilities. In order to improve the margins on our new business, we expect to continue raising prices and are working to better position our supply chain to service this business.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses were $3.4 million or 7.8% of sales in 2007 compared to 9.3% of sales in 2006. This improvement was due to economies of scale as a result of the increase in sales. SG&A expense increased $713,000 or 26.8% in 2007 compared to 2006 due to additional costs to support our business growth and development, including additional personnel, increased marketing expenditures and investments in information technology resources. In addition, in 2007, we incurred non-cash charges of $86,000 for

Table of Contents

investor relations services expense through the issuance of warrants and $58,000 for employee and director stock option expenses . No such expenses were incurred in 2006. Non-cash related option expense in 2008 for options granted in 2007 is anticipated to aggregate $1.1 million.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including SFP, aggregating approximately $3.3 million and $4.8 million in 2007 and 2006, respectively. Costs incurred in 2006 were primarily for non-clinical testing of SFP. Expenditures in 2007 included expenditures for non-clinical testing and costs related to preparation for human clinical testing of SFP.

R&D spending is expected to be between $4 million and $5 million in 2008 as a result of the human clinical trials, depending on the timing of certain expenditures.

Interest Expense, Net

Net interest expense in 2007 increased by $173,393 compared to 2006 largely due to a decrease in interest income on short term investments of $140,265. Interest income in 2006 was the result of the investment of the net proceeds of the $8.3 million stock offering that occurred in the first quarter of 2006. Those funds have been largely used for the development and approval of SFP during 2006 and 2007.

Income Tax Expense

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

Critical Accounting Estimates and Judgments

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

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

Revenue recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Our products are generally sold domestically on a delivered basis and as a result we do not

recognize revenue until delivered to the customer with title transferring upon completion of the delivery. For our international sales, we recognize revenue upon the transfer of title as defined by standard shipping terms and conventions uniformly recognized in international trade.

Table of Contents

Allowance for doubtful accounts

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

Impairments of long-lived assets

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

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

Accounting for income taxes

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

Liquidity and Capital Resources

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

In 2007, we used $3.4 million in cash to fund operating activities which included research and development costs of $3.26 million and an increase of $1.2 million in our accounts receivable in 2007 resulting from the overall growth in our business. We incurred cash expenditures for fixed assets aggregating approximately $925,000. To fund these expenditures, we used available cash resources and borrowed on our line of credit. Also in November 2007, we

completed a private offering of common stock and warrants and raised net equity capital of $12.74 million. We intend to use the majority of the cash we raised to fund business development initiatives and primarily for human clinical testing of SFP.

We expect to add additional manufacturing facilities and equipment to continue expanding our production and distribution network in 2008, which will require additional capital. We anticipate that we will enter into equipment leasing arrangements and other lending arrangements to fund the majority of capital expenditures associated with

Table of Contents

facility expansions or additions. If we require additional working capital to support facility or business growth, we believe our current working capital line will be sufficient to meet our short term working capital needs.

Over the next year, we anticipate spending approximately $4 million to $5 million on SFP testing and approval. Should our testing and clinical trial expenses exceed our capital resources, we will need to seek additional sources of financing to complete the FDA approval process for SFP.

We are currently a defendant in litigation with a former lessor who is seeking damages aggregating $1.7 million for breach of contract and related claims. We intend to vigorously defend against these claims. We are responsible for our legal costs. As a result, an adverse judgment or settlement in this matter could result in a significant cash expenditure.

Our cash resources include cash generated from our business operations and the remaining proceeds from our November 2007 offering. As of December 31, 2007, we had $11.1 million in cash.

The maximum amount of borrowing permitted under our working capital line is $2.75 million. As of December 31, 2007, we had unused borrowing capacity of $2.75 million under our working capital line. The working capital line is due to expire on April 1, 2008. We are in the process of negotiating an extension of this line with the bank lender and expect to receive an extension on substantially the same terms as currently exist or enter into an agreement with another lender under similar terms. The terms of our working capital line and the related borrowing limitations are discussed in Note 7 of our Consolidated Financial Statements. We believe that these sources of liquidity and capital resources will be adequate to fund our cash requirements for 2008 and may be adequate for our long term needs as well. However, we may need to raise additional capital in order to execute our strategic plan. In our efforts to obtain additional capital resources, we will evaluate both debt and equity financing as potential sources of funds. We will also evaluate alternative sources of business development funding, licensing agreements with international marketing partners, sub-licensing of certain products for certain markets as well as other potential funding sources. Should we not be able to obtain additional financing, we may be forced to alter our strategy, delay spending on development initiatives or take other actions to conserve cash resources.

Item 8. ***Financial Statements***

The Consolidated Financial Statements of the Registrant required by this item are set forth on pages F-1 through F-17 and incorporated herein by reference.

Item 9. ***Changes In and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A(T). ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and

instances of fraud, if any, within a company have been detected.

As of December 31, 2007, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2007 in ensuring that information required to be disclosed by us

Table of Contents

under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the Exchange Act rules and forms due to the material weaknesses described below. As a result, we performed additional analysis and other post-closing procedures to ensure our consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, management believes the consolidated financial statements included in this Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Management s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). The Company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making its assessment of internal control over financial reporting, management used the criteria described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. In conjunction with our auditors, management identified two material weaknesses in the Company s internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies which when aggregated, results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by employees in the normal course of their assigned functions. As a result of these material weaknesses, we concluded that the Company s internal control over financial reporting was not effective as of December 31, 2007 based on the criteria in Internal Control Integrated Framework. This material weakness in internal control resulted in several adjustments to the financial statements which in the aggregate resulted in a net increase to our net loss for 2007 of approximately $76,000. We are taking steps to address these material weaknesses which could possibly have led to a material misstatement in our financial statements if not detected and corrected.

We identified a material weakness in our internal control for revenue recognition. Our policy is to recognize revenue upon transfer of title to our customer. In determining revenue recognition by period we had used the delivery date generated by our order entry system to determine the date of delivery and transfer of title. However, we determined that our actual delivery schedule sometimes deviates from the order entry system generated delivery date. This resulted in errors due to recording revenue on certain orders not delivered by December 31, 2007 and not recording revenue on certain orders that were delivered by December 31, 2007. We have modified our sales cut-off procedures to ensure that orders delivered before the end of our fiscal period are properly identified and recorded in the appropriate period and that orders in-transit are not recorded as revenue until actually delivered to our customer.

We also identified a material weakness in our internal control for financial reporting due to incomplete and undocumented supervisory review of account reconciliations and closing procedures which resulted in errors occurring related to certain accrued liability and prepaid expense accounts. Several changes to accounting procedures were made in 2007 that did not receive adequate supervisory review to ensure and document that the transactions were recorded as intended. In particular, we incurred large non-recurring expenditures with third parties for product testing and research for drug development and approval. These were unusual and complicated transactions with a degree of complexity different from our normal business operations and under which expense recognition and funding of those expenses were not consistent by period. We have taken corrective action to improve our review procedures for account reconciliations and closing procedures and to document supervisory review of these account reconciliations and closing procedures.

This Annual Report on Form 10-K does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management s report in this Annual Report on Form 10-K.

Table of Contents

Changes in Internal Controls

The Company maintains a system of internal controls that are designed to provide reasonable assurance that its books and records accurately reflect the Company s transactions and that its established policies and procedures are followed. There was no change in our internal control over financial reporting identified in connection with such evaluation that occurred during our fiscal quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Since December 31, 2007, the Company has implemented actions for the remediation of the identified material weaknesses, as described above.

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

Approval of Discretionary Bonuses

On December 17, 2007, the Compensation Committee of the Board of Directors approved the payment of a discretionary bonus to the Company s executive officers for their efforts on behalf of the Company in 2007. The award reflects recognition for management and leadership during the year, as well as the progress in the testing of the Company s SFP product and the Company s success in raising the development capital necessary to fund clinical trials of SFP**.** These are the first bonuses awarded to our executive officers since 2000.

Name	Title	2007 Bonus
Robert L. Chioini	President, CEO and Chairman of the Board	$ 40,000
Thomas E. Klema	Chief Financial Officer, Secretary And Treasurer	$ 25,000

Approval of Executive Salary Adjustments

On January 14, 2008, following a review of a salary benchmarking study of over 200 similarly situated companies, the Compensation Committee approved the changes to base salaries for the Company s executive officers disclosed in the table below. Executive compensation had not been previously benchmarked or peer reviewed with a formal study by the Board or the Compensation Committee, These are the first salary increases awarded to our executive officers since 2000. The increases became effective as of January 1, 2008.

Name	Title	2007 Salary	2008 Salary
Robert L. Chioini	President, CEO and Chairman of the Board	$ 275,000	$ 465,000
Thomas E. Klema	Chief Financial Officer, Secretary And Treasurer	$ 160,000	$ 275,000

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

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

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

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

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

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

Table of Contents

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2007:

Plan Category	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 securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,807,035	$ 3.42	245,000
Equity compensation plans not approved by security holders			
Total	3,807,035	$ 3.42	245,000

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

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

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

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

Item 15. ***Exhibits.***

(a) Exhibits

The following documents are filed as part of this report. Those exhibits previously filed and incorporated herein by reference are identified below. Exhibits not required for this report have been omitted. Our Commission file number is 000-23-661.

3(i).1 Articles of Incorporation of the Company, incorporated by reference 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 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 the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(i).4	4 Certificate of Amendment to Articles of Incorporation of the Company, incorporated by reference to the Company s Registration Statement on Form SB-2, File No. 333-31991.
3(ii)	Amended and Restated Bylaws of the Company, filed as an exhibit to the Company s Current Report on Form 8-K on December 20, 2007 and incorporated herein by reference.
4.1	Form of Warrant, filed as an exhibit to the Company s Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
4.2	RJ Aubrey Warrant Agreement, dated November 28, 2007, filed as an exhibit to the Company s Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.
*10.1	Rockwell Medical Technologies, Inc. 1997 Stock Option Plan, incorporated by reference to Rockwell s Proxy Statement for the Annual Meeting of Shareholders filed with the Securities and Exchange Commission on April 17, 2006.
10.2	Lease Agreement dated March 12, 2000 between the Company and DFW Trade Center III Limited Partnership, incorporated by reference to the annual report on Form 10-KSB filed March 30, 2000.

Table of Contents

10.3	Lease Agreement dated October 23, 2000 between the Company and International-Wixom, LLC, incorporated by reference to the quarterly report on Form 10-QSB filed November 14, 2000.
10.4	Licensing Agreement between the Company and Charak LLC and Dr. Ajay Gupta dated January 7, 2002 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934), incorporated by reference to the annual report on Form 10-KSB filed April 1, 2002.
10.5	Supply Agreement between the Company and DaVita, Inc. dated March 7, 2003 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934), incorporated by reference to the annual report on Form 10-KSB filed March 28, 2003.
10.6	Supply Agreement between the Company and DaVita, Inc. dated May 5, 2004 (with certain portions of the exhibit deleted under a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934), incorporated by reference to the quarterly report on Form 10-QSB filed on May 17, 2004.
10.7	Loan and Security Agreement dated as of March 29, 2005 between the Company and Standard Federal Bank National Association, incorporated by reference to the annual report on Form 10-KSB filed March 31, 2005.
10.8	Revolving Note dated as of March 29, 2005 executed by the Company for the benefit of Standard Federal Bank National Association, incorporated by reference to the annual report on Form 10-KSB filed March 31, 2005.
10.9	Unconditional Guaranty dated as of March 29, 2005 executed by Rockwell Transportation, Inc. for the benefit of Standard Federal Bank National Association, incorporated by reference to the annual report on Form 10-KSB filed March 31, 2005.
10.10	Second Amendment of Industrial Lease Agreement between Rockwell Medical Technologies, Inc. and DCT DFW, LP dated August 17, 2005, incorporated by reference to Exhibit 99.1 on Form 8-K filed on August 19, 2005.
10.11	Amending Agreement made the 16th day of January, 2006, by and between Dr. Ajay Gupta, Charak LLC and Rockwell Medical Technologies, Inc., incorporated by reference to the annual report on Form 10-KSB filed March 31, 2006.
10.12	Letter dated March 29, 2006 from LaSalle Bank Midwest National Association to Rockwell Medical Technologies, Inc., incorporated by reference to Exhibit 99.1 to Form 8-K filed with the Securities and Exchange Commission on April 11, 2006.
10.13	Securities Purchase Agreement between Rockwell Medical Technologies, Inc. and Emerald Asset Advisors, LLC dated June 22, 2006 incorporated by reference to Exhibit 10.1 on Form 8-K filed with the Securities and Exchange Commission on June 23, 2006.
10.14	Registration Rights Agreement between Rockwell Medical Technologies, Inc. and Emerald Asset Advisors, LLC dated June 22, 2006, incorporated by reference to Exhibit 10.2 on Form 8-K filed with the Securities and Exchange Commission on June 23, 2006.
10.15	Letter dated March 23, 2007 from LaSalle Bank Midwest National Association to Rockwell Medical Technologies, Inc., incorporated by reference to the Annual Report on Form 10-KSB filed on March 27, 2007.
*10.16	Rockwell Medical Technologies, Inc. 2007 Long Term Incentive Plan, incorporated by reference to the Proxy Statement for the Annual Meeting of Shareholders filed on April 18, 2007.
10.17	Consulting Agreement, dated as of October 3, 2007, filed as an exhibit to the Company s Current Report on Form 8-K on October 9, 2007 and incorporated herein by reference.
10.18	Common Stock Purchase Agreement dated November 28, 2007, between the Company and certain Purchasers, filed as an exhibit to the Company s Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.

10.19 Registration Rights Agreement, dated November 28, 2007, between the Company and certain Purchasers, filed as an exhibit to the Company s Current Report on Form 8-K on December 4, 2007 and incorporated herein by reference.

Table of Contents

*10.20	Form of Nonqualified Stock Option Agreement (Director Version), filed as an exhibit to the Company s Current Report on Form 8-K on December 20, 2007 and incorporated herein by reference.
*10.21	Form of Nonqualified Stock Option Agreement (Employee Version), filed as an exhibit to the Company s Current Report on Form 8-K on December 20, 2007 and incorporated herein by reference.
10.22	Lease Agreement dated March 19, 2008 between the Company and EZE Management Properties Limited Partners.
14.1	Rockwell Medical Technologies, Inc. Code of Ethics, incorporated by reference to the Definitive Proxy Statement for the 2004 Annual Meeting of Shareholders filed April 23, 2004.
21.1	List of Subsidiaries, incorporated by reference to Exhibit 21.1 to the Company s Registration Statement on Form SB-2, File No. 333-31991.
23.1	Consent of Plante & Moran, PLLC.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a).
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Current management contracts or compensatory plans or arrangements.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ROCKWELL MEDICAL TECHNOLOGIES, INC. (Registrant)

By: /s/ ROBERT L. CHIOINI

Robert L. Chioini
President and Chief Executive Officer

Date: March 21, 2008

Pursuant to Section 13 or 15(d) of the Exchange Act, this report has been signed by the following persons on behalf of registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ROBERT L. CHIOINI Robert L. Chioini	President, Chief Executive Officer and Director (Principal Executive Officer)	March 21, 2008
/s/ THOMAS E. KLEMA Thomas E. Klema	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 21, 2008
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 21, 2008
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 21, 2008
/s/ PATRICK J. BAGLEY Patrick J. Bagley	Director	March 21, 2008

INDEX TO FINANCIAL STATEMENTS

Table of Contents

PLANTE & MORAN, PLLC LETTERHEAD

REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

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

We have audited the consolidated balance sheet of Rockwell Medical Technologies, Inc. and Subsidiary as of December 31, 2007 and 2006 and the related consolidated statements of income, shareholders equity, and cash flows for the years ended December 31, 2007 and 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Rockwell Medical Technologies, Inc. and Subsidiary is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above, present fairly, in all material respects, the financial position of Rockwell Medical Technologies, Inc. and Subsidiary as of December 31, 2007 and 2006, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ Plante & Moran, PLLC

Auburn Hills, Michigan
March 20, 2008

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2007 and 2006
(Whole Dollars)

	December 31, 2007	December 31, 2006
ASSETS		
Cash and Cash Equivalents	$ 11,097,092	$ 2,662,873
Accounts Receivable, net of a reserve of $69,000 in 2007 and $72,500 in 2006	4,687,229	3,474,402
Inventory	2,559,051	2,660,098
Other Current Assets	302,573	261,473
Total Current Assets	18,645,945	9,058,846
Property and Equipment, net	2,840,331	2,587,771
Intangible Assets	270,446	457,846
Goodwill	920,745	920,745
Other Non-current Assets	125,667	127,625
Total Assets	$ 22,803,134	$ 13,152,833
LIABILITIES AND SHAREHOLDERS EQUITY		
Notes Payable & Capitalized Lease Obligations	$ 194,239	$ 369,551
Accounts Payable	2,982,899	2,920,258
Accrued Liabilities	1,122,737	1,114,592
Customer Deposits	337,396	48,274
Total Current Liabilities	4,637,271	4,452,675
Long Term Notes Payable & Capitalized Lease Obligations	204,837	326,045
Shareholders Equity:		
Common Shares, no par value, 13,815,186 and 11,500,349 shares issued and outstanding	33,415,106	23,147,709
Common Share Purchase Warrants, 1,204,169 and -0- shares issued and outstanding	3,038,411	
Accumulated Deficit	(18,492,491)	(14,773,596)
Total Shareholders Equity	17,961,026	8,374,113
Total Liabilities And Shareholders Equity	$ 22,803,134	$ 13,152,833

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the Years Ended December 31, 2007 and 2006
(Whole Dollars)

	2007	2006
Sales	$ 43,045,304	$ 28,638,859
Cost of Sales	40,015,466	25,837,294
Gross Profit	3,029,838	2,801,565
Selling, General and Administrative	3,374,458	2,661,419
Research and Product Development	3,263,733	4,777,976
Operating Income (Loss)	(3,608,353)	(4,637,830)
Interest (Income) Expense, net	110,542	(62,851)
Income (Loss) Before Income Taxes	(3,718,895)	(4,574,979)
Income Tax Expense		
Net Income (Loss)	$ (3,718,895)	$ (4,574,979)
Basic And Diluted Earnings (Loss) Per Share	$ (.32)	$ (.41)

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

For The Years Ended December 31, 2007 and 2006
(Whole Dollars)

	Common Shares		Purchase Warrants		Accumulated	Total Shareholders
	Shares	Amount	Warrants	Amount	Deficit	Equity
Balance as of December 31, 2005	8,886,948	$ 12,628,539	3,591,385	$ 1,414,876	$ (10,198,617)	$ 3,844,798
Issuance of Common Shares	245,995	836,601				836,601
Exercise of Purchase Warrants	2,367,406	9,523,210	(2,367,406)	(1,255,517)		8,267,693
Expiration of Warrants		159,359	(1,223,979)	(159,359)		
Net Loss					(4,574,979)	(4,574,979)
Balance as of December 31, 2006	11,500,349	$ 23,147,709	-0-	-0-	$ (14,773,596)	$ 8,374,113
Issuance of Common Shares	2,314,837	10,209,459				10,209,459
Issuance of Purchase Warrants			1,204,169	3,038,411		3,038,411
Stock Option Based Expense		57,938				57,938
Net Loss					(3,718,895)	(3,718,895)
Balance as of December 31, 2007	13,815,186	$ 33,415,106	1,204,169	$ 3,038,411	$ (18,492,491)	$ 17,961,026

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For The Years Ended December 31, 2007 and 2006
(Whole Dollars)

	2007	2006
Cash Flows From Operating Activities:		
Net (Loss)	$ (3,718,895)	$ (4,574,979)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	949,739	756,868
Warrants issued for Services	85,911	
Stock Option Compensation	57,938	
Loss (Gain) on Asset Disposal	17,710	(4,539)
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(1,212,827)	(638,330)
(Increase) Decrease in Inventory	101,047	(608,279)
(Increase) in Other Assets	(39,142)	(61,146)
Increase (Decrease) in Accounts Payable	62,641	1,124,865
Increase in Other Liabilities	297,267	598,559
Changes in Assets and Liabilities	(791,014)	415,669
Cash (Used) In Operating Activities	(3,398,611)	(3,406,981)
Cash Flows From Investing Activities:		
Purchase of Equipment	(924,608)	(907,554)
(Increase) Decrease in Restricted Cash Equivalents		
Purchase of Intangible Assets	(8,189)	(105,730)
Cash (Used) In Investing Activities	(932,797)	(1,013,284)
Cash Flows From Financing Activities:		
Proceeds From Borrowings on Line of Credit	1,800,000	
Payments on Line of Credit	(1,800,000)	(1,800,000)
Issuance of Common Shares and Purchase Warrants	13,161,959	9,104,294
Payments on Notes Payable	(396,332)	(520,187)
Cash Provided By Financing Activities	12,765,627	6,784,107
Increase In Cash	8,434,219	2,363,842
Cash At Beginning Of Period	2,662,873	299,031
Cash At End Of Period	$ 11,097,092	$ 2,662,873
Supplemental Cash Flow disclosure:		

		2007	2006
Interest Paid		$ 159,444	$ 126,316
Non-Cash Investing and Financing Activity	Equipment Acquired Under Capital Lease Obligations	$ 99,812	$ 133,120

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or ESRD . We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States.

We are regulated by the Federal Food and Drug Administration under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We have received 510(k) approval from the FDA to market hemodialysis solutions and powders. We also have 510(k) approval to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer. We have obtained global licenses for certain dialysis related drugs for which we are developing and seeking FDA approval to market.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc.

All intercompany balances and transactions have been eliminated.

Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer s location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale. At December 31, 2007 and 2006 we had customer deposits of $337,396 and $48,274, respectively.

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

Shipping and Handling Revenue and Costs

Our products are generally priced on a delivered basis with the price of delivery included in the overall price of our products which is reported as sales. Separately identified freight and handling charges are also included in sales. Our trucks that deliver our products to our customers sometimes generate backhaul revenue from hauling freight for other

third parties. Revenue from backhaul activity is recognized upon completion of the delivery service.

We include shipping and handling costs, including expenses of Rockwell Transportation, Inc.. in cost of sales.

Cash and Cash Equivalents

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accounts Receivable

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

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for normal maintenance and repairs are charged to expense as incurred. Property and equipment are depreciated using the straight-line method over their useful lives, which range from three to ten years. Leasehold improvements are amortized using the straight-line method over the shorter of their useful lives or the related lease term.

Licensing Fees

License fees related to the technology, intellectual property and marketing rights for dialysate iron covered under certain issued patents have been capitalized and are being amortized over the life of the related patents which is generally 17 years.

Goodwill, Intangible Assets and Long Lived Assets

The recorded amounts of goodwill and other intangibles from prior business combinations are based on management s best estimates of the fair values of assets acquired and liabilities assumed at the date of acquisition. Goodwill is not amortized; however, it must be tested for impairment at least annually. Amortization continues to be recorded for other intangible assets with definite lives over their estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or circumstances indicate that carrying amounts may not be recoverable.

An impairment review of goodwill, intangible assets, and property and equipment is performed annually or whenever a change in condition occurs which indicates that the carrying amounts of assets may not be recoverable. Such changes may include changes in our business strategies and plans, changes to our customer contracts, changes to our product lines and changes in our operating practices. We use a variety of factors to assess the realizable value of long-lived assets depending on their nature and use.

The useful lives of other intangible assets are based on management s best estimates of the period over which the assets are expected to contribute directly or indirectly to our future cash flows. Management annually evaluates the

remaining useful lives of intangible assets with finite useful lives to determine whether events and circumstances warrant a revision to the remaining amortization periods. It is reasonably possible that management s estimates of the carrying amount of goodwill and the remaining useful lives of other intangible assets may change in the near term.

Income Taxes

A current tax liability or asset is recognized for the estimated taxes payable or refundable on tax returns for the year. Deferred tax liabilities or assets are recognized for the estimated future tax effects of temporary differences

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

between book and tax accounting and operating loss and tax credit carryforwards. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as an income tax expense.

Research and Product Development

We recognize research and product development costs as expenses as incurred. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including iron supplemented dialysate, aggregating approximately $3,264,000 and $4,778,000 in 2007 and 2006, respectively.

We are conducting human clinical trial on iron supplemented dialysate and we recognize the costs of the human clinical trial as the costs are incurred and services performed over the duration of the trial.

Stock Options

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

We estimate the fair value of compensation involving stock options utilizing the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, and an expected forfeiture rate, and is subject to various assumptions. We believe the valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, the issuance of new options.

Net Earnings per Share

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an antidilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	2007	2006
Basic Weighted Average Shares Outstanding	11,771,381	11,189,001
Effect of Dilutive Securities	-0-	-0-
Diluted Weighted Average Shares Outstanding	11,771,381	11,189,001

For 2007 and 2006, the dilutive effect of stock options and in 2007 common share purchase warrants have not been included in the average shares outstanding for the calculation of diluted loss per share as the effect would be anti-dilutive as a result of our net loss in both periods.

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

At December, 31, 2007, potentially dilutive securities comprised 3,807,035 stock options exercisable at prices from $.55 to $6.50 and 1,079,169 common share purchase warrants exercisable at $7.18, 90,000 common share purchase warrants exercisable at $7.00, 90,000 common share purchase warrants exercisable at $7.50 and 80,000 common share purchase warrants exercisable at $10.00.

At December 31, 2006 potentially dilutive securities comprised 3,219,235 stock options exercisable at prices from $.55 to $4.55 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. 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, 2007, one customer accounted for more than 10% of our sales, representing 52% of our sales. For the year ended December 31, 2006, one customer accounted for more than 10% of our total sales, representing 33% of total sales. Our accounts receivable from this customer was $1,268,000 and $925,000 as of December 31, 2007 and 2006, respectively. We are dependent on a key customer and the loss of its business would have a material adverse effect on our business, financial condition and results of operations. Our international sales including products sold to domestic distributors that are delivered internationally aggregated 5% and 18% of overall sales in 2007 and 2006, respectively.

4. Inventory

Components of inventory as of December 31, 2007 and 2006 are as follows:

	2007	2006
Raw Materials	$ 1,096,191	$ 717,876
Finished Goods	1,462,860	1,942,222
Total	$ 2,559,051	$ 2,660,098

5. Property and Equipment

Major classes of Property and Equipment, stated at cost, as of December 31, 2007 and 2006 are as follows:

	2007	2006
Leasehold Improvements	$ 229,941	$ 446,150
Machinery and Equipment	4,333,693	3,891,890
Office Equipment and Furniture	519,278	479,427
Laboratory Equipment	339,380	304,992
Transportation Equipment	389,477	637,634
	5,811,770	5,760,093
Accumulated Depreciation	(2,971,439)	(3,172,322)
Net Property and Equipment	$ 2,840,331	$ 2,587,771

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Included in the table above are assets under capital lease obligations with a cost of $791,276 and $1,041,372 and a net book value of $520,905 and $697,519, as of December 31, 2007 and 2006, respectively.

Depreciation expense was $754,150 for 2007 and $714,165 for 2006.

6. Goodwill and Intangible Assets

Total goodwill was $920,745 at December 31, 2007 and 2006. We completed our annual impairment tests as of November 30, 2007 and 2006 and determined that no adjustment for impairment of goodwill was required.

We have entered into several global licensing agreements for certain patents covering therapeutic drug compounds and vitamins to be delivered using our dialysate product lines. We intend to seek FDA approval for these products. We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset. As of December 31, 2007 we have capitalized licensing fees of $369,536, net of accumulated amortization of $99,090. During 2007, we terminated a licensing agreement related to a patent which we determined we would not benefit from. As a result, we determined that the remaining unamortized cost of that licensing agreement of $146,366 was impaired and expensed this amount, which is included in research and product development expense in the consolidated income statement. As of December 31, 2006, we capitalized licensing fees of $615,868, net of accumulated amortization of $158,022.

Our policy is to amortize licensing fees over the life of the patents pertaining to the licensing agreements. We recognized amortization expense of $49,223 in 2007, and $42,703 in 2006. Estimated amortization expense for licensing fees for 2008 through 2012 is approximately $32,000 per year. One of the licensing agreements requires additional payments upon achievement of certain milestones.

7. Line of Credit

On March 29, 2006 and March 23, 2007, we renewed our line of credit with a financial institution. The loan agreement provides for revolving borrowings by us of up to $2,750,000. We are permitted to borrow up to 80% of our eligible accounts receivable and up to 40% of our eligible inventory up to $600,000. Borrowings under the loan agreement are secured by accounts receivable, inventory and certain other assets. The annual interest rate payable on revolving borrowings under the loan agreement is the lender s prime rate plus 75 basis points. The lender s commitment to make revolving borrowings under the loan agreement expires on April 1, 2008. As of December 31, 2007 and 2006, we had no outstanding borrowings under this line of credit.

8. Notes Payable & Capital Lease Obligations

Notes Payable

In August 2001, we entered into a financing agreement with a financial institution to fund $1,000,000 of equipment capital expenditures for our manufacturing facilities. The note payable required monthly payments of principal and interest aggregating $20,884 through June 2007. The note was paid off in 2007. The note had a balance of $122,206 at December 31, 2006.

Capital Lease Obligations

We entered into capital lease obligations primarily related to equipment with a fair market value aggregating $99,812 and $133,120 for the years ended December 31, 2007 and 2006, respectively. In addition, we have other capital lease obligations related to financing other equipment. These capital lease obligations require even monthly installments through 2011 and interest rates on the leases range from 5% to 15.0%. These obligations under capital leases had outstanding balances of $399,076 and $573,390 at December 31, 2007 and 2006, respectively.

Table of Contents

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, 2008	$ 227,017
Year ending December 31, 2009	190,277
Year ending December 31, 2010	29,763
Year ending December 31, 2011	1,313
Total minimum payments on capital lease obligations	448,371
Interest	(49,295)
Present value of minimum lease payments	399,076
Current portion of capital lease obligations	(194,239)
Long-term capital lease obligations	$ 204,837

9. Operating Leases

We lease our production facilities and administrative offices as well as certain equipment used in our operations. The lease terms range from monthly to seven years. Lease payments under all operating leases were $1,833,670 and $1,597,127 for the years ended December 31, 2007 and 2006, respectively.

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

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

Year ending December 31, 2008	$ 1,437,709
Year ending December 31, 2009	1,269,248
Year ending December 31, 2010	1,073,376
Year ending December 31, 2011	587,552
Year ending December 31, 2012	462,112
Thereafter	26,973
Total	$ 4,856,970

10. Income Taxes

We recognized no income tax expense or benefit for the years ended December 31, 2007 and 2006. We incurred a net loss in both 2007 and 2006 primarily related to research and development spending for drug approval. Our business without these drug approval costs would have reported a loss in 2007 while 2006 was profitable. However, we have retained a valuation allowance against our net deferred tax assets due to our limited history of taxable income coupled with anticipated future spending on our product development plans which may offset some or all of our income in the next two years.

Table of Contents

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:

	2007	2006
Tax Expense Computed at 34% of Pretax Income	$ (1,264,000)	$ (1,555,000)
Effect of Permanent Differences Principally Related to Non-deductible expenses		
Effect of Change in Valuation Allowance	(1,264,000)	(1,555,000)
Total Income Tax Benefit	$ -0-	$ -0-

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

	2007	2006
Total Deferred Tax Assets	$ 6,092,000	$ 4,244,000
Total Deferred Tax Liabilities	(379,000)	(173,000)
Valuation Allowance Recognized for Deferred Tax Assets	(5,713,000)	(4,071,000)
Net Deferred Tax Asset	$ -0-	$ -0-

Deferred tax liabilities result primarily from the use of accelerated depreciation for tax reporting purposes. Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $17,417,000 that expire between 2012 and 2026.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized upon the generation of future taxable income during the periods in which those temporary differences become deductible. Due to anticipated spending on research and development over the next several years, coupled with our limited history of operating income, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2007 and 2006.

The Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), as of January 1, 2007. FIN 48 clarifies the guidance for the recognition and measurement of income tax benefits related to uncertain tax positions in accordance with SFAS No. 109, Accounting for Income Taxes. The impact of this change in accounting was immaterial, and the amount of unrecognized tax benefits related to uncertain tax positions is not significant at December 31, 2007.

11. Capital Stock

Our authorized capital stock consists of 20,000,000 common shares, no par value per share, of which 13,815,186 shares were outstanding at December 31, 2007 and 11,500,349 shares were outstanding at December 31, 2006; 2,000,000 preferred shares, none of which were issued or outstanding at either December 31, 2007 or December 31, 2006 and 1,416,664 shares of 8.5% non-voting cumulative redeemable Series A Preferred Shares, $1.00 par value, of which none were outstanding at either December 31, 2007 or December 31, 2006.

During 2007, we issued 2,314,837 common shares and 1,079,169 common share purchase warrants, as noted below, and realized net cash proceeds of approximately $13,200,000. This total includes 2,158,337 common shares issued pursuant to a private offering of our common shares with institutional investors for which we received gross proceeds of $12,950,000. The private offering consisted of a unit priced at $6.00, which included one common share and a warrant to purchase one-half of a common share at an exercise price of $7.18 per share. We realized net proceeds of $12,743,000 after deducting legal, registration, accounting and other expenses related to this offering. The shares issued under this stock purchase agreement were later registered for resale and such registration statement was declared effective by the Securities and Exchange Commission on January 29, 2008. We are required

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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

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

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

Common Shares

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

Warrants

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

We also issued 180,000 warrants in exchange for services which are vested on a monthly basis over a one year period with 90,000 of such warrants exercisable at $7.00 and 90,000 of such warrants exercisable at $7.50. The warrants have a four year term expiring October 3, 2011. As of December 31, 2007, 45,000 of the warrants with an exercise price of $7.00 were earned and vested.

Warrants issued in 2007 were valued using the Black Scholes model. The net proceeds from our private placement of our common shares and common share purchase warrants described above were prorated between the fair market value of our common shares issued and the Black Scholes valuation of the warrants.

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

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

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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

In 2006, we issued 2,342,406 Common Shares upon New Warrant exercises, for which we received gross proceeds of $9,135,000. All remaining unexercised Public Warrants expired on January 26, 2006.

12. Long Term Incentive Plan & Stock Options

Long Term Incentive Plan & Stock Options

The Board of Directors adopted the Rockwell Medical Technologies, Inc., 2007 Long Term Incentive Plan (LTIP) on April 11, 2007 and the shareholders approved the LTIP on May 24, 2007. There are 1,000,000 common shares reserved for issuance under the LTIP. The Compensation Committee of the Board of Directors (the Committee) is responsible for the administration of the plan including the grant of stock based awards and other financial incentives including performance based incentives to employees, non-employee directors and consultants.

Upon approval of the LTIP, the 1997 Stock Option Plan (the Old Plan) was terminated as to future grants. No options were granted under the Old Plan in 2007 or in 2006.

The Committee determines the terms and conditions of options and other equity based incentives including, but not limited to, the number of shares, the exercise price, term of option and vesting requirements. The Committee approved stock option grants under the LTIP in December 2007. These stock option awards were granted with an exercise price equal to the market price of the Company s stock on the date of the grant. The options expire 10 years from the date of grant or upon termination of employment and vest in three equal annual installments beginning on the first anniversary of the date of grant.

Our standard stock option agreement allows for the payment of the exercise price of vested stock options either through cash remittance in exchange for newly issued shares, or through non-cash exchange of previously issued shares held by the recipient in exchange for our newly issued shares. The latter method results in no cash being received by us, but also results in a lower number of total shares being outstanding subsequently as a direct result of this exchange of shares. Shares returned to us in this manner would be retired. In 2007, the Company received cash proceeds of $474,828 in exchange for shares issued upon exercise of options during the year. No income tax benefits were recognized during 2007 or 2006 related to stock option activity as the Company has a full valuation allowance recorded against its deferred tax assets.

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of the status of the LTIP and the Old Plan excluding options granted to consultants is as follows:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2005	3,359,335	2.12	$ 6,087,407
Granted	-0-		
Exercised	(134,100)	3.37	$ 363,124
Cancelled	(6,000)	4.17	
Outstanding at December 31, 2006	3,219,235	2.68	$ 14,368,196
Granted	785,000	6.43	
Exercised	(156,500)	3.03	$ 342,853
Cancelled	(40,700)	5.26	
Outstanding at December 31, 2007	3,807,035	3.42	$ 15,293,591

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Options	Remaining Contractual Life	Weighted Exercise Price	Number of Options	Weighted Average Exercise Price
$.55 to $1.50	649,500	1.0-5.0 yrs.	$ .77	649,500	$ .77
$1.81 to $2.79	1,320,035	1.1-7.5 yrs.	$ 2.26	1,320,035	$ 2.26
$3.00 to $4.55	1,082,500	5.7-8.0 yrs.	$ 4.29	1,082,500	$ 4.29
$5.87 to $6.50	755,000	9.8-10.0 yrs.	$ 6.45	-0-	
Total	3,807,035	6.5 yrs.	$ 3.42	3,052,035	$ 2.66

	Number of Unvested Options	Weighted Average Fair Market Value at Grant Date

As of December 31, 2006		
Granted	785,000	$ 4.37
Forfeited	(30,000)	
Vested		
As of December 31, 2007	755,000	

The per share weighted average fair market values at the date of grant for options granted to employees during the year ended December 31, 2007 was $6.45. The fair market values of stock options granted during the year ended December 31, 2007 was determined using the Black Scholes option pricing model using the following assumptions: dividend yield of 0.0 percent, risk free interest rates of 3.7-4.3%, volatility of 75% and expected lives of 6 years. We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. The Company did not grant any stock options during the year ended December 31, 2006. The Company primarily bases its determination of expected volatility through its assessment of the historical volatility of its common shares. The Company does not believe that it is able to rely on its historical exercise and post-vested termination activity to provide accurate data for estimating our expected term for use in determining the fair value of these options. Therefore, as allowed by Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment* , the Company has opted to use the simplified method

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for estimating its expected term equal to the midpoint between the vesting period and the contractual term. The contractual term of the option is 10 years from the date of grant and the vesting term of the option is three years from date of grant. Risk free interest rates utilized are based upon published U.S. Treasury yield curves at the date of the grant for the expected option term.

For the year ended December 31, 2007, we recognized compensation expense of $57,938 related to options granted to employees in 2007 with a corresponding credit to common stock. At December 31, 2007, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately $3,253,000, which is expected to be amortized to expense on a straight line basis over the next three years. This estimate is subject to change based upon future events which include, but are not limited to, changes in estimated forfeiture rates, and the issuance of new options.

As of December 31, 2007, the remaining number of common shares available for equity awards under the LTIP was 245,000.

13. Contingencies

We are the defendant in a legal dispute with two entities related to each other that leased a facility and equipment to us. The plaintiffs are seeking damages of $1.7 million for breach of contract and multiple related claims stemming from our termination of the lease. We plan to vigorously defend against these claims and have not accrued any losses for this contingency, our expectations regarding the ultimate resolution of the matter could change.

14. Supplemental Cash Flow Information

We entered into non-cash transactions described below during the years ended December 31, 2007 and 2006 which have not been included in the Consolidated Statement of Cash Flows.

We entered into capital leases on equipment with a cost of $99,812, and $133,120 for the years ended December 31, 2007 and 2006, respectively, and financed those with capital lease obligations.

15. Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS 157). SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of 2008. The Company is currently evaluating the effect that the adoption of SFAS 157 will have on its consolidated results of operations and financial condition and is not yet in a position to determine such effects.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 expands the use of fair

value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, such as debt issuance costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to

Table of Contents

ROCKWELL MEDICAL TECHNOLOGIES, INC. AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS 159, changes in fair value are recognized in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company in the first quarter of 2008. The Company currently is determining whether fair value accounting is appropriate for any of its eligible items and cannot estimate the impact, if any, that SFAS 159 will have on its consolidated results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141R). SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for fiscal years beginning after December 15, 2008, and will be adopted by the Company in the first quarter of 2009. The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 141R on its consolidated results of operations and financial condition.