NxStage Medical, Inc.
Form 10-K
February 28, 2013
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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, 2012

OR

¨ **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: 000-51567

NxStage Medical, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3454702**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
350 Merrimack Street, Lawrence, MA	**01843**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant s Telephone Number, Including Area Code:

(978) 687-4700

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

Common Stock, $0.001 par value

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 þ No ¨

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 ¨ 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 ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. þ

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

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

The aggregate market value of common stock held by non-affiliates of the registrant was approximately $870 million, as of June 30, 2012, based on the last reported sale price of the registrant s common stock on the NASDAQ Global Select Market on June 29, 2012.

There were 59,348,796 shares of the registrant s common stock outstanding as of the close of business on February 25, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for its 2012 Annual Meeting of Stockholders to be held on May 23, 2013 are hereby incorporated by reference in response to Part III, Items 10, 11, 12, 13 and 14 of the Annual Report on Form 10-K.

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NXSTAGE MEDICAL, INC.

2012 ANNUAL REPORT ON FORM 10-K

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CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This report and certain information incorporated by reference herein contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to: the market adoption of our products in the U.S. and internationally; the growth of the home, critical care and in-center dialysis markets in general and the home dialysis market in particular; the development and commercialization of our products; changes in the historical purchasing patterns and preferences of our key customers, including DaVita HealthCare Partners Inc., or DaVita, and Fresenius Medical Care, or Fresenius; the adequacy of our funding; our ability to achieve and sustain positive cash flows; expectations with respect to future demand for our products and revenue growth; the timing and success of our initiatives to improve our gross profit as a percentage of revenues; expectations with respect to our operating expenses and achieving our business plan; expectations with respect to achieving profitable operations; expectations with respect to achieving improvements in product reliability; the timing and success of the submission, acceptance and approval of regulatory filings and the impact of any changes in the regulatory environment with respect to our products or business; the scope of patent protection with respect to our products; expectations with respect to the findings of our FREEDOM study and other ongoing clinical studies evaluating home and/or more frequent hemodialysis; expectations as to the continued availability of raw materials, components, and finished goods, including from key single source suppliers; expectations with respect to our ability to supply on a timely and uninterrupted basis all products ordered by our customers; expectations with respect to our litigation with Gambro Renal Products, Inc., or Gambro; the impact of any new business development initiatives, such as centers of excellence, on our business and customer relationships; and the impact of new and future changes to reimbursement for chronic dialysis treatments. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words expect , anticipate , intend , plan , believe , seek , estimate , potential , continue , predict , may , and similar expressions are intended to iden forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed below in Risk Factors , Management s Discussion and Analysis of Financial Condition and Results of Operations , and elsewhere in this report.

You should read these forward-looking statements carefully because they discuss our expectations about our future performance, contain projections of our future operating results or our future financial condition or state other forward-looking information. You should be aware that the occurrence of any of the events described under Risk Factors and elsewhere in this report could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

We cannot guarantee future results, events, levels of activity, performance or achievements. The forward-looking statements contained in this report represent our expectations as of the date of this report and should not be relied upon as representing our expectations as of any other date. Subsequent events and developments will cause our expectations to change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

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PART I

For convenience, in this Annual Report on Form 10-K, NxStage, we, us, and the Company refer to NxStage Medical, Inc. and our consolidated subsidiaries, taken as a whole.

Item 1. *Business*

Overview

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the NxStage System One, or System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis clinics. Given its design, the System One is particularly well-suited for home hemodialysis and a range of dialysis therapies including more frequent dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared or approved for commercial sale in the United States, or U.S., Canada and certain other markets for the treatment of acute and chronic kidney failure and fluid overload. The System One is also CE marked in the European Union, or EU, with the intended purpose of treating acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the U.S. Food and Drug Administration, or FDA, for home hemodialysis as well as therapeutic plasma exchange, or TPE, in a clinical environment. We also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of end-stage renal disease, or ESRD. These products are cleared or approved for commercial sale in the U.S., Canada and certain other markets. These products are also CE marked in the EU. We believe our largest product market opportunity is for our System One used in the home dialysis market for the treatment of ESRD.

ESRD, which affects over 550,000 people in the U.S. and 2 million people worldwide, is an irreversible, life-threatening loss of kidney function that is treated predominantly with dialysis. Dialysis is a kidney replacement therapy that removes toxins and excess fluids from the bloodstream and, unless the patient receives a kidney transplant, is required for the remainder of the patient s life. Approximately 70% of ESRD patients in the U.S. rely on life-sustaining dialysis treatment. Hemodialysis, the most widely prescribed type of dialysis, typically consists of treatments in a dialysis clinic three times per week, with each session lasting three to five hours. Approximately 8% of U.S. ESRD dialysis patients receive some form of dialysis treatment at home, most of whom treat themselves with peritoneal dialysis, or PD, although surveys of physicians and healthcare professionals suggest that a larger proportion of patients could take responsibility for their own care. We believe that approximately 10-15% of the over 385,000 U.S. ESRD patients currently receiving dialysis treatment would be appropriate candidates for home hemodialysis with the NxStage System One. Clinical data also suggests that hemodialysis therapy administered five or six times per week, commonly referred to as more frequent therapy, better mimics the natural functioning of the human kidney and can lead to improved clinical outcomes, including lower mortality and improved survival, significant improvements in left ventricular mass, reductions in antihypertensive medications, reduced fluid overload, reduced depression and improvements in health-related quality of life. We believe there is an unmet need for a hemodialysis system that allows more frequent and easily administered therapy at home, as well as in other settings, and we have designed our system to address this and other kidney replacement markets. Given the clinical and quality of life benefits associated with more frequent hemodialysis therapy, nearly all of our System One patients in the home market receive treatment between five or six times a week.

Measuring a little over a foot tall, the System One is the smallest commercially available hemodialysis system. It consists of a compact, portable and easy-to-use cycler, disposable drop-in cartridge and high purity premixed fluid. The System One has a self-contained design and simple user interface making it easy to operate by a trained patient and his or her trained partner in any setting prescribed by the patient s physician. Unlike

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traditional dialysis systems, our System One does not require any special disinfection and its operation does not require specialized electrical or plumbing infrastructure or modifications to the home. Patients can bring the System One home, plug it in to a conventional electrical outlet and operate it, thereby eliminating what can be expensive plumbing and electrical household modifications required by other traditional dialysis systems. Because of its portability, patients also have the freedom to travel with the System One. We market the System One to dialysis clinics for chronic home hemodialysis treatment. The clinics in turn provide the System One to ESRD patients.

We also market the System One to hospitals for treatment of acute kidney failure and fluid overload. It is estimated that there are over 200,000 cases of acute kidney failure in the U.S. each year. The clinical flexibility of our System One, coupled with its ease-of-use and portability, make our system well suited for hospital critical care environments.

In addition to the System One, we sell a line of extracorporeal disposable products for use primarily for in-center dialysis treatments for patients with ESRD. These products, which we obtained in connection with our October 2007 acquisition of Medisystems Corporation which we refer to as the Medisystems Acquisition, include hemodialysis blood tubing sets, A.V. fistula needles and apheresis needles. Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981, and has achieved leading positions in the U.S. market for both hemodialysis blood tubing sets and AV fistula needles. Streamline, our next generation blood tubing set product, which was introduced in 2007, is designed to provide improved patient outcomes and lower costs to dialysis clinics. Our needle products line includes AV fistula needles incorporating safety features, first introduced in 1995, including PointGuard Anti-Stick Needle Protectors and MasterGuard technology, and ButtonHole needles, first introduced in 2002.

For the year ended December 31, 2012, our revenues were $242.1 million and we incurred a net loss of $15.2 million. As of December 31, 2012, we had cash and cash equivalents of $106.4 million, total assets of $311.9 million and total stockholders equity of $197.6 million.

Since inception, we have incurred negative operating margins and losses every quarter. At December 31, 2012, we had an accumulated deficit of approximately $345.0 million. We have continued to make improvements in our gross margins for our products; however, we cannot provide assurance that our gross margins will continue to improve or, if they do improve, the rate at which they will improve. Continued improvements in gross margins are dependent on many factors, including growing revenues, reducing costs of revenues by lowering manufacturing costs, implementing design and process improvements, obtaining better purchasing terms and prices and increasing reliability of our products. Additionally, we expect our operating expenses to continue to increase as we grow and expand our business. Our ability to become profitable and the timing and sustainability of doing so depend principally upon continued improvements in gross margins, growing revenues, and the leverage of our operating infrastructure including after taking into account the effects of any investment in selling and marketing or research and development activities or investment in new business development, including our activities to establish dialysis centers as part of our centers of excellence initiative. Additionally, our profitability will be negatively impacted beginning in 2013 due to the 2.3% medical device excise tax that will be assessed on nearly all of our products sold in the U.S.

Over the past several years, we have improved our cash flows from operating activities and continue to work towards our long term goal of sustained positive cash flows from operating activities. However, there can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross profit, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment, and the rate at which we invest in selling and marketing, research and development or new business development activities, including centers of excellence.

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We were incorporated in Delaware in 1998 under the name QB Medical, Inc., and later changed our name to NxStage Medical, Inc. Our principal executive offices are located at 350 Merrimack Street, Lawrence, Massachusetts 01843.

Additional financial information regarding our business segments and geographic data about our assets is contained in Management s Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of Part II, and in our notes to Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K.

Our Products and Services

The System One

Our primary product, the NxStage System One, is a small, portable, easy-to-use hemodialysis system. Sales of the System One and related disposables accounted for approximately 67%, 66% and 64% of our total sales for the years ended December 31, 2012, 2011 and 2010, respectively.

The System One includes the following components:

The NxStage Cycler. A compact portable electromechanical device containing pumps, control mechanisms, safety sensors and remote data capture functionality.

The NxStage Cartridge. A single-use, disposable, integrated treatment cartridge that loads simply and easily into the cycler. The cartridge incorporates a proprietary volumetric fluid management system and includes a pre-attached dialyzer.

Premixed Dialysate. The System One uses high-purity premixed dialysate for hemodialysis applications. The volume of fluids used varies with treatment options, prescription, and setting. We supply our premixed dialysate in sterile five liter bags or through the use of our PureFlow SL accessory. The PureFlow SL module allows for the preparation of dialysate fluid in the patient s home using ordinary tap water and dialysate concentrate thereby reducing the need for bagged fluids for in-home treatments.

Streamline & ReadySet

Streamline was introduced in 2007, as our next generation blood tubing set product. Streamline features an efficient and airless design intended to result in superior clinical and economic performance and is designed to reduce treatment time, minimize waste and optimize dose delivery. Streamline also includes our patented LockSite needleless access sites, eliminating the need for sharp needles or costlier guarded needles to be used with the tubing set in connection with dialysis therapy, which is intended to facilitate a clinician s ability to satisfy Occupational Safety and Health Administration, or OSHA, anti-stick requirements. We recently completed the process of transitioning nearly all of our end users to Streamline. As a result, sales of our Streamline product accounted for approximately 19% and 11% of our total sales for the year ended December 31, 2012 and 2011, respectively.

The ReadySet blood tubing set was introduced for use in hemodialysis in 1993. Historically, sales of ReadySet represented the majority of our blood tubing set sales. As a result of nearly all of our end users transitioning to Streamline, sales of ReadySet have declined to minimal levels during 2012 from approximately 9% and 15% of our total sales for the years ended December 31, 2011 and 2010, respectively.

AV Fistula and Apheresis Needles

Our AV fistula and apheresis needles have been designed to achieve a smooth blood flow throughout the treatment, intended to result in less clotting, lower pressure drops, and less stress on the patient s blood. A

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significant amount of our needles sold are branded MasterGuard, and include our Fingershield® anchor designed to protect the operator from inadvertent needle stick injury. We also offer ButtonHole needles, first introduced in 2002, for hemodialysis therapies as an alternative to our AV fistula needles with MasterGuard. This needle is used by patients that employ the constant-site technique , whereby a fistula needle is inserted in the same place each treatment. Published clinical experience suggests that the incidence of pain, hematoma, and infiltrations at the needle insertion site can be reduced by utilizing the constant-site technique. Our ButtonHole AV fistula needle has an anti-stick, dull bevel design well-suited for the constant-site technique, while also being designed to reduce the risk of accidental needle sticks. Sales of needles accounted for approximately 11%, 11% and 12% of our total sales for the years ended December 31, 2012, 2011 and 2010, respectively.

Our Business by Segment

The results of our operations are included in two separately reportable segments, System One and In-Center. We distribute our products in three markets: home, critical care and in-center. In the System One segment we derive our revenues from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients within a home like setting, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. In the In-Center segment, we derive our revenues from the sale of blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers, and needles for apheresis in the in-center market. Other business activities relate primarily to the manufacturing of dialyzers for sale to Asahi Kasei Kuraray Medical Co., or Asahi, certain business development activities, including our early work on establishing centers of excellence, which are dialysis clinics focused on the provision of home therapies including home hemodialysis, and certain corporate expenses, specifically research and development and general and administrative expenses, which are excluded from the segment operating performance measures.

System One

We began marketing the System One to perform hemodialysis for ESRD patients in September 2004, and we began marketing our System One specifically for home use in July 2005, after the System One was cleared by the FDA for home hemodialysis. We market the System One to independent dialysis clinics as well as dialysis clinics that are part of national or regional chains, providing clinics with improved access to the developing home dialysis market, and the ability to expand their patient base by adding home-based patients without adding clinic infrastructure. As Medicare regulations require that all chronic ESRD patients be under the care of a dialysis clinic, whether they are treated at home, in clinic or with a kidney transplant, we do not sell the System One directly to patients.

For each month that a patient is treated with the System One, we bill the clinic for the purchase of the related disposable cartridges and treatment fluids necessary to perform treatment. A significant majority of System One equipment in the home market is purchased, rather than rented, by our customers including our two largest customers in the home market, DaVita and Fresenius. After selling or renting a System One to a clinic, our clinical educators train the clinic s nurses and dialysis technicians on the proper use of the System One using our proprietary training materials. We are not responsible for, and do not provide patient training. We rely on our customers trained technicians and nurses to train home patients, their partners and other technicians and nurses using the System One.

Patient training takes place at the clinic primarily during the patient s prescribed, more frequent, two- to three-hour treatment sessions. Training typically takes two to three weeks and includes basic instruction on ESRD, the operation of the System One and the insertion by the patient or their partner of needles into the patient s vascular access site. Training sessions are presently reimbursed by Medicare or private insurance.

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The System One cycler sold to hospitals in the critical care market is based on the same technology platform used in the home market but has additional features that offer a wider range of therapies, including TPE, and includes an additional display module, called OneView, which is designed to facilitate easier medical record charting and troubleshooting. Most of our customers in the critical care market use our System One to perform prolonged or continuous renal replacement therapy, also referred to as CRRT, for their acute kidney failure or fluid overload patients. We are specifically focusing our sales efforts in the critical care market on those large institutions that we believe are most dedicated to prolonged or continuous renal replacement therapy for patients with acute kidney failure and believe in ultrafiltration as an earlier-stage treatment option for fluid overload.

We primarily sell the System One cycler to customers in the critical care market; we also sell related disposable cartridges and treatment fluids necessary to perform dialysis treatment. After selling or renting a System One to a hospital, our clinical educators generally train the hospital s intensive care unit, or ICU, and acute dialysis nurses on the proper use of the System One using our proprietary training materials. We then rely on the trained nurses to train other nurses. By adopting this train the trainer approach, our sales nurses do not need to return to the hospital each time a new nurse needs to be trained. We also sell one-and two-year service contracts following the expiration of our standard one-year warranty period for System One hardware. We sell a bio-medical training program, whereby we train bio-medical engineers on how to service and repair certain aspects of the System One in the critical care setting.

Ownership of U.S. dialysis clinics is highly consolidated. While there are over 5,500 Medicare-certified dialysis outpatient facilities in the United States, DaVita and Fresenius in the aggregate control approximately two-thirds of the U.S. dialysis market. The remaining market comprises smaller chains and independent clinics and hospitals.

DaVita and Fresenius are our two largest and most significant customers in the System One segment. Direct sales to DaVita represented 31%, 31% and 34% of our System One segment revenues during 2012, 2011 and 2010, respectively. Further, DaVita constitutes over 40% of our home hemodialysis patients. Direct sales to Fresenius represented 17%, 14% and 10% of our System One segment revenues during 2012, 2011 and 2010, respectively.

In July 2010, we entered into a First Amended and Restated National Service Provider Agreement, or the Amended Agreement, with DaVita expiring on June 30, 2013. The Amended Agreement supersedes our earlier agreement with DaVita entered into on February 7, 2007. Pursuant to the terms of the Amended Agreement, we agreed to continue to supply to DaVita the System One and PureFlow SL and related supplies for home hemodialysis therapy and DaVita committed to continue to purchase, rather than rent, nearly all of its future System One equipment needs. After June 30, 2013, the term of the Amended Agreement may be automatically extended on a monthly basis unless terminated by either party pursuant to the Amended Agreement.

The Amended Agreement includes a modest increase to DaVita s pricing from the levels under the original 2007 agreement, and continues DaVita s right to receive most favored nation pricing for the System One and related supplies for home hemodialysis therapy, subject to certain requirements, including DaVita achieving certain System One home patient growth targets. It also provides for certain pricing discounts, structured to be paid as a warrant in lieu of cash; we believe DaVita will not be able to earn the outstanding warrants. We expect that DaVita will continue to be a significant customer in the home market; however, there can be no assurance that we will enter into a new agreement with DaVita at similar terms if at all.

In-Center

We sell primarily blood tubing sets and needles to customers in the in-center market. In this market, our customers are independent dialysis clinics as well as dialysis clinics that are part of national or regional chains. Although in many instances we have direct contractual relationships with our customers, the majority of our sales in this market are made through distributors in order to leverage national networks, shipping efficiencies and

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existing customer relationships. We plan our manufacturing and distribution activities based on distributor purchase orders. Finished goods are shipped directly to distributor warehouses. We support distributor selling and marketing efforts with brand marketing support and a team of clinical educators who assist with clinical in-service activities.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Our two largest distributors are Gambro Renal Products, Inc., or Gambro and Henry Schein, Inc., or Henry Schein. Revenues from Gambro represented approximately 36%, 40% and 36% of our In-Center segment revenues during 2012, 2011 and 2010, respectively. Revenues from Henry Schein represented approximately 34%, 38% and 44% of our In-Center segment revenues during 2012, 2011 and 2010, respectively. Our distribution agreement with Gambro will expire in June 2014. Our distribution agreement with Henry Schein will expire in April 2014.

DaVita is also a significant customer in the in-center market. Sales of our products through distributors to DaVita accounted for approximately half of In-Center segment revenues during 2012, 2011 and 2010. DaVita has contractual purchase commitments under two agreements: one with us for needles and one with Gambro for blood tubing sets. DaVita s purchase obligations with respect to needles will expire under an agreement with us in April 2013. The agreement contemplates ongoing sales of products following April 2013. We continue to work with DaVita to execute a new agreement with respect to needles and we expect DaVita will continue to be a significant customers in the in-center market; however, there can be no assurance that we will enter into a new agreement with DaVita at similar terms if at all. Gambro s long term product supply agreement with DaVita entered into in connection with the sale of Gambro s U.S. dialysis clinic business to DaVita, obligates DaVita to purchase a significant majority of its blood tubing set requirements from Gambro. In December 2012, Baxter International, Inc., or Baxter, announced that it had entered into a definitive agreement to acquire Gambro in early 2013. Our distribution agreement with Gambro, which expires in June 2014 and survives a Gambro change of control, contractually obligates Gambro to exclusively supply our blood tubing sets to DaVita.

International

We sell the System One and certain of our other products internationally, primarily through distributors. Products sold to distributors are shipped directly to distributor warehouses and the distributors sell or rent our products to dialysis providers or hospitals and are responsible for marketing, clinic training and equipment servicing and repair. In the future, we expect to expand to a direct sales model in a limited number of countries. To date, our international sales have been quite limited, and we are still very early in our international commercialization efforts.

Marketing, Customer Support

We have a sales force that calls on dialysis clinics, nephrologists and hospitals. In addition to specialized sales representatives, we also employ nurses in our sales force as clinical educators to support our sales efforts. We have a staff of Customer Support Specialists to assist patients, clinics and hospitals with product orders and deliveries, and also provide technical support 24 hours a day, seven days a week through a dedicated staff of Technical Support Representatives, to respond to questions raised by patients, clinics and hospitals concerning the System One. Our direct sales efforts focus almost exclusively on the home and critical care markets as we rely heavily on distributors to sell our products in the in-center market.

In the home market we use a depot service model for equipment servicing and repair while we generally service equipment sold to customers in the critical care market in the field. For our home market customers, if a device requires repair, we arrange for a replacement device to be shipped to the site of care, whether it is a patient s home or a clinic, and for pick up and return to us of the system requiring service. This shipment is done by common carrier, and, as there are no special installation requirements, the patient or clinic can quickly and easily set up the new machine. The nature of the hospital critical care settings, coupled with the practices of other ICU dialysis equipment suppliers, necessitates an option for on-site support for our systems installed in this environment, or for the use of a trained bio-medical engineer.

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Competition

The dialysis therapy market is mature, consolidated and competitive. Our System One in the critical care market competes against Gambro, Fresenius, B. Braun and others. In December 2012, Baxter International, Inc., or Baxter, announced that it had entered into a definitive agreement to acquire Gambro in early 2013. Our product lines in the in-center market compete directly against products produced by Fresenius, Gambro, Nipro, Baxter, JMS and others. Our competitors each market one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offer products that have been in use for longer than our System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales and distribution channels, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy and Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products that may afford them a significant competitive advantage.

We believe the competition in the market for kidney dialysis equipment and supplies is based primarily on:

- product quality;
- ease-of-use;
- cost effectiveness;
- sales force coverage; and
- clinical flexibility and performance.

Our System One in the home market is currently the only portable system specifically indicated for use in the home market in the U.S. In 2011, Fresenius, our second largest customer in the System One segment, with nearly all of those sales in the home market, obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy. Fresenius is also seeking clearance to market its Portable Artificial Kidney, or PAK, in the U.S. for in-center use, and plans to later introduce the product in the home.

There is also an increasing interest in the home dialysis market from other competitors. Baxter has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, for the development of a new home hemodialysis system specifically intended for nocturnal use. Baxter has commented that they have completed one of the clinical studies intended to support FDA clearance of this system and that they have started enrollment for a Canadian nocturnal clinical study intended to support CE marking in the EU. Baxter has indicated that it hopes to complete the conformity assessment process and CE mark for its system in the EU in 2013. Baxter has also indicated that it hopes to complete additional clinical studies and to file for regulatory approval for a home hemodialysis nocturnal indication in the U.S. in 2014.

Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of the products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the home market, it could adversely affect our sales and growth. We also are unable to predict what impact the Fresenius home hemodialysis systems will have on our sales to Fresenius or our overall home market performance.

For the critical care market, we believe we compete favorably in terms of product quality and ease of use due to our System One design, portability, drop-in cartridge and use of premixed fluids. We believe we also compete favorably on the basis of clinical flexibility, given the System One s ability to perform hemofiltration, hemodialysis and ultrafiltration. We believe we compete favorably in terms of cost-effectiveness for hospitals that perform continuous renal replacement therapies, or CRRT. In the fluid overload market, which is a very

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small component of our critical care market, drug therapy is currently the most common and preferred treatment. To date, ultrafiltration has not been broadly adopted and, if the medical community does not accept ultrafiltration as clinically useful, cost-effective and safe, we will not be able to successfully compete against existing pharmaceutical therapies and other device based technologies in the treatment of fluid overload.

For the in-center market, where we sell needles and blood tubing sets, we believe that we compete favorably in terms of product quality, ease-of-use, cost effectiveness, clinical flexibility and performance. We also compete favorably in terms of branding, as Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981. We compete unfavorably in terms of sales force coverage, as we rely nearly exclusively on distributors, rather than our own direct sales force.

Our primary competitors are large, well-established businesses with significantly more financial and personnel resources and greater commercial infrastructures than ours. We believe our ability to compete successfully will depend largely on our ability to:

- continuously improve our products and develop and obtain clearance for new products;
- establish the infrastructures necessary to support a growing home, critical care and in-center dialysis products business;
- maintain and improve product quality;
- continue to develop sales and marketing capabilities; and
- achieve cost reductions.

Our ability to successfully market our products for the treatment of kidney failure could also be adversely affected by pharmacological and technological advances in preventing the progression of chronic ESRD and/or in the treatment of acute kidney failure, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants. There can be no assurance that competitive pressure or pharmacological or technological advancements will not have a material adverse effect on our business.

Clinical Experience and Results

Significant clinical literature strongly supports that daily or more frequent hemodialysis therapy can lead to improved clinical outcomes, including lower mortality and improved survival, reduction in left ventricular mass, reduction in hypertension and use of antihypertensive medications, improved nutritional status, and overall improvement in quality of life, including improvements related to overall physical and mental health, depressive symptoms, sleep, restless legs syndrome and post-dialysis recovery time.

In early 2006, we enrolled the first patient in our post-market FREEDOM (Following Rehabilitation, Economics, and Everyday Dialysis Outcome Measurements) study, which is designed to quantify the clinical and economic benefits of daily home therapy administered to Medicare patients with the System One versus conventional thrice-weekly dialysis. The FREEDOM study is a prospective, multi-center, observational study, of 500 Medicare patients in over 70 clinical centers. The study compares Medicare patients using the System One with a matched cohort of patients from the U.S. Renal Data System, or USRDS, patient database treated with traditional in-center thrice weekly dialysis, to help define differences in the cost of care and patient outcomes between the daily home setting and the dialysis clinic setting. Comparing the study group of patients using the System One to a USRDS database group matched in terms of demographics, co-morbidities, geography, number of years on dialysis and other key factors, should allow a valuable comparison to be made without the time and cost challenges of a crossover study, in which patients would be followed for a given time on each type of therapy.

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Our goal is to provide further insights into more frequent dialysis and its cost-effectiveness as well as to confirm the significant reported potential benefits of daily therapy on patient quality of life and rehabilitation. Published U.S. government data estimates the total health care cost burden of a Medicare dialysis patient at over $81,000 annually, with dialysis treatments representing approximately 25% of this cost, and the cost of hospitalizations, drugs and physician fees representing over 60%.

Interim four and twelve month results from our ongoing FREEDOM study show daily home hemodialysis treatment made possible by the System One therapy significantly improves select measures of patient quality-of-life as compared to conventional, thrice-weekly in-center treatment. Specific improvements identified to date include a reduction in post dialysis recovery time (the average time to resume normal activity), returning significant quality time to patients each week. Other benefits include a reduction in depressive symptoms, improvements in select physical and mental health quality of life domains, a reduction in antihypertensive medications, improvements in sleep and restless legs syndrome and improvements in overall quality of life and physical intimacy. These results have been published in major peer review journals including the *Journal of the American Society of Nephrology* and the *American Journal of Kidney Disease*.

In a NxStage-funded study of Medicare patients starting NxStage home hemodialysis therapy from 2005-2007 (n=1,873) compared to traditional in-center dialysis patients during the same period (n=9,365), risk of death was found to be significantly lower, and three-year survival significantly higher, in the NxStage population versus the matched in-center hemodialysis cohort. This study was published in the *Journal of the American Society of Nephrology* in early 2012.

The Frequent Hemodialysis Network (FHN) Trial Group (2010) conducted a randomized clinical trial to determine whether increasing hemodialysis frequency would result in beneficial changes in left ventricular mass, self-reported physical health, and other intermediate outcomes among patients undergoing maintenance hemodialysis. Patients were randomly assigned to undergo hemodialysis six times per week (frequent hemodialysis, 125 patients) or three times per week (conventional hemodialysis, 120 patients) for 12 months. The investigators concluded that frequent hemodialysis, as compared with conventional hemodialysis, was associated with favorable results with respect to the composite outcomes of death or change in left ventricular mass and death or change in a physical-health composite score but prompted more frequent interventions related to vascular access.

In 2010 we completed an approved Investigational Device Exemption, or IDE, clinical study intended to support a home nocturnal indication for the System One. Enrollment started in the first quarter of 2008 and we submitted the associated 510(k) to the FDA in 2010. We met our primary safety and efficacy endpoints for the study; nevertheless, in 2011, the FDA notified us that their standards for what will be required for a home nocturnal clearance changed from what was required in our approved IDE. As a result, the FDA did not clear our 510(k) application for home nocturnal use. In July 2012, the FDA approved a continuation of our IDE study designed to support a nocturnal indication for the System One. We have re-started the trial. After completion of the trial, we will resubmit an application for a home nocturnal clearance.

In addition to the FREEDOM and nocturnal studies, we have completed two significant clinical trials with the System One for ESRD therapy, a post-market study of chronic daily hemofiltration and a study under an FDA-approved IDE. We have also completed a study of ultrafiltration with the System One for fluid overload associated with Congestive Heart Failure, or CHF.

In the IDE study, we compared center-based and home-based daily dialysis with the System One. That study was a prospective, multi-center, two-treatment, two-period, open-label, cross-over study. The first phase of the study consisted of 48 treatments, six per week, in an eight-week period performed in-center, while the second phase consisted of the same number of treatments performed in an in-home setting. Between the two phases, there was a two-week transition period conducted primarily in the patient s home. Prior to study initiation, enrolled patients were to have been on at least two weeks of daily hemodialysis with the System One in an in-

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center environment. The objective of the study was to evaluate equivalence on a per-treatment basis between the delivery of hemodialysis with our system in-center and at home. The result of the investigation showed that the safety and effectiveness of hemodialysis with our system in each setting was equivalent.

Research and Development

Our research and development organization has focused on developing innovative technical approaches that address the limitations of current dialysis systems and disposable products. Our development team has skills across the range of technologies required to develop and maintain dialysis systems and products. These areas include filters, tubing sets, mechanical systems, fluids, software and electronics. In response to physician and patient feedback and our own assessments, we are continually working on enhancements to our product designs to improve ease-of-use, functionality, reliability and safety and to reduce product cost. In addition, we are engaged in development activities focused around our next generation system for home hemodialysis and a system for Peritoneal dialysis. We also seek to develop new products that supplement our existing product offerings and intend to continue to actively pursue opportunities for the research and development of complementary products.

For the years ended December 31, 2012, 2011 and 2010, we incurred research and development expenses of $17.1 million, $14.4 million and $12.9 million, respectively.

Intellectual Property

We seek to protect our investment in the research, development, manufacturing and marketing of our products through the use of patent, trademark, copyright and trade secret law. We own rights to a number of patents, trademarks, copyrights, trade secrets and other intellectual property directly related and important to our business both in the U.S. and abroad. We also have domestic and foreign pending patent applications.

Patents for individual products extend for varying periods of time according to the date a patent application is filed or a patent is granted and the term of the patent protection available in the jurisdiction granting the patent. The scope of protection provided by a patent can vary significantly from country to country.

The following table lists all of our issued U.S. and international patents owned by us as of December 31, 2012.

Patent No.	Regime	Title	Issue Date	Expiration Date
5385372	US	Luer Connector With Integral Closure	1/31/1995	1/31/2012
5520640	US	Blood Air Trap Chamber	5/28/1996	5/28/2013
5562636	US	Needle Protector Sheath	10/8/1996	7/15/2014
5562637	US	Needle Protector Sheath	10/8/1996	7/15/2014
5643190	US	Flow-Through Treatment Device	7/1/1997	1/17/2015
5704924	US	Easy Use Needle Protector Sheath	1/6/1998	1/11/2016
5772624	US	Reusable Blood Lines	6/30/1998	7/20/2015
5772638	US	Protector For Needle	6/30/1998	9/17/2016
5817043	US	Flow-Through Treatment Device	10/6/1998	1/17/2015
5824213	US	Separable Hemodialysis System	10/20/1998	9/7/2014
5895368	US	Blood Set Priming Method And Apparatus	4/20/1999	9/23/2016
5895571	US	Separable Hemodialysis System Connected By A Movable Arm	4/20/1999	9/7/2014
5951529	US	Needle Protector Sheath	9/14/1999	7/15/2014
5951870	US	Automatic Priming Of Blood Sets	9/14/1999	10/21/2017
5980741	US	Bubble Trap With Flat Side Having Multipurpose Supplemental Ports	11/9/1999	8/1/2017

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Patent No.	Regime	Title	Issue Date	Expiration Date
5983947	US	Docking Ports For Medical Fluid Sets	11/16/1999	3/3/2017
6042570	US	Needle Point Protection Sheath	3/28/2000	2/11/2019
6051134	US	Bubble Trap Having Common Inlet/Outlet Tube	4/18/2000	11/19/2014
6089527	US	Squeeze Clamp For Flexible Tubing	7/18/2000	10/3/2017
6113062	US	Squeeze Clamp	9/5/2000	1/28/2019
6117342	US	Bubble Trap With Directed Horizontal Flow And Method Of Using	9/12/2000	11/26/2016
6165149	US	Reusable Blood Lines	12/26/2000	7/20/2015
6177049	US	Reversing Flow Blood Processing System	1/23/2001	6/10/2018
6187198	US	Automatic Priming Of Connected Blood Sets	2/13/2001	10/21/2017
6193694	US	Needle Point Protection Sheath	2/27/2001	2/11/2019
6196519	US	Squeeze Clamp For Flexible Tubing	3/6/2001	10/3/2017
6206954	US	Blood Set And Chamber	3/27/2001	5/13/2018
6290665	US	Blood Set Priming Method And Apparatus	9/18/2001	9/23/2016
6299589	US	Flow-Through Treatment Method	10/9/2001	1/17/2015
6319465	US	Reversing Flow Blood Processing System Having Reduced Clotting Potential	11/20/2001	6/3/2019
6344139	US	Arterial And Venous Blood Tubing Set	2/5/2002	10/21/2017
6387069	US	Blood Set Priming Method And Apparatus	5/14/2002	9/23/2016
6440095	US	Pump Segment Having Connected Parallel Branch Line	8/27/2002	12/31/2015
6517508	US	Set For Blood Processing	2/11/2003	11/3/2019
6517522	US	Tubular Intravenous Set	2/11/2003	4/3/2020
6554789	US	Layered Fluid Circuit Assemblies And Methods For Making Them	4/29/2003	2/14/2017
6572576	US	Method And Apparatus For Leak Detection In A Fluid Line	6/3/2003	7/7/2021
6572641	US	Devices For Warming Fluid And Methods Of Use	6/3/2003	4/9/2021
6579253	US	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	6/17/2003	2/25/2020
6582385	US	Hemofiltration System Including Ultrafiltrate Purification And Re-Infusion System	6/24/2003	2/20/2018
6589482	US	Extracorporeal Circuits For Performing Hemofiltration Employing Pressure Sensing Without An Air Interface	7/8/2003	2/14/2017
6595943	US	Systems And Methods For Controlling Blood Flow And Waste Fluid Removal During Hemofiltration	7/22/2003	2/14/2017
6595965	US	Needle Protector Sheath	7/22/2003	7/15/2014
6596234	US	Reversing Flow Blood Processing System	7/22/2003	3/14/2019
6616635	US	Tubular Intravenous Set	9/9/2003	7/26/2020
6620119	US	Reusable Blood Lines	9/16/2003	11/12/2015
6638477	US	Fluid Replacement Systems And Methods For Use In Hemofiltration	10/28/2003	2/25/2020
6638478	US	Synchronized Volumetric Fluid Balancing Systems And Methods	10/28/2003	2/14/2017
6649063	US	Method For Performing Renal Replacement Therapy Including Producing Sterile Replacement Fluid In A Renal Replacement Therapy Unit	11/18/2003	7/12/2021
6666839.0	US	Method of Using Reusable Blood Lines	12/23/2003	7/20/2015
6673314	US	Interactive Systems And Methods For Supporting Hemofiltration Therapies	1/6/2004	2/14/2017

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Patent No.	Regime	Title	Issue Date	Expiration Date
6685680	US	Tapered Intravenous Cannula	2/3/2004	4/20/2019
6695807	US	Blood Flow Reversing System	2/24/2004	1/18/2022
6702561	US	Devices And Methods For Potting A Filter For Blood Processing	3/9/2004	7/12/2021
6743193	US	Hermetic Flow Selector Valve	6/1/2004	7/17/2021
6755801	US	Dialysis Pressure Monitoring With Clot Suppression	6/29/2004	11/8/2019
6830553	US	Blood Treatment Systems And Methods That Maintain Sterile Extracorporeal	12/14/2004	2/14/2017
6852090	US	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow	2/8/2005	2/14/2017
6955655.0	US	Hemofiltration System	10/18/2005	2/14/2017
6979309	US	Systems And Methods For Performing Blood Processing And/or Fluid Exchange Procedures	12/27/2005	2/14/2017
7004924	US	Methods, Systems, And Kits For The Extracorporeal Processing Of Blood	2/28/2006	2/11/2018
7025744	US	Injection Site For Male Luer Or Other Tubular Connector	4/11/2006	8/9/2024
7040142	US	Method And Apparatus For Leak Detection In Blood Circuits Combining External Fluid Detection And Air Infiltration Detection	5/9/2006	1/4/2022
7056308	US	Medical Device With Elastomeric Penetrable Wall And Inner Seal	6/6/2006	11/1/2022
7087033.0	US	Method And Apparatus For Leak Detection In A Fluid Line	8/8/2006	8/22/2021
7112273	US	Volumetric Fluid Balance Control For Extracorporeal Blood Treatment	9/26/2006	9/26/2023
7147613	US	Measurement Of Fluid Pressure In A Blood Treatment Device	12/12/2006	2/14/2017
7166084	US	Blood Set Priming Method And Apparatus	1/23/2007	7/22/2017
7214312	US	Fluid Circuits, Systems, And Processes For Extracorporeal Blood Processing	5/8/2007	7/12/2021
7226538	US	Fluid Processing Apparatus	6/5/2007	7/13/2021
7267658	US	Renal Replacement Therapy Device For Controlling Fluid Balance Of Treated Patient	9/11/2007	2/24/2018
7300413	US	Blood Processing Machine And System Using Fluid Circuit Cartridge	11/27/2007	5/4/2021
7337674	US	Pressure Detector For Fluid Circuits	3/4/2008	6/14/2024
7338460	US	Blood Processing Machine Fluid Circuit Cartridge	3/4/2008	6/9/2018
7347849	US	Modular Medical Treatment Replaceable Component	3/25/2008	6/30/2018
7419597	US	Fluid, Circuits, Systems, And Processes For Extracorporeal Blood Processing	9/2/2008	7/12/2021
7470265	US	Dual Access Spike For Infusate Bags	12/30/2008	1/11/2024
7473238	US	Hemofiltration Systems And Methods That Maintain Sterile Extracorporeal Processing Conditions	1/6/2009	8/11/2020
7544300	US	Batch Filtration System For Preparation Of Sterile Fluid For Renal Replacement Therapy	6/9/2009	1/7/2024
7569047	US	Medical Device With Elastomeric Penetrable Wall	8/4/2009	11/11/2024
7588684	US	Systems And Methods For Handling Air And/or Flushing Fluids In A Fluid Circuit	9/15/2009	7/13/2021
7591804	US	Short-Winged Needle And Guard	9/22/2009	5/24/2027
7686778	US	Waste Balancing For Extracorporeal Blood Treatment Systems	3/30/2010	7/7/2026

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Patent No.	Regime	Title	Issue Date	Expiration Date
7749393	US	Batch Filtration System For Preparation Of Sterile Fluid For Renal Replacement Therapy	7/6/2010	1/7/2024
7758082	US	Fluid Line Connector Safety Device	7/20/2010	5/5/2028
7771379	US	Functional Isolation Of Upgradeable Components To Reduce Risk In Medical Treatment Devices	8/10/2010	2/4/2023
7776001	US	Registration Of Fluid Circuit Components In A Blood Treatment Device	8/17/2010	10/28/2023
7776219	US	Methods, Devices, And Systems For Hemodilution	8/17/2010	8/11/2021
7780619	US	Blood Treatment Apparatus	8/24/2010	2/14/2017
7790043	US	Systems And Methods For Handling Air And/Or Flushing Fluids In A Fluid Circuit	9/7/2010	7/13/2021
7892208	US	Medical Tubing Set Sheath	2/22/2011	6/12/2028
7901579	US	Blood Treatment Dialyzer/Filter For Permitting Gas Removal	3/8/2011	3/1/2026
7976711	US	Batch Filtration System For Preparation Of Sterile Fluid For Renal Replacement Therapy	7/12/2011	1/7/2024
8002727	US	Methods And Apparatus For Leak Detection In Blood Processing Systems	8/23/2011	9/24/2026
8042838	US	Fluid Line Connector Safety Device	10/25/2011	12/5/2027
8092414	US	Diaphragm Pressure Pod For Medical Fluids	1/10/2012	12/12/2029
8190651	US	System and method for identifying and pairing devices	5/29/2012	2/3/2030
8192387	US	Last-chance quality check and/or air/pathogen filter for infusion systems	6/5/2012	10/29/2024
8202420	US	Batch filtration system for preparation of sterile fluid for renal replacement therapy	6/19/2012	1/7/2024
8210049	US	Pressure measurement device	7/3/2012	5/4/2031
8235931	US	Waste balancing for extracorporeal blood treatment systems	8/7/2012	2/10/2025
8251973	US	Medical devices and methods for assisting in sub-scab access	8/28/2012	2/20/2029
3809563	JP	Easy Use Needle Protector Sheath	6/2/2006	12/20/2016
3843414	JP	Closure Needle Protector Sheath	8/25/2006	7/5/2015
4416368	JP	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	12/4/2009	11/29/2020
4118	JP	Flow-Through Treatment Device	5/2/2008	7/17/2017
4118	JP	Method And Apparatus For Leak Detection In A Fluid Line	5/2/2008	7/8/2022
4387631	JP	Layered Fluid Circuit Assemblies And Methods For Making Them	10/9/2009	11/29/2020
4416368	JP	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	12/4/2009	11/29/2020
4416797	JP	Improved Methods And Apparatus For Leak Detection In Blood Processing Systems	12/4/2009	11/5/2024
4734343	JP	Filtration System For Preparation Of Fluids For Medical Applications	4/28/2011	1/9/2026
4739019	JP	Injection Site For Male Luer Or Other Tubular Connector	5/13/2011	10/2/2023
1235613	IT	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	2/9/2011	11/29/2020

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Patent No.	Regime	Title	Issue Date	Expiration Date
1425063	IT	Method And Apparatus For Leak Detection In A Fluid Line	9/8/2010	7/8/2022
1691882	IT	Apparatus For Leak Detection In Blood Processing System	9/8/2010	11/5/2024
1838356	IT	Filtration System For Preparation Of Fluids For Medical Applications	10/20/2010	1/9/2026
2012906	IT	Tubing Clamp For Medical Applications	8/11/2010	4/9/2027
969887	GB	Hemofiltration System	11/16/2005	2/5/2018
1235612	GB	Synchronized Volumetric Fluid Balancing Systems And Methods	1/13/2010	11/29/2020
1235613	GB	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	2/9/2011	11/29/2020
1235614	GB	Interactive Systems And Methods For Supporting Hemofiltration Therapies	8/15/2012	11/29/2020
1425063	GB	Method And Apparatus For Leak Detection In A Fluid Line	9/8/2010	7/8/2022
1592494	GB	Preparing Replacement Fluid	6/24/2009	1/7/2024
1691882	GB	Apparatus For Leak Detection In Blood Processing System	9/8/2010	11/5/2024
1838356	GB	Filtration System For Preparation Of Fluids For Medical Applications	10/20/2010	1/9/2026
2012906	GB	Tubing Clamp For Medical Applications	8/11/2010	4/9/2027
602004022	GB	Preparing Replacement Fluid	6/24/2009	1/7/2024
1235613	FR	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	2/9/2011	11/29/2020
1235614	FR	Interactive Systems And Methods For Supporting Hemofiltration Therapies	8/15/2012	11/29/2020
1425063	FR	Method And Apparatus For Leak Detection In A Fluid Line	9/8/2010	7/8/2022
1691882	FR	Apparatus For Leak Detection In Blood Processing System	9/8/2010	11/5/2024
1838356	FR	Filtration System For Preparation Of Fluids For Medical Applications	10/20/2010	1/9/2026
2012906	FR	Tubing Clamp For Medical Applications	8/11/2010	4/9/2027
000023148-0001	EU	Blood Treatment Machine And Parts Thereof	4/1/2003	4/1/2028
1235612	DE	Synchronized Volumetric Fluid Balancing Systems And Methods	1/13/2010	11/29/2020
1235613	DE	Fluid Processing Systems And Methods Using Extracorporeal Fluid Flow Panels Oriented Within A Cartridge	2/9/2011	11/29/2020
1235614	DE	Interactive Systems And Methods For Supporting Hemofiltration Therapies	8/15/2012	11/29/2020
1425063	DE	Method And Apparatus For Leak Detection In A Fluid Line	9/8/2010	7/8/2022
1531894	DE	Blood Treatment Machine Comprising An Air/Pyrogen Filter	8/8/2012	6/5/2023
1691882	DE	Apparatus For Leak Detection In Blood Processing System	9/8/2010	11/5/2024
1838356	DE	Filtration System For Preparation Of Fluids For Medical Applications	10/20/2010	1/9/2026
2012906	DE	Tubing Clamp For Medical Applications	8/11/2010	4/9/2027

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Patent No.	Regime	Title	Issue Date	Expiration Date
602004022	DE	Preparing Replacement Fluid	6/24/2009	1/7/2024
2153091	CA	Needle Protector Sheath	1/29/2008	6/30/2015
2530440	CA	Medical Device With Elastomeric Penetrable Wall And Inner Seal	8/10/2010	6/28/2024
2593580	CA	Filtration System For Preparation Of Fluids For Medical Applications	11/23/2010	1/9/2026
717410	AU	Easy Use Needle Protector Sheath	7/6/2000	12/20/2016
743589	AU	Needle Point Protector Sheath	5/16/2002	2/9/2020

In addition to the issued patents and pending patent applications owned by us, in the U.S. and selected non-U.S. markets, we possess trade secrets and proprietary know-how relating to our products. Any of our trade secrets, know-how or other technology not protected by a patent could be misappropriated, or independently developed by, a competitor and could, if independently invented and patented by a competitor, under some circumstances, be used to prevent us from further use of such information, know-how or technology.

Our strategy is to develop patent portfolios for our research and development projects. We monitor the activities of our competitors and other third parties with respect to their use of intellectual property. We intend to aggressively defend the patents we hold, and we intend to vigorously contest claims other patent holders may bring against us.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. While we attempt to ensure that our products and methods do not infringe other parties patents and proprietary rights, our competitors may assert that our products, or the methods that we employ, are covered by patents held by them. In addition, our competitors may assert that future products and methods we may market infringe their patents.

We require our employees, consultants and advisors to execute confidentiality agreements with us. We also require our employees to agree to disclose and assign to us all inventions conceived by them during their employment with us. Similar obligations are imposed upon consultants and advisors performing work for us relating to the design or manufacture of our product. Despite efforts taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Manufacturing

The manufacture of our products is accomplished through a complementary combination of outsourcing and internal production. We have manufacturing facilities in Mexico, Germany and Italy. We manufacture System One equipment and disposables and In Center bloodlines and service System One equipment at our facility in Tijuana Mexico. We manufacture our dialyzer filters at a facility in Germany owned by Asahi and operated by us and perform molding activities at our facility in Italy. We outsource the manufacture of premixed dialysate, needles, and some components.

We have single-source suppliers for a number of raw materials and components as well as finished goods and sterilization services. In most instances, alternative sources of supply are available, although switching to an alternative source would, in some instances, take time and could lead to product supply delays. Where obtaining a second source is more difficult, we have tried to establish supply agreements that better protect our continuity of supply, although we do not have supply agreements with all of our single-source suppliers. Where we have no agreements in place, where economically feasible, we work to maintain enough inventory of the single-sourced component to allow us to satisfy our requirements for the component while we secure an alternative source of supply. Two of our most critical single source supply relationships are with Membrana GmbH, or Membrana, and Kawasumi Laboratories, or Kawasumi.

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Membrana supplies the fibers used in the filters pre-attached to our System One cartridges under an agreement that expires in December 2023. We granted Membrana exclusive supply rights to System One products through 2016. We also have the right to obtain fiber from Asahi, pursuant to an agreement we signed with Asahi in 2009. In the event Membrana is unable for any reason to supply fiber to us, we would try to shift to fiber supplied by Asahi, however, this would take time to accomplish and we do not presently have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the U.S. There can be no assurance that any interruption in supply of fiber from Membrana would not hurt our business, at least in the near term.

Kawasumi manufactures all of our needle products under an agreement that expires in February 2017, with opportunities to extend the term beyond that date. We have committed to purchase from Kawasumi a minimum quantity of needles over the term of the contract. In the event Kawasumi supplies no more than the amount of their required maximum monthly supply or Kawasumi is unable for any reason to supply needle products to us, we may not have enough needle supply to meet the demands of our customers. Our supply chain maintains a limited extra supply of needles to mitigate against the risk of intermittent shortfalls in needle supply, at least in the short term. However, any significant interruption in Kawasumi s ability to supply products to us would impair our business, at least in the near term.

We purchase the majority of our premixed dialysate, both bicarbonate- and lactate-based, from Laboratorios PISA, or PISA. Our supply agreement with PISA extends through December 2015, with opportunities to extend the term beyond that date. We have committed to purchase from PISA a minimum quantity of premixed dialysate over the term of the agreement, which we believe is less than our anticipated requirements. We also purchase or have agreements that allow purchase of premixed dialysate from other qualified suppliers. With these relationships, we believe we have a stable supply of premixed dialysate for our customers.

Government Regulation

We are subject to government regulation in the countries in which we conduct business. In the U.S., numerous laws and regulations govern all the processes by which medical devices are brought to market. In the foreign countries in which we market and sell our products, we are subject to local regulations affecting, among other things, design and product standards, packaging and labeling and promotion requirements.

Food and Drug Administration

In the U.S., our products are subject to regulation by the Food and Drug Administration, or the FDA, which regulates our products as medical devices. The FDA regulates the design, development, clinical testing, manufacture, labeling, distribution, import and export, sale and promotion of medical devices. Noncompliance with applicable FDA 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.

Unless an exemption applies, all medical devices must receive either 510(k) clearance or pre-market approval, or PMA, approval, from the FDA before they may be commercially distributed in the U.S.

The FDA classifies medical devices into one of three classes:

Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;

Class II devices, generally requiring 510(k) pre-market clearance before they may be commercially marketed in the U.S.; and

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Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

Submissions to obtain 510(k) clearance and pre-market approval must be accompanied by a user fee, unless exempt. In addition, the FDA can impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

FDA Regulatory Clearance Status

We currently have all of the regulatory clearances required to market the System One in the U.S. in both the home and critical care markets. The FDA has cleared the System One for the treatment, under a physician s prescription, of renal failure or fluid overload using hemofiltration, hemodialysis and/or ultrafiltration. The FDA has also specifically cleared the System One for home hemodialysis use under a physician s prescription.

We received our first clearance from the FDA for a predecessor model to the System One in January 2001 for hemofiltration and ultrafiltration. In July 2003, we received expanded clearance from the FDA for the System One for hemodialysis, hemofiltration and ultrafiltration. Then in June 2005, we received FDA clearance specifically allowing us to promote home hemodialysis using the System One. In October 2010, NxStage received FDA clearance for its Therapeutic Plasma Exchange (TPE) cartridge for use with the NxStage System One in a clinical environment. To date we have received a total of 27 product clearances from the FDA since our inception in December 1998 for our System One and related products. We continue to seek opportunities for product improvements and feature enhancements, which will, from time to time, require FDA clearance before market launch.

We have received a total of 25 product clearances to market Medisystems products that support the in-center market. These clearances, the first of which was received in 1981, cover blood tubing sets used for hemodialysis, needle sets used in hemodialysis and apheresis, and other components such as intravenous administration sites, Medics and transducer protectors, used primarily for hemodialysis.

FDA Clearance Procedures

510(k) Clearance Pathway. When we are required to obtain a 510(k) clearance for a device that we wish to market, we must submit a pre-market notification to the FDA demonstrating that the device is substantially equivalent to (1) a device that was legally marketed prior to May 28, 1976 and for which the FDA has not yet required premarket approval; (2) a device which has been reclassified from Class III to Class II or I; or (3) a novel device classified into Class I or II through de novo classification. If the FDA agrees that the device is substantially equivalent to the predicate, it will subject the device to the same classification and degree of regulation as the predicate device, thus effectively granting clearance to market it. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission of the notification (or in some instances 30 days under what is referred to as a special 510(k) submission), but the response may be a request for additional information or data, sometimes including clinical data. As a practical matter, pre-market clearance can take significantly longer, including up to one year or more.

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that constitutes a major change in its intended use, would require a new 510(k) clearance or could require pre-market approval. In the first instance, the manufacturer may determine that a change does not require a new 510(k) clearance. The FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained.

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Pre-market Approval Pathway. A pre-market approval application must be submitted if the device cannot be cleared through the 510(k) process. The pre-market approval process is much more demanding than the 510(k) pre-market notification process. A pre-market approval application must be supported by extensive data and information including, but not limited to, technical, preclinical and clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device. After the FDA determines that a pre-market approval application is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted pre-market approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New pre-market approval applications or supplemental pre-market approval applications are required for modifications that affect the safety or effectiveness of the device. These types of changes include changes to the manufacturing process, labeling, use and design of the approved device. PMA supplements often require submission of the same type of information as a pre-market approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original pre-market approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. A clinical trial is almost always required to support a pre-market approval application and is sometimes required for a 510(k) pre-market notification. Clinical trials for devices that involve significant risk, referred to as significant risk devices, require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the institutional review board, or IRB, overseeing the clinical trial. If FDA fails to respond to an IDE application within 30 days of receipt, the application is deemed approved, but IRB approval would still be required before a study could begin. Products that are not significant risk devices are deemed to be non-significant risk devices under FDA regulations, and are subject to abbreviated IDE requirements, including informed consent, IRB approval of the proposed clinical trial and submission of certain reports to the IRB. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB at each clinical study site and in accordance with applicable regulations and policies including, but not limited to, the FDA s good clinical practice, or GCP, requirements.

Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include, among others:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulations, which require manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices;
- labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved, or off-label, uses and impose other restrictions on labeling and promotional activities;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

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the FDA s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

regulations pertaining to voluntary recalls; and

notices of corrections or removals.

MDR Regulations. The MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to a death or serious injury. To date, a majority of our MDRs had been submitted to comply with the FDA s blood loss policy for routine dialysis treatments. This policy, which is no longer in effect, required manufacturers to file MDR reports related to routine dialysis treatments if the patient experiences blood loss greater than 20cc.

FDA Inspections. We have registered with the FDA as a medical device manufacturer. The FDA seeks to ensure compliance with regulatory requirements through periodic, unannounced facility inspections and these inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following:

warning letters or untitled letters;

fines, injunctions, and civil penalties;

administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;

voluntary or mandatory recall or seizure of our products;

customer notification, or orders for repair, replacement or refund;

operating restrictions, partial suspension or total shutdown of production;

refusal to review pre-market notification or pre-market approval submissions;

rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and

criminal prosecution.

The FDA has inspected our Lawrence, Massachusetts facility and quality system multiple times. In our first inspection, one observation was made, but was rectified during the inspection, requiring no further response from us. Our subsequent inspections, including our most recent inspection in January 2013, resulted in no inspectional observations. Medisystems has been inspected by the FDA on multiple occasions, and all inspections resulted in no action indicated. We cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities.

Foreign Regulation of Medical Devices

We are also subject to regulations in the foreign countries in which we market and sell our products. We currently have limited sales in countries outside of the U.S. Foreign regulations, which may vary substantially from country to country, relate to, among other things, product standards, packaging, labeling and promotion requirements, import restrictions, tariff regulations, duties and tax requirements.

Clearance or approval of our products by regulatory authorities comparable to the FDA, or in the case of the EU the affixing of the CE mark, may be necessary in foreign countries prior to marketing the product in those countries, whether or not FDA clearance has been obtained. The regulatory requirements for medical devices vary significantly from country to country. They can involve requirements for additional testing and may be time

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consuming and expensive. We cannot provide assurance that we will be able to obtain regulatory approvals in any other markets or affix the CE mark to new products in the EU.

In the specific case of the EU, manufacturers of medical devices are required to conduct an assessment of the conformity of the devices with the Essential Requirements found in Annex I to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Devices Directive and to affix a CE Mark to these devices prior to marketing these within the EU. The Essential Requirements govern the quality, safety and performance of the medical devices. The classification of individual medical devices will determine whether the participation by a notified body in the conformity assessment process will be necessary. Notified bodies are private organizations that are licensed by the competent authorities of individual EU Member States to conduct conformity assessment procedures and to verify the conformity of manufacturers and their medical devices with the Essential Requirements.

If, where the participation by a notified body is necessary, the outcome of the conformity assessment procedure is positive the notified body will issue a related CE Certificate of Conformity. The manufacturer of the device will then complete the technical file for the medical device and, after having prepared and signed a related Declaration of Conformity, affix the CE mark to the product.

Demonstration of conformity of medical devices and their manufacturers with the Essential Requirements laid down in Annex I of the Medical Devices Directive must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Where necessary, this will include evaluation of clinical data generated in clinical investigations conducted with the medical devices. Conduct of clinical investigations in the EU is governed by detailed regulatory obligations. These include the requirement of prior authorization of the investigation by the competent authorities of the EU Member States in which the investigation takes place and the requirement to obtain a positive opinion concerning the investigation protocol from a competent Ethics Committee. The conduct of clinical investigations in the EU can be expensive and challenging and the outcome of such investigations is uncertain. There are no guarantees that the data generated in the clinical investigation would be sufficient to support CE marking of the medical device. Moreover, the clinical investigation may be suspended or discontinued by the competent authorities of the EU Member States or on the advice of the Ethics Committee.

The Medical Devices Directive requires manufacturers to maintain a Technical File related to their products. Manufacturers must also comply with quality system requirements. Such compliance can be demonstrated by, among other things, a certificate of compliance with ISO 13485:2003.

CE Certificates of Conformity have been issued in relation to all of our products that require such Certificates and we have affixed a CE mark to these products. However, if we introduce any substantial change to any of our CE marked medical devices in the EU this will require an additional conformity assessment process in relation to the modifications and modification of the related CE Certificates of Conformity and Declarations of Conformity. Substantial changes include the introduction of a new intended purpose for the medical device, a change in its design or a change in the device quality management system. There is little guidance concerning modifications that should be considered a substantial change. As the manufacturer of the medical device we would have sole responsibility for determining whether any modification constitutes a substantial change. There is a risk that the competent authorities of the EU Member States or our notified body may disagree with our assessment of the changes introduced to our products. The competent authorities of the EU Member States or our notified body also may also come to a different conclusion to the FDA concerning any change made to our products.

After the product has been CE marked and placed on the market in the EU, we must comply with a number of regulatory requirements relating to:

- registration of medical devices;
- pricing and reimbursement of medical devices;

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establishment of post-marketing surveillance and adverse event reporting procedures;

field safety corrective actions, including product recalls and withdrawals;

marketing and promotion of medical devices;

interactions with physicians.

Failure to comply with these requirements may result in enforcement measures being taken against us by the competent authorities of the EU Member States. These can include fines, administrative penalties, compulsory product withdraws, injunctions and criminal prosecution. Such enforcement measures would have an adverse effect on our capacity to market our products in the EU and, consequently, on our business and financial position.

The System One cycler and related cartridges are regulated as medical devices in Canada under the Canadian Medical Device Regulations and in the EU under the Medical Device Directive. We have received four product licenses from Canada. We have conducted conformity assessment and affixed the CE mark in the EU to our System One and associated ancillaries.

Our blood tubing sets, AV fistula needles, apheresis needles, and other ancillary products are regulated as medical devices in Canada under the Canadian Medical Device Regulations and in the EU, under the Medical Device Directive. We maintain six Medical Device Licenses in Canada under the Medisystems brand name for these products. We have conducted conformity assessment and affixed the CE mark in the EU for AV fistula needles, apheresis needles, and other ancillary products.

Fraud and Abuse Laws

U.S. federal healthcare laws apply when our customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded healthcare programs. The principal federal fraud and abuse laws include: (1) the Anti-Kickback Statute, which prohibits the offer or payment of any remuneration for the purpose of inducing or rewarding referrals of items or services reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded healthcare program; and (3) criminal healthcare fraud statutes that prohibit false statements and improper claims to any third-party payors. There are often similar state anti-kickback and false claims laws that apply to state-funded Medicaid and other healthcare programs, as well as to private third-party payors. In addition, the U.S. Foreign Corrupt Practices Act and UK Anti-Bribery Act can be used to prosecute companies in the U.S. for arrangements with physicians or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the laws of that country.

Similar laws are increasingly being introduced in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medical devices is prohibited. The provision of benefits or advantages to physicians is also governed by the national antibribery laws of the EU Member States. One such example is the UK Bribery Act. Infringement of these laws can lead to substantial fines and imprisonment.

Anti-Kickback Statutes

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing any remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for the furnishing of a good or service for which payment may be made in whole or part under a federal healthcare program, such as Medicare or Medicaid, or for the purchase, lease or ordering of such items. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of free supplies or equipment, credit arrangements,

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payments of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal healthcare programs, the statute has been violated. The law contains a few statutory exceptions, including payments to bona fide employees, certain discounts and certain payments to group purchasing organizations. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for its products. In addition, kickback arrangements can provide the basis for an action under the Federal False Claims Act, which is discussed in more detail below.

The Anti-Kickback Statute is broad and potentially prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services, or OIG, issued a series of regulations, known as the safe harbors, beginning in July 1991. These safe harbors set forth provisions that, if all the applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within a safe harbor does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. If scrutinized, arrangements that implicate the Anti-Kickback Statute, and that do not fall within a safe harbor, are analyzed by the OIG and other enforcement authorities on a case-by-case basis.

Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of medical device manufacturers and other healthcare companies, and recently have brought cases against individuals or entities with personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. Settlements of these cases by healthcare companies have involved significant fines and/or penalties and in some instances criminal pleas.

In addition to the federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payors, including commercial health insurance companies.

The national legislation of many foreign countries includes provisions equivalent in content and consequences to the federal Anti-Kickback Statute.

False Claims Laws

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Manufacturers can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused the submission of false claims, including through arrangements that violate the Anti-Kickback Statute. The Federal Civil False Claims Act also includes whistle blower provisions that allow private citizens to bring suit against an entity or individual on behalf of the U.S. and to recover a portion of any monetary recovery. Many of the recent highly publicized settlements in the healthcare industry related to sales and marketing practices have been cases brought under the False Claims Act. The majority of states also have statutes or regulations similar to the federal false claims laws, which apply to items and services reimbursed under Medicaid and other state programs. Several states have false claims laws that apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

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The national legislation of many foreign countries includes provisions equivalent in content and consequences to the federal false claims laws.

Compliance Program

The healthcare laws and fraud and abuse laws applicable to our business are complex and subject to variable interpretations. We maintain certain compliance review, education and training and other programs to further our commitment to high standards of ethical and legal conduct and to minimize the likelihood that we would engage in conduct or enter into arrangements in violation of applicable authorities. For example, we have (1) established a compliance team consisting of representatives from our Legal, Finance, Human Resources, Regulatory Affairs/Quality Assurance and Commercial departments that meets regularly; (2) established a compliance hotline that permits our employees to report anonymously any compliance issues that may arise; and (3) instituted other safeguards intended to help prevent any violations of the applicable fraud and abuse laws and healthcare laws, and to remediate any situations that could give rise to violations. We also review our transactions and agreements, both past and present, with qualified legal counsel to help ensure they are compliant.

Through our compliance efforts, we constantly strive to structure our business operations and relationships with our customers to comply with all applicable legal requirements. However, many of the laws and regulations applicable to us are broad in scope and may be interpreted or applied by prosecutorial, regulatory or judicial authorities in ways that we cannot predict. Thus, it is possible that governmental entities or other third parties could interpret these laws differently or assert non-compliance with respect to one or more of our business operations and relationships. Moreover, the standards of business conduct expected of healthcare companies under these laws and regulations have become more stringent in recent years, even in instances where there has been no change in statutory or regulatory language. While there have been no claims asserted against us for alleged non-compliance with fraud and abuse laws or other healthcare laws, if a claim were asserted and we were not to prevail, possible penalties and sanctions could have a material effect on our financial statements or our ability to conduct our operations.

Privacy and Security

We endeavor to comply with all applicable privacy and security laws and regulations although the failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause us to lose customers. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the rules promulgated thereunder require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information (PHI) known as the HIPAA Privacy and Security Rules. Most healthcare facilities that purchase and use our products are covered entities. We are not a covered entity but with the expansion of our service offering to include other services and/or activities for or on behalf of covered entities, we are a business associate, as such term is defined by HIPAA, with respect to these specific services and/or activities. HIPAA requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates which, among other things, obligate the business associates to safeguard the covered entity s PHI against improper use and disclosure. We have business associate agreements with respect to certain new services provided by us with certain of our customers that are also covered entities. Pursuant to the terms of these agreements, we agree, among other things, not to use or further disclose the covered entity s PHI except as permitted or required by the agreements or as required by law, to use reasonable safeguards to prevent unauthorized disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. If we were to violate any of these agreements we could lose customers and be exposed to liability and our reputation and business could be harmed.

The Health Information Technology for Economic and Clinical Health Act, or HITECH made significant amendments to the HIPAA Privacy and Security Rules. Under HITECH, business associates obligations with respect to PHI are no longer solely contractual in nature. HITECH strengthened and expanded HIPAA and made a number of HIPAA Privacy Rule requirements and a majority of HIPAA Security Rule requirements directly

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applicable to business associates. As a business associate, we are subject to these laws and HIPAA civil and criminal penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA and significantly strengthened enforcement by requiring the U.S. Department of Health and Human Services (HHS) to conduct periodic audits to confirm compliance and authorizing state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. As a business associate, these new provisions require us to incur compliance related costs and could restrict our business operations. We are unable to predict what additional legislation or regulation in the area of privacy of personal information, including personal health information, could be enacted and what effect it could have on our operations and business.

In addition, many other state and federal laws regulate the use and disclosure of health information, including state medical privacy laws and federal and state consumer protection laws. In many cases, these laws are not necessarily preempted by HIPAA, particularly if they afford greater protection to the individual than does HIPAA. These various laws may be subject to varying interpretations by courts and government agencies creating potentially complex compliance issues for our business. The national legislation of foreign countries includes provisions that impose obligations equivalent to or, in some cases, more extensive than those provided in HIPAA. These provisions may impose obligations with which we are required to comply and related penalties if we fail to fulfill our obligations. Compliance with these obligations may require us to incur compliance related costs and may restrict our business operations. Concerns or allegations about our practices with regard to the privacy or security of personal health information or other privacy-related matters, even if unfounded or even if we are in compliance with applicable laws, could damage our reputation and harm our business.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information. The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the US. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines, and other administrative penalties and harm our business.

The draft Data Protection Regulation is expected to introduce new data protection requirements in the EU and substantial fines for breaches of data protection rules. If the draft Data Protection Regulation is adopted in its current form it may increase our responsibility and liability concerning personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

Reimbursement

Home and In-Center Markets

Medicare regulations require that all chronic ESRD patients be under the care of a dialysis clinic, whether they are treated at home or in-clinic. We sell or rent our System One to dialysis clinics and sell our needles and blood tubing sets to dialysis clinics. These clinics, in turn, are reimbursed by Medicare, Medicaid and private insurers. According to the 2011 USRDS Annual Data Report, Medicare is the primary payor for approximately 80% of prevalent dialysis patients using hemodialysis and peritoneal dialysis. The report also indicates that approximately 10% of patients are covered by commercial insurance with Medicare as the secondary payor, with the remaining 10% of patients classified by the USRDS as other or unknown. Certain centers have reported that the NxStage more frequent home dialysis therapy attracts a higher percentage of commercial insurance patients than other forms of dialysis.

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Medicare. Medicare generally provides health insurance coverage for persons who are age 65 or older and for persons who are completely disabled. For ESRD patients, however, Medicare coverage is not dependent on age or disability. Patients are eligible for Medicare based solely on ESRD. Coverage for patients eligible for Medicare based solely on ESRD begins on the first day of the fourth month after the patient begins dialysis treatments. During the three-month waiting period either Medicaid, private insurance or the patient is responsible for payment for dialysis services. Medicare waives this waiting period for individuals who participate in a home dialysis training program, or are hospitalized for a kidney transplant and the surgery occurs within a specified time period.

For ESRD patients under age 65 who have any employer group health insurance coverage, regardless of the size of the employer or the individual s employment status, Medicare coverage is generally secondary to the employer coverage during the 30-month period that follows the establishment of Medicare eligibility or entitlement based on ESRD. During the period, the patient s existing insurer is responsible for paying primary benefits at the rate specified in the plan, which may be a negotiated rate or the healthcare provider s usual and customary rate. As the secondary payor during this period, Medicare will make payments up to the applicable Medicare payment rate for dialysis services to supplement any primary payments by the employer group health plan if the plan covers the services but pays only a portion of the charge for the services.

Medicare generally is the primary payor for ESRD patients after the 30-month coordination period. Under current rules, Medicare is also the primary payor for ESRD patients during the 30-month period under certain circumstances. Medicare remains the primary payor when an individual becomes eligible for Medicare on the basis of ESRD if, (1) the individual was already age 65 or over or was eligible for Medicare based on disability and (2) the individual s private insurance coverage is not by reason of current employment or, if it is, the employer has fewer than 20 employees in the case of eligibility by reason of age, or fewer than 100 employees in the case of eligibility by reason of disability. The rules regarding entitlement to primary Medicare coverage when the patient is eligible for Medicare on the basis of both ESRD and age, or disability, have been the subject of frequent legislative and regulatory changes and there can be no assurance that these rules will not be unfavorably changed in the future.

When Medicare is the primary payor for services furnished by dialysis clinics, it reimburses dialysis clinics for 80% of the allowable rate, leaving the secondary insurance or the patient responsible for the remaining 20%.

As a result of the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which was signed into law in 2008, effective January 1, 2011 the Centers for Medicare and Medicaid Services, or CMS, implemented a new prospective payment system for dialysis services that includes more items and services within the prospective payment. Under this new ESRD prospective payment system, CMS makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all renal dialysis services and home dialysis and includes certain drugs (including erythropoiesis stimulating agents, or ESAs, iron, and Vitamin D). It has replaced the former system which paid facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that were not included in the composite rate. With a vast majority of U.S. ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can sell or rent our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient s physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level pursuant to local coverage determinations or on a case-by-case basis, based on documentation provided by our customers. If more frequent therapy is prescribed, a clinic s decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic s patients. Medicare is switching from intermediaries to Medicare administrative contractors and is further consolidating the jurisdictions covered by those contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare

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reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. Based on an analysis of historical Medicare payment files by the UM-KECC, those delivering more frequent dialysis at home receive reimbursement, on average, for 1.5 times the number of treatments per month versus conventional dialysis, although this amount varies by jurisdiction. This variance arises from Medicare Administrative Contractor/Fiscal Intermediary policies, as well as from varying center billing practices. Currently, only 3 of the Medicare Administrative Contractors have formal Local Coverage Determinations (LCDs); the majority do not have a formal policy and thus review claims on a case-by-case basis. As there is no consistent national standard for obtaining medical justification a clinic s decision as to how much it is willing to spend on home more frequent dialysis equipment and services will be at least partly dependent on the level of confidence the center has in the predictability of receiving reimbursement from Medicare for additional treatments per week based on submitted claims for medical justification. Although access to home more frequent hemodialysis continues to grow, we believe that current Medicare reimbursement leads to adoption rates lower than rates commensurate with the percentage of patients experts believe can perform and medically benefit from this therapy. We believe more predictable Medicare reimbursement with less administrative burden, including improving Medicare reimbursement for home hemodialysis training, would allow adoption of more frequent home hemodialysis at rates more consistent with what are deemed to be appropriate by the expert medical community.

A stated goal of 2010 s prospective payment system was to encourage home dialysis. It did not have a positive impact on the adoption of home and/or more frequent hemodialysis or the price for which we can sell our products. However, the prospective payment system has had a significant positive impact on the adoption of peritoneal dialysis as evidenced by the significantly increased training rates for peritoneal dialysis. We believe this increased focus on peritoneal dialysis growth and peritoneal dialysis training has been to the detriment of home hemodialysis training rates, as home training resources, including home training nurses in particular, have been more devoted to peritoneal dialysis training, leaving less time for home hemodialysis training.

As part of the American Taxpayer Relief Act of 2012 Congress delayed CMS s plan to expand the prospective payment system s single bundled payment to include oral medications until 2016 and further instructed CMS to recalculate the base payment rate under the ESRD PPS for services furnished on or after January 1, 2014, to account for changes in utilization of renal dialysis drugs since the ESRD PPS was implemented. As a result of this statute, the base payment rate is expected to be reduced in 2014. This change could affect the adoption of home and/or more frequent hemodialysis in the future.

Medicaid. Medicaid programs are state-administered programs partially funded by the federal government. These programs are intended to provide coverage for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured. For those who are eligible, the programs serve as supplemental insurance programs for the Medicare co-insurance portion and provide certain coverage, for example, self-administered outpatient prescription medications, that is not covered by Medicare. For ESRD treatment, state regulations generally follow Medicare reimbursement levels and coverage without any co-insurance amounts, which is pertinent mostly for the three-month waiting period. Certain states, however, require beneficiaries to pay a monthly share of the cost based upon levels of income or assets.

Private Insurers. Some ESRD patients have private insurance that covers dialysis services. Healthcare providers receive reimbursement for ESRD treatments from the patient or private insurance during a waiting period of up to three months before the patient becomes eligible for Medicare. In addition, if the private payor is an employer group health plan, it is generally required to continue to make primary payments for dialysis services during the 30-month period following eligibility or entitlement to Medicare. In general, employers may not reduce coverage or otherwise discriminate against ESRD patients by taking into account the patient s eligibility or entitlement to Medicare benefits. It is generally believed that private insurance pays significantly more for dialysis services than Medicare and these patients with private insurance are generally viewed as more profitable to dialysis service providers. In 2012, both United Healthcare and Aetna established formal policies covering home hemodialysis for its beneficiaries.

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Critical Care

For Medicare patients, both acute kidney failure and fluid overload therapies provided in an in-patient hospital setting are reimbursed under a traditional Medicare severity diagnosis related group, or MS-DRG, system. Under this system, reimbursement is determined based on a patient s primary diagnosis and is intended to cover all of the hospital s costs of treating the patient. The presence of acute kidney failure or fluid overload increases the severity of the primary diagnosis and, accordingly, could increase the amount reimbursed. The longer hospitalization stays and higher labor needs, which are typical for patients with acute kidney failure and fluid overload, must be managed for care of these patients to be cost-effective. We believe that there is a significant incentive for hospitals to find a more cost-efficient way to treat these patients in order to improve hospital economics for these therapies.

Reimbursement Outside of the U.S.

The use of our products outside the U.S. is similarly affected by reimbursement policies adopted by foreign regulatory agencies, government managed health care systems and private insurance. Reimbursement for the treatment in the EU Member States of patients using medical devices is governed by complex mechanisms established on a national level in each country. These mechanisms vary widely among the EU Member States. Moreover, these mechanisms evolve constantly, reflecting the efforts of these countries to reduce public spending on healthcare. As a result, obtaining reimbursement for the treatment of patients using medical devices has become more and more challenging. We cannot, therefore, guarantee that the treatment of patients with our products would be reimbursed in any EU Member State.

The rules on the International coverage and reimbursement of medical devices outside the U.S. and EU vary widely from country to country and often hospital to hospital. In addition, healthcare reform proposals and medical cost containment measures in many foreign countries could, among other things, limit the use of our products and treatments in those countries and further reduce reimbursement available for such use or eliminate coverage altogether. These reforms or cost containment measures, including the uncertainty in the medical community regarding their nature and effect, could have an adverse effect on our customers purchasing decisions regarding our products and treatments within these regions.

Our Employees

As of December 31, 2012, we had approximately 2,700 employees, including full-time, part-time and seasonal or temporary employees. From time to time we also employ independent contractors to support our engineering, marketing, sales, clinical and administrative organizations. Most of our employees are involved in the manufacture of our products and are employed outside of the U.S., with the significant majority employed in Mexico.

Executive Officers

Our executive officers as of February 28, 2013 were as follows:

Name	Age	Position
Jeffrey H. Burbank	50	Chief Executive Officer
Robert S. Brown	54	Senior Vice President, Chief Financial Officer and Treasurer
Thomas F. Shea	50	Senior Vice President, Manufacturing Operations
Todd M. Snell	42	Senior Vice President of Quality, Regulatory and Clinical Affairs
Winifred L. Swan	48	Senior Vice President, General Counsel and Secretary
Joseph E. Turk, Jr.	45	President, North America

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Jeffrey H. Burbank has been our Chief Executive Officer and a director of the Company since December 1998.

Robert S. Brown has been our Senior Vice President, Chief Financial Officer and Treasurer since November 2006.

Thomas F. Shea has been our Senior Vice President of Manufacturing Operations since March 2008. Prior to joining NxStage, from 1999 through 2007, Mr. Shea held positions in Plant and Global Business Management at Jabil Incorporated.

Todd M. Snell joined the Company as our Senior Vice President of Quality, Regulatory and Clinical Affairs in September 2012. Prior to joining NxStage, Mr. Snell was the Vice President of Quality Assurance and Regulatory Affairs for Vascular Therapies at Covidien from June 2010 to August 2012. He also served as the Vice President of Quality Assurance and Regulatory Compliance at Genzyme Genetics from March 2007 to June 2010.

Winifred L. Swan has been our Senior Vice President since January 2005 and our Vice President and General Counsel since November 2000.

Joseph E. Turk, Jr. has been our President of North American Operations since December 2010, Senior Vice President, Commercial Operations since January 2005 and our Vice President, Sales and Marketing since May 2000.

Where To Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through our website (www.nxstage.com) under the Investor Information caption as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to the rules of the SEC. We are not including the information contained on our website as part of, or incorporating it by reference into, this report. You may read and copy materials that we have filed with the SEC at the SEC s public reference room located 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. In addition, our SEC filings are available to the public on the SEC s website (www.sec.gov).

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

In addition to the factors discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report, the following are some of the important risk factors that could cause our actual results to differ materially from those projected in any forward-looking statements.

Risks Related to our Business

We expect to derive a significant percentage of our future revenues from the sale or rental of our System One and the related products used with the System One and a limited number of other products.

Since our inception, we have devoted a substantial amount of our efforts to the development of the System One and the related products used with the System One. We commenced marketing the System One and the related disposable products to the critical care market in February 2003. We commenced marketing the System One for chronic hemodialysis treatment in September 2004. Prior to the Medisystems Acquisition, on October 1, 2007, nearly 100% of our revenues were derived from the rental or sale of our System One and the sale of related disposables. Although the Medisystems Acquisition broadened our product offerings, we expect that in 2013 and in the foreseeable future, we are likely to derive a significant percentage of our revenues from the System One, and that we will derive the remainder of our revenues from the sale of a few key disposable products, including blood tubing sets and needles. To the extent that any of our primary products are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted, and we do not have other significant products in development that could readily replace these revenues.

We cannot accurately predict the size of the home dialysis market, and it may be smaller, and may develop more slowly than we expect.

We believe our largest future product market opportunity is the home dialysis market. However, this market is presently very small and adoption of home hemodialysis treatment options has been limited. The most widely adopted form of dialysis therapy used in a setting other than a dialysis clinic is peritoneal dialysis. Based on the most recently available data from the U.S. Renal Data System, or USRDS, approximately 8% of U.S. ESRD dialysis patients receive some form of dialysis treatment at home with either peritoneal dialysis or home hemodialysis. Because the adoption of home hemodialysis has been limited to date, the number of patients and their partners who desire to, and are capable of, administering hemodialysis treatment with a system such as the System One is unknown and there is limited data upon which to make estimates. In addition, many dialysis clinics do not presently have the infrastructure in place to support home hemodialysis and most do not have the infrastructure in place to support a significant home hemodialysis patient population. Our long-term growth will depend on the number of patients who adopt home hemodialysis and how quickly they adopt it, which in turn is driven by the number of physicians willing to prescribe home hemodialysis and the number of dialysis clinics able or willing to establish and support home hemodialysis therapy.

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered more than three times a week, the market adoption of our System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for U.S. Medicare patients, by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. A recent study presented by the UM-KECC at the 2011 American Society of Nephrology meeting showed that in 2009 the average number of Medicare payments per month for home hemodialysis was approximately 1.5 times that of in-center hemodialysis (17.3 vs. 11.6, respectively). The total number of treatments paid varied across Medicare Administrative Contractors and Fiscal Intermediaries. There was a positive correlation between number of paid treatments per month and home hemodialysis utilization in a given jurisdiction. However, some customers may not receive or pursue additional reimbursement in all cases and providing medical justification

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for treatments beyond three times per week increases administrative burden. Although access to home more frequent hemodialysis continues to grow, we believe that current Medicare reimbursement leads to adoption rates lower than rates commensurate with the percentage of patients experts believe can perform and medically benefit from this therapy. We believe that more predictable Medicare reimbursement with less administrative burden, including improving Medicare reimbursement for home hemodialysis training, would allow adoption of more frequent home hemodialysis at rates more consistent with what are deemed to be appropriate by the expert medical community.

New regulations particularly impacting home hemodialysis technologies can also negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. We saw the impact of such regulations in 2008, when the Centers for Medicare and Medicaid Services, or CMS, released new Conditions for Coverage applicable to our customers. These Conditions for Coverage imposed water testing requirements on our patients using our PureFlow SL product. These water testing requirements increase the burden of our therapy for our patients and may impair market adoption, especially for our PureFlow SL product. To the extent additional regulations are introduced unique to the home environment, market adoption could be even further impaired.

We are in a developing market and we will need to continue to devote significant resources to developing the home market. We cannot be certain that this market will develop, how quickly it will develop or how large it will be.

Current Medicare reimbursement rates, at three times per week, limit the price at which we can market our home products, and adverse changes to reimbursement would likely negatively affect the adoption or continued sale of our home products.

As a result of legislation passed by the U.S. Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the U.S. for ESRD. Effective January 1, 2011,CMS implemented the new prospective payment system for dialysis treatment. Under this new ESRD prospective payment system, CMS makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all renal dialysis services and home dialysis and includes certain drugs (including erythropoiesis stimulating agents, or ESAs, iron, and Vitamin D). This payment system replaced the former system which paid facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that were not included in the composite rate. With a vast majority of U.S. ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can sell or rent our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient s physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level pursuant to local coverage determinations or on a case-by-case basis, based on documentation provided by our customers. If more frequent therapy is prescribed, a clinic s decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic s patients. Medicare is switching from using Fiscal Intermediaries to process Medicare claims to using Medicare Administrative Contractors and is further consolidating the jurisdictions covered by those contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. Based on an analysis of historical Medicare payment files by the UM-KECC, those delivering more frequent dialysis at home receive reimbursement, on average, for 1.5 times the number of treatments per month versus conventional dialysis, although this amount varies by jurisdiction. This variance arises from Medicare Administrative Contractor/Fiscal Intermediary policies, as well as from varying center

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billing practices. Currently, only 3 of the Medicare Administrative Contractors have formal Local Coverage Determinations (LCDs); the majority do not have a formal policy and thus review claims on a case-by-case basis. As there is no consistent national standard for obtaining medical justification a clinic s decision as to how much it is willing to spend on home more frequent dialysis equipment and services will be at least partly dependent on the level of confidence the center has in the predictability of receiving reimbursement from Medicare for additional treatments per week based on submitted claims for medical justification. Although access to home more frequent hemodialysis continues to grow, we believe that current Medicare reimbursement leads to adoption rates lower than rates commensurate with the percentage of patients experts believe can perform and medically benefit from this therapy. We believe more predictable Medicare reimbursement with less administrative burden, including improving Medicare reimbursement for home hemodialysis training, would allow adoption of more frequent home hemodialysis at rates more consistent with what are deemed to be appropriate by the expert medical community.

A stated goal of CMS s 2010 prospective payment system was to encourage home dialysis. It did not have a positive impact on the adoption of home and/or more frequent hemodialysis or the price for which we can sell our products. However, the prospective payment system has had a significant positive impact on the adoption of peritoneal dialysis as evidenced by the significantly increased training rates for peritoneal dialysis. We believe this increased focus on peritoneal dialysis growth and peritoneal dialysis training has been to the detriment of home hemodialysis training rates, as home training resources, including home training nurses in particular, have been more devoted to peritoneal dialysis training, leaving less time for home hemodialysis training.

As part of the American Taxpayer Relief Act of 2012 Congress delayed CMS s plan to expand the prospective payment system s single bundled payment to include oral medications until 2016 and further instructed CMS to recalculate the base payment rate under the ESRD PPS for services furnished on or after January 1, 2014, to account for changes in utilization of renal dialysis drugs since the ESRD PPS was implemented. As a result of this statute, the base payment rate is expected to be reduced in 2014. This change could affect the adoption of home and/or more frequent hemodialysis in the future.

Beginning April 1, 2013, Medicare payments for all items and services, including dialysis services, likely will be reduced by up to 2% under the automatic spending reductions (known as sequestration) required by the Budget Control Act of 2011, Pub. L. No. 112-25 (BCA), as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240 (ATRA). The BCA imposes sequestration on most federal programs, excluding Medicaid, Social Security, and certain other programs, because Congress failed to enact legislation by January 15, 2012, to reduce federal deficits by $1.2 trillion over ten years. Under the BCA, cuts to Medicare payments or items and services are capped at 2% and will take effect on the first day of the first month following the issuance of a sequestration order. The ATRA delayed implementation of sequestration from January 2, 2013, to March 1, 2013, and as a result, the Medicare cuts will take effect April 1, 2013, unless Congress enacts legislation to cancel or delay the cuts. These cuts would adversely impact Medicare payment for all dialysis treatments and could affect adoption for home dialysis and/or more frequent hemodialysis.

We have a history of net losses and an accumulated deficit of $345.0 million at December 31, 2012. We cannot guarantee if, when and the extent to which we will become profitable, or that we will be able to maintain profitability if it is achieved.

Since inception, we have incurred negative operating margins and losses every quarter. At December 31, 2012, we had an accumulated deficit of approximately $345.0 million. We expect our operating expenses to continue to increase as we grow and expand our business. While we have achieved positive gross profit for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross profit as a percentage of revenues will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable.

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Our customers in the System One and In-Center segments are highly consolidated, with concentrated buying power.

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Collectively, these entities provide treatment to approximately two-thirds of U.S. dialysis patients; and this percentage may continue to grow with further market consolidation. DaVita, for example, announced in September 2011 that it completed the acquisition of DSI Renal, Inc. More recently, in February 2012, Fresenius finalized their purchase of Liberty Dialysis Holdings, Inc., the holding company for Liberty Dialysis and Renal Advantage. With less than one-third of United States dialysis patients cared for by independent dialysis clinics, our market adoption, at least within the U.S., would be more constrained without the presence of both DaVita and Fresenius as customers.

Additionally, Fresenius is not only a dialysis service provider, it is also the leading manufacturer of dialysis equipment worldwide. In February 2011, Fresenius obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy. DaVita does not manufacture dialysis equipment, but has certain dialysis supply purchase obligations to Gambro, a dialysis equipment manufacturer, under a long-term preferred supplier agreement. Fresenius may choose to offer its dialysis patients only the dialysis equipment Fresenius manufactures, including its 2008K system. DaVita may choose to offer their dialysis patients the equipment it contractually agreed to offer in its agreement with Gambro. Fresenius and DaVita may also choose to otherwise limit access to the equipment manufactured by competitors. DaVita is our most significant customer, and we expect it to continue to be, at least for the foreseeable future. Fresenius is also our second largest customer in the System One segment. Our agreements with DaVita, Fresenius and other large home market customers are intended to support the continued expansion of patient access to home hemodialysis with the System One, but like all our agreements with home market customers, our agreements with DaVita, Fresenius and other large customers are not requirements contracts and they contain no minimum purchase volumes. Our Amended and Restated National Service Provider Agreement with DaVita expires on June 30, 2013, which term will be automatically extended on a monthly basis thereafter unless terminated by either party. Our agreement with Fresenius, which was scheduled to terminate at the end of 2012, was recently automatically extended by one year to the end of 2013. We have no assurance that our sales to DaVita, Fresenius or other large customers will continue to grow, and we cannot predict what impact Fresenius 2008K system will have on our sales to Fresenius in the home market or our overall performance in the home market going forward. Given the significance of DaVita and Fresenius as customers in the home market, any adverse change in either customer s ordering or clinical practices, as might be the case in periodic contract negotiations or which could be caused by our adoption of any new business development initiatives, such as the development of centers of excellence, would have a significant adverse impact on our home market revenues, especially in the near term.

DaVita is a key customer for our System One and In-Center product lines. The partial or complete loss of DaVita as a customer would materially impair our financial results, at least in the near term.

DaVita is our most significant customer. Sales through distributors to DaVita of products accounted for approximately half of In-Center segment revenues during 2012. Direct sales to DaVita represented 31% of our System One segment revenues during the same period. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. Although we expect that DaVita will continue to be a significant customer in the home market, we cannot be certain that DaVita will continue to purchase and/or rent the System One or add additional System One patients in the future. Our Amended and Restated National Service Provider Agreement with DaVita expires on June 30, 2013, which term will be automatically extended on a monthly basis thereafter unless terminated by either party. Unless terminated, our contract for needles with DaVita, which includes certain minimum order requirements, expires in April 2013, and there can be no assurance that this contract will be renewed. Our failure to renew this agreement would adversely impact our In-Center revenues, at least in the near term. In June 2009, we entered into a five year distribution agreement in the U.S. with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets to DaVita. In December 2012, Baxter International, Inc. announced its intent to acquire Gambro. Our U.S. distribution agreement with Gambro continues through June 2014 and survives change of control. However, it is unclear

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what impact, if any, Baxter s pending acquisition of Gambro may have with respect to this distribution relationship thereafter. The partial or complete loss of DaVita as a customer for any of these product lines would adversely affect our business, at least in the near term.

We face additional risks from the acquisition or development of new lines of business, including in connection with our development of centers of excellence focused on the provision of home hemodialysis services.

In connection with our evaluation of growth opportunities for the Company, it is possible that we may in the future acquire or develop a new line of business or products. We made such a strategic acquisition in connection with our acquisition of Medisystems Corporation in 2007. More recently, we initiated activity to establish owned dialysis centers as part of our centers of excellence initiative. These centers are dialysis clinics focused on the provision of home dialysis services. There are substantial risks and uncertainties associated with any change in business lines or strategy, particularly in instances where our customers may perceive the new activity or business line to be in direct competition with their business, which could, in turn, lead them to stop or reduce their purchases of products from us. In addition to the external risks any such new businesses or strategies may represent, we may face internal risks relating to developing knowledge of and experience in the new business, recruiting professionals, as well as business execution risks. New strategies and businesses may also require significant investment and involvement of our senior management, which will take away from the time they ordinarily spend on the remainder of our business. Failure to manage these risks in the development and implementation of new businesses or strategies successfully could materially and adversely affect our business, results of operations and financial condition.

We have a Loan and Security Agreement with Silicon Valley Bank, or SVB, the terms of which may restrict our current and future operations, and which could affect our ability to respond to changes in our business and to manage our operations.

We have an agreement with SVB for a $15.0 million revolving line of credit with a maturity date of March 31, 2014. The agreement is secured by all or substantially all of our assets. Borrowings under the agreement bear interest at prime with a floor of 3.25%. Pursuant to the agreement, we are subject to certain financial covenants relating to liquidity requirements and adjusted EBITDA. The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy.

As of the date hereof, we do not have an outstanding balance under the revolving line of credit. However, were we to draw on the line of credit, in the event we fail to satisfy our covenants, or otherwise go into default, SVB has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Certain of these remedies would likely have a material adverse effect on our business.

We compete against other dialysis equipment manufacturers with much greater financial resources and established products and customer relationships, which may make it difficult for us to penetrate the market and achieve significant sales of our products. Our competitors may also introduce new products or features that could impair the competitiveness of our own product portfolio.

Our System One is currently the only portable system specifically indicated for use in the home market in the U.S. However, there is one other product in the market now with a home clearance, and a number of other products that are under development and may be released in the next several years, that are, or will be, competitive to our System One in the home market. In 2011, Fresenius, our second largest customer in the System One segment, with nearly all of those sales in the home market, obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy. More recently, Fresenius announced that it is seeking clearance for its sorbent technology within the critical care setting. Fresenius is also seeking clearance for its Portable Artificial Kidney, or PAK, to market in the U.S. for in-center use with plans to later introduce the

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product in the home. Baxter has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, for the development of a new home hemodialysis system. Baxter has commented that they have completed enrollment in one of the clinical studies intended to support FDA clearance of this system and are enrolling patients in a Canadian nocturnal clinical study to support CE marking in the EU. Baxter has indicated that it hopes to obtain CE mark for this system in the EU in 2013 and to file for regulatory approval in the U.S. in 2014 for a home hemodialysis nocturnal indication. Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of these products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the home market, it could adversely affect our sales and growth. We are also unable to predict what impact the Fresenius home hemodialysis systems will have on our sales to Fresenius or our overall home market performance.

Our System One in the critical care market competes against Gambro, of which Baxter recently announced its intent to acquire, Fresenius, B. Braun and others. Our product lines in the in-center market compete directly against products produced by Fresenius, Gambro, Nipro, B. Braun, Baxter, JMS CO., LTD and others.

Our competitors in each of our markets sell one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offers products that have been in use for a longer time than our System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy and, Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our products, including our System One. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of ESRD and/or in the treatment of acute kidney failure or fluid overload. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

Our continued growth is dependent on our development and successful commercialization of new and improved products.

Our future success will depend in part on our timely development and introduction of new and improved products that address changing market requirements. To the extent that we fail to introduce new and innovative products, including without limitation the next generation System One, or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological, regulatory or other reasons, to successfully develop and introduce new or improved products could reduce our growth rate or otherwise damage our business. We cannot assure you that our developments will keep pace with the marketplace or that our new or improved products will adequately meet the requirements of the marketplace.

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The success and growth of our business will depend upon our ability to achieve expanded market acceptance of our System One.

In the home market, we have to convince five distinct constituencies involved in the choice of dialysis therapy, namely operators of dialysis clinics, nephrologists, dialysis nurses, patients and payors (private payors and Medicare), that the System One provides an effective alternative to other existing dialysis equipment. In the in-center market, we have to convince all of these constituencies, but to a lesser degree, patients, that our blood tubing sets and needles provide an effective alternative to other dialysis disposables. In the critical care market, we have to convince hospital purchasing groups, hospitals, nephrologists, dialysis nurses and critical care nurses that our system provides an effective alternative to other existing dialysis equipment. Each of these constituencies use different considerations in reaching their decision. Lack of acceptance by any of these constituencies will make it difficult for us to grow our business. We may have difficulty gaining widespread or rapid acceptance of any of our products, including the System One, for a number of reasons including:

- the failure by us to demonstrate to operators of dialysis clinics, hospitals, nephrologists, dialysis nurses, patients and others that our products are equivalent or superior to existing therapy options;
- competition from products sold by companies with longer operating histories and greater financial resources, more recognizable brand names and better established distribution networks and relationships with hospitals or dialysis clinics;
- the failure by us to continue to improve product reliability and the ease of use of our products;
- limitations on the existing infrastructure in place to support home hemodialysis, including without limitation, home hemodialysis training nurses, and the willingness, cost associated with, and ability of dialysis clinics to build that infrastructure;
- the ownership and operation of some dialysis providers by companies that also manufacture and sell competitive dialysis products;
- the introduction of competing products or treatments that may be more effective, easier to use or less expensive than ours;
- regulations that impose additional burden on patients and their caregivers, such as the Medicare conditions for coverage which impose additional water testing requirements in connection with the use of our PureFlow SL;
- the number of patients willing and able to perform therapy independently, outside of a traditional dialysis clinic, may be smaller than we estimate; and
- the availability of satisfactory reimbursement from healthcare payors.

If we are unable to convince additional hospitals and healthcare providers of the benefits of our products for the treatment of acute kidney failure and fluid overload, we will not be successful in increasing our market share in the critical care market.

We sell the System One in the critical care market for use in the treatment of acute kidney failure and fluid overload. Physicians currently treat most acute kidney failure patients using conventional hemodialysis systems or dialysis systems designed specifically for use in the intensive care unit, or ICU. We will need to convince hospitals and healthcare providers that using the System One is as effective as using conventional hemodialysis systems or ICU-specific dialysis systems for treating acute kidney failure or fluid overload and that it provides advantages over conventional systems or other ICU-specific systems because of its significantly smaller size, ease of operation and clinical flexibility. In addition, the impact of tightened credit markets on hospitals could impair the manner in which we sell products in the critical care market. Hospitals facing pressure to reduce capital spending may choose to delay capital equipment purchases or seek alternative financing options.

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Our business and results of operations may be negatively impacted by general economic and financial market conditions and such conditions may increase other risks that affect our business.

Global macro-economic conditions and the world s financial markets continue to experience some degree of turmoil, resulting in reductions in available credit, foreign currency fluctuations and volatility in the valuations of securities generally. In general, we believe demand for our products in the home and in-center market will not be substantially affected by the changing market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, there is no assurance that future economic changes or global uncertainties would not negatively impact our business, especially the manner and pace in which we sell equipment in the System One segment or delay equipment placements. Hospitals or clinics facing pressure to reduce capital spending may choose to rent equipment rather than purchase it outright, or to enter into other less-capital intensive purchase structures with us, which may, in turn, have a negative impact on our cash flows. Uncertainty in the general economic environment and governmental spending on public health programs may also lead to a reduction in hospital days (particularly those due to elective procedures) and delays in capital purchases, both of which can negatively impact our critical care business. Our ability to sell products internationally is particularly vulnerable to adverse impacts from global macro economic conditions. Government funded hospitals in various international markets may seek to defer capital purchases or tenders. Distributors with reduced access to capital may be less willing to purchase our equipment outright, impairing our ability to sell our products. Further, unfavorable changes in foreign exchange rates versus the U.S. dollar would increase our product costs which would negatively impact our gross profit and gross profit as a percentage of revenues.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels, and in foreign countries, for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States and other countries. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs.

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation through the passage of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152). Among other initiatives, these laws impose a 2.3% excise tax on domestic sales of certain medical devices after December 31, 2012. This legislation also applies a productivity adjustment to the Medicare payment rates for dialysis facilities that could cause variable annual decreases in annual adjustments to payment rates as of 2012. Our profitability will be negatively impacted beginning 2013 due to the 2.3% medical device excise which will be assessed on nearly all of our products sold in the U.S. The productivity adjustments may impact our revenues when the amount of the adjustments is announced, however, we cannot predict with any certainty the effect such legislation will have on us. If significant reforms are made to the healthcare system in the U.S., or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

The governments of foreign countries are actively pursuing similar actions intended to reduce costs related to provision of healthcare. The results of these actions may also have a material adverse effect on our financial condition and results of operations.

As our business continues to grow, we may have difficulty managing our growth and expanding our operations successfully.

As our business continues to grow, we will need to expand our manufacturing, sales and marketing and on-going development capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various partners, suppliers, manufacturers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our information technology infrastructure, operational, financial and management controls

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and reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Also, if demand for our products continues to grow we may not be able to increase our manufacturing capacity at that facility fast enough to meet customer demand.

If we are unable to maintain strong product reliability for our products, our ability to maintain or grow our business and achieve profitability could be impaired. Transition of supply or manufacturing locations of products can also lead to product quality and reliability issues which could impair our ability to maintain or grow our business and achieve profitability.

Product reliability issues associated with any of our product lines could lead to decreases in customer satisfaction and our ability to grow or maintain our revenues and could negatively impact our reputation. Further, any unfavorable changes in product reliability would result in increased service and distribution costs which negatively impacts our gross profit and operating profit and increases our working capital requirements. We continue to work to maintain strong product reliability for all products. If we are unable to maintain strong product reliability for our existing products, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

We also need to establish strong product reliability for all new products we offer. With new products, we are more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature. We also choose from time to time to transition the manufacturing and supply of products and components to different suppliers or locations. As we make these changes, we are more exposed to risks relating to product quality and reliability until the manufacturing processes mature. Like all transitions of this nature, they could also lead us to incur additional costs in the short term, which would negatively impact our gross profits in the short term.

We have a significant amount of System One field equipment, and our inability to effectively manage this asset could negatively impact our working capital requirements and future profitability.

Because our home market relies upon an equipment service swap model and, for some of our customers, an equipment rental model, our ability to manage System One equipment is important to minimizing our working capital requirements. Both factors require that we maintain a significant level of field equipment of our System One and PureFlow SL hardware. In addition, our gross margins may be negatively impacted if we have excess equipment deployed, and unused, in the field. If we are unable to successfully track, service and redeploy equipment, we could (1) incur increased costs, (2) realize increased cash requirements and/or (3) have material write-offs of equipment. This would negatively impact our working capital requirements and future profitability.

If kidney transplantation becomes a viable treatment option for more patients with ESRD, or if medical or other solutions for renal replacement become viable, the market for our products may be limited.

While kidney transplantation is the treatment of choice for most ESRD patients, it is not currently a viable treatment for most patients due to the limited number of donor kidneys, the high incidence of kidney transplant rejection and the higher surgical risk associated with older ESRD patients. According to USRDS data, in 2008, approximately 17,700 patients received kidney transplants in the U.S. The development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants or any other advances in kidney transplantation could limit the market for our products. The development of viable medical, pharmaceutical, or other solutions for renal replacement or prolonging kidney life may also limit the market for our products.

We are currently party to litigation and could be subject to additional litigation claims from time to time.

On February 28, 2012 a civil complaint was filed against us in the US District Court for the District of Massachusetts by Gambro Renal Products, Inc., or Gambro (Case No. 1:12cv 10370-PBS). The complaint alleges

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that we violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and Massachusetts General Laws Chapter 93A by making false and misleading statements about our and Gambro s allegedly competing products in the critical care market in commercial and promotional activities. The complaint also alleges that we wrongfully interfered with contractual and advantageous relationships of Gambro s critical care business. Gambro seeks compensatory and treble damages, disgorgement of profits and injunctive relief. We believe the suit is without merit and intend to defend the claim vigorously.

From time to time, we are also threatened with individual actions involving our business, including without limitation, products liability claims. If any of our employees or products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. There are no active claims against us, except for the Gambro litigation. However, there can be no assurance that no additional claims may be filed against us in the future.

Any claims made against us could adversely affect our reputation, which could damage our position in the market. While we maintain insurance, including products and general liability insurance, claims may be brought against us that could result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. In addition, our insurance policies have various exclusions, and we may be subject to a claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by any insurance. Claims can also be time consuming, distracting, and expensive to defend and could result in a diversion of management and financial resources away from our primary business, in which case our business may suffer.

We maintain insurance at levels deemed adequate by management; however, future claims could exceed our applicable insurance coverage.

We maintain insurance for property and general liability, directors and officers liability, product liability, workers compensation, and other coverage in amounts and on terms deemed adequate by management based on our expectations for future claims. Future claims could, however, exceed our applicable insurance coverage, or our coverage could not cover the applicable claims.

We face risks associated with having international manufacturing operations, and if we are unable to manage these risks effectively, our business could suffer.

We operate manufacturing facilities in Germany, Italy and Mexico. We also purchase components, products and supplies from foreign vendors. We are subject to a number of risks and challenges that specifically relate to these international operations, and we may not be successful if we are unable to meet and overcome these challenges. Significant among these risks are risks relating to foreign currency, in particular the Euro, Peso and Thai Baht. We did not hedge our foreign currency transactions during 2011 or 2010 but did engage in hedging transactions beginning in 2012 on Peso denominated expenses. To the extent we fail to control our exchange rate risk, our gross profit as a percentage of revenues and profitability could suffer and our ability to maintain mutually beneficial and profitable relationships with foreign vendors could be impaired. In addition to these risks, through our international operations, we are exposed to costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods, difficulty managing operations in multiple locations, local regulations that may restrict or impair our ability to conduct our operations and increased compliance costs, health issues, such as pandemic disease risk, and natural disasters, such as flooding, hurricanes and earthquakes, which could disrupt our manufacturing and logistical and import activities. For example, the earthquakes experienced in northern Italy during the second quarter of 2012 resulted in the temporary suspension of manufacturing within our facility in Italy. Although supply to our customers was not interrupted, there is no guarantee that we will not experience any future interruption in our ability to supply product at any of our facilities or third party facilities, or that any such interruptions will not increase our product costs or impair our product quality or reliability, at least in the near term. Furthermore, in certain locations, such as Mexico, we are also exposed to risks associated with local instability, including threats of increased violence, which could lead to disruptions in supply at our manufacturing facilities or key vendors.

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We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. We also obtain sterilization services from a single supplier. We also manufacture certain of our products at only one manufacturing facility. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand, and a substantial loss in revenues.

We depend upon a number of single-source suppliers for certain of raw materials and components as well as finished goods and sterilization services. Two of our most critical single-source supply relationships are with Membrana and Kawasumi. Our dependence upon these and other single-source suppliers of raw materials, components, finished goods and sterilization services, as well as our dependence on our manufacturing facilities, exposes us to several risks, including disruptions in supply, price increases, late deliveries, and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation, or customers switching to competitive products. Any interruption in supply could be particularly damaging to our customers using the System One to treat chronic ESRD and who need access to the System One and related disposables to continue their therapy.

Finding alternative sources for these raw materials, components, finished goods and sterilization services would be difficult and in many cases entail a significant amount of time, disruption and cost. Although we believe our supply chain has sufficient inventory of raw materials, components and finished goods to withstand a temporary disruption in supply from any single source supplier or manufacturing location, any permanent or long term disruption in supply from any single source supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, at least in the near term.

Membrana is our sole supplier of the fiber used in our filters for System One products. We are contractually prevented from obtaining an alternative source of fiber for our System One products. Our relationship with Asahi could afford us back-up supply in the event of an inability to supply by Membrana, however, switching to Asahi fiber at this time would likely entail significant delays and difficulties. We do not have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the U.S. Additionally, the performance of Asahi fiber in our System One has not yet been validated.

Kawasumi is our only supplier of needles that we sell to our customers. Kawasumi s contractual obligation to supply needles to us expires in February 2017, with opportunities to extend the term beyond that date. Kawasumi s contractual obligation to supply needles to us can be, at times, less than our forecasted demand. In the event Kawasumi supplies no more than the amount of their required maximum monthly supply, we may not have enough needle supply to meet the demands of our customers. The flooding experienced by Kawasumi at its bloodline manufacturing facility in Thailand did not impact its needle manufacturing operations. However, there can be no assurance that its operations will not be impacted by any other event which could lead to an interruption in supply. Our supply chain maintains a limited extra supply of needles to mitigate against the risk of intermittent shortfalls in needle supply, at least in the short term. However, any significant interruption in Kawasumi s ability to supply products to us would impair our business, at least in the near term.

Until recently, we had purchased some of our finished goods blood tubing sets from Kawasumi, headquartered in Tokyo, Japan, with manufacturing facilities in Thailand, with the remainder manufactured at our facility in Tijuana, Mexico. While Kawasumi s contractual obligation to manufacture bloodlines expired in February 2012, flooding at the site of Kawasumi s bloodline manufacturing facility in Thailand prevented Kawasumi from supplying any further bloodlines to us prior to the expiration of that agreement. Although we have transitioned bloodline supply from Kawasumi to our Tijuana facility, and believe that the Tijuana facility can produce any products that Kawasumi supplied and/or was unable to supply, there is no guarantee that we will not experience any interruption in our ability to supply any of our bloodlines, or that the transition of this supply will not increase our product costs or impair our product quality or reliability, at least in the near term.

We also have manufacturing facilities in Mexico, Germany and Italy. The loss of any of these facilities due to fire, natural disaster, war, strike, or other cause beyond our control could cause significant production delays,

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an inability to meet customer demand, and a substantial loss in revenues. The earthquakes experienced in northern Italy during the second quarter of 2012 resulted in the temporary suspension of manufacturing within our facility in Italy. Although supply to our customers was not interrupted, natural disasters, such as the earthquake, highlight the risks associated with key manufacturing facilities. In 2011, we decided not to renew our agreement with Entrada. As a result of that decision, we have transitioned the activities from Entrada s facilities to our Tijuana facility. The consolidation of bloodline manufacturing and manufacturing and service of the System One to our facility in Tijuana has increased the risks associated with any loss of that facility for any reason.

Our In-Center segment relies heavily upon third-party distributors.

We sell the majority of our In-Center segment products through several distributors, which collectively account for substantially all of In-Center revenues, with Gambro and Henry Schein being our most significant distributors. In December 2012, Baxter announced that it has entered into a definitive agreement to acquire Gambro. Our distribution agreement with Henry Schein expires in April 2014, which term shall be automatically extended for additional one year periods until either party provides prior notice of its intent to terminate. Our distribution agreement with Gambro expires in June 2014. The loss of Gambro or Henry Schein as our distributors for any reason could materially adversely affect our business, at least in the near term.

Unless we can demonstrate sufficient product differentiation in our In-Center segment products that we introduce in the future, we will continue to be susceptible to further pressures to reduce product pricing and more vulnerable to the loss of our blood tubing set or needle business to competitors in the dialysis industry.

Our blood tubing set and needle businesses have historically been commodities businesses. Our products continue to compete favorably in the dialysis blood tubing set and needle business, but are increasingly subject to pricing pressures, especially given recent market consolidation in the U.S. dialysis services industry, with Fresenius and DaVita collectively controlling approximately two-thirds of the U.S. dialysis services business. Unless we can successfully demonstrate to customers the differentiating features of the Streamline blood tubing set, MasterGuard needle, Buttonhole needle or products that we introduce in the future, we may be susceptible to further pressures to reduce our product pricing and more vulnerable to the loss of our blood tubing set and needle business to competitors in the dialysis industry. Our needle agreement with DaVita, under which DaVita had committed to purchase a significant percentage of its needle requirements from us, is scheduled to expire in April 2013. If we are unable to negotiate an extension of this agreement, our needle sales will decline, at least in the near term.

The activities of our business involve the import of finished goods into the U.S. from foreign countries, subject to customs inspections and duties, and the export of components and certain other products from other countries into Germany, Mexico, Thailand and Italy. To a lesser, but increasing degree, our business also involves the export of finished goods from the U.S. to foreign countries. If we misinterpret or violate these laws, or if laws governing our exemption from certain duties change, we could be subject to significant fines, liabilities or other adverse consequences.

We import into the U.S. disposable medical supplies from our manufacturing facilities and vendors located outside the U.S. We have manufacturing facilities in Mexico, Germany and Italy and export various components and assemblies related to those operations. To a lesser, but increasing degree, our business also involves the export of finished goods from the U.S. to foreign countries. The import and export of these items are subject to extensive laws and regulations with which we need to comply. To the extent we fail to comply with these laws or regulations, or fail to interpret our obligations accurately, we may be subject to significant fines, liabilities, import holds and a disruption to our ability to deliver product, which could cause our combined businesses and operating results to suffer. To the extent there are modifications to the Generalized System of Preferences or cancellation of the Nairobi Protocol Classification such that our products would be subject to duties, our profitability would also be negatively impacted.

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The success of our business depends on the services of each of our senior executives as well as certain key engineering, scientific, manufacturing, clinical and marketing personnel, the loss of whom could negatively affect the combined businesses.

Our success has always depended upon the skills, experience and efforts of our senior executives and other key personnel, including our research and development and manufacturing executives and managers. Much of our expertise is concentrated in relatively few employees, the loss of whom for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the future resignation of any employee. We maintain key person insurance for only one of our executives, Jeffrey Burbank, our Chief Executive Officer.

Risks Related to the Regulatory Environment

We are subject to significant regulation, primarily by the FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals.

Our products are medical devices subject to extensive regulation in the U.S., and in foreign markets in which we are currently present or which we may wish to enter. To market a medical device in the U.S., approval or clearance by the FDA is required, either through the pre-market approval process or the 510(k) clearance process. We have obtained the FDA clearance necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications of our products. Regulatory pathways for such clearances may be difficult to define and could change. For example, in 2010 we completed an approved IDE study intended to support a home nocturnal indication for the System One. Enrollment started in the first quarter of 2008 and we submitted the associated 510(k) to the FDA in 2010. We met our primary safety and efficacy endpoints for the study; nevertheless, in 2011, the FDA notified us that their standards for what will be required for a home nocturnal clearance may change from what was required in our approved IDE. As a result, the FDA did not clear our 510(k) application for home nocturnal use. In July 2012, the FDA approved a continuation of our IDE study designed to support a nocturnal indication for the System One. We have re-started the trial. After completion of the trial, we will be resubmitting an application for a home nocturnal clearance. We cannot be certain when this clearance will be obtained. We also cannot provide assurance of when this or other clearances or approvals might be issued, if at all. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Although the 510(k) regulation has not been formally changed, the FDA has announced that it is intending to implement modifications to the 510(k) process. Any changes in regulatory policies could have an adverse effect on our ability to sell and promote our products and our business as a whole.

The regulatory approval procedure in the EU differs from the FDA clearance process. Manufacturers are required to demonstrate compliance of their medical devices with the essential requirements provided in the medical devices directives and related guidance. Although conformity assessment procedures are conducted by notified bodies, the decision to affix the CE mark to a medical device and related responsibility and liability for devices marketed in the EU remains with the manufacturer of the devices. Although we take all available measures to ensure compliance with applicable regulatory obligations in the EU extensive forthcoming revisions to current EU medical device legislation may impose additional obligations. We cannot provide assurance that we will be able to comply with any such new obligations imposed on medical devices currently on the EU market within the deadlines imposed by the new legislation. New obligations may also adversely affect our ability to introduce new products onto the EU market in a timely manner.

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Modifications to our marketed devices may require new regulatory clearances or pre-market approvals, or may require us to cease marketing or recall the modified devices until clearances or approvals are obtained.

Any modifications to a 510(k) cleared device that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, requires the submission of another 510(k) pre-market notification to address the change. Although in the first instance we may determine that a change does not rise to a level of significance that would require us to make a pre-market notification submission, the FDA may disagree with us and can require us to submit a 510(k) for a significant change in the labeling, technology, performance specifications or materials or major change or modification in intended use, despite a documented rationale for not submitting a pre-market notification. We have modified various aspects of our products and have filed and received clearance from the FDA with respect to some of the changes in the design of our products. If the FDA requires us to submit a 510(k) for any modification to a previously cleared device, or in the future a device that has received 510(k) clearance, we may be required to cease marketing the device, recall it, and not resume marketing until we obtain clearance from the FDA for the modified version of the device. Also, we may be subject to regulatory fines, penalties and/or other sanctions authorized by the Federal Food, Drug, and Cosmetic Act. In the future, we intend to introduce new products and enhancements and improvements to existing products. We cannot provide assurance that the FDA will clear any new product or product changes for marketing or what the timing of such clearances might be. In addition, new products or significantly modified marketed products could be found to be not substantially equivalent and classified as products requiring the FDA s approval of a pre-market approval application, or PMA, before commercial distribution would be permissible. PMAs usually require substantially more data than 510(k) submissions and their review and approval or denial typically takes significantly longer than a 510(k) decision of substantial equivalence. Also, PMA products require approval supplements for any change that affects safety and effectiveness before the modified device may be marketed. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our products, which will have a negative effect on our revenues growth.

Any substantial changes to a CE marked device may require further conformity assessment of the device by a notified body before the modified device is introduced onto the EU market. Substantial changes include the introduction of a new intended purpose for the device, a change in its design or a change in the device quality management system. There is limited guidance to assist us in determining whether a change that we make to a device should be considered substantial. However, as the manufacturer of the medical device we have sole responsibility for determining whether the change constitutes a substantial change. There is a risk that the competent authorities of the EU Member States or our notified body may disagree with our assessment of the changes introduced to our products. The competent authorities of the EU Member States or our notified body may also come to a different conclusion to the FDA concerning any change made to our products. Delays in conduct of any conformity assessment will cause delays in our ability to sell our products in the EU which will have a negative effect on our revenues growth.

Even if we obtain the necessary regulatory clearances or approvals, if we or our suppliers fail to comply with ongoing regulatory requirements our products could be subject to restrictions or withdrawal from the market.

We are subject to the Medical Device Reporting, or MDR, regulations that require us to report to the FDA if our products may have caused or contributed to patient death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. Similar obligations are imposed in foreign countries. We must also file reports of device corrections and removals and adhere to the FDA s rules on labeling and promotion. Our failure to comply with these or other applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following:

untitled letters, warning letters, fines, injunctions and civil penalties;

administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;

customer notification, or orders for repair, replacement or refund;

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voluntary or mandatory recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusal to review pre-market notification or pre-market approval submissions;

rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and

criminal prosecution.

We must file similar reporting outside of the U.S. where our products are distributed. For example, after the product has been CE marked and placed on the market in the EU, we must comply with a number of regulatory requirements relating to:

registration of medical devices;

pricing and reimbursement of medical devices;

establishment of post-marketing surveillance and adverse event reporting procedures;

field safety corrective actions, including product recalls and withdrawals;

marketing and promotion of medical devices;

interactions with physicians.

Failure to comply with these requirements may result in enforcement measures being taken by the competent authorities of the EU Member States. These can include fines, administrative penalties, compulsory product withdrawals, injunctions and criminal prosecution. Such enforcement measures would have an adverse effect on the marketing of our products in the EU and, consequently, on our business and financial position.

Our products are subject to market withdrawals or product recalls after receiving FDA clearance or approval, and market withdrawals and product recalls could cause the price of our stock to decline and expose us to product liability or other claims or could otherwise harm our reputation and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. These could lead to a government mandated or voluntary recall by us. The FDA has the authority to require the recall of our products in the event a product presents a reasonable probability that it would cause serious adverse health consequences or death. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We believe that the FDA or foreign regulatory authorities would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. From time to time over our history we have chosen to voluntarily recall certain products that were defective. We have never had a mandatory government recall. Although we do not believe that any of our recent recalls have had any long term negative effect on our business, we cannot be sure that other recalls would not materially divert management attention and financial resources, cause the price of our stock to decline,

expose us to product liability or other claims, or harm our reputation with customers.

If we or our contract manufacturers fail to comply with FDA s Quality System Regulations, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.

Our finished goods manufacturing processes, and those of some of our contract manufacturers, are required to comply with the FDA s Quality System Regulations, or QSRs, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. Foreign regulatory authorities impose similar obligations. The FDA enforces its QSRs

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through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. The FDA has inspected our Lawrence, Massachusetts facility and quality system multiple times. In our first inspection, one observation was made, but was rectified during the inspection, requiring no further response from us. Our subsequent inspections, including our most recent inspection in 2010, resulted in no inspectional observations. Medisystems has been inspected by the FDA on multiple occasions, and all inspections resulted in no action indicated. While all of our previous inspections have resulted in no significant observations, we cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities, or that future inspections would have the same result.

If one of our manufacturing facilities or those of any of our contract manufacturers fails to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action, including issuing a public warning letter, shutting down our manufacturing operations, embargoing the import of components from outside of the U.S., recalling our products, refusing to approve new marketing applications, instituting legal proceedings to detain or seize products or imposing civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products in a manner not consistent with our products cleared indications for use or with other state or federal laws governing the promotion of our products.

Our promotional materials and other product labeling must comply with FDA and other applicable laws and regulations. If the FDA determines that our promotional materials or other product labeling constitute promotion of an unapproved, or uncleared use, it could request that we modify our materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. Other regulatory agencies, federal, state and foreign, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our product, including how we use endorsements and testimonials. If our promotional materials are inconsistent with these guidelines or regulations, we could be subject to enforcement actions, which could result in significant fines, costs and penalties. Our reputation could also be damaged and the adoption of our products could be impaired.

Medical devices in the EU may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the EU Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Our promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the EU governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public. If our promotional materials do not comply with these laws and industry codes we could be subject to penalties that could include significant fines. Our reputation could also be damaged and the adoption of our products could be impaired.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products outside the U.S.

In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products outside of the U.S. We are currently selling the System One in the EU, Australia and other select markets. We are assessing other international markets for the System One as well. Our In-Center products are presently sold in the U.S. as well as in several other countries, through distributors. We presently have CE marking as well as Canadian regulatory authority to sell our System One as well as certain other products in Canada, the EU, Australia and selected other geographies. However, in order to market directly our products in other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional

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testing. In addition, the time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in other markets beyond these we are currently in, which could negatively affect our overall market penetration. Additionally, any loss of foreign regulatory approvals, for any reason, could negatively affect our business.

New regulatory requirements can impose additional burdens on us, and our business could be adversely affected if we are unable to timely satisfy all applicable new requirements.

New regulations impacting our product technologies are periodically adopted in the U.S. as well as other countries. These regulations may require us to change our existing product technologies in order to continue marketing our products. This may expose us to increased costs, as well as risks that we may be unable to satisfy the new regulatory requirements. One example of this type of new regulation is found in IEC 60601-1:2005 (3rd edition), which was published in December 2005. In this publication, new standards are listed as general requirements concerning basic product safety and the essential performance of equipment. Some of these new standards became effective on June 1, 2012 in the EU and will become effective on June 30, 2013 in the U.S. Our ability to sell or market product in certain foreign jurisdictions could be negatively affected and if we are unable to adhere to this or other regulations. This would have a negative impact on our business.

We have obligations under our contracts with dialysis clinics and hospitals to protect the privacy of patient health information.

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we learn patient names and addresses when we ship our System One supplies to home hemodialysis patients. We may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customer s staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. U.S. federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA and the rules promulgated thereunder require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information (PHI) known as the HIPAA Privacy and Security Rules. Most healthcare facilities that purchase and use our products are covered entities. We are not a covered entity but with the expansion of our service offering to include other services and/or activities for or on behalf of covered entities, we are a business associate, as such term is defined by HIPAA, with respect to these specific services and/or activities. HIPAA requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates which, among other things, obligate the business associates to safeguard the covered entity s PHI against improper use and disclosure. We have business associate agreements with respect to certain new services provided by us with certain of our customers that are also covered entities. Pursuant to the terms of these agreements, we agree, among other things, not to use or further disclose the covered entity s PHI except as permitted or required by the agreements or as required by law, to use reasonable safeguards to prevent unauthorized disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. If we were to violate any of these agreements we could lose customers and be exposed to liability and/or our reputation and business could be harmed.

The Health Information Technology for Economic and Clinical Health Act, or HITECH made significant amendments to the HIPAA Privacy and Security Rules. Under HITECH, business associates obligations with

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respect to PHI are no longer solely contractual in nature. HITECH strengthened and expanded HIPAA and made a number of HIPAA Privacy Rule requirements and a majority of HIPAA Security Rule requirements directly applicable to business associates. As a business associate, we are subject to these laws and HIPAA civil and criminal penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA and significantly strengthened enforcement by requiring the U.S. Department of Health and Human Services (HHS) to conduct periodic audits to confirm compliance and authorizing state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. As a business associate, these new provisions require us to incur compliance related costs and could restrict our business operations. We are unable to predict what additional legislation or regulation in the area of privacy of personal information, including personal health information, could be enacted and what effect that could have on our operations and business.

In addition, many other state and federal laws regulate the use and disclosure of health information, including state medical privacy laws and federal and state consumer protection laws. In many cases, these laws are not necessarily preempted by HIPAA, particularly if they afford greater protection to the individual than does HIPAA. These various laws may be subject to varying interpretations by courts and government agencies creating potentially complex compliance issues for our business. The national legislation of foreign countries includes provisions that impose obligations equivalent to or, in some cases, more extensive than those provided in HIPAA. These provisions may impose obligations with which we are obliged to comply and related penalties if we fail to fulfill our obligations. Compliance with these obligations may require us to incur compliance related costs and may restrict our business operations. Concerns or allegations about our practices with regard to the privacy or security of personal health information or other privacy-related matters, even if unfounded or even if we are in compliance with applicable laws, could damage our reputation and harm our business.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information. The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly referred to as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the US. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business.

The draft Data Protection Regulation is expected to introduce new data protection requirements in the EU and substantial fines for breaches of data protection rules. If the draft Data Protection Regulation is adopted in its current form it may increase our responsibility and liability concerning personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. This may be onerous and increase our cost of doing business.

We are subject to federal and state laws prohibiting kickbacks and false and fraudulent claims which, if violated, could subject us to substantial penalties. Additionally, any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The federal healthcare program Anti-Kickback Statute, and similar state laws, prohibit payments that are intended to induce health care professionals or others either to refer patients or to purchase, lease, order or arrange for or recommend the purchase, lease or order of healthcare products or services. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care

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organizations. In addition, some state statutes, most notably laws in Massachusetts and Vermont, impose outright bans on certain gifts to physicians. Some of these laws, referred to as aggregate spend or gift laws, carry substantial fines if they are violated. The federal Physician Payments Sunshine Act was enacted by Congress in 2010 as part of the comprehensive health care reform legislation, and the implementing regulations, released in February 2013, will require us to begin collecting certain data on payments and other transfers of value to physicians and teaching hospitals beginning in August 2013 for public reporting by March 31, 2014. It is widely anticipated that public reporting under the Sunshine Act will result in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals.

These anti-kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If we were to offer or pay inappropriate inducements to purchase our products, we could be subject to a claim under the federal healthcare program Anti-Kickback Statute or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws.

Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to government healthcare programs or other payors, manufacturers can be held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all prescribing decisions, including the decision as to whether to order dialysis services more frequently than three times per week. Nevertheless, we cannot provide assurance that the government will regard any billing errors that may be made as inadvertent or that the government will not examine our role in providing information to our customers and physicians concerning the benefits of more frequent therapy. Likewise, our financial relationships with customers, physicians, or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial. Moreover, an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

Increasingly, foreign countries are adopting laws similar in application and consequence to the anti-kickback and false claims laws in the U.S. If we fail to comply with these laws we may face civil or criminal penalties. The negative consequences of any failure to comply with these laws may also harm our ability to operate in foreign countries and have a negative effect on our reputation that discourages third parties from doing business with us.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

Historically, our marketing efforts had been confined nearly exclusively to the U.S. In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products internationally. In some foreign countries, particularly in the EU, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take

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considerable time after a device has been CE marked. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the U.S., which would negatively affect the long-term growth of our business. Further, reimbursement provided to our products in other jurisdictions could change, positively or negatively. In the event reimbursements were to be negatively changed, such as, for example, in the United Kingdom, our ability to sell our products could be impaired.

Failure to comply with the U.S. Foreign Corrupt Practices Act or UK Anti-Bribery Act could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign controlled subsidiaries. Through our international activities, we are also subject to the UK Anti-Bribery Act and other similar anti-bribery laws. While we have policies and procedures in place designed to prevent noncompliance, we can make no assurance that our employees or other agents will not engage in prohibited conduct under these laws for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by state and federal regulations or foreign country laws, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage.

Risks Related to Operations

Resin is a key input material to the manufacture of our products and System One cartridge. Oil prices affect both the pricing and availability of this material. Escalation of oil prices could affect our ability to obtain sufficient supply of resin at the prices we need to manufacture our products at current rates of profitability.

We currently source resin from a small number of suppliers. Rising oil prices over the last several years have resulted in significant price increases for this material. We cannot guarantee that prices will not continue to increase. Our contracts with customers restrict our ability to immediately pass on these price increases, and we cannot guarantee that future pricing to customers will be sufficient to accommodate increasing input costs.

Distribution costs represent a significant percentage of our overall costs, and these costs are dependent upon fuel prices. Increases in fuel prices could lead to increases in our distribution costs, which, in turn, could impair our ability to achieve profitability.

We currently incur significant inbound and outbound distribution costs. Our distribution costs are dependent upon fuel prices. Increases in fuel prices could lead to increases in our distribution costs, which could impair our ability to achieve profitability.

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We have labor agreements with our production employees in Italy and in Mexico. We cannot guarantee that we will not in the future face strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or in Italy, anti-union behavior, that may cause production delays and negatively impact our ability to deliver our products on a timely basis.

Our wholly-owned subsidiary in Italy has a national labor contract with Contratto collettivo nazionale di lavoro per gli addetti all industria della gomma cavi elettrici ed affini e all industria delle materie plastiche, and our wholly-owned subsidiary in Mexico has entered into a collective bargaining agreement with a Union named Mexico Moderno de Trabajadores de la Baja California C.R.O.C. We have not to date experienced strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes, or in Italy, anti-union behavior, however we cannot guarantee that we will not be subject to such activity in the future. Any such activity would likely cause production delays, and negatively affect our ability to deliver our production commitments to customers, which could adversely affect our reputation and cause our combined businesses and operating results to suffer. Additionally, some of our key single source suppliers have labor agreements. We cannot guarantee that we will not have future disruptions, which could adversely affect our reputation and cause our business and operating results to suffer

We do not have long-term supply contracts with many of our third-party suppliers.

We purchase raw materials and components from third-party suppliers, including some single source suppliers, through purchase orders and do not have long-term supply contracts with many of these third-party suppliers. Many of our third-party suppliers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We do not maintain large volumes of inventory from most of our suppliers. If we inaccurately forecast demand for finished goods, our ability to meet customer demand could be delayed or interrupted and our competitive position and reputation could be harmed. In addition, if we fail to effectively manage our relationships with these suppliers, we may be required to change suppliers, which would be time consuming and disruptive and could lead to disruptions in product supply, which could permanently impair our customer base and reputation. Although we believe our supply chain has sufficient inventory of raw materials, components and finished goods to withstand a temporary disruption in supply from any single source supplier, any permanent or long term disruption in supply from any single source supplier could lead to supply delays or interruptions which would damage our business, at least in the near term.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property and prevent its use by third parties, we will lose a significant competitive advantage.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our proprietary technology and prevent others from duplicating our products. However, these means may afford only limited protection and may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- permit us to gain or maintain a competitive advantage.

Any of our patents, including those we may license, may be challenged, invalidated, circumvented or rendered unenforceable. We cannot provide assurance that we will be successful should one or more of our patents be challenged for any reason. If our patent claims are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired, which could make our products less competitive.

We cannot specify which, if any, of our patents individually or as a group will permit us to gain or maintain a competitive advantage. We cannot provide assurance that any pending or future patent applications we hold

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will result in an issued patent or that if patents are issued to us, that such patents will provide meaningful protection against competitors or against competitive technologies. The issuance of a patent is not conclusive as to its validity or enforceability. The U.S. federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. Competitors may also be able to design around our patents. Our patents and patent applications cover particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, it would likely have an adverse effect on our sales.

The laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the U.S. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products or services and our competitors could commercialize similar technologies, which could result in a decrease in our revenues and market share.

Our products could infringe the intellectual property rights of others, which may lead to litigation that could itself be costly, could result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our products.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Products to provide kidney replacement therapy have been available in the market for more than 30 years and our competitors hold a significant number of patents relating to kidney replacement devices, therapies, products and supplies. Although no third party has threatened or alleged that our products or methods infringe their patents or other intellectual property rights, we cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. If our business is successful, the possibility may increase that others will assert infringement claims against us.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenues;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and trade secrets and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover or reverse engineer trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of other companies.

Many of our employees were previously employed at other medical device companies focused on the development of dialysis products, including our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against these claims, litigation could result in substantial costs, damage to our reputation and be a distraction to management.

Risks Related to our Common Stock

Our stock price is likely to be volatile, and the market price of our common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early stage companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing of market launch and/or market acceptance of our products;
- timing of achieving profitability from operations;
- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;
- developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers;
- disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across the border, or the failure of third party suppliers to produce needed products or components;
- reports by officials or health or medical authorities, the general media or the FDA regarding the potential benefits of the System One or of similar dialysis products distributed by other companies or of more frequent or home dialysis;
- announcements by the FDA of non-clearance or non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;
- product recalls;

defaults under our material contracts, including without limitation our credit agreement;

regulatory developments in the United States and foreign countries;

changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments, or the willingness of Medicare contractors to pay for more than three treatments a week where medically justified;

litigation involving our company or our general industry or both;

announcements of technical innovations or new products by us or our competitors;

developments or disputes concerning our patents or other proprietary rights;

our ability to manufacture and supply our products to commercial standards;

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- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- departures of key personnel; and
- investors general perception of our company, our products, the economy and general market conditions.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Anti-takeover provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us. In addition, these provisions may frustrate or prevent attempts by our stockholders to replace or remove members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- advance notice requirements for nominations of directors or stockholder proposals; and
- the requirement that board vacancies be filled by a majority of our directors then in office.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the offer may be considered beneficial by some stockholders.

If there are substantial sales of our common stock in the market by our large existing stockholders, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell a large number of shares of common stock, the market price of our common stock could decline significantly. We have 59,308,533 shares of common stock outstanding as of December 31, 2012. Except where sales are made pursuant to an effective registration statement, shares held by our affiliates may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which approximates 593,085 shares, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale. With the higher trading volumes we have recently observed in our stock, the number of shares that can be sold by our affiliates pursuant to Rule 144 is significantly above the 1% of shares outstanding limitation of Rule 144 as of the time of the filing of this report.

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At December 31, 2012, subject to certain conditions, holders of an aggregate of approximately 6.3 million shares of our common stock have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission, or SEC. If we register their shares of common stock, they can more easily sell those shares in the public market.

As of December 31, 2012, 8.3 million shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan, outstanding stock options and unvested restricted stock. As of December 31, 2012, 4.7 million shares were subject to outstanding options, of which 3.9 million were exercisable and can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144.

We have filed resale registration statements covering shares of our common stock that we sold in a May 2008 private placement. If the holders of these shares or shares issued pursuant to the terms of the warrant are unable to sell these shares under the respective registration statements, we may be obligated to pay them damages, which could harm our financial condition. Further, these resale registration statements could result in downward pressure on the price of our common stock and may affect the ability of our stockholders to realize the current trading price of our common stock.

In 2008, we sold an aggregate of 9,555,556 shares of our common stock and warrants to purchase an additional 1,911,111 shares of our common stock in a private placement. We were required to register the common stock and the common stock issuable upon exercise of the warrants with the Securities and Exchange Commission, which we did on August 8, 2008. If the holders of the shares or the accompanying warrant shares are unable to sell such shares or warrant shares under the registration statement for more than 30 days in any 365 day period after the effectiveness of the registration statement, we may be obligated to pay damages equal to up to 1% of the share purchase price per month that the registration statement is not effective and the investors are unable to sell their shares.

Investors should be aware that the current or future market price of their shares of our common stock could be negatively impacted by the sale or perceived sale of all or a significant number of these shares that are available for sale pursuant to these registration statements or that will be available for sale in the future.

Our outstanding warrants may result in substantial dilution to our stockholders.

Warrants held by certain investors in our 2008 private placement could result in the issuance of up to 1.4 million additional shares of common stock. The issuance and sale of any of these shares could result in substantial dilution to our stockholders in the form of immediate and substantial dilution in net tangible book value per share.

We may grow through additional acquisitions, which could dilute our existing shareholders and could involve substantial integration risks.

As part of our business strategy, we may acquire other businesses and/or technologies in the future. We may issue equity securities as consideration for future acquisitions that would dilute our existing stockholders, perhaps significantly depending on the terms of the acquisition. We may also incur additional debt in connection with future acquisitions, which, if available at all, may place additional restrictions on our ability to operate our business. Acquisitions may involve a number of risks, including:

- difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;
- potential disruption of our ongoing business and distraction of management;
- potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;

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- difficulty in incorporating acquired technology and rights into our products and technology;
- unanticipated expenses and delays in completing acquired development projects and technology integration;
- management of geographically remote units both in the United States and internationally;
- impairment of relationships with partners and customers;
- customers delaying purchases of our products pending resolution of product integration between our existing and our newly acquired products;
- entering markets or types of businesses in which we have limited experience;
- potential loss of key employees of the acquired company; and
- inaccurate assumptions of the acquired company s product quality and/or product reliability.

As a result of these and other risks, we may not realize anticipated benefits from our acquisitions. Any failure to achieve these benefits or failure to successfully integrate acquired businesses and technologies could seriously harm our business.

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

Not applicable.

Item 2. ***Properties***

Our Corporate Headquarters are located at a facility in Lawrence, Massachusetts under a lease expiring in 2023 that will allow us to lease up to 141,000 square feet over a period of eight years. The facility is also used for research and development, general and administrative support functions, customer service and IT support services.

We have a manufacturing facility totaling 206,500 square feet in Tijuana, Mexico with leases expiring beginning in 2016 that supports both our System One and In-Center segments.

We also lease a 36,300 square foot manufacturing facility in Modena, Italy with leases expiring beginning in 2018 which supports our System One and In-Center segments.

We have a 12,369 square foot manufacturing and research and development facility in Rosdorf, Germany with a lease expiring in December 2013 with an option to extend which principally supports our System One segment.

We also operate a 50,110 square foot manufacturing facility owned by Asahi in Goettingen, Germany where we manufacturer products for our System One segment and for sale to Asahi.

We believe that our existing facilities are adequate for our current needs and that suitable additional or alternative space will be available on commercially reasonable terms at such time as it becomes needed.

Item 3. ***Legal Proceedings***

A civil complaint was filed against the Company on February 28, 2012 in the U.S. District Court for the District of Massachusetts by Gambro Renal Products, Inc., or Gambro (Case No. 1:12cv10370-PBS). The complaint alleges that the Company has violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Massachusetts General Laws Chapter 93A by making false and misleading statements about the Company s and Gambro s allegedly competing products in the critical care market in commercial and

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promotional activities. The complaint also alleges that the Company wrongfully interfered with contractual and advantageous relationships of Gambro in its critical care business. Gambro seeks compensatory and treble damages, disgorgement of profits and injunctive relief. We believe the suit is without merit and intend to defend the Company vigorously. At this time we do not believe a loss is probable and we are not able to estimate a range of possible loss.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the NASDAQ Global Select Market under the symbol NXTM . The following table sets forth, for the periods indicated, the high and low closing sale prices of our common stock.

	High	Low
2012		
First Quarter	21.54	16.55
Second Quarter	19.20	14.99
Third Quarter	17.04	12.19
Fourth Quarter	13.73	10.61
2011		
First Quarter	26.80	19.41
Second Quarter	24.68	17.25
Third Quarter	21.06	16.96
Fourth Quarter	23.77	16.96

Holders

On February 20, 2013, the last reported sale price of our common stock was $11.57 per share. As of February 20, 2013, there were approximately 62 holders of record of our common stock and approximately 3,750 beneficial holders of our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock. We anticipate that we will retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future. Our loan agreement with SVB restricts our ability to pay dividends. Please see the section entitled Liquidity and Capital Resources in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operation, for more information about our loan agreement with SVB.

Comparative Stock Performance Graph

The following performance graph and related information shall not be deemed soliciting material or to be filed with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

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The comparative stock performance graph below compares the cumulative stockholder return on our common stock for the period from December 31, 2007 through December 31, 2012 with the cumulative total return on (i) the Total Return Index for the NASDAQ Stock Market (U.S. Companies), which we refer to as the NASDAQ Composite Index, and (ii) the NASDAQ Medical Equipment Index. This graph assumes the investment of $100 on December 31, 2007 in our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index and assumes all dividends are reinvested. Measurement points are the last trading days of the three month period ended March 31, June 30, September 30, and December 31, during 2012, 2011, 2010, 2009 and 2008.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among NxStage Medical, Inc, the NASDAQ Composite Index,

and the NASDAQ Medical Equipment Index

* $100 invested on 12/31/07 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

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

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read together with the information under Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the notes to those consolidated financial statements included elsewhere in this Annual Report. The selected statements of comprehensive loss data for the years ended December 31, 2012, 2011 and 2010 and balance sheet data as of December 31, 2012 and 2011 set forth below have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of comprehensive loss data for the years ended December 31, 2009 and 2008 and balance sheet data as of December 31, 2010, 2009 and 2008 set forth below have been derived from the audited consolidated financial statements for such years not included in this Annual Report.

	Years Ended December 31,				
	2012	2011	2010	2009	2008
	(In thousands, except per share data)				
Statement of Comprehensive Loss Data:					
Revenues	$ 242,132	$ 217,256	$ 179,218	$ 148,676	$ 128,763
Cost of revenues	149,324	139,648	121,091	111,812	108,387
Gross profit	92,808	77,608	58,127	36,864	20,376
Operating expenses:					
Selling and marketing	40,485	37,550	34,166	30,047	27,965
Research and development	17,111	14,437	12,900	9,814	8,890
Distribution	18,888	17,916	14,751	13,918	14,267
General and administrative	27,530	23,206	22,774	19,532	19,239
Total operating expenses	104,014	93,109	84,591	73,311	70,361
Loss from operations	(11,206)	(15,501)	(26,464)	(36,447)	(49,985)
Other expense, net	(2,914)	(5,002)	(4,480)	(6,755)	(852)
Net loss before income taxes	(14,120)	(20,503)	(30,944)	(43,202)	(50,837)
Provision for income taxes	1,033	899	768	265	374
Net loss	$ (15,153)	$ (21,402)	$ (31,712)	$ (43,467)	$ (51,211)
Net loss per share, basic and diluted	$ (0.26)	$ (0.39)	$ (0.66)	$ (0.93)	$ (1.23)
Weighted-average shares outstanding, basic and diluted	57,890	54,217	48,188	46,627	41,803
Comprehensive loss	$ (14,615)	$ (21,555)	$ (32,192)	$ (43,283)	$ (51,374)

	December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 106,439	$ 102,909	$ 104,339	$ 21,720	$ 26,642
Working capital	122,235	123,470	119,089	36,037	34,362
Total assets	311,949	291,708	286,094	196,978	212,066
Long-term liabilities(1)	75,126	109,723	97,574	78,267	52,580
Accumulated deficit	(344,981)	(329,828)	(308,426)	(276,714)	(233,247)
Total stockholders equity(1)(2)(3)	197,591	151,186	152,129	89,446	122,447

(1) In May 2012, we repaid in full all principal and interest in the aggregate amount of $45.2 million under our term loan and security agreement with Asahi through the issuance of 2.5 million shares of our common stock.

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(2) In November 2010, we issued and sold 3.7 million shares of common stock pursuant to an underwriting agreement with Canaccord Genuity. Net proceeds from the sale were $73.4 million.

(3) In May 2008, we issued and sold 5.6 million unregistered shares of common stock and warrants to purchase 1.1 million shares of our common stock. In August 2008, we issued and sold an additional 4.0 million share of common stock and warrants to purchase 0.8 million shares of our common stock. The aggregate net proceeds of both sales was $42.3 million.

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

Overview

The results of our operations are included in two separately reportable segments, System One and In-Center. Other business activities relate primarily to the manufacturing of dialyzers for sale to Asahi, certain business development activities, including our early work on establishing centers of excellence which are dialysis clinics focused on the provision of home therapies, including home hemodialysis, and certain corporate expenses, specifically research and development and general and administrative expenses, which are excluded from the segment operating performance measures. In the System One segment we derive our revenues from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients within a homelike setting, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. In the In-Center segment, we derive our revenues from the sale of blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers and needles for apheresis, which is referred to as the in-center market.

Financial Performance

During 2012, we grew our revenues 11% from $217.3 million during 2011 to $242.1 million during 2012, with growth occurring in each market: home, critical care and in-center. Home revenues continue to drive the growth increasing $15.1 million, or 14%, during 2012 compared to 2011, driven by an increase in the number of patients prescribed to use and centers offering the System One. We have continued to increase both the average number of patients at existing centers and centers offering the System One, primarily through existing relationships with service providers, including DaVita and Fresenius. Critical care market revenues increased $4.5 million, or 13%, during 2012 compared to 2011, primarily due to increased sales of disposables from our growing installed base of System One equipment. In 2013, we expect to see continued growth in our System One revenues, primarily driven by the annuity nature of our business, as well as the life-sustaining, non-elective nature of dialysis therapy. Our two largest customers in the home market, DaVita and Fresenius, will be important to that growth. If the purchasing patterns of either of these customers adversely change, our business will be adversely affected, at least in the near term. In-center revenues increased $3.2 million, or 4%, during 2012 compared to 2011 driven by increased sales of needle products due to increased end user demand. We expect future demand will continue to be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users.

We continue to see improvements in our financial performance below the revenue line. We have not yet achieved profitable operating margins, but we continue to improve gross profit as a percentage of revenues from 32% during 2010 to 36% during 2011 to 38% during 2012. The improvement in gross profit as a percentage of revenues was mainly attributable to higher relative sales of higher margin products, lower product costs and favorable changes in foreign exchange rates versus the U.S. Dollar, partially offset by costs incurred by manufacturing transition costs related to the startup of the new Dialyzer manufacturing plant in Germany and costs related to the earthquakes in the second quarter of 2012 affecting our manufacturing facility in northern Italy. While we expect to continue to improve gross profit as a percentage of revenues as a result of various initiatives, including the expansion and rationalization of our manufacturing network, these improvements will

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continue to be offset in the short-term by associated costs and will be impacted favorably and unfavorably by fluctuations in foreign exchange rates versus the U.S. dollar.

We are encouraged by the improvements to our operating margins and are continuing to work toward our long-term goal of achieving profitable operating margins. However, there can be no assurance that we will be able to continue to improve our operating margins or achieve positive operating margins. Improvements to our operating margins depend principally upon continued improvements in gross margins, growing revenues, and the leverage of our operating infrastructure including after taking into account the effects of any investment in selling and marketing or research and development activities or investment in new business development, including with respect to centers of excellence. Additionally, our operating margins will be negatively impacted beginning in 2013 due to the 2.3% medical device excise tax which will be assessed on nearly all of our products sold in the U.S.

Statement of Comprehensive Loss Components

Revenues

In the System One segment we derive our revenues from the sale and rental of equipment and the sale of disposable products in the home and critical care markets. In the home market, customers purchase or rent the System One equipment, including cycler and PureFlow SL, and then purchase the related disposable products based on a specific patient prescription. In the critical care market, we sell or rent the System One and related disposables to hospital customers. In the In-Center segment, we derive our revenues from the sale of needles and blood tubing sets. Nearly all of our sales in the In-Center segment are through supply and distribution contracts with distributors.

In the home market the majority of our revenue is derived from recurring sales of disposable products. For customers that purchase the System One, we recognize revenue from the equipment sale ratably over the expected service obligation period. For customers that rent the System One, we recognize revenue on a monthly basis. We recognize revenues related to the disposable products upon delivery. Over time, as more home patients are treated with the System One and more systems are placed in patient homes, we expect to derive a growing recurring revenue stream from the sale of related disposables.

Our contracts with dialysis centers in the home market for ESRD home dialysis patients generally include terms providing for the sale of disposable products to accommodate up to the number of prescribed treatments per month per patient and the purchase or monthly rental of System One cyclers and, in most instances, our PureFlow SL hardware. These contracts typically have a term of one to seven years, and may be renewed on a month-to-month basis thereafter, subject to a 30-day termination notice. Under these contracts, if home hemodialysis is prescribed, supplies are shipped directly to patient homes and paid for by the treating dialysis center. We also include vacation delivery terms, providing for the shipment of products to a designated vacation destination for a specified number of vacation days. We derive a small amount of revenues from the sale of supplementary products and services such as ancillaries, reserve inventory and special deliveries.

In the critical care market we recognize revenues from direct product sales at the time of shipment or, if applicable, delivery in accordance with contract terms. Our contracts with hospitals generally include terms providing for the sale of our System One hardware and disposables, although we also provide a hardware rental option. These contracts typically have a term of one year. We derive a small amount of revenues from the sale of one-and two-year service contracts following the expiration of our standard one-year warranty period for System One hardware. To further support service in the critical care market, we have a bio-medical training program, whereby we train bio-medical engineers on how to service and repair certain aspects of the System One in the critical care setting. Bio-medical training is typically provided under a two-year contract following the expiration of our standard one-year warranty period for System One hardware. As more System One equipment is placed within hospitals, we expect to continue to derive a growing recurring revenue stream from the sale of disposable

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cartridges and fluids as well as, to a much lesser degree, from the sale of service and bio-medical training contracts.

In the In-Center segment nearly all sales to end users are structured through supply and distribution contracts with several significant distributors; however, in many instances we have direct contractual relationships with our end user customers. These contracts typically contain minimum volume commitments with negotiated pricing triggers at different volume tiers.

In addition to contractually determined volume discounts, we offer certain customers rebates based on sales to specific end users and discounts for early payment. Our revenues are presented net of these rebates and discounts. As of December 31, 2012, we had $2.1 million and $1.0 million reserved against trade accounts receivable for future rebates and discounts for customers in our In-Center and System One segments, respectively. We recorded $6.4 million, $6.7 million, and $5.5 million during 2012, 2011 and 2010, respectively, as a reduction of In-Center segment revenues and $5.5 million, $3.0 million and $2.3 million during 2012, 2011 and 2010, respectively, as a reduction of System One segment revenues in connection with rebates and discounts.

The majority of our revenues have been generated from sales to customers in the U.S. We sell our System One and certain of our other products internationally, primarily through distributors. For sales to our international distributors that occurred prior to January 1, 2011, we recognize revenues from the equipment sale ratably over the expected term of our remaining service obligation, which is five years. For sales occurring on or after January 1, 2011, we recognize revenues from equipment sales at the time of shipment or, if applicable, delivery in accordance with contract terms. Disposable product revenues has continually been recognized upon delivery. We also manufacture and sell dialyzers to Asahi and recognize revenues at time of shipment in accordance with contract terms.

Cost of Revenues

Cost of revenues consists primarily of direct product costs, material and labor required to manufacture our products, service of System One equipment that we sell or rent to customers and manufacturing overhead. It also includes the cost of inspecting, servicing and repairing System One equipment prior to sale or during the warranty period and stock-based compensation for certain personnel. The cost of our products depends on several factors, including the efficiency of our manufacturing operations, the cost at which we can obtain labor and products from third-party suppliers, product reliability and related servicing costs and the design of our products.

Operating Expenses

Selling and Marketing. Selling and marketing expenses consist primarily of salary, benefits and stock-based compensation for sales and marketing personnel, travel, promotional and marketing materials and other expenses associated with providing clinical training to our customers. Included in selling and marketing are the costs of clinical educators, usually nurses, we employ to teach our customers about our products and prepare our customers to instruct their patients and their partners in the operation of our products and customer service and technical support personnel.

Research and Development. Research and development expenses consist primarily of salary, benefits and stock-based compensation for research and development personnel, supplies, materials and expenses associated with product design and development, clinical studies, regulatory submissions, reporting and compliance and expenses incurred for outside consultants or firms who furnish services related to these activities.

Distribution. Distribution expenses include the freight costs of delivering our products to our customers or our customers patients, depending on the market and the specific agreements with our customers, salary, benefits and stock-based compensation for distribution personnel and the cost of any equipment lost or damaged in the distribution process. We use common carriers and freight companies to deliver our products and do not

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operate our own delivery service. Also included in this category are the expenses of shipping products under warranty from customers back to our service center for repair and the related expense of shipping a replacement product to our customers or their patients.

General and Administrative. General and administrative expenses consist primarily of salary, benefits and stock-based compensation for our executive management, legal and finance and accounting staff, fees of outside legal counsel, fees for our annual audit and tax services, and general expenses to operate the business, including insurance and other corporate-related expenses. Also included in general and administrative expenses beginning in 2013 will be tax expenses incurred related to the medical device excise tax.

Comparison of Years Ended December 31, 2012 and 2011

Revenues

Our revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
System One segment				
Home	$ 123,589	51%	$ 108,489	50%
Critical Care	39,540	16%	34,991	16%
Total System One segment	163,129	67%	143,480	66%
In-Center segment	76,927	32%	73,776	34%
Other	2,076	1%		
Total	$ 242,132	100%	$ 217,256	100%

In the home market, revenues increased $15.1 million, or 14%, during 2012 compared to 2011, driven by the increase in the number of patients prescribed to use and centers offering the System One. During 2012, we increased both the number of patients at existing centers and centers offering the System One, primarily through our existing relationships with service providers, including DaVita and Fresenius. Critical care market revenues increased $4.5 million, or 13%, during 2012 compared to 2011, primarily due to increased sales of disposables from our growing number of System One equipment placed within hospitals, partially offset by lower sales of our System One equipment. Sales of our System One equipment in the critical care market are subject to fluctuation due to timing of sales and the overall capital spending environment. We expect future demand for our products and revenue growth in both the home and critical care markets to be strong as we further penetrate these markets, expand internationally, and leverage the annuity nature of our business. However, this revenue growth will be slightly offset on an ongoing basis by lower deferred revenue recognized on previously sold System One equipment in the U.S. home market as a result of equipment reaching the end of its relative revenue amortization period. Further, the U.S. dialysis market is highly consolidated with DaVita and Fresenius providing treatment to approximately two-thirds of U.S. dialysis patients. Our customers in the U.S. home market have a range of treatment options available, including traditional in-center dialysis and peritoneal dialysis. Convincing our customers, in particular DaVita and Fresenius, to make investments in their training infrastructure to expand their offering of home hemodialysis using our System One will be important to our continued revenue growth in the future. If the purchasing patterns of either DaVita or Fresenius adversely change, our business would be negatively affected, at least in the near term. Additionally, our System One revenue will continue to be susceptible to fluctuations in international equipment sales and changes in inventory levels at our international distributors.

In-Center segment revenues increased $3.2 million, or 4%, during 2012 compared to 2011. The increase in revenues was driven by higher sales of needles due to increased end user demand. While revenues continue to be susceptible to fluctuations in inventory levels at our distributors, end user demand of both our blood tubing sets

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and our needle products continues to grow at a rate equal to or greater than the growth in the ESRD population. However, we expect future revenues will continue to be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users. In-Center revenues will also be negatively impacted, at least in the near term, if we are unable to negotiate an extension of DaVita s needle purchase agreement with us which is scheduled to terminate in April 2013.

Other revenues relate to dialyzers sold to Asahi pursuant to our Dialyzer Production Agreement.

Gross Profit

Our gross profit and gross profit as a percentage of revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
System One segment	$ 74,402	46%	$ 60,847	42%
In-Center segment	19,153	25%	16,761	23%
Subtotal	93,555	39%	77,608	36%
Other	(747)	(36)%		n/a
Gross Profit	$ 92,808	38%	$ 77,608	36%

Gross profit increased $15.2 million, or 20%, and increased as an overall percentage of revenue during 2012 compared to 2011 driven in large part by the System One segment. Gross profit for the System One segment increased $13.6 million, or 22%, during 2012 compared to 2011. In addition to the impact of increased revenues, the improvement in gross profit and gross profit as a percentage of revenue in the System One segment was attributable to several factors, including lower product costs driven by certain cost savings initiatives, improvement in product design and reliability and continued leveraging of our manufacturing infrastructure, favorable impact of foreign exchange rate fluctuations versus the U.S. dollar and increased relative sales of higher margin products.

Gross profit for the In-Center segment increased $2.4 million, or 14%. In addition to the impact of increased revenues, the improvement of gross profits and gross profit as a percentage of revenues in the In Center segment was attributable to favorable foreign exchange rate fluctuations versus the U.S. dollar, favorable pricing for certain products and lower manufacturing costs partially offset by costs related to the earthquakes in the second quarter of 2012 affecting our manufacturing facility in northern Italy.

The Other category relates to the manufacturing of dialyzers for sale to Asahi and includes related start-up production costs for the new manufacturing plant in Germany. We expect that this relationship should provide us with long term cost efficiencies through increased dialyzer production volumes.

We expect gross profit as a percentage of revenues will continue to improve in the long-term for three general reasons, all of which we expect will reduce costs in the future. First, we expect to introduce additional process improvements and product design changes that have inherently lower costs than the costs associated with our current products. Second, we anticipate that increased volume, expansion and improved leverage of our manufacturing operations and rationalization of our supply chain will lead to lower costs and better purchasing terms and prices. Finally, we expect to continue to improve product reliability, which would reduce unit service costs. However, there is no certainty that our expectations or the projected timing associated with our expectations will be achieved with respect to these cost reduction plans. Further, these improvements in gross profit as a percentage of revenues may be offset in the short-term for five general reasons, all of which could negatively impact gross profit. First, we manufacture a large majority of our products internationally and purchase products from foreign companies in other than U.S. dollars and, therefore, our product costs are subject

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to fluctuations due to changes in foreign currency exchange rates. Any unfavorable fluctuations in foreign exchange rates versus the U.S. dollar would negatively impact our gross profit as a percentage of revenues. Second, we expect that we will continue to incur higher transportation costs driven by increased prices from carriers and changes in fuel prices. Third, we may see an increase in service costs as the existing System One equipment ages and increases in the cost of certain raw materials. We may not be able to pass these costs along to our customers through higher prices for our products. Fourth, we expect future demand for our products to continue to grow; however, higher relative sales of lower margin products, including the sale of dialyzers to Asahi, and certain pricing strategies would have a negative impact on gross profit as a percentage of revenues. Finally, rationalization and consolidation of our manufacturing operations, in an effort to drive long-term gross margin improvement, will require us to incur additional costs in the short-term.

Selling and Marketing

Our selling and marketing expenses and selling and marketing expenses as a percentage of revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
System One segment	$ 33,728	21%	$ 31,619	22%
In-Center segment	5,539	7%	5,215	7%
Other	1,218	n/a	716	n/a
Total Selling and marketing	$ 40,485	17%	$ 37,550	17%

Selling and marketing expenses increased $2.9 million, or 8%, during 2012 compared to 2011. The increase in selling and marketing expense was primarily the result of increased personnel and personnel-related costs and increased spending due to expanded marketing programs within both segments.

Selling and marketing expenses for the System One segment decreased as a percentage of revenues during 2012 compared to 2011 due to our initiative to continue to leverage our infrastructure. Selling and marketing expenses for the In-Center segment remained consistent as a percentage of revenues during 2012 compared to 2011 due to our efforts to continue to broaden our marketing programs while still leveraging our existing infrastructure. Selling and marketing expenses for our Other category relates primarily to personnel and personnel related costs related to business development activities, including our centers of excellence initiative. We anticipate that selling and marketing expenses will continue to increase as we increase public awareness of the System One in the home market, broaden our marketing and business development initiatives, and support growth in international markets.

Research and Development

Our research and development expenses and research and development expenses as a percentage of revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
Research and development	$ 17,111	7%	$ 14,437	7%

Research and development expenses increased $2.7 million, or 19%, during 2012 compared to 2011 but remained consistent as a percentage of revenues. The increase was primarily due to increased personnel and personnel-related costs and increased project related spending. For the near term, we expect research and development expenses will increase as we seek to further develop and enhance our System One, invest in our peritoneal dialysis product development program and expand our product portfolio.

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Distribution

Our distribution expenses and distribution expenses as a percentage of revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
System One segment	$ 16,325	10%	$ 14,892	10%
In-Center segment	2,563	3%	3,024	4%
Total Distribution	$ 18,888	8%	$ 17,916	8%

Distribution expenses increased $1.0 million, or 5%, during 2012 compared to 2011 due to increased business volumes but remained consistent as a percentage of revenues. Distribution expenses for the System One segment remained consistent as a percentage of revenues. Distribution network efficiencies were offset by higher carrier rates. Distribution expenses for the In-Center segment decreased in absolute dollars and as a percentage of revenues primarily due to decreased costs associated with shipping certain of our products from our international manufacturing locations to our customers. We expect that distribution expenses over the long term will increase at a lower rate than revenues due to expected efficiencies gained from increased business volume and improved reliability of System One equipment. However, these favorable impacts may be offset by overall increases in fuel costs and enhanced distribution services.

General and Administrative

Our general and administrative expenses and general and administrative expenses as a percentage of revenues for 2012 and 2011 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2012		2011	
General and administrative	$ 27,530	11%	$ 23,206	11%

General and administrative expenses increased $4.3 million, or 19%, during 2012 compared to 2011 but remained constant as a percentage of revenues. The increase in general and administrative expenses was primarily the result of increased professional services, personnel and personnel-related costs and other related infrastructure costs. We expect general and administrative expenses to increase beginning in 2013 due to the medical device excise tax which will be assessed on nearly all of our products sold in the U.S. However, over time we expect general and administrative expenses will decrease as a percentage of revenues as we continue to leverage our existing infrastructure.

Other Expense

Interest expense decreased $1.9 million during 2012 compared to 2011. In May 2012, we repaid our term loan with Asahi through the issuance of shares of our common stock. Interest expense ceased upon repayment; however, the repayment resulted in the early recognition of approximately $1.0 million of unamortized debt discount during the second quarter of 2012.

The change in other (expense) income, net during both periods is derived primarily by foreign currency gains and losses.

Provision for Income Taxes

The provision for income taxes of $1.0 million in 2012 and $0.9 million in 2011 relates to the profitable operations of certain foreign entities and changes in reserves for uncertain tax positions. Refer to Note 11 to our consolidated financial statements for the year ended December 31, 2012 for further discussion of tax positions.

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Comparison of Years Ended December 31, 2011 and 2010

Revenues

Our revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
System One segment				
Home	$ 108,489	50%	$ 85,762	48%
Critical Care	34,991	16%	28,093	16%
Total System One segment	143,480	66%	113,855	64%
In-Center segment	73,776	34%	65,363	36%
Total	$ 217,256	100%	$ 179,218	100%

In the home market, revenues increased $22.7 million, or 27%, during 2011 compared to 2010, with the significant majority resulting from an increase in the number of patients prescribed to use the System One. During 2011, we increased both the average number of patients at existing centers and centers offering the System One, primarily through our existing relationships with service providers, including DaVita and Fresenius. Home market revenues also increased due to increased sales to our international distributors. Critical care market revenues increased $6.9 million, or 25%, during 2011 compared to 2010, primarily due to increased sales of disposables from our growing number of System One equipment placed within hospitals and increased sales of the System One resulting from our efforts to further penetrate the market.

In-Center segment revenues increased $8.4 million, or 13%, during 2011 compared to 2010. The increase in revenues was driven by higher sales of our Streamline blood tubing sets due to increased end user demand and increased inventory levels at our distributors largely driven by the transition of the majority of their blood tubing set requirements from our ReadySet to our Streamline product. While revenues continue to be susceptible to fluctuations in inventory levels at our distributors, end user demand of both our blood tubing sets and our needle products continues to grow.

Gross Profit

Our gross profit and gross profit as a percentage of revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
System One segment	$ 60,847	42%	$ 42,620	37%
In-Center segment	16,761	23%	15,507	24%
Gross Profit	$ 77,608	36%	$ 58,127	32%

Gross profit increased $19.5 million, or 34%, and increased as an overall percentage of revenue during 2011 compared to 2010 driven in large part by the System One segment. Gross profit for the System One segment increased $18.2 million, or 43%, during 2011 compared to 2010, due to increased revenues and improvement in gross profit as a percentage of revenues. The improvement in gross profit as a percentage of revenues was attributable to several factors, including lower product manufacturing and service costs driven by continued leveraging of our manufacturing infrastructure, certain cost saving initiatives and improvements in product design and reliability, and lower depreciation expense on our field equipment assets resulting from the change in the useful life of certain of these assets from five to seven years.

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Gross profit for the In-Center segment increased in absolute dollars but decreased slightly as a percentage of revenues during 2011 compared to 2010. The change in gross profit was driven by increased revenues offset by costs incurred relating to the transition of certain blood tubing sets from a contract manufacturer to our own manufacturing facility, increased freight costs and increased resin costs as a result of higher oil prices.

Selling and Marketing

Our selling and marketing expenses and selling and marketing expenses as a percentage of revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
System One segment	$ 31,619	22%	$ 29,377	26%
In-Center segment	5,215	7%	4,789	7%
Other	716			
Total Selling and marketing	$ 37,550	17%	$ 34,166	19%

Selling and marketing expenses increased $3.4 million or 10% during 2011 compared to 2010. The increase in selling and marketing expense was primarily the result of increased personnel and personnel-related costs and increased spending due to expanded marketing programs within both segments.

Selling and marketing expenses for the System One segment decreased as a percentage of revenues during 2011 compared to 2010 due to our initiative to continue to leverage our infrastructure. Selling and marketing expenses for the In-Center segment remained consistent as a percentage of revenues during 2011 compared to 2010 due to our efforts to continue to broaden our marketing programs while still leveraging our existing infrastructure.

Research and Development

Our research and development expenses and research and development expenses as a percentage of revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
Research and development	$ 14,437	7%	$ 12,900	7%

Research and development expenses increased $1.5 million, or 12%, during 2011 compared to 2010 but remained consistent as a percentage of revenues. The increase was primarily due to increased project related spending.

Distribution

Our distribution expenses and distribution expenses as a percentage of revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
System One segment	$ 14,892	10%	$ 12,960	11%
In-Center segment	3,024	4%	1,791	3%

Total Distribution	$ 17,916	8%	$ 14,751	8%

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Distribution expenses increased $3.2 million, or 21%, during 2011 compared to 2010 due to increased business volumes but remained consistent as a percentage of revenues. Distribution expenses for the System One segment decreased as a percentage of revenues, due primarily to efficiencies gained from economies of scale resulting from increased business volume, improved product reliability of our System One and PureFlow SL hardware and efficiencies in our distribution network. Distribution expenses as a percentage of revenues for the In-Center segment increased due primarily to increased costs associated with shipping certain of our products from our international manufacturing locations to our customers and overall increased fuel prices.

General and Administrative

Our general and administrative expenses and general and administrative expenses as a percentage of revenues for 2011 and 2010 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2011		2010	
General and administrative	$ 23,206	11%	$ 22,774	13%

General and administrative expenses increased $0.4 million, or 2%, during 2011 compared to 2010 but decreased as a percentage of revenues. The increase in general and administrative expenses was primarily the result of increased professional services and other infrastructure related costs.

Other Income and Expense

Interest income is derived primarily from investments in money market funds.

Interest expense increased $0.1 million during 2011 compared to 2010, due primarily to compounding interest on the interest amounts deferred until maturity with our term loan and security agreement from Asahi.

The change in other (expense) income, net during both periods is derived primarily by foreign currency gains and losses.

Provision for Foreign Income Taxes

The provision for income taxes of $0.9 million in 2011 and $0.8 million in 2010 relates primarily to the profitable operations of certain of our foreign entities.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of December 31, 2012, our accumulated deficit was $345.0 million and we had cash and cash equivalents of $106.4 million, with nearly all of that cash located in the U.S., and working capital of $122.2 million.

Over the past several years, we have improved our cash flows from operating activities and continue to work towards our long term goal of sustained positive cash flows from operating activities. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements including any investment in selling and marketing activities to increase public awareness in the System One, research and development activities to develop new products and enhance our existing products and our centers of excellence initiative.

Our ongoing cash requirements include funding normal working capital requirements including inventory and field equipment assets. Field equipment assets include System One equipment rented to customers in the home market

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and our service pool of equipment which is equipment owned and maintained by us that is swapped for equipment owned or rented by our customers that needs repair or maintenance. While a majority of our home market customers have committed to purchase, rather than rent, the significant majority of their future System One equipment requirements thereby reducing our working capital cash requirements, there can be no assurance that we will be able to continue to expand or sustain this level of equipment placements that are purchased rather than rented. Additionally, any excess rental or service swap equipment would increase our working capital requirements.

Investments in purchases of property and equipment have increased within the last two years as a result of our efforts to rationalize, consolidate and expand our manufacturing operations. The level of investment in property and equipment in the future will be dependent on our manufacturing requirements for existing and new products and the level of activity with respect to our centers of excellence initiative.

We have a loan and security agreement with SVB for a $15.0 million revolving line of credit with an original maturity date of April 1, 2012. On May 7, 2012, we entered into an amendment to this agreement which extended the maturity date to March 31, 2014 and reduced the interest rate on borrowings to prime with a floor of 3.25%. Financial covenants and other terms remain essentially unchanged. The agreement, as amended, has certain financial covenants, contains certain customary events of default and is secured by all or substantially all of our assets. At December 31, 2012, we were in compliance with the covenants, there were no outstanding borrowings against the credit commitment, and we had $15.0 million of the credit commitment available for borrowing.

On May 4, 2012, we repaid in full all principal and interest in the aggregate amount of $45.2 million under our Term Loan and Security Agreement dated June 5, 2009 with Asahi through the issuance of 2,456,246 shares of our common stock, which after the retention by the Company of 28,351 shares for the payment of certain minimum withholding taxes, resulted in a net issuance to Asahi of 2,427,895 shares. As a result, the Term Loan and Security Agreement was terminated. The shares were issued pursuant to a Subscription, Sale and Purchase Agreement between us and Asahi dated May 4, 2012. In connection with the issuance of the shares, we entered into a Registration Rights Agreement with Asahi. Pursuant to the Registration Rights Agreement, subject to certain conditions, we were required to register these shares for resale under a registration statement filed with the SEC, which we have done, and to use commercially reasonable efforts to keep such registration statement continuously effective until such time as all of the shares have been publicly sold or may be sold pursuant to Rule 144 without restrictions, whichever is earlier.

Pursuant to our Dialyzer Production Agreement entered into in May 2009 with Asahi we agreed to oversee the construction of a new manufacturing facility in Germany funded by Asahi and operate the facility upon its completion. Construction was completed during the fourth quarter of 2012 at which time we began manufacturing dialyzers in this new facility for our own use and for sale to Asahi. We are required to pay Asahi a fixed amount per dialyzer manufactured for our own use in the new facility, with such payments capped at fifty percent of the cost of the new facility paid by Asahi, or approximately $8.2 million. If the agreement is terminated by us, Asahi has the option to require us to purchase the new facility from them or if the agreement is terminated by Asahi, we have the option to purchase the new facility from them. In either case the purchase price is equal to one hundred percent of the then net book value of the new facility, as calculated in accordance with GAAP.

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. The plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of $1.9 million and $1.6 million at December 31, 2012 and 2011, respectively, for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2012, 2011 or 2010.

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The following table sets forth the components of our cash flows for the periods indicated (in thousands):

	Years Ended December 31,	
	2012	2011
	(In thousands)	
Net cash provided by (used in) operating activities	$ 6,241	$ (1,516)
Net cash used in investing activities	(7,694)	(5,156)
Net cash provided by financing activities	4,726	5,386
Foreign exchange effect on cash and cash equivalents	257	(144)
Net cash flow	$ 3,530	$ (1,430)

Net cash provided by (used in) operating activities. Net cash provided by (used in) operating activities increased by $7.8 million during 2012. Net loss after adjustments for non-cash charges, such as depreciation, amortization and stock-based compensation expense, had a favorable impact on cash flows increasing to a positive $23.4 million during 2012 versus a positive $17.8 million during 2011. Additionally, working capital requirements decreased with lower inventory requirements and higher total liabilities relative to the prior year, including accrued expenses and other liabilities. We expect working capital to fluctuate from quarter to quarter due to various factors including inventory requirements and timing of payments from our customers and to our vendors. Cash flow from deferred revenues decreased $5.6 million during 2012 compared to 2011, reflecting an increase of $2.9 million of amortization of deferred revenues into revenues from $16.0 million during 2011 to $18.9 million during 2012 and lower sales of new home equipment during 2012 compared to 2011 as a result of the timing of patient additions and the timing of conversion of rental equipment to sold equipment.

Non-cash transfers from inventory to field equipment for the placement of units with our customers decreased $4.8 million during 2012 compared to 2011. Non-cash transfers from field equipment to deferred costs of revenues decreased $2.2 million during 2012 compared to 2011. These activities fluctuate due to the timing of home patient additions, efficiencies in our customers utilization of purchased equipment and equipment levels required for our service pool.

Net cash used in investing activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, primarily for our manufacturing facilities as a result of our efforts to rationalize, consolidate and expand our manufacturing operations, along with purchases of equipment for research and development and information technology. The increase of $2.5 million in purchases of property and equipment during 2012 compared to 2011 was driven by capital improvements to and expansion of certain of our manufacturing facilities to accommodate the increased demand for our Streamline blood tubing sets and capital spending on our new corporate headquarters. A significant majority of the capital related to our new corporate headquarters was funded by our landlord through a $4.3 million tenant improvement allowance.

Net cash provided by financing activities. During 2012 and 2011 we received $5.2 million and $8.0 million, respectively, of proceeds from stock option and purchase plans. Proceeds from stock option and purchase plans is subject to fluctuation based on the number of options exercises and, to a lesser extent, the weighted-average exercise price. Cash inflows during 2012 were reduced by $0.5 million of cash to reflect the value of shares of our common stock that were surrendered by Asahi in payment for the required minimum withholding taxes on the term loan and security agreement. Cash inflows during 2011 were reduced by $2.5 million of cash to reflect the value of shares of our common stock that were surrendered by employees in payment for the minimum required withholding taxes associated with awards under our annual Bonus and Performance Share Plans.

Off-Balance Sheet Arrangements

We do not have any significant off-balance sheet arrangements.

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Contractual Obligations

The following table summarizes our contractual commitments as of December 31, 2012 and the effect those commitments are expected to have on liquidity and cash flow in future periods (in thousands):

	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
Capital lease obligations	$ 15,358	$ 1,345	$ 2,657	$ 2,312	$ 9,044
Operating lease obligations	25,838	2,461	5,337	5,637	12,403
Purchase obligations	168,256	43,876	43,463	32,317	48,600
Total	$ 209,452	$ 47,682	$ 51,457	$ 40,266	$ 70,047

Our capital lease obligations include our capital lease obligation due to Asahi related to manufacturing facility in Germany along with $5.8 million representing the estimated residual value of the manufacturing facility in Germany at the end of the estimated lease term which only becomes due and payable at Asahi s option if the agreement between us and Asahi is terminated by us.

Our purchase obligations include purchase commitments for System One components, primarily for equipment and fluids along with needles for our In-Center segment pursuant to contractual agreements with several of our suppliers that are in the normal course of business. Certain of these commitments may be extended and/or canceled at our option.

The contractual commitments included in the table above do not include postemployment benefit obligations and unrecognized tax benefits. We maintain postemployment benefit plans for employees in certain foreign subsidiaries and may be required to make cash outlays related to the settlement of these obligations. However, the timing of such cash outlays is uncertain. Please see Footnote 12 to our consolidated financial statements for the year ended December 31, 2012 for further details. We may be required to make cash outlays related to our unrecognized tax benefits. However, we are unable to make reasonably reliable estimates of the period of cash settlement, if any, with the respective taxing authorities. Please see Footnote 11 to our consolidated financial statements for the year ended December 31, 2012 for further details.

Summary of Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ substantially from our estimates.

Note 2 to the consolidated financial statements for the year ended December 31, 2012 describes the significant accounting policies used in the preparation of our consolidated financial statements. A summary of those accounting policies and estimates that we believe are most critical to fully understanding and evaluating our financial results is set forth below. This summary should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K.

Revenue Recognition

We recognize revenue from product sales and services when earned. Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured.

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Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors, revenue is recognized at the time of sale if a reasonable estimate of future returns or credit can be made. If a reasonable estimate of future returns or credit cannot be made, we recognize revenue using the sell-through method. Under the sell-through method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

In addition to contractually determined volume discounts, in many agreements we offer rebates based on sales to specific end customers and discounts for early payment. Rebates and discounts are recorded as a reduction of sales and trade accounts receivable, based on our best estimate of the amount of probable future rebate or discount on current sales.

We enter into multiple-element arrangements that may include a combination of equipment, related disposables and services. Effective January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*, as required, using the prospective method as permitted under the guidance. Accordingly, this guidance is being applied to all revenue arrangements entered into or materially modified on or after January 1, 2011. The impact of adopting this amended guidance on our results of operations has been limited to products sold internationally through distributors in the System One segment, which revenue has not been significant in the current or historical periods. ASU No. 2009-13 amended the previous guidance for multiple-element arrangements. Pursuant to the amended guidance in ASU 2009-13 our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer, and the consideration received is allocated among the separate units based on their respective selling price, and the applicable revenue recognition criteria are applied to each of the separate units.

Under the amended guidance we determine selling price using vendor specific objective evidence (VSOE), if it exists, otherwise third-party evidence of selling price is used. If neither VSOE nor third-party evidence of selling price exists for a unit of accounting, we use best estimated selling price (BESP). We generally expect that we will not be able to establish third-party evidence due to the nature of our products and the markets in which we compete, and, as such, we typically will determine selling price using VSOE or BESP.

We determine BESP for an individual element based on consideration of both market and Company-specific factors, including the selling price and profit margin for similar products, the cost to produce the deliverable and the anticipated margin on that deliverable and the characteristics of the varying markets in which the deliverable is sold.

The adoption of the amended guidance did not change the accounting for arrangements entered into prior to January 1, 2011. Therefore, these arrangements with multiple elements were divided into separate units of accounting if there was objective and reliable evidence of fair value of the undelivered items and if other criteria were met, including whether the delivered element had stand-alone value to the customer. If either criteria were not met, the arrangement was accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment were deferred and are recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery.

System One Segment

We derive revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and/or PureFlow SL hardware and purchases a specified number of disposable products and service.

For customers that purchase the System One and PureFlow SL hardware, in the home U.S. market, due to the depot service model whereby equipment requiring service is picked up and a replacement device is shipped to

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the site of care, we recognize fees received from equipment sale as revenue on a straight-line basis over the expected term of our remaining service obligation and direct costs relating to the delivered equipment are deferred and amortized over the same expected period as the related revenue. Disposable products revenue is recognized on a monthly basis upon delivery.

Under the rental arrangements revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

Our sales arrangements with our international distributors are structured as direct product sales and have no significant post delivery obligations with the exception of standard warranty obligations. However, under the previous guidance, for arrangements entered into prior to January 1, 2011 we determined that we could not account for the sale of equipment as a separate unit of accounting and, therefore, the fees received upon the completion of delivery of equipment were deferred and recognized as revenue on a straight-line basis over the expected term of our remaining service obligation and direct costs relating to the delivered equipment were amortized over the same expected period as the related revenue. Under the amended guidance, for arrangements entered into or materially modified on or after January 1, 2011, we will recognize revenues and related direct costs upon delivery in accordance with contract terms. Disposable product revenue is recognized on a monthly basis upon delivery under both the previous and amended guidance.

In the critical care market, we structure sales of the System One and disposable products as direct product sales and have no significant post delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms. Certain of these arrangements provide for training, technical support and extended warranty services to our customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranty, the service revenue is recognized ratably over the warranty period.

In-Center Segment

Our In-Center segment sales are structured as direct product sales primarily through distributors, and we have no significant post delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms. Some of our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be canceled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

Inventory Valuation

Inventories are valued at the lower of cost or estimated market. We regularly review our inventory quantities on hand and related cost and record a provision for excess or obsolete inventory primarily based on remaining shelf-life and estimated forecast of product demand. We also review our inventory value to determine if it reflects lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margins, purchase commitments and other factors in evaluating net realizable value. The medical device industry is characterized by rapid development and technological advances as well as regulatory and quality manufacturing guidelines that could result in obsolescence of inventory. Additionally, our estimates of future product demand may prove to be inaccurate.

Field Equipment

Field equipment consists of equipment being utilized under disposable-based rental agreements as well as service pool cyclers. Service pool cyclers are cyclers owned and maintained by us that are swapped for cyclers that need repairs or maintenance by us while being rented or owned by a patient. We continually monitor the number of cyclers in the service pool, as well as cyclers that are in-transit or otherwise not being used by a patient, and assess whether there are any indicators of impairment for such equipment. We also review field

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equipment carrying value for reasonableness. We consider factors such as actual equipment disposals and our ability to verify the equipment s existence in the field to identify lost equipment. Charges for lost equipment are included in distribution expenses.

We capitalize field equipment at cost and amortize field equipment through cost of revenues using the straight-line method over an estimated useful life. We review the estimated useful life of our field equipment periodically for reasonableness and make changes when appropriate. Factors considered in determining the reasonableness of the useful life include expected future design improvements, equipment age and actual equipment disposals.

Accounting for Stock-Based Awards

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally equals the vesting period, based on the number of awards that are expected to vest. Estimating the fair value for stock options requires judgment, including the expected term of our stock options, volatility of our stock, expected dividends, risk-free interest rates over the expected term of the options and the expected forfeiture rate. In connection with our performance based programs, we make assumptions principally related to the number of awards that are expected to vest after assessing the probability that certain performance criteria will be met.

Valuation of Intangibles and Other Long-Lived Assets

For our long-lived assets including intangible assets, we assess the carrying value of these assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important include, but are not limited to, significant underperformance relative to historical or projected future results, significant negative industry factors and significant changes in strategy or operations that negatively affect the utilization of our long-lived assets. If an impairment review is triggered, we evaluate the carrying value of intangible assets based on estimated undiscounted future cash flows over the remaining useful life of the assets and comparing that value to the carrying value of the assets. The amount of impairment, if any, is measured based on fair value, which is determined using projected discounted future operating cash flows. The cash flows that are used contain our best estimates, using appropriate and customary assumptions and projections at the time. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record additional impairment charges.

Goodwill

We assess goodwill for impairment annually in the fourth quarter and whenever events or circumstances indicate impairment may exist. This test includes first a qualitative assessment and then, if necessary, a quantitative assessment to determine if the fair value of a reporting unit is less than its carrying amount. Factors considered in the qualitative assessment include, but are not limited to, both macroeconomic conditions and entity-specific conditions. For the quantitative assessment, the reporting unit s fair value is estimated using a discounted cash flow approach. Our reporting units are our System One and In-center operating segments. Assessing the impairment of goodwill requires us to make assumptions and judgments including the identification of reporting units and determination of the fair value of the net assets of our reporting units based on estimates of future cash flows and the selection of discount rates. Changes in these estimates and assumptions could materially affect the estimated fair values of reporting units and could result in a goodwill impairment charge in a future period. However, our annual impairment testing indicated no significant risk of impairment based upon various factors including the positive performance of our reporting units and positive industry and economic trends.

Accounting for Income Taxes

We periodically assess our income tax positions and record tax benefits for all years subject to examination based upon our evaluation of the facts, circumstances and information available at the reporting date. If our

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judgment as to the likely resolution of the position changes, if the matter is ultimately settled or if the statute of limitation expires, the effects of the change would be recognized in the period in which the change, resolution or expiration occurs.

We conduct business globally and file income tax returns in the U.S. federal jurisdiction, various states and foreign jurisdictions. We evaluate the need for foreign income tax provisions or reserves based on our evaluation of inter-company transfer pricing. We evaluate the need for valuation allowances on our deferred tax assets based on positive and negative evidence about our ability to realize deferred tax attributes. We have accumulated significant losses since our inception in 1998. Utilization of the net operating losses may be subject to limitations and certain tax years in the respective tax jurisdictions remain open to examination.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements for the year ended December 31, 2012 included in this Annual Report on Form 10-K.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Interest Rate Risk

Our interest rate risk is currently limited to our investments. However, this risk is mitigated given our investment portfolio currently consists of treasury obligation money market funds. We manage our investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain a high degree of liquidity to meet operating needs and obtain competitive returns subject to prevailing market conditions. Our investment policy specifies the credit quality standards for our investments and limits the amount of exposure from any single issue, issuer or type of investment.

Foreign Currency Exchange Risk

All of our revenues and a majority of our expenses are denominated in U.S. dollars. However, we operate a manufacturing and research facility in Germany, a manufacturing and service facility in Mexico and a manufacturing facility in Italy and we purchase materials for those facilities and pay our employees at those facilities in Euros and Pesos. In addition, we purchase products for resale in the U.S. from foreign companies and have agreed to pay them in currencies other than the U.S. dollar, including the Euro and the Thai Baht. As a result, we are potentially exposed to adverse as well as beneficial movements in foreign currency exchange rates. For example, a hypothetical 10% adverse change in the Euro, Peso and Thai Baht could have the effect of reducing our gross profit by approximately $7.0 million.

To minimize the impact of foreign currency exchange rate fluctuations certain of our long-term supply agreements include foreign exchange risk sharing at different exchange rate levels limiting our exposure to fluctuations in foreign exchange rates. In 2012 we also began using foreign exchange forward contracts on Peso denominated expenses to further reduce our exposure to foreign currency exchange rate fluctuations. These contracts are entered into with large financial institutions and have a duration of up to twelve months. These contracts are designated as cash flow hedges and are carried on our balance sheet at fair value, with the effective portion of the contracts gains or losses included in cost of revenues in the same period as the related hedged item is recognized. As of December 31, 2012, the notional amount of our outstanding contracts that are designated as cash flow hedges was approximately $7.8 million. Based on our analysis, a hypothetical adverse foreign exchange rate movement of 10 percent against our contracts would have resulted in a net loss in fair value of these contracts of approximately $0.8 million.

In addition, we are exposed to foreign currency exchange risk related to certain foreign currency denominated receivable and payable balances. We utilize natural hedges to mitigate this exposure.

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Item 8. ***Financial Statements and Supplementary Data***

NXSTAGE MEDICAL, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NxStage Medical, Inc.

We have audited the accompanying consolidated balance sheets of NxStage Medical, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012. 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of NxStage Medical, Inc. and subsidiaries at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NxStage Medical, Inc. s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 28, 2013

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NXSTAGE MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2012	2011
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 106,439	$ 102,909
Accounts receivable, net	18,990	15,808
Inventory	33,504	32,775
Prepaid expenses and other current assets	2,534	2,777
Total current assets	161,467	154,269
Property and equipment, net	36,320	17,599
Field equipment, net	10,101	12,182
Deferred cost of revenues	38,028	41,132
Intangible assets, net	19,819	22,615
Goodwill	42,421	42,698
Other assets	3,793	1,213
Total assets	$ 311,949	$ 291,708
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 16,645	$ 15,634
Accrued expenses	20,400	15,165
Other current liabilities	2,187	
Total current liabilities	39,232	30,799
Deferred revenues	59,262	57,014
Long-term debt		43,235
Other long-term liabilities	15,864	9,474
Total liabilities	114,358	140,522
Commitments and contingencies (Note 10)		
Stockholders equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of December 31, 2012 and 2011		
Common stock: par value $0.001, 100,000,000 shares authorized; 59,850,117 and 56,167,090 shares issued as of December 31, 2012 and 2011, respectively	59	56
Additional paid-in capital	551,594	489,542
Accumulated deficit	(344,981)	(329,828)
Accumulated other comprehensive income (loss)	470	(68)
Treasury stock, at cost: 541,584 and 480,923 shares as of December 31, 2012 and 2011, respectively	(9,551)	(8,516)
Total stockholders equity	197,591	151,186
Total liabilities and stockholders equity	$ 311,949	$ 291,708

See accompanying notes to these consolidated financial statements.

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NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,		
	2012	2011	2010
	(In thousands, except per share data)		
Revenues	$ 242,132	$ 217,256	$ 179,218
Cost of revenues	149,324	139,648	121,091
Gross profit	92,808	77,608	58,127
Operating expenses:			
Selling and marketing	40,485	37,550	34,166
Research and development	17,111	14,437	12,900
Distribution	18,888	17,916	14,751
General and administrative	27,530	23,206	22,774
Total operating expenses	104,014	93,109	84,591
Loss from operations	(11,206)	(15,501)	(26,464)
Other expense:			
Interest expense	(2,766)	(4,714)	(4,597)
Other (expense) income, net	(148)	(288)	117
	(2,914)	(5,002)	(4,480)
Net loss before income taxes	(14,120)	(20,503)	(30,944)
Provision for income taxes	1,033	899	768
Net loss	$ (15,153)	$ (21,402)	$ (31,712)
Net loss per share, basic and diluted	$ (0.26)	$ (0.39)	$ (0.66)
Weighted-average shares outstanding, basic and diluted	57,890	54,217	48,188
Other comprehensive loss:			
Foreign currency gain (loss)	$ 125	$ (136)	$ (486)
Other gain (loss)	413	(17)	6
Comprehensive loss	$ (14,615)	$ (21,555)	$ (32,192)

See accompanying notes to these consolidated financial statements.

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NXSTAGE MEDICAL, INC

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

	Common Stock		Additional		Other Comprehensive		Total
	Shares	Amount	Paid-In Capital	Accumulated Deficit	Income (Loss)	Treasury Stock	Stockholders Equity
			(in thousands except share data)				
Balance at December 31, 2009	46,795,859	$ 47	$ 365,548	$ (276,714)	$ 565	$	$ 89,446
Comprehensive loss:							
Net loss				(31,712)			(31,712)
Other comprehensive loss					(480)		(480)
Total comprehensive loss							(32,192)
Issuance of common stock, net of issuance costs	3,680,000	4	73,350				73,354
Exercise of stock options	1,831,253	1	12,034			(642)	11,393
Exercise of warrants	250,610		415				415
Shares issued under employee restricted stock plans	1,251,746	1				(4,070)	(4,069)
Shares issued under employee bonus plans	160,707		1,600			(513)	1,087
Shares issued under employee stock purchase plan	61,387		638				638
Shares issued to Directors in lieu of cash	11,755		186				186
Stock-based compensation expense			11,871				11,871
Balance at December 31, 2010	54,043,317	53	465,642	(308,426)	85	(5,225)	152,129
Comprehensive loss:							
Net loss				(21,402)			(21,402)
Other comprehensive loss					(153)		(153)
Total comprehensive loss							(21,555)
Exercise of stock options	1,352,289	1	8,207			(758)	7,450
Exercise of warrants	327,970	1	3,555				3,556
Shares issued under employee restricted stock plans	267,557	1	(3,733)			(1,588)	(5,320)
Shares issued under employee bonus plans	128,228		2,807			(945)	1,862
Shares issued under employee stock purchase plan	38,777		691				691
Shares issued to Directors in lieu of cash	8,952		182				182
Stock-based compensation expense			12,191				12,191
Balance at December 31, 2011	56,167,090	$ 56	$ 489,542	$ (329,828)	$ (68)	$ (8,516)	$ 151,186
Comprehensive loss:							
Net loss				(15,153)			(15,153)
Other comprehensive loss					538		538
Total comprehensive loss							(14,615)
Issuance of common stock, net of issuance costs	2,456,246	2	45,074			(522)	44,554
Exercise of stock options	913,066	1	6,344			(513)	5,832

Shares issued under employee restricted stock plans	200,587		(1,173)				(1,173)
Shares issued under employee bonus plans	47,533		878				878
Shares issued under employee stock purchase plan	56,691		731				731
Shares issued to Directors in lieu of cash	8,904		138				138
Stock-based compensation expense			10,060				10,060
Balance at December 31, 2012	59,850,117	$ 59	$ 551,594	$ (344,981)	$ 470	$ (9,551)	$ 197,591

See accompanying notes to these consolidated financial statements.

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NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2012	2011	2010
		(In thousands)	
Cash flows from operating activities:			
Net loss	$ (15,153)	$ (21,402)	$ (31,712)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	23,673	23,087	22,379
Stock-based compensation	11,403	13,093	15,351
Other	3,517	3,064	2,319
Changes in operating assets and liabilities:			
Accounts receivable	(3,141)	(1,773)	235
Inventory	(14,545)	(16,371)	(28,744)
Prepaid expenses and other assets	(1,623)	(1,491)	(877)
Accounts payable	839	(1,047)	(2,781)
Accrued expenses and other liabilities	5,263	(324)	10,065
Deferred revenues	(3,992)	1,648	16,876
Net cash provided by (used in) operating activities	6,241	(1,516)	3,111
Cash flows from investing activities:			
Purchases of property and equipment	(7,694)	(5,156)	(1,556)
Decrease in other assets			340
Net cash used in investing activities	(7,694)	(5,156)	(1,216)
Cash flows from financing activities:			
Issuance of common stock			73,354
Proceeds from exercise of stock options and warrants and employee stock purchase plans	5,248	7,965	12,446
Purchase of treasury stock	(522)	(2,533)	(4,583)
Repayments on loans and lines of credit		(46)	(54)
Net cash provided by financing activities	4,726	5,386	81,163
Foreign exchange effect on cash and cash equivalents	257	(144)	(439)
Increase (decrease) in cash and cash equivalents	3,530	(1,430)	82,619
Cash and cash equivalents, beginning of year	102,909	104,339	21,720
Cash and cash equivalents, end of year	$ 106,439	$ 102,909	$ 104,339

See accompanying notes to these consolidated financial statements.

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NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the NxStage System One, or System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis clinics. Given its design, the System One is particularly well-suited for home hemodialysis and a range of dialysis therapies including more frequent dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared or approved for commercial sale in the U.S., Canada and certain other markets for the treatment of acute and chronic kidney failure and fluid overload. The System One is also CE marked in the EU for treatment of acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the FDA for home hemodialysis as well as TPE in a clinical environment. We also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of ESRD. These products are cleared or approved for commercial sale in the U.S., Canada and certain other markets. These products are also CE marked in the EU. We believe our largest product market opportunity is for our System One used in the home dialysis market for the treatment of ESRD.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of NxStage Medical, Inc. and our wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

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

Revenue Recognition

We recognize revenue from product sales and services when earned. Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured.

Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors, revenue is recognized at the time of sale if a reasonable estimate of future returns or credit can be made. If a reasonable estimate of future returns or credit cannot be made, we recognize revenue using the sell-through method. Under the sell-through method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

In addition to contractually determined volume discounts, in many agreements we offer rebates based on sales to specific end customers and discounts for early payment. Rebates and discounts are recorded as a reduction of sales and trade accounts receivable, based on our best estimate of the amount of probable future rebate or discount on current sales.

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We enter into multiple-element arrangements that may include a combination of equipment, related disposables and services. Effective January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*, as required, using the prospective method as permitted under the guidance. Accordingly, this guidance is being applied to all revenue arrangements entered into or materially modified on or after January 1, 2011. The impact of adopting this amended guidance on our results of operations has been limited to products sold internationally through distributors in the System One segment, which revenue has not been significant in the current or historical periods. ASU No. 2009-13 amended the previous guidance for multiple-element arrangements. Pursuant to the amended guidance in ASU 2009-13 our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer, and the consideration received is allocated among the separate units based on their respective selling price, and the applicable revenue recognition criteria are applied to each of the separate units.

Under the amended guidance we determine selling price using vendor specific objective evidence (VSOE), if it exists, otherwise third-party evidence of selling price is used. If neither VSOE nor third-party evidence of selling price exists for a unit of accounting, we use best estimated selling price (BESP). We generally expect that we will not be able to establish third-party evidence due to the nature of our products and the markets in which we compete, and, as such, we typically will determine selling price using VSOE or BESP.

We determine BESP for an individual element based on consideration of both market and Company-specific factors, including the selling price and profit margin for similar products, the cost to produce the deliverable and the anticipated margin on that deliverable and the characteristics of the varying markets in which the deliverable is sold.

The adoption of the amended guidance did not change the accounting for arrangements entered into prior to January 1, 2011. Therefore, these arrangements with multiple elements were divided into separate units of accounting if there was objective and reliable evidence of fair value of the undelivered items and if other criteria were met, including whether the delivered element had stand-alone value to the customer. If either criteria were not met, the arrangement was accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment were deferred and are recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery. The adoption of the amended guidance did not have a material impact on our revenues during 2011 and 2012.

System One Segment

We derive revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and/or PureFlow SL hardware and purchases a specified number of disposable products and service.

For customers that purchase the System One and PureFlow SL hardware, in the home U.S. market, due to the depot service model whereby equipment requiring service is picked up and a replacement device is shipped to the site of care, we recognize fees received from equipment sale as revenue on a straight-line basis over the expected term of our remaining service obligation and direct costs relating to the delivered equipment are deferred and amortized over the same expected period as the related revenue. Disposable products revenue is recognized on a monthly basis upon delivery.

Under the rental arrangements revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

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Our sales arrangements with our international distributors are structured as direct product sales and have no significant post delivery obligations with the exception of standard warranty obligations. However, under the previous guidance, for arrangements entered into prior to January 1, 2011 we determined that we could not account for the sale of equipment as a separate unit of accounting and, therefore, the fees received upon the completion of delivery of equipment were deferred and recognized as revenue on a straight-line basis over the expected term of our remaining service obligation and direct costs relating to the delivered equipment were amortized over the same expected period as the related revenue. Under the amended guidance, for arrangements entered into or materially modified on or after January 1, 2011, we will recognize revenues and related direct costs upon delivery in accordance with contract terms. Disposable product revenue is recognized on a monthly basis upon delivery under both the previous and amended guidance.

In the critical care market, we structure sales of the System One and disposable products as direct product sales and have no significant post delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms. Certain of these arrangements provide for training, technical support and extended warranty services to our customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranty, the service revenue is recognized ratably over the warranty period.

In-Center Segment

Our In-Center segment sales are structured as direct product sales primarily through distributors, and we have no significant post delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms. Some of our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be canceled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

Foreign Currency Translation and Transactions

Assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates, and income and expense items are translated at average rates of exchange prevailing during the year. Gains and (losses) realized from transactions denominated in foreign currencies, including intercompany balances not considered permanent investments, are included in the consolidated statements of comprehensive loss within other (expense) income, net and totaled $(0.1) million, $(0.3) million and $0.1 million during 2012, 2011 and 2010, respectively.

Cash and Cash Equivalents

We consider all highly-liquid investments purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents include amounts invested in treasury obligation money market funds. Cash equivalents are stated at cost plus accrued interest, which approximates market value.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, derivatives and accounts receivable. To mitigate such risk, with respect to cash and cash equivalents, we place our cash in bank deposit accounts with financial institutions that have investment grade ratings and capital ratios exceeding minimum Federal Reserve Adequacy Guidelines and in treasury obligation money market funds. To mitigate concentration of credit risk with respect to derivatives we enter into transactions with highly-rated financial institutions and frequently monitor the credit worthiness of our counterparties.

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Concentration of credit risk with respect to accounts receivable is primarily limited to certain customers to whom we make substantial sales. Two customers represented 16% and 12% of accounts receivable at December 31, 2012 and two customers represented 14% and 13% of accounts receivable at December 31, 2011. To reduce risk, we routinely assess the financial strength of our customers and closely monitor their amounts due and, as a result of our assessment, believe that our accounts receivable credit risk exposure is limited. Historically, we have not experienced any significant credit losses related to an individual customer or group of customers in any particular market or geographic area. We maintain an allowance for doubtful accounts based on an analysis of historical losses from uncollectible accounts, aging of unpaid accounts receivable balances and risks identified for specific customers who may not be able to make required payments. Provisions for the allowance for doubtful accounts are recorded in general and administrative expenses in the accompanying consolidated statements of comprehensive loss.

Activity related to allowance for doubtful accounts consisted of the following (in thousands):

Year Ended	Balance at Beginning of Year	Provision (Recoveries)	Write-offs	Balance at End of Year
December 31, 2012	$ 510	$	$ (86)	$ 424
December 31, 2011	$ 601	$	$ (91)	$ 510
December 31, 2010	$ 725	$ (86)	$ (38)	$ 601

We use and are dependent upon a number of single source suppliers of raw materials, components, finished goods and sterilization services. We are dependent on the ability of our suppliers to provide products on a timely basis and on favorable pricing terms. The loss of certain principal suppliers or a significant reduction in product availability from principal suppliers would have a material adverse effect on us, at least in the near term. We believe that our relationships with our suppliers are satisfactory.

Fair Value Measures

Certain financial and non financial assets and liabilities recorded at fair value have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standard. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves for similar instruments and model-derived valuations whose inputs are observable. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

Derivative Instruments and Hedging

Derivative instruments, namely our foreign exchange forward contracts, are recognized on the balance sheet at fair value at the balance sheet date. Changes in the fair value of derivatives that are designated and highly effective as cash flow hedges are recorded either in cost of revenues or deferred in accumulated other comprehensive income (loss) and subsequently recognized in cost of revenues in the same period the hedged items are recognized. The ineffective portion of derivative instruments designated as cash flow hedges, are recorded in other income (expense), net. If the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, the gains and losses on the related derivative instrument are recognized in earnings and any related gains and losses recorded in other comprehensive income (loss) are reclassified into earnings.

Inventory

Inventory is stated at the lower of cost, determined using the first-in first-out method (FIFO), or market (net realizable value). We record a provision for any excess or obsolete inventory when warranted based on remaining shelf-life and estimated forecast of product demand. We also review our inventory value to determine if it reflects the lower of cost or market based on factors such as inventory items sold at negative gross margins and purchase commitments.

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Property and Equipment and Field Equipment

Property and equipment and field equipment are recorded at cost less accumulated depreciation. Depreciation is provided over the estimated useful lives of the related assets using the straight-line method for financial statement purposes. The estimated useful life of our assets are periodically reviewed for reasonableness. Changes in useful lives are accounted for prospectively. Repairs and maintenance are expensed as incurred. When property and equipment are retired, sold or otherwise disposed of, the asset s carrying amount and related accumulated depreciation are removed from the accounts and any gain or loss is included in operations. When field equipment is sold, the asset s carrying amount and related accumulated depreciation is removed from the accounts and any gain or loss is deferred and recognized in operations on a straight-line basis over the same period as the related revenues or included in operations.

We capitalize certain costs, including internal payroll and external direct project costs, incurred in connection with developing or obtaining software designated for internal use. These costs are included in property and equipment and are amortized over the estimated useful lives of the related software.

Construction-in-process is stated at cost, which includes the cost of construction and other direct costs attributable to the construction. No provision for depreciation is made on construction-in-process until such time as the relevant assets are completed and put into use. Construction-in-process at December 31, 2012 and 2011 primarily represents the costs of building, machinery and equipment under installation.

Field equipment consists of equipment being utilized under disposable-based rental agreements as well as service pool equipment. Service pool equipment is equipment owned and maintained by us that are swapped for equipment that need repairs or maintenance by us while being rented or owned by a customer. We record a provision for any excess, lost or damaged equipment when warranted based on an assessment of the equipment in the service pool. Write-downs for equipment are included in distribution expenses.

The estimated useful lives of property and equipment and field equipment are as follows:

	Estimated Useful Life
Buildings	30 years
Manufacturing equipment and tooling	3 to 12 years
Leasehold improvements	Lesser of the lease term (including any renewal periods if appropriate) or estimated useful life of the asset
Computer and office equipment	3 to 5 years
Molds	5 to 7 years
Furniture	5 to 7 years
Field equipment	5 to 7 years

Intangibles and Other Long Lived Assets

Intangible assets are carried at cost less accumulated amortization. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets, ranging from eight to fourteen years. Long-lived assets, including intangible assets, are tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. The amount of impairment, if any, is measured based on fair value, which is determined using estimated discounted cash flows to be generated from such assets or group of assets. During 2012, 2011 and 2010, no such impairment was recognized. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

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Goodwill

We test goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the goodwill might be impaired. This impairment test is performed annually during the fourth quarter. This test includes first a qualitative assessment and then, if necessary, a quantitative assessment to determine if the fair value of a reporting unit is less than its carrying amount. Factors considered in the qualitative assessment include, but are not limited to, both macroeconomic conditions and entity-specific conditions. For the quantitative assessment the reporting unit s fair value is estimated using a discounted cash flow or other fair value measurement. Our reporting units are our System One and In-center operating segments. When testing goodwill for impairment we primarily look to the fair value of the System One segment, as substantially all of the goodwill was allocated to the System One segment. During 2012 and 2011 we utilized the qualitative assessment and concluded, in both years, that it is more likely than not that the fair value of our reporting units is greater than their carrying value. In 2010 we utilized the quantitative assessment, as required pursuant to the GAAP in effect at that time and no such impairment was indicated.

Stock-Based Compensation

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award. We use the Black-Scholes option pricing model to estimate the fair value of stock options and quoted market prices of our common stock to estimate fair value of restricted stock. Historically, we used the simplified method, as defined in Staff Accounting Bulletin No. 107, to estimate the expected term. We now believe we have sufficient internal historical data to refine the expected term assumption. As such, beginning in March 2011, the expected term is estimated based on the contractual term of each grant and takes into account the historical experience and relevant factors concerning expected exercise and termination behavior of participants. The risk free interest rate for each grant is equal to the U.S. Treasury rate in effect at the time of grant for instruments with an expected life similar to the expected term. Historically, because of our limited trading history as a public company, the stock volatility assumption was based on an analysis of our historical volatility and the volatility of the common stock of comparable companies in the medical device and technology industries. Beginning in March 2011, the stock volatility assumption is based solely on our historical volatility as we now believe that is more indicative of the option grant s expected volatility in the future. The dividend yield of zero is based upon the fact that we have not historically granted cash dividends, and do not expect to issue dividends in the foreseeable future.

We recognize stock-based compensation expense over the requisite service period, which generally equals the vesting period, net of forfeitures. Forfeiture rates are estimated based on historical pre-vesting forfeiture history and are updated on a quarterly basis to reflect actual forfeitures of unvested awards and other known events. For awards that vest based on employment, we recognize the associated compensation expense on a straight-line basis. For performance based awards, we recognize expense using the graded vesting methodology based on the number of shares expected to vest. Compensation expense associated with these performance based awards is adjusted quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date the results are determined.

Warranty Costs

We accrue estimated costs that we may incur under our product warranty programs at the time the product revenue is recognized, based on contractual rights and historical experience. Warranty expense is included in cost of revenues in the consolidated statements of comprehensive loss. The following is a rollforward of our warranty accrual (in thousands):

Year Ended	Balance at Beginning of Year	Provision	Usage	Balance at End of Year
December 31, 2012	$ 380	$ 540	$ (596)	$ 324
December 31, 2011	$ 268	$ 695	$ (583)	$ 380
December 31, 2010	$ 205	$ 452	$ (389)	$ 268

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Distribution Expenses

Distribution expenses are charged to operations as incurred and consist of costs incurred in shipping product to and from customers and the cost of any equipment lost or damaged in the distribution process. Shipping and handling costs billed to customers are included in revenues.

Research and Development Costs

Research and development costs are charged to operations as incurred.

Income Taxes

We record the tax effect of transactions when such transactions are recorded in our consolidated statement of comprehensive loss. We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates. Our provision for income taxes represents the amount of taxes currently payable, if any, plus the change in the amount of net deferred tax assets or liabilities. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis.

We periodically assess our exposures related to our provisions for income taxes and accrue for contingencies that may result in potential tax obligations. For those positions where it is more likely than not that a tax benefit will be sustained, we record the largest amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the financial statements. We recognize interest and penalties for uncertain tax positions in income tax expense.

We conduct business globally and file income tax returns in the U.S. federal jurisdiction, various states and foreign jurisdictions. We have accumulated significant losses since our inception in 1998. Utilization of the net operating losses may be subject to limitations and certain tax years in the respective tax jurisdictions remain open to examination.

Subsequent Events

Events occurring subsequent to December 31, 2012 have been evaluated for potential recognition or disclosure in the consolidated financial statements.

Recent Accounting Pronouncements

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity and, instead, requires presentation of total comprehensive income, which includes the components of net income, and the components of other comprehensive income, either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance is required to be applied retrospectively. We have chosen to disclose comprehensive loss, which consists of the components of net loss and other comprehensive income (loss), as part of one continuous statement, referred to as the Consolidated Statement of Comprehensive Loss. Other than a change in presentation, the implementation of this guidance did not impact our financial statements.

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3. Inventory

Inventory includes material, labor and overhead. The components of inventory are as follows (in thousands):

	December 31,	
	2012	2011
Purchased components	$ 16,322	$ 12,532
Work in process	8,390	9,109
Finished goods	8,792	11,134
	$ 33,504	$ 32,775

4. Property and Equipment, Field Equipment and Deferred Cost of Revenues

Property and Equipment, net

The components of property and equipment, net are as follows (in thousands):

	December 31,	
	2012	2011
Manufacturing equipment and tooling	$ 22,305	$ 12,599
Leasehold improvements	8,566	4,089
Computer and office equipment	2,942	2,021
Molds	3,698	2,312
Furniture	1,421	248
Buildings	7,621	
Land	1,207	
Construction-in-process	5,889	11,414
	53,649	32,683
Less accumulated depreciation	(17,329)	(15,084)
Property and equipment, net	$ 36,320	$ 17,599

Depreciation expense, including amortization of capital leases, for property and equipment was $3.7 million, $3.4 million and $3.3 million during 2012, 2011 and 2010, respectively. Included in construction-in-process is $2.2 million and $0.4 million of capitalized computer development costs at December 31, 2012 and 2011, respectively.

Our property and equipment includes the following amounts for assets subject to capital leases (amounts in thousands):

	December 31, 2012
Manufacturing facility in Germany	$ 16,324
Other assets subject to capital leases	1,616
Less accumulated depreciation	(176)
Assets subject to capital leases, net	$ 17,764

Manufacturing Facility in Germany

Pursuant to our Dialyzer Production Agreement entered into in May 2009 with Asahi we agreed to oversee construction of a new manufacturing facility in Germany. Asahi funded construction costs of the facility,

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including land, building and equipment; however, given our involvement during construction we were considered the owner of the facility for accounting purposes and therefore, as required, we recorded the cost of the new facility within property and equipment on our consolidated balance sheet along with a corresponding liability within other long-term liabilities for the construction cost funded by Asahi.

Pursuant to the Dialyzer Production Agreement, we agreed to operate the facility and manufacture dialyzers for our own use and for sale to Asahi under a manufacturing agreement during the initial term of the agreement through June 2021 and thereafter, unless either party provides notice of its intent not to renew. Asahi agreed to pay us cost including material, labor and overhead (but excluding depreciation on the new facility), plus applicable statutory value added or turnover tax established or required by law for each dialyzer manufactured by us for Asahi. We are required to pay Asahi a fixed amount per dialyzer manufactured for our own use in the facility, with such payments capped at fifty percent of the cost of the facility paid by Asahi. If the agreement is terminated subsequent to completion of construction by us, Asahi has the option to require us to purchase the facility from them or if the agreement is terminated by Asahi, we have the option to purchase the facility from them. In either case the purchase price is equal to one hundred percent of the then net book value of the facility, as calculated in accordance with GAAP.

In December 2012 construction of the facility was completed, at which time the asset was placed in service at a total cost of $16.3 million. Given our continued involvement in the facility, we were precluded from derecognizing the cost of the facility or the corresponding liability. Therefore, the facility asset, including building and equipment, will continue to be recorded within property and equipment, net on our consolidated balance sheet and will be depreciated on a straight-line basis over its estimated useful life. The corresponding liability has been divided into two separate components, a capital lease obligation and deferred revenue, based on their relative fair values of $10.1 million and $6.2 million, respectively.

The fair value of the capital lease obligation was determined based on the present value of the financing payments due plus the residual value guarantee. The key assumptions used to determine the fair value of this liability included our incremental borrowing rate, the fixed amount per dialyzer payment due to Asahi totaling fifty percent of the cost of the facility paid by Asahi, and the estimated residual value of the facility assets at the end of the estimated lease term all of which we determined to be Level 3 inputs within the fair value hierarchy. The capital lease obligation has been classified with other long-term liabilities within our consolidated balances sheet with the amount expected to be paid within one year classified within other current liabilities. The capital lease obligation will be decreased by payments made to Asahi for dialyzers manufactured for our own use and increased by interest expense.

The fair value of the deferred revenue was determined using a cost plus a reasonable margin for contract manufacturing in Germany, Level 3 inputs within the fair value hierarchy. The deferred revenue will be recognized in revenues on a straight-line basis over the expected term of if Dialyzer Production Agreement.

Field Equipment, net

The components of field equipment, net are as follows (in thousands):

	December 31,	
	2012	**2011**
Field equipment	$ 43,891	$ 45,040
Less accumulated depreciation	(33,790)	(32,858)
Field equipment, net	$ 10,101	$ 12,182

Depreciation expense for field equipment, which is recorded in costs of revenues in the consolidated statements of comprehensive loss, was $3.7 million, $5.4 million and $8.1 million during 2012, 2011 and 2010, respectively.

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Deferred Costs of Revenues

Amortization expense of direct costs relating to deferred equipment revenues was $13.5 million, $11.5 million and $8.1 million during 2012, 2011 and 2010, respectively.

5. Intangible Assets

The components of intangible assets, net are as follows (in thousands):

	December 31, 2012		December 31, 2011		Estimated Useful Life
	Cost	Accumulated Amortization	Cost	Accumulated Amortization	
Bloodline, needle and other patented and unpatented technology	$ 6,200	$ (4,069)	$ 6,200	$ (3,294)	8 years
Trade names	2,300	(862)	2,300	(698)	14 years
Customer relationships	26,000	(9,750)	26,000	(7,893)	14 years
Intangible assets, net	$ 34,500	$ (14,681)	$ 34,500	$ (11,885)	

We recognized amortization expense of $2.8 million during each of 2012, 2011 and 2010.

The estimated future aggregated amortization expense for intangible assets as of December 31, 2012 is as follows (in thousands):

2013	$ 2,796
2014	2,796
2015	2,603
2016	2,021
2017	2,021
Thereafter	7,582
	$ 19,819

6. Net Loss per Share

Basic net loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period. The computation of diluted loss per share is similar to basic loss per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potentially dilutive common stock equivalents had been issued.

The following potentially dilutive common stock equivalents, as calculated using the treasury stock method, were not included in the computation of diluted net loss per share as their effect would have been anti-dilutive due to the net loss incurred (in thousands):

Years Ended December 31,		
2012	2011	2010

Options to purchase common stock	1,602	3,057	3,072
Unvested restricted stock	196	382	913
Warrants to purchase common stock	921	1,053	989
Total	2,719	4,492	4,974

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7. Accrued Expenses

The components of accrued expenses are as follows (in thousands):

	December 31, 2012	2011
Payroll, compensation and related benefits	$ 8,320	$ 6,288
Distribution expenses	3,175	1,738
General and administrative expenses	2,337	2,062
Accrued taxes	2,475	1,570
Other	4,093	3,507
Total	$ 20,400	$ 15,165

8. Debt and Capital Lease Obligations

Term Loan and Security Agreement with Asahi

Our debt obligation outstanding at December 31, 2011 of $44.5 million, gross of a $1.3 million discount, related to the principal and deferred interest outstanding under our term loan and security agreement with Asahi entered into in June 2009. The obligation included a $40.0 million term loan, payable in one balloon payment at maturity, and bore interest at a rate of 8% per annum payable in arrears on November 1st and May 1st, with fifty percent of such interest deferred until the maturity date in May 2013. The term loan could be prepaid, without penalty, at our option. The borrowings under the term loan and security agreement were recorded at their estimated fair value at issuance, net of a $3.7 million discount. The discount was recorded to interest expense over the expected term of the agreement, through May 2013.

In May 2012, we repaid in full all principal and interest in the aggregate amount of $45.2 million under our term loan and security agreement with Asahi through the issuance of 2,456,246 shares of our common stock, which after the retention by us of 28,351 shares for the payment of certain minimum withholding taxes, resulted in a net issuance to Asahi of 2,427,895 shares. As a result, the term loan and security agreement was terminated. The extinguishment of this debt gave rise to early recognition of approximately $1.0 million of unamortized debt discount which was recorded as additional interest expense during 2012.

Loan and Security Agreement with SVB

We have a loan and security agreement with SVB that provides for a $15.0 million revolving line of credit. This agreement, as amended, has a maturity date of March 31, 2014 and borrowings under the agreement, as amended, bear interest at a rate of prime with a floor of 3.25%. The agreement, as amended, is secured by all or substantially all of our assets, includes certain financial covenants relating to liquidity requirements and adjusted EBITDA, and contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. At December 31, 2012, we were in compliance with the covenants, and there were no outstanding borrowings against the credit commitment.

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Capital Lease Obligations

Our capital lease obligations consist of certain property and equipment financed through capital leases and our capital lease obligation due to Asahi related to manufacturing facility in Germany. Approximate future minimum payments under our capital leases as of December 31, 2012 are as follows (in thousands):

2013	$ 1,345
2014	1,352
2015	1,305
2016	1,308
2017	1,004
Thereafter(1)	9,044
Total minimum lease payments	15,358
Less: Amount representing interest	(3,802)
Present value of future minimum lease payments	$ 11,556

(1) Amount includes $5.8 million representing the estimated residual value of the manufacturing facility in Germany at the end of the estimated lease term, which only becomes due and payable at Asahi s option if the agreement between us and Asahi is terminated by us.

9. Business Segment and Geographic Information

The results of our operations are included in two separately reportable segments, System One and In-Center. The results of our international business have been aggregated into the System One reportable segment. Other business activities relates primarily to the manufacturing of dialyzers for sale to Asahi, certain business development activities, including our early work on establishing centers of excellence which are dialysis clinics focused on the provision of home therapies, including home hemodialysis, and certain corporate expenses, specifically research and development and general and administrative expenses, which are excluded from the segment operating performance measures.

The accounting policies of the reportable segments are the same as those described in Note 2. The profitability measure employed by us and our chief operating decision maker, or CODM, for making decisions about allocating resources to segments and assessing segment performance is segment profit (loss), which consists of revenues less cost of revenues, selling and marketing and distribution expenses.

Within the System One segment, we derive revenues from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients within a homelike setting, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. Within the System One segment, we sell a similar technology platform of the System One with different features to the home and critical care markets. Some of our largest customers in the home market provide outsourced renal dialysis services to some of our customers in the critical care market. Sales of product to both markets are made primarily through dedicated sales forces and distributed directly to the customer, or the patient, with certain products sold through distributors internationally.

Within the In-Center segment, we sell blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers and needles for apheresis. Nearly all In-Center products are sold through national distributors.

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Our reportable segments consist of the following (in thousands):

	System One	In-Center	Other	Total
Year Ended December 31, 2012				
Revenues from external customers	$ 163,129	$ 76,927	$ 2,076	$ 242,132
Segment profit (loss)	24,349	11,051	(46,606)	(11,206)
Depreciation and amortization	18,245	1,461	3,967	23,673
Segment assets	80,041	20,582	211,326	311,949
Year Ended December 31, 2011				
Revenues from external customers	$ 143,480	$ 73,776	$	$ 217,256
Segment profit (loss)	14,336	8,522	(38,359)	(15,501)
Depreciation and amortization	18,277	1,255	3,555	23,087
Segment assets	84,732	17,165	189,811	291,708
Year Ended December 31, 2010				
Revenues from external customers	$ 113,855	$ 65,363	$	$ 179,218
Segment profit (loss)	283	8,927	(35,674)	(26,464)
Depreciation and amortization	17,563	1,303	3,513	22,379
Segment assets	86,469	16,329	183,296	286,094

Substantially all of our revenues are derived from the sale of the System One and related products, which cannot be used with any other dialysis system, and from needles and blood tubing sets to customers located in the U.S.

The following table summarizes the number of customers who individually make up greater than ten percent of total revenues:

	Years Ended December 31,		
	2012	2011	2010
Customer A	21%	21%	22%
Customer B	11%	13%	16%
Customer C	12%	13%	13%
Customer D	11%	9%	6%

Sales to Customer A and D are nearly all in the System One segment and sales to Customer B and C are to significant distributors in the In-Center segment. A portion of Customer B s sales of our products are to Customer A. All of Customer C s sales of our products are to Customer A.

The following table presents a reconciliation of the total segment assets to total assets (in thousands):

	December 31,	
	2012	2011
Total segment assets	$ 100,623	$ 101,897
Corporate assets:		
Cash and cash equivalents	106,439	102,909
Property and equipment, net	36,320	17,599
Intangible assets, net	19,819	22,615
Goodwill	42,421	42,698
Prepaid and other assets	6,327	3,990
Total assets	$ 311,949	$ 291,708

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Long-lived tangible assets consist of property and equipment, net and field equipment, net. The following table presents total long-lived tangible assets by geographic area (in thousands):

	December 31,		
	2012	2011	2010
United States	$ 20,967	$ 15,302	$ 16,796
Europe	21,505	13,138	4,536
Mexico	3,949	1,341	618
	$ 46,421	$ 29,781	$ 21,950

10. Commitments and Contingencies

Purchase Commitments

We enter into arrangements to purchase inventory requiring minimum purchase commitments in the ordinary course of business.

We purchase all of our needles from Kawasumi under an agreement which expires in February 2017 and includes provisions requiring us to purchase certain annual minimum quantities of needles.

In January 2007, we entered into a long-term supply agreement with Membrana, pursuant to which Membrana has agreed to supply, on an exclusive basis, capillary membranes for use in the filters used with the System One for ten years. In exchange for Membrana s agreement to pricing reductions based on volumes ordered, we have agreed to purchase a base amount of membranes per year from Membrana. The agreement may be terminated by either party upon a material breach, generally following a 45-day cure period, or upon the insolvency of the other party.

Operating Leases

We maintain our corporate headquarters in Lawrence, Massachusetts and maintain our manufacturing operations in Mexico, Germany, and Italy. Our corporate headquarters lease has an initial term of eleven years through mid-2023 with an early termination provision after seven years, subject to certain terms and conditions, with two, five year options to extend beyond the initial term on substantially the same terms and at rent equal to ninety-five percent of the then fair market value. The lease agreement for our headquarters included a tenant improvement allowance paid by the landlord of $4.3 million, which has been recorded as both a leasehold improvement and a deferred rent obligation. Our leased manufacturing facilities are subject to lease agreements with termination dates beginning in December 2013. Our lease agreements contain certain provisions that require us to pay executory costs such as real estate taxes, operating expenses and common utilities. The total amount of rental payments due over the lease term is being charged to rent expense on the straight-line method over the term of the lease. Rent expense was $2.2 million during 2012, $1.8 million during 2011 and $1.7 million during 2010.

The future minimum rental payments as of December 31, 2012 under our operating leases are as follows (in thousands):

2013	$ 2,461
2014	2,554
2015	2,783
2016	2,822
2017	2,815
Thereafter	12,403
	$ 25,838

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Contingencies

A civil complaint was filed against us on February 28, 2012 in the U.S. District Court for the District of Massachusetts by Gambro Renal Products, Inc., or Gambro (Case No. 1:12cv10370-PBS). The complaint alleges that we violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Massachusetts General Laws Chapter 93A by making false and misleading statements about our and Gambro s allegedly competing products in the critical care market in commercial and promotional activities. The complaint also alleges that we wrongfully interfered with contractual and advantageous relationships of Gambro in its critical care business. Gambro seeks compensatory and treble damages, disgorgement of profits and injunctive relief. We believe the suit is without merit and intend to defend the Company vigorously. At this time we do not believe a loss is probable and we are not able to estimate a range of possible loss.

11. Income Taxes

The following is a summary of income (loss) before income taxes by geography (in thousands):

	Years Ended December 31,		
	2012	2011	2010
U.S.	$ (16,026)	$ (23,074)	$ (32,845)
Foreign	1,906	2,571	1,901
Total	$ (14,120)	$ (20,503)	$ (30,944)

The components of the provision (benefit) for income taxes are as follows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Current:			
U.S. - State	$ 52	$	$
Foreign	1,357	899	768
Total Current	1,409	899	768
Deferred:			
Foreign	(376)		
Total Deferred	(376)		
Total Provision	$ 1,033	$ 899	$ 768

The provision for income taxes of $1.0 million, $0.9 million and $0.8 million during 2012, 2011 and 2010, respectively, relates to the profitable operations of certain foreign entities. The benefit for income taxes during 2012 relates to a reduction in the valuation allowance of certain foreign entities.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate is as follows:

	Years Ended December 31,		
	2012	2011	2010
Federal statutory rate	34.0%	34.0%	34.0%

Stock compensation	(5.6)%	(1.3)%	9.2%
State income tax, net of federal tax benefit	2.0%	3.6%	5.3%
Valuation allowance	(31.4)%	(41.1)%	(53.0)%
Increase in tax reserves	(5.6)%		
Other, net	(0.7)%	0.4%	2.0%
Effective tax rate	(7.3)%	(4.4)%	(2.5)%

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The change in our effective tax rate from 2011 to 2012 was due primarily to an increase in reserves for uncertain tax positions partially offset by the favorable impact of the release of a valuation allowance on net international deferred tax assets.

Deferred income tax assets and liabilities reflect the tax effects of differences in the recognition of income and expense items for tax and financial reporting purposes. Deferred tax assets (liabilities), the majority of which are non-current, are made up of the following (in thousands):

	December 31,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	$ 103,856	$ 108,816
Tax credits	7,450	6,638
Capitalized research and development	3,984	5,185
Other	7,619	174
Total deferred tax assets	122,909	120,813
Deferred tax liabilities:		
Fixed assets	(329)	(1,805)
Intangible assets	(7,244)	(8,550)
Other		(63)
Total deferred tax liabilities	(7,573)	(10,418)
Net deferred tax assets before valuation allowance	115,336	110,395
Less Valuation allowance	(114,682)	(110,395)
Net deferred tax assets	$ 654	$

As of December 31, 2012, we had U.S. federal and state net operating loss carryforwards of approximately $330 million and $180 million, respectively, available to offset future taxable income. A portion of the federal net operating loss, $45 million, is attributable to excess tax deductions related to stock-based compensation. We will realize the benefit of these excess tax deductions through increases in shareholder s equity in future periods when and if the losses are utilized to reduce future tax payments. The federal and state net operating loss carryforwards will expire between 2013 and 2032 if not utilized. Utilization of the net operating loss carryforwards may be subject to annual limitations due to the ownership percentage change limitations provided by the Internal Revenue Code Section 382 and similar state provisions. In the event of a deemed change in control under Internal Revenue Code Section 382, an annual limitation imposed on the utilization of net operating losses may result in the expiration of all or a portion of the net operating loss carryforwards. We also had federal and state research and development credit carryforwards of $4.7 million and $2.3 million, respectively, which begin to expire in 2015 if not utilized. We also had foreign tax credits of approximately $1.2 million that will expire between 2018 and 2021 if not utilized.

During 2012, the deferred tax valuation allowance increased by approximately $4.3 million, primarily as the result of increases to stock-based compensation and intangibles, partially offset by the release of the foreign valuation allowances. A full valuation allowance has been recorded in the accompanying consolidated financial statements to offset our U.S. deferred tax assets because the future realizability of such assets is uncertain. In 2012, we have removed the valuation allowance on our net international deferred tax assets. We believe that the future realization of these assets is more likely than not given cumulative profitability and expected future tax profits in the foreign jurisdictions.

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The below table details the changes in unrecognized tax benefits, which if recognized would favorably impact our effective tax rate (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Balance at beginning of the year	$ 678	$ 450	$ 117
Tax positions taken for the current year	389	228	333
Balance at end of year	$ 1,067	$ 678	$ 450

We had gross unrecognized tax benefits of $1.5 million and $0.7 million, respectively, as of December 31, 2012 and 2011 that, if recognized, would result in a reduction of our effective tax rate. In 2013, it is reasonably possible that we will reduce the balance of our unrecognized tax benefits by $1.5 million due to the application of statute of limitations and settlements with taxing authorities, all of which would reduce our effective tax rate. We had interest and penalties of $0.4 million as of December 31, 2012.

Our current intention is to reinvest the total amount of our unremitted earnings, which have not been significant to date, in the local international jurisdiction or to repatriate the earnings only when tax-effective. As such, we have not provided for U.S. taxes on the unremitted earnings of our international subsidiaries. Upon repatriation of those earnings, in the form of dividends or otherwise, we would be subject to U.S. income taxes (subject to an adjustment for foreign tax credits) and withholding taxes payable to the various foreign countries. Determination of the amount of the unrecognized deferred U.S. income tax liability is not practical due to the complexity associated with this hypothetical calculation; however, unrecognized foreign tax credits would be available to reduce some portion of the U.S. liability.

12. Stock Plans and Stock-Based Compensation

Stock Incentive Plans

We maintain the 2005 Stock Incentive Plan, or the 2005 Plan, that governs awards to both employees and non-employees. The 2005 Plan replaced and superseded our 1999 Stock Option and Grant Plan, or the 1999 Plan, except that awards granted under the 1999 Plan remain in effect pursuant to their original terms. Pursuant to the 2005 Plan, each share award issued after May 28, 2009 other than options or stock appreciation rights will reduce the number of total shares available for grant by 1.23 shares for shares granted from May 28, 2009 through May 26, 2011 and 1.62 shares for shares granted thereafter. A total of 13.5 million shares have been authorized for grant under the 2005 Plan and, at December 31, 2012, 2.7 million shares remained available for future grant.

Unless otherwise specified by our Board of Directors or Compensation Committee of the Board, stock options issued to employees under the 2005 Plan expire seven years from the date of grant and generally vest over a period of four years. In general, all stock options issued under the 1999 Plan expire ten years from the date of grant and the majority of these awards granted under the 1999 Plan were exercisable upon the date of grant into restricted common stock, which vested over a period of four years. Stock option grants to directors expire five years from the date of grant and vest 100% on date of grant. We settle stock option exercises and restricted stock vesting with newly issued common shares.

We also maintain a performance based restricted stock plan, or the Performance Share Plan, in which we commit to grant shares of restricted stock to certain employees and executive officers based on the achievement of certain annual corporate financial performance metrics. The restricted stock, if awarded, vests over a requisite service period of three years. Further, we maintain a bonus plan, or Corporate Bonus Plan, for the benefit of our employees. Payout under the Corporate Bonus Plan is based on individual performance and the achievement of certain annual corporate financial performance metrics and is paid in shares of our common stock, or in cash, at the discretion of the Compensation Committee of the Board. The estimated payout under the Corporate Bonus

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Plan is recognized as compensation expense during the performance year and is classified as a liability, until settlement, on our consolidated balance sheet. The compensation expense associated with the Corporate Bonus Plans for the 2012, 2011 and 2010 performance years that has been or is expected to be paid in shares of our common stock has been classified as stock-based compensation expense.

Our 2005 Employee Stock Purchase Plan, or the 2005 Purchase Plan, authorized the issuance of up to 0.7 million shares of common stock to participating employees through a series of periodic offerings. Each six-month offering period begins in January and July. An employee becomes eligible to participate in the 2005 Purchase Plan once he or she has been employed for at least three months and is regularly employed for at least 20 hours per week for more than three months in a calendar year. The price at which employees can purchase common stock in an offering is 95 percent of the closing price of our common stock on the NASDAQ Global Select Market on the lower of the first or last day of the offering period, unless otherwise determined by the Board of Directors or Compensation Committee of the Board. As of December 31, 2012, 0.2 million shares were available for future issuance under the 2005 Purchase Plan.

Stock Options

A summary of the status of stock options granted under all of our plans at December 31, 2012, and changes during the year then ended, is as follows:

Stock Options	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (In thousands)	Average Remaining Contractual Life (In years)
Outstanding at beginning of year	5,290,509	$ 9.29		
Granted	463,098	$ 16.76		
Exercised	(913,066)	$ 6.95		
Forfeited or expired	(101,618)	$ 12.96		
Outstanding at end of year	4,738,923	$ 10.39	$ 13,817	3.17
Fully vested and exercisable	3,854,064	$ 9.33	$ 13,232	2.73
Fully vested, exercisable and expected to vest	4,653,888	$ 10.30	$ 13,761	3.14

The aggregate intrinsic value for stock options is calculated based on the market price of our common stock as of December 31, 2012, less the exercise price of the underlying awards, excluding out-of-the-money awards. The total fair value of options that vested during 2012, 2011 and 2010 was $5.1 million, $7.5 million and $6.6 million, respectively. The aggregate intrinsic value of options exercised during 2012, 2011 and 2010 was $8.8 million, $18.7 million and $21.7 million, respectively. The aggregate intrinsic value of options exercised is calculated based on the market price of our common stock on the exercise date, less the exercise price of underlying award.

The weighted-average fair value of options granted during 2012, 2011 and 2010 was $9.23, $11.23 and $5.84 per option, respectively. The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2012	2011	2010
Expected life (in years)	4.50	4.61 to 4.75	4.75
Risk-free interest rate	0.67% to 0.90%	1.35% to 2.16%	1.17% to 2.58%
Expected stock price volatility	70%	64% to 70%	64% to 65%
Expected dividend yield			

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Restricted Stock

The total fair value of restricted stock that vested was $3.7 million, $5.8 million and $1.8 million during 2012, 2011 and 2010, respectively. The weighted-average fair value of restricted stock granted during 2012, 2011 and 2010 was $16.89, $18.75 and $10.00 per unit, respectively. The following table summarizes the status of the unvested restricted stock:

	Shares	Weighted Average Grant-date Fair Value	Aggregate Intrinsic Value (In thousands)	Weighted Average Remaining Contractual Life (In years)
Unvested at December 31, 2011	590,760	$ 14.81		
Granted	449,678	$ 16.89		
Vested	(308,946)	$ 11.89		
Forfeited	(79,288)	$ 17.67		
Unvested at December 31, 2012	652,204	$ 17.22	$ 7,337	2.56

The aggregate intrinsic value for restricted stock is calculated based on the market price of our common stock as of December 31, 2012.

Employee Stock Purchase Plan

The weighted-average fair value of stock purchase rights granted as part of the 2005 Purchase Plan during 2012, 2011 and 2010 was $4.57, $6.12 and $2.72 per share, respectively. The fair value of the employees stock purchase rights was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2012	2011	2010
Expected life (in months)	6	6	6
Risk-free interest rate	0.06% to 0.15%	0.10% to 0.19%	0.20% to 0.22%
Expected stock price volatility	70%	64%	64%
Expected dividend yield			

There were 56,691, 38,777 and 61,387 shares issued under the 2005 Purchase Plan during 2012, 2011 and 2010, respectively, which resulted in share-based compensation expense of $0.2 million during each of 2012, 2011 and 2010.

Stock-based Compensation Expense

The following table presents stock-based compensation expense included in the consolidated statements of comprehensive loss (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Cost of revenues	$ 1,168	$ 1,881	$ 2,347
Selling and marketing	4,186	5,117	5,540
Research and development	1,372	1,230	2,222
General and administrative	4,677	4,865	5,242
Total stock-based compensation expense	$ 11,403	$ 13,093	$ 15,351

As of December 31, 2012, approximately $14 million of unrecognized stock compensation cost related to nonvested stock options and restricted stock (net of estimated forfeitures) is expected to be recognized over a weighted-average period of 2.9 years.

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Other Compensation Plans

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. These unfunded plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of $1.9 million and $1.6 million at December 31, 2012 and 2011, respectively, as other long-term liabilities for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2012, 2011 and 2010.

13. Employee Benefit Plan

We have a 401(k) retirement plan, or the 401(k) Plan, for the benefit of eligible employees, as defined. Each participant may elect to contribute up to 25% of his or her compensation to the 401(k) Plan each year, subject to certain IRS limitations. We contribute 100% of the first 3% of the employee s contribution and 50% of the next 2% of the employee s contribution. We contributed $1.3 million, $1.2 million and $1.0 million to the 401(k) Plan during 2012, 2011 and 2010, respectively.

14. Stockholders Equity

We received 32,310, 40,089 and 36,112 shares of common stock that were surrendered in payment for the exercise of stock options during 2012, 2011 and 2010, respectively. We received 115,730 and 288,992 shares during 2011 and 2010, respectively, that were surrendered by employees in payment for the minimum required withholding taxes associated with awards under our Corporate Bonus and Performance Share Plans. We received 28,351 shares of common stock during 2012 that were surrendered for the payment of certain minimum withholding taxes related to the repayment of our Term Loan and Security Agreement with Asahi.

In connection with our Amended and Restated National Service Provider Agreement with DaVita we issued to DaVita a warrant that may vest and become exercisable to purchase up to 5,500,000 shares of our common stock based upon the achievement of certain DaVita performance criteria through June 2013. At December 31, 2012, 3,575,000 shares are issuable under the warrant, subject to performance criteria which we do not expect DaVita to meet. The warrants have an exercise price of $14.22 per share, are non-transferable, must be exercised in cash and, if vested, expire during 2013.

In November 2010, we filed an automatic shelf registration statement on Form S-3, which will allow us to offer and sell, from time to time in one or more offerings of common or preferred stock, debt securities or warrants for the purchase of common or preferred stock as we deem prudent or necessary to raise capital at a later date. On November 23, 2010, we completed the sale of 3,680,000 shares of our common stock pursuant to an underwriting agreement with Canaccord Genuity at a price of $20.04 per share. We received proceeds of $73.4 million, net of related expenses.

In connection with the sale of our common stock in a private placement during 2008 we issued warrants to purchase 1,900,000 shares of our common stock. These warrants have an exercise price of $5.50 per share and contain a net share settlement feature. Additional provisions require us, in the event of a change of control, to pay promptly to the warrant holder an amount calculated by the Black-Scholes option pricing formula. Such payment is required to be in cash or shares in the same proportion that other stockholders receive in such change of control transaction. At December 31, 2012, 1,439,293 warrants are outstanding and expire on May 28, 2013 or August 1, 2013.

15. Derivative Instruments and Hedging

We operate a manufacturing and service facility in Mexico and we purchase materials and pay our employees at that facility in Pesos, and as such, we are potentially exposed to adverse as well as beneficial

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movements in foreign currency exchange rates. To minimize the impact of foreign currency exchange rate fluctuations on these Peso denominated expenses, during the first quarter of 2012 we instituted a foreign currency cash flow hedging program, and began entering into foreign exchange forward contracts. These contracts have a duration of up to twelve months and are designated as cash flow hedges. The counterparties to these foreign exchange forward contracts are creditworthy financial institutions; therefore, we do not consider the risk of counterparty nonperformance to be material. As of December 31, 2012, the notional amount of our outstanding contracts that are designated as cash flow hedges was $7.8 million. The fair value of these contracts at December 31, 2012 was an asset of $0.4 million recorded on the balance sheet in prepaid expenses and other current assets. Gains or losses related to hedge ineffectiveness recognized in earnings were not material during 2012. Given the short-term nature of our contracts any gains or losses recorded within accumulated other comprehensive income (loss) will be recognized in earnings within the next twelve months.

The following table presents the effect of these contracts designated as cash flow hedges on our consolidated financial statements (in thousands):

Year Ended December 31, 2012	Gain (Loss) Recognized in OCI (Effective Portion)	Gain (Loss) Reclassified from OCI into Income (Effective Portion)	Classification within the Condensed Consolidated Statement of Comprehensive Loss
Foreign exchange forward contracts	$ 498	$ 109	Cost of revenues

16. Fair Value Measurements

The following table presents assets and liabilities measured at fair value on a recurring basis and their level within the value hierarchy (in thousands):

December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Money market funds(1)	$ 84,778	$	$	$ 84,778
Foreign exchange forward contracts(2)		423		423
Liabilities				
Foreign exchange forward contracts(2)		2		2

(1) Money market funds are included within cash and cash equivalents.

(2) Foreign exchange forward contracts are included within prepaid expenses and other current assets or other current liabilities depending on the gain (loss) position.

We did not have any transfers between Level 1 and Level 2 or transfers in or out of Level 3 during 2012.

We measure the fair value of our foreign exchange forward contracts classified as derivative instruments using an income approach, based on prevailing market forward rates less the contract rate multiplied by the notional amount. The product of this calculation is then adjusted for counterparty risk.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, prepaid expenses and other current and non-current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

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17. Supplemental Cash Flow Information

The following additional information is provided with respect to the consolidated statements of cash flows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Supplemental Disclosures:			
Cash paid for interest	$ 1,457	$ 1,623	$ 1,628
Cash paid for taxes	586	587	365
Noncash Investing and Financing Activities:			
Transfers from inventory to field equipment	$ 12,172	$ 16,943	$ 20,567
Transfers from field equipment to deferred cost of revenues	10,360	12,586	21,185
Payment of Corporate Bonus in common stock	878	2,807	1,600
Market value of shares received in payment for exercise of stock options	513	758	642
Construction-in-process financed by construction liability	8,343	7,700	
Settlement of debt through the issuance of common stock	45,219		
Leasehold improvements paid by the landlord	4,300		
Property and equipment acquired under capital lease	1,615		
Increase in deferred revenues related to the new manufacturing facility in Germany	6,124		

18. Quarterly Financial Data

18. Quarterly Financial Data (Unaudited)

The following table sets forth selected quarterly information (unaudited) (in thousands, except per share data):

	Three Months Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Revenues	$ 56,951	$ 59,009	$ 61,152	$ 65,020
Gross profit	21,312	22,389	23,748	25,359
Net loss	(5,144)	(5,063)	(2,582)	(2,364)
Net loss per common share, basic and diluted	$ (0.09)	$ (0.09)	$ (0.04)	$ (0.04)
	Three Months Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
Revenues	$ 50,564	$ 53,768	$ 55,903	$ 57,021
Gross profit	18,033	18,865	19,540	21,170
Net loss	(6,010)	(5,550)	(5,278)	(4,564)
Net loss per common share, basic and diluted	$ (0.11)	$ (0.10)	$ (0.10)	$ (0.08)

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Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***
None.

Item 9A. ***Controls and Procedures***
Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2012, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to achieve their stated purpose.

No change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Report on Internal Control over Financial Reporting

We, as management of NxStage Medical, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to the rules and regulations of the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officer, or persons performing similar functions, and effected by the company s board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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Management has evaluated the effectiveness of its internal control over financial reporting as of December 31, 2012, based on the control criteria established in a report entitled Internal Control Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on such evaluation, we have concluded that NxStage s internal control over financial reporting is effective as of December 31, 2012.

The independent registered public accounting firm of Ernst & Young LLP, as auditors of NxStage s consolidated financial statements, has issued an attestation report on its assessment of NxStage s internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NxStage Medical, Inc.

We have audited NxStage Medical, Inc. and subsidiaries internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NxStage Medical, Inc. and subsidiaries management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A 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. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, NxStage Medical, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NxStage Medical, Inc. and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, changes in stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012, and our report dated February 28, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 28, 2013

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

PART III

We have included information about our executive officers in Part I of the report under the caption Executive Officers .

The information required by Part III, Items 10-14 of this report is incorporated by reference from our definitive proxy statement for our 2013 Annual Meeting of Stockholders. Such information will be contained in the sections of such proxy statement captioned Stock Ownership of Certain Beneficial Owners and Management, Proposal 1 Election of Directors, Corporate Governance, Information about Executive and Director Compensation, Certain Relationships and Related Transactions, and Other Matters Section 16(a) Beneficial Ownership Reporting Compliance.

Certain documents relating to the registrant s corporate governance, including the Code of Business Conduct and Ethics, which is applicable to the registrant s directors, officers and employees and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of the registrant s Board of Directors, are available on the registrant s website at http://www.nxstage.com.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) *Financial Statements*

The following consolidated financial statements are filed as part of this Annual Report under Item 8 Financial Statements and Supplementary Data :

(b) *Exhibits*

The exhibits listed in the Exhibit Index immediately preceding the exhibits are incorporated herein by reference and are filed as part of this Annual Report on Form 10-K.

(c) *Financial Statement Schedules*

None. No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are either not applicable or the required information has been included in the accompanying notes to the consolidated financial statements.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

NXSTAGE MEDICAL, INC.

By: /s/ Jeffrey H. Burbank
Jeffrey H. Burbank
President and Chief Executive Officer
February 28, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey H. Burbank Jeffrey H. Burbank	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2013
/s/ Robert S. Brown Robert S. Brown	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	February 28, 2013
/s/ Philippe O. Chambon Philippe O. Chambon, M.D., Ph.D.	Chairman of the Board of Directors	February 28, 2013
/s/ Robert G. Funari Robert G. Funari	Director	February 28, 2013
/s/ Daniel A. Giannini Daniel A. Giannini	Director	February 28, 2013
/s/ Earl R. Lewis Earl R. Lewis	Director	February 28, 2013
/s/ Craig W. Moore Craig W. Moore	Director	February 28, 2013

/s/ Reid S. Perper Reid S. Perper	Director	February 28, 2013
/s/ Barry M. Straube Barry M. Straube, M.D.	Director	February 28, 2013
/s/ Jean Mixer Jean Mixer	Director	February 28, 2013

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EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Restated Certificate of Incorporation	S-1/A	3.4	10/7/2005	333-126711
3.2	Amended and Restated By-Laws	S-1/A	3.5	10/7/2005	333-126711
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	10/7/2005	333-126711
4.2	Form of Securities Purchase Agreement, dated May 22, 2008 and a schedule of signatories thereto	8-K	4.1	5/23/2008	000-51567
4.3	Form of Warrant to Purchase Common Stock	8-K	4.2	5/23/2008	000-51567
10.1#	1999 Stock Option and Grant Plan, as amended	S-1/A	10.1	10/7/2005	333-126711
10.2#	Form of Incentive Stock Option Agreement under the 1999 Stock Option and Grant Plan, as amended	S-1/A	10.2	10/7/2005	333-126711
10.3#	Form of Nonstatutory Stock Option Agreement under the 1999 Stock Option and Grant Plan, as amended	S-1/A	10.3	10/7/2005	333-126711
10.4#	2005 Stock Incentive Plan, as amended by Amendment No. 1, together with Form of Incentive Stock Option Agreement, Form of Nonstatutory Stock Option Agreement and Form of Restricted Stock Agreement	10-Q	10.3	11/7/2007	000-51567
		S-1/A	10.22	10/20/2005	333-126711
		10-K	10.5	3/16/2007	000-51567
10.5#	2005 Employee Stock Purchase Plan, as amended by Amendment No. 1	10-K	10.5	3/7/2008	000-51567
10.6#	Employment Agreement dated October 19, 2005 between the Registrant and Jeffrey H. Burbank	S-1/A	10.12	10/20/2005	333-126711
10.7#	Employment Agreement dated October 18, 2005 between the Registrant and Joseph E. Turk, Jr.	S-1/A	10.15	10/20/2005	333-126711
10.8#	Employment Agreement dated October 18, 2005 between the Registrant and Winifred L. Swan	S-1/A	10.16	10/20/2005	333-126711
10.9#	Employment Agreement dated November 27, 2006 between Registrant and Robert S. Brown	10-K	10.1	3/16/2007	000-51567
10.10#	Form of Indemnification Agreement entered into between the Registrant and each of its Directors and Executive Officers	S-1/A	10.21	9/21/2005	333-126711
10.11#	Director Compensation Policy	10-Q	10.2	5/5/2006	000-51567
10.12	Standard Form Commercial Lease dated October 17, 2000 between the Registrant and Heritage Place, LLC, as amended by Modification to Standard Form Commercial Lease	S-1	10.1	7/19/2005	333-126711
10.13	Supply Agreement dated as of January 5, 2007 between the Registrant and Membrana GmbH	10-K	10.27	3/16/2007	000-51567

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Exhibit Number	Description	Incorporated by Reference to Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.14	First Amended and Restated National Service Provider Agreement dated as of July 22, 2010 between the Registrant and DaVita Inc.	10-Q	10.01	8/6/2010	000-51567
10.15	Extracorporeal Disposables Distribution Agreement, dated July 25, 2007, by and between Medisystems Corporation and Henry Schein	10-Q	10.40	11/7/2007	000-51567
10.16	Supply and Distribution Agreement, dated February 1, 2001 by and between Medisystems Corporation and Kawasumi Laboratories, Inc.	10-Q	10.60	11/7/2007	000-51567
10.17	Investors Rights Agreement dated June 30, 1999 between the Registrant and the Investors, as amended on January 24, 2000, May 24, 2001, April 15, 2003, August 18, 2004, December 23, 2004 and July 8, 2005	S-1	10.90	7/19/2005	333-126711
10.18	Needle Purchase Agreement, dated January 6, 2008, by and between the Registrant and DaVita Inc.	10-K	10.37	3/7/2008	000-51567
10.19	Shelter Agreement, dated March 21, 2007 by and among the Registrant, Entrada Partners and Entrada Group de Mexico, S. de R.L. de C.V.	10-Q	10.60	5/9/2007	000-51567
10.20	Supply and Distribution Agreement, dated May 6, 2008, by and between Medisystems Corporation and Kawasumi Laboratories, Inc.	10-Q	10.43	8/8/2008	000-51567
10.21	Supply Agreement, dated April 10, 2009, by and between the Registrant and Laboratorios PiSA	10-Q/A	10.45	10/19/2009	000-51567
10.22	Extracorporeal Disposables Distribution Agreement, dated June 15, 2009, by and between Medisystems Corporation and Gambro Renal Products, Inc.	10-Q	10.46	8/7/2009	000-51567
10.23	Amendment, dated as of March 10, 2010, to the Term Loan and Security Agreement, effective June 5, 2009, by and between the Registrant, EIR Medical, Inc., Medisystems Services Corporation, Medisystems Corporation, as Borrowers, and Asahi Kasei Kuraray Medical, Co., Ltd., as the Lender	10-Q	10.49	5/5/2010	000-51567
10.24	Technology and Trademark License Agreement effective June 15, 2009 by and between the Registrant and Asahi Kasei Kuraray Medical Co., Ltd.	10-Q	10.48	8/7/2009	000-51567
10.25	Loan and Security Agreement, dated March 10, 2010, by and among Silicon Valley Bank, as the Lender, and the Registrant, EIR Medical, Inc., Medisystems Corporation and Medisystems Services Corporation, as Borrowers	10-Q/A	10.48	7/22/2010	000-51567

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Exhibit Number	Description	Incorporated by Reference to Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.26	Warrant to Purchase Shares of Common Stock, dated July 22, 2010, issued to DaVita Inc.	10-Q	10.20	8/6/2010	000-51567
10.27	Registration Rights Agreement, dated July 22, 2010, between the Registrant and DaVita Inc.	10-Q	10.30	8/6/2010	000-51567
10.28	Amendment, dated March 29, 2011, to the Loan and Security Agreement, dated March 10, 2010, by and among Silicon Valley Bank, as the Lender, and the Registrant, EIR Medical, Inc., Medisystems Corporation and Medisystems Services Corporation, as Borrowers	10-Q	10.33	5/4/2011	000-51567
10.29	Lease, dated as of June 22, 2011 by and between Registrant and 350 Riverwalk, LLC	10-Q/A	10.33	10/7/2011	000-51567
10.30#	Amendment No. 3 to 2005 Stock Incentive Plan of NxStage Medical, Inc	10-Q	10.34	8/3/2011	000-51567
10.31	Amendment dated May 7, 2012, to the Loan and Security Agreement, dated March 10, 2010, as amended on March 29, 2011, by and among Silicon Valley Bank, as the Lender, and the Registrant, EIR Medical, Inc., Medisystems Corporation and Medisystems Services Corporation, as Borrowers	10-Q	10.35	5/8/2012	000-51567
10.32	Subscription, Sale and Purchase Agreement, dated as of May 4, 2012, by and between NxStage Medical, Inc. and Asahi Kasei Medical Co., Ltd.	10-Q	10.36	5/8/2012	000-51567
10.33	Registration Rights Agreement, dated as of May 4, 2012, by and between NxStage Medical, Inc. and Asahi Kasei Medical Co., Ltd.	10-Q	10.37	5/8/2012	000-51567
*10.34	Employment Agreement dated February 2, 2008 between Registrant and Thomas F. Shea				
*10.35	Employment Agreement dated August 2, 2012 between Registrant and Todd M. Snell				
*21.1	List of Subsidiaries				
*23.1	Consent of Ernst & Young LLP				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14a or 15d-14a, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14a or 15d-14a, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				

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Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
*32.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				
*101.INS	XBRL Instance Document				
*101.SCH	XBRL Taxonomy Extension Schema				
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase				
*101.LAB	XBRL Taxonomy Extension Label Linkbase				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase				

* Filed herewith.

Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement filed as an Exhibit to this report pursuant to 15(a) and 15(c) of Form 10-K.