ROCKWELL MEDICAL TECHNOLOGIES INC
Form 10-K
March 16, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

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** *(Address of principal executive offices)*	**48393** *(Zip Code)*

(248) 960-9009
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

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, 2008 was $90,884,500. For purposes of this computation, shares of common stock held by our executive officers, directors and common shareholders with 10% or more of the outstanding shares of common stock were excluded. Such determination should not be deemed an admission that such officers, directors and beneficial owners are, in fact, affiliates.

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

Documents Incorporated by Reference

Portions of the Registrant s definitive Proxy Statement pertaining to the 2009 Annual Meeting of Shareholders (the Proxy Statement) to be filed pursuant to Regulation 14A are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

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PART I

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

Forward Looking Statements

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

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

Item 1. *Description of Business.*

General

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

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

therapy for the delivery of iron supplementation for anemic dialysis patients which we refer to as dialysate iron and more specifically as soluble ferric pyrophosphate (SFP). To realize a commercial benefit from this therapy, and pursuant to the licensing agreement, we must complete clinical trials and obtain U.S. Food and Drug Administration (FDA) approval to market iron supplemented dialysate. We also plan to seek foreign market approval for this product. We believe this product will substantially improve iron maintenance therapy and, if approved, will compete for the global market for iron maintenance therapy. Based on reports from manufacturers of

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intravenous (IV) iron products, the market size in the United States for IV iron therapy for all indications is approximately $500,000,000 per year. We estimate the global market for IV iron therapy is in excess of $850 million per year. We cannot, however, give any assurance that this product will be approved by the FDA or, if approved, that it will be successfully marketed.

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

How Hemodialysis Works

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

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

Dialysis Industry Trends

Hemodialysis treatments are generally performed in independent clinics or hospitals with the majority of dialysis services performed by regional and national for profit dialysis chains. We estimate that there are approximately 5,000 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 63% of the domestic hemodialysis market. According to industry statistics published by the U.S. Renal Data Systems (USRDS), 345,000 patients in the United States were receiving dialysis treatments at the end of 2006. The domestic dialysis industry has experienced steady patient population growth over the last two decades. In the last five years, the patient growth rate has averaged 4% per year. Population segments with the highest incidence of ESRD are also among the fastest growing within the U.S. population including the elderly, Hispanic and African-American population segments. Recent U.S. demographic projections indicate that the incidence of ESRD is expected to increase in the years ahead and is expected to exceed current incidence levels.

ESRD incidence rates vary by country with some higher and some lower than the United States. Based on industry reports, the global ESRD population is estimated to be over 2 million and to be growing at a rate of approximately 6% annually. The three major dialysis markets are the United States, the European Union and Japan, which together represent between approximately 55-60% of the total global treatments based on industry estimates.

Our Strategy

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

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

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

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

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

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

Products

We manufacture, sell, distribute and deliver hemodialysis concentrates as well as a full line of ancillary hemodialysis products to hemodialysis providers and distributors located in 37 states as well as a number of foreign countries, primarily in Latin America, Asia and Europe. Hemodialysis concentrates are comprised of two primary product types, which are generally described as acidified dialysate concentrate, also known as acid concentrate, and bicarbonate.

Renal Pure Liquid Acid Concentrate

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

Dri-Sate® Dry Acid Concentrate & Mixing System

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

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

RenalPure Powder Bicarbonate Concentrate

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

SteriLyte® Liquid Bicarbonate Concentrate

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

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Ancillary Products

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

Iron Supplemented Dialysate

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

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

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

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

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

We plan to conduct the testing required to obtain FDA approval to market SFP in the United States. We are currently conducting human clinical trials of SFP. A Phase II clinical trial on our licensed iron supplemented dialysate product under an Investigational New Drug (IND) exemption was completed by our licensor prior to us licensing the product.

We are currently conducting a second Phase II study with the primary objective to determine the optimal dosage to test in our pivotal studies. It is our intention to commence Phase III clinical trials after the FDA approves our Phase III protocol and following successful completion of our dose ranging study.

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Distribution and Delivery Operations

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

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

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

Sales and Marketing

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

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

Competition

Dialysis Concentrate and Supplies Competition

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

Fresenius treats over 125,000 dialysis patients in North America and operates approximately 1,700 clinics. It also has a renal products business that manufactures a broad array of equipment and supplies, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. In addition to its captive customer base in its own clinics, Fresenius also serves other clinic chains and independent clinics with its broad array of products. Fresenius manufactures its concentrate in its own regional manufacturing facilities. Fresenius operates an extensive warehouse network in the United States serving its captive customer base and other independent clinics.

Gambro manufactures and sells hemodialysis machines, dialyzers and other ancillary supplies. Until the end of 2006, Gambro marketed its concentrate solutions to dialysis chains and independent clinics. Gambro sold products to its own clinics until October 2005 when it sold those clinics to DaVita, Inc. (DaVita), our largest customer. Concurrent with Gambro s exit from the concentrate business in late 2006, we began to service many of the DaVita clinics previously serviced by Gambro. DaVita currently services approximately 110,000 patients in 1,400 clinics.

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

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

Iron Maintenance Therapy Market Competition

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

The other major supplier in the IV iron market is Watson Pharmaceutical, Inc. (Watson). Watson markets a product called Ferrlecit® 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.

Advanced Magnetics, Inc. is also seeking FDA approval for Ferumoxytol, a parenteral iron product. The New Drug Application for Ferumoxytol is currently under FDA review. We believe that both Ferumoxytol and Ferinject® are primarily intended to target the pre-ESRD markets and other indications such as oncology but if approved by the FDA they may compete in the ESRD market as well.

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

CMS has historically paid providers for dialysis treatments in two parts: the composite rate and separately reimbursed drugs and services. CMS reimbursement practices are changing, which we think may benefit our marketing efforts. CMS will begin implementation of a fully bundled reimbursement rate in 2011 and is intended to be fully implemented by 2014. This change is expected to result in a single composite rate per treatment, thereby eliminating reimbursement for individual drugs to providers. While the precise terms and structure of the reimbursement

procedures under this capitated rate program are not expected to be known until 2010, we believe that the provider market may find the potential economic advantages of our iron supplemented dialysate to be an attractive alternative to IV iron drugs. Providers may be attracted to SFP over IV iron products due to the lower cost of administration and the potential for improved therapeutic response from ESA treatments.

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Quality Assurance and Control

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

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

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

Government Regulation

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

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

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

Medical Device Approval and Regulation

A medical device may be marketed in the United States only with prior authorization from the FDA unless it is subject to a specific exemption. Devices classified as Class I devices (general controls) or Class II devices (general and special controls) are eligible to seek 510(k) clearance. Such clearance generally is granted when submitted information establishes that a proposed device is substantially equivalent in intended use to a legally marketed device that is not subject to premarket approval. A legally marketed device is a pre-amendment device that was legally marketed prior to May 28, 1976 and which has not been significantly changed or modified and for which the

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FDA has not called for pre-market approval (PMA) applications, or a device found to be substantially equivalent through the 510(k) process or a device which has been reclassified from Class III to Class II or Class I. The FDA in recent years has been requiring a more rigorous demonstration of substantial equivalence than in the past, including requiring clinical trial data in some cases. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new 510(k) submissions. We have been advised that it usually takes from three to six months from the date of submission to obtain 510(k) clearance, and may take substantially longer. Our hemodialysis concentrates, liquid bicarbonate and other ancillary products are categorized as Class II devices.

A device which sustains or supports life, prevents impairment of human health or which presents a potential unreasonable risk of illness or injury is categorized as a Class III device. A Class III device generally must receive approval through a PMA application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We have been advised that it usually takes from one to three years to obtain approval after filing the request, and may take substantially longer.

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

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

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

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

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

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

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

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

Drug Approval and Regulation

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

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

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

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

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

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

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

Manufacturing facilities are subject to periodic inspections for compliance with regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may also have similar regulations. We expend significant time, money and effort in the area of quality assurance to fully comply with all applicable requirements. FDA approval to manufacture a drug is site specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

Other government regulations

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations.

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

Product License Agreements

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

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

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

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

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

Trademarks & Patents

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

We were issued patents in the U.S. and Canada for our Dri-Sate Dry Acid Concentrate method and apparatus for preparing liquid dialysate which expire on September 17, 2019.

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

Suppliers

We believe the raw materials and packaging materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products distributed by us are generally available from several potential suppliers. Our principal suppliers include Roquette, Inc., Church & Dwight Co. Inc. and US Salt Company. Key suppliers of services for our clinical trials, including contract research organizations, lab testing services and other service providers, are available from a number of potential vendors.

Customers

We operate in one market segment which involves the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process to hemodialysis clinics. For the years ended December 31, 2008 and 2007, one customer, DaVita, Inc., accounted for 51% and 52% of our sales, respectively. Our accounts receivable from this customer were $2,620,000 and $1,268,000 as of December 31, 2008 and 2007, respectively. We are dependent on this key customer and the loss of its business would have a material adverse effect on our business, financial condition and results of operations. No other customers accounted for more than 10% of our sales. Our international sales, including products sold to domestic distributors that are delivered internationally, aggregated 10% and 5% of overall sales in 2008 and 2007, respectively.

Employees

As of December 31, 2008, we had approximately 250 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an at-will basis.

Research & Development

We have licensed an iron maintenance therapy product for the treatment of iron deficiency in anemic dialysis patients which we refer to as SFP. We are required to pay the cost of obtaining FDA approval to market the product in order to realize any benefit from commercialization of the product, which we expect will take several years and be costly to us. We completed our pre-clinical testing in 2007 and commenced a Phase IIb, dose ranging study in late 2007. In 2008, we continued to conduct a Phase IIb clinical trial with the primary objective to determine the drug dosage for our pivotal studies. We engaged outside service providers, contract research organizations, consultants and legal counsel

to assist us with clinical trials, product development and obtaining regulatory approval. In addition, we incurred ongoing expenses related to obtaining additional protection of the intellectual property underlying our licensing agreements. In 2008 and 2007, we incurred aggregate expenses related to the commercial development of SFP of approximately $3.8 million and $3.3 million, respectively. We expect to complete the Phase IIb study in 2009 and to commence preparation for Phase III clinical studies. We estimate that we will spend approximately $3.5-$4.0 million in 2009 on research and development for SFP.

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

Where You Can Get Information We File with the SEC

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 am to 3 pm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website on the internet that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. The address of the SEC s Web site is http://www.sec.gov. These reports are also available on our website at http://www.rockwellmed.com.

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

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

RISKS RELATED TO OUR BUSINESS

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

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results. One customer in particular accounted for 51% of our total sales during 2008. If we were to lose this customer or our relationship with any of our other major national and regional dialysis chain customers, it would have a substantial negative impact on our cash flow and operating results and could have a detrimental impact on our ability to continue our operations in their current form or to continue to execute our business strategy. If we lost a substantial portion of our business, we would be required to take actions to conserve our cash resources and to mitigate the impact of any such losses on our business operations.

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

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

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

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

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

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

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

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

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

A significant portion of our costs are for chemicals and fuel which are subject to pricing volatility based on demand and are highly influenced by the overall level of economic activity. Since 2007, we have experienced dramatic increases in our costs which we have not yet been able to fully recover from our customers through price increases. While we have recently changed certain vendors and realized cost decreases in several of our key cost inputs, we may be subject to future cost increases which may negatively impact our results if we are unable to recover those cost increases. If we are unable to improve our gross profit margins by reducing our costs and increasing our prices, our business may remain unprofitable.

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

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

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

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

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We depend on government funding of healthcare.

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

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

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

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

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

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

We depend on key personnel.

Our success depends heavily on the efforts of Robert L. Chioini, our President and Chief Executive Officer, Dr. Richard Yocum MD, our Vice President of Drug Development & Medical Affairs, and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for managing our sales and marketing efforts. Dr. Yocum is primarily responsible for managing our product development efforts. None of our executive management are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini, Dr. Yocum or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

Our business is highly regulated.

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

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current : 1px"> *Level 2 Level 3 Total* Company common stock $124,401,123 $— $— $124,401,123 Common stocks - other 1,016,857 — — 1,016,857 Mutual funds 153,775,956 — — 153,775,956 Money market funds 20,205,485 — — 20,205,485 Self-directed brokerage account 10,331,592 — — 10,331,592

Total investments in fair value hierarchy

309,731,013

— —

309,731,013

Stable value fund* 25,600,304 Common/collective trust funds* 114,708,913 Total investments at fair value $309,731,013 $— $— $ 450,040,230

* Investments measured at fair value using net asset value per share (or its equivalent) as a practical expedient have not been classified in the fair value hierarchy. The fair value amounts presented in the hierarchy tables for such investments are intended to permit reconciliation of the fair value hierarchy to the investments at fair value line item presented in the statements of net assets available for benefits. Such investments have no redemption restrictions or unfunded commitments and redemptions of these investments may occur each business day.

There were no transfers of investments between levels of the fair value hierarchy during 2015.

(9) Benefits Payable

Included in net assets available for benefits are amounts allocated to individuals who have elected to withdraw from the Plan, but have not been paid as of December 31, 2015 or 2014. Plan assets allocated to these participants were $0 for 2015 and $351,393 for 2014.

first horizon national corporation savings Plan

Notes to Financial Statements

December 31, 2015 and 2014

(10) Reconciliation of Financial Statements to Form 5500

The following is a reconciliation of net assets available for benefits per the financial statements to the Form 5500 expected to be filed for December 31, 2015 and 2014:

	2015	2014
Net assets available for benefits per the financial statements	$460,754,445	$459,221,891
Less: Benefits payable	—	(351,393)
Add: Adjustment to contract value	—	510,831
Net assets available for benefits per the Form 5500	$460,754,445	$459,381,329

The following is a reconciliation of benefits paid to participants per the financial statements to the Form 5500 expected to be filed for 2015:

	2015
Benefits paid to participants per the financial statements	$36,944,703
Less: accrual for prior year	(351,393)
Add: accrual for current year	—
Benefits paid to participants per the Form 5500	$36,593,310

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Notes to Financial Statements

December 31, 2015 and 2014

(10) Reconciliation of Financial Statements to Form 5500 (continued)

The following is a reconciliation of the total increase in net assets available for benefits per the financial statements to the Form 5500 expected to be filed for 2015:

	2015
Total increase in assets per the financial statements	$1,532,554
Cumulative adjustment to contract value	(510,831)
Cumulative benefits payable	351,393
Net income (loss) per the Form 5500	$1,373,116

(11) Subsequent Events Evaluation

The Plan has evaluated subsequent events through the date that the financial statements were filed with the Securities and Exchange Commission.

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Schedule H, Line 4i - Schedule of Assets (Held at End of Year),

Plan Number: 002

EIN: 62-0803242

December 31, 2015

(a)	(b) Identity of issue, borrower, lessor, or similar party	(c) Description of investment including maturity date, rate of interest, collateral, par, or maturity value	(d) Cost	(e) Current value
	Goldman Sachs Financial Square Government	Money market fund	(1)	$20,307,096
	First Horizon Self Directed Brokerage Account	Self-directed brokerage account	(1)	12,719,849
	Invesco Stable Value Fund	Common/collective - stable value fund	(1)	26,381,454
	BlackRock Life Path Index 2020 Fund	Common/collective trust fund	(1)	6,912,596
	BlackRock Life Path Index 2025 Fund	Common/collective trust fund	(1)	9,540,084
	BlackRock Life Path Index 2030 Fund	Common/collective trust fund	(1)	5,671,119
	BlackRock Life Path Index 2035 Fund	Common/collective trust fund	(1)	4,941,381
	BlackRock Life Path Index 2040 Fund	Common/collective trust fund	(1)	3,943,345
	BlackRock Life Path Index 2045 Fund	Common/collective trust fund	(1)	4,736,335
	BlackRock Life Path Index 2050 Fund	Common/collective trust fund	(1)	343,796
	BlackRock Life Path Index 2055 Fund	Common/collective trust fund	(1)	294,373
		Common/collective trust fund	(1)	4,673,209

	BlackRock Life Path Index Retirement			
	BlackRock US Debt Index F	Common/collective trust fund	(1)	4,535,449
	BlackRock MSCI ACWI EX US Fund	Common/collective trust fund	(1)	5,984,358
	BlackRock Russell 2000 Index Fund	Common/collective trust fund	(1)	6,511,165
	BlackRock Equity Index F	Common/collective trust fund	(1)	63,091,031
		Total common/collective trust funds		121,178,241
	Dodge & Cox Balanced Fund	Mutual fund	(1)	39,429,872
	T Rowe Price Institution Large Cap Value Fd	Mutual fund	(1)	13,994,322
	Mainstay Large Cap Growth Fund	Mutual fund	(1)	9,648,765
*	Dodge & Cox International	Mutual fund	(1)	9,724,129
*	Harding Loevner International Equity Instl	Mutual fund	(1)	9,724,129
**	Royce Premier Instl	Mutual fund	(1)	15,365,304
**	DFA U.S. Targeted Value I	Mutual fund	(1)	15,365,304
	Goldman Sachs Core Fixed Income	Mutual fund	(1)	13,561,182
	Lord Abbett Developing Growth Fund Inc	Mutual fund	(1)	13,089,122
		Total mutual funds		139,902,129
***	First Horizon National Corporation	First Horizon National Corporation common stock fund, 9,724,305.18 units	(1)	129,032,777
***	Participant Loans	Loan fund, interest rates ranging from 3.25% to 8.25%, collateralized by participants' right, title and interest in and to the Plan, maturity dates range from 2016-2025	(1)	9,111,449
	Segregated participant investments:			
	Fidelity Inst'l Govt Portfolio	Money market fund	(1)	212,589
	Exxon Mobil Corporation	Corporate stock, 7,558 shares	(1)	589,146
	Murphy Oil Corporation	Corporate stock, 3,000 shares	(1)	67,350
	Murphy USA Inc	Corporate stock, 750 shares	(1)	45,555

Total corporate stock	702,051
	$459,547,635

* Presented in the aggregate to participants as the Non-US Equity Fund.

** Presented in the aggregate to participants as the Small Cap Value Fund.

*** Indicates party-in-interest to the Plan.

(1) Cost information is omitted for Plan assets which are participant-directed.

See accompanying report of independent registered public accounting firm.

EXHIBITS

The following documents are filed as exhibits to this Form 11-K:

1. Consent of Independent Registered Public Accounting Firm [Mayer Hoffman McCann P.C.].

SIGNATURES

The Plan. Pursuant to the requirements of the Securities Exchange Act of 1934, the Pension, Savings and Flexible Plan Committee of the First Horizon National Corporation Savings Plan ("Plan") has duly caused this annual report to be signed on behalf of the Plan by the undersigned hereunto duly authorized.

FIRST HORIZON
NATIONAL
CORPORATION
SAVINGS PLAN

Date: July 7, 2016 By:/s/ Tanya L. Hart
Tanya L. Hart
Senior Vice President – Executive Compensation Manager, and Member of the Pension, Savings and Flexible Compensation Committee

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EXHIBIT INDEX

No.	Description
23.1	Consent of Independent Registered Public Accounting Firm [Mayer Hoffman McCann P.C.]