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NxSTAGE®

2009 Annual Report

Dear Shareholder,

2009 was a pivotal year for NxStage®. Despite the challenging economic backdrop that persisted throughout much of 2009, NxStage continued to make progress in key areas. As a result, we improved both our financial and operating profile, and I believe we have entered 2010 a stronger and strategically positioned player in the renal care industry.

Consistent with our mission to improve the lives of people with kidney failure, we expanded patient and provider access to the clinical and quality of life benefits possible with our innovative products. Of equal importance, we strengthened our balance sheet, grew revenues, improved gross margins, narrowed our Adjusted EBITDA loss, and reduced cash usage. Our ability to drive predictable improvements underscores our underlying operating and financial strength.

During the year, we also expanded with partners including Asahi Kasei Kuraray Medical, B. Braun, Gambro, Kimal for distribution in the UK and Ireland, and, recently, Nordic Medcom for Scandinavia and Dirinco for the Netherlands. We look forward to expanding the opportunities for our products worldwide.

We made this progress by leveraging our technical innovation and executing against strategic initiatives to build and further expand our opportunities within the Home, Critical Care, and In-center markets.

I believe the gains we made in 2009 reinforce the following:

- First, they support our belief that we are building an economically successful and sustainable business. The strong operating leverage within our business is evident as we drive adoption in the Home market and grow a large recurring revenue base.
- Second, they highlight our ability to execute against operational objectives to deliver more predictable results.
- And lastly, they provide a good indication that we are on track to achieve our goals and increase value for all our stakeholders.

While we still have work to do, I remain confident that we are well positioned to deliver continued improvements and drive meaningful growth in 2010 and beyond.

The Home Market

Full-year revenues for the Home market increased 31% over 2008. This performance is a result of our execution against the four key drivers we have identified for market adoption: reimbursement, clinical data, our "Go Deep" market strategy, and product development. We made progress against each of these key initiatives in 2009. Highlights include:

Reimbursement: Within the context of discussions around health care reform and changes to reimbursement via the proposed CMS 'bundle' expected to be implemented in 2011, it is increasingly apparent that there is a tremendous opportunity for NxStage to deliver value to patients, providers, and payors through our efforts to provide significant clinical and quality of life benefits, lower mortality, and lower total cost of care. We will continue our work in this area with the goal of more predictable, appropriate, and simple reimbursement for more frequent home hemodialysis.

Clinical Data: Results from our landmark FREEDOM study demonstrated a nearly 50% reduction in the average number of prescribed anti-hypertensive medications over 12 months. We also showed that the number of patients able to completely discontinue anti-hypertensive medications doubled at 12 months. FREEDOM data also demonstrated a 40% reduction in expected mortality – even when including deaths 60 days after switching from our therapy – and improvements in both sleep quality and restless leg syndrome. Looking ahead, the interim FREEDOM economic data, which will analyze total cost of care, may highlight one of our strongest value propositions at a time when providers and payors are assessing costs within the "bundled" environment.

"Go Deep" Strategy: Our value proposition to dialysis centers continue to resonate as trends within "go deep" metrics strengthened throughout 2009:

- Centers with greater than 10 patients grew 31%;
- Centers with greater than 20 patients grew 71%; and
- Markets where we have greater than 5% penetration increased by 33%.

Our objective for 2010 is to grow our relationships with providers an further broaden access to NxStage's life-changing therapy.

Product: Our System One™ remains the only portable hemodialysi system cleared for use in the home. We expect to extend our many year technology lead over any potential competitors with produc evolution. In February 2010, we completed our nocturnal study an submitted the 510k application for expanded labeling for FDA reviev We'll continue to work to expand our indication and provide more clin cal proof in support of the System One to raise the competitive barrie to entry.

The Critical Care Market

Despite market conditions throughout 2009, we grew Critical Care rev enues by approximately 20% over 2008. While we remain cautious o the timing of machine sales to hospitals, we continue to grow our larg installed base and build a pipeline of opportunities. We believe that w continue to increase market share. In addition, our value propositio is well aligned with the needs of our critical care customers: simpl technology that reduces staff workload while delivering the therapie that clinicians require for their patients.

The In-center Market

The In-center market is a strategic business for NxStage as it prc vides scale and efficiency, contributing to overall corporate gross ma gins and cash flow. Throughout 2009, we improved our visibility t end- user demand by moving more customers to multi-year contract While revenues will continue to be susceptible to changes in orderin and delivery patterns, we believe that our innovative technology an product portfolio remain drivers for end-user demand.

In closing, I am pleased with the performance of the Company opera tionally, financially, and strategically. We have matured and improve over the year. We have a strong team, and I believe we are positione for growth and improved cash flow in 2010. Our financial prioritie for 2010 remain focused on driving continued quarter-on-quarter im provements in four key areas: revenue, gross margin, Adjusted EBI DA, and cash.

I am particularly pleased that, as we grow, we remain committed t clinical research and maintaining both our high levels of patient an customer support and our relentless focus on further improving th safety, ease of use, and value of all our products.

On behalf of NxStage, I extend my sincere thanks to you, our share holders, for your continued support.

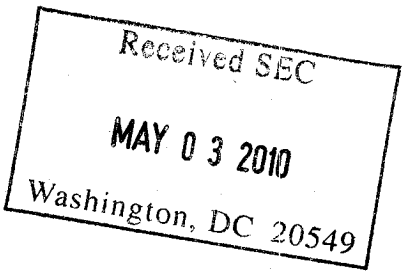
Sincerely,

Jeff Burbank, Founder
CEO and President

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K



Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2009

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 of Incorporation)	*(I.R.S. Employer Identification No.)*
439 S. Union St., 5th Floor, 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 ıct. Yes ☐ No ☑

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

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

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

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

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

arge accelerated filer ☐ 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 ct). Yes ☐ No ☑

The aggregate market value of common stock held by non-affiliates of the registrant was approximately $96.8 million, as of ıne 30, 2009, based on the last reported sale price of the registrant's common stock on the NASDAQ Global Market on June 30, 2009.

There were 47,278,328 shares of the registrant's common stock issued and outstanding as of the close of business on March 9,)10.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2010 Annual Meeting of Stockholders to be held on May 27, 010 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.

NXSTAGE MEDICAL, INC.

2009 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; the growth of the home, critical care and in-center dialysis markets in general and the home hemodialysis market in particular; the development and commercialization of our products; changes in the historical purchasing patterns and preferences of our major customers, including DaVita Inc.; the adequacy of our funding, our need for and our ability to obtain additional funding; the timing of when we might achieve improvements to our gross margins and operating expenses; 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, the scope of patent protection with respect to our products, expectations with respect to the clinical findings of our FREEDOM study, the impact of possible future changes to reimbursement for chronic dialysis treatments and the impact of current economic conditions on our business. 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 identify 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.

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, or "daily," dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared by the United States Food and Drug Administration, or FDA, for home hemodialysis as well as hospital and clinic-based dialysis. We also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of end-stage renal disease, or ESRD, which we refer to as the in-center market. We believe our largest future product market opportunity is for our System One used in the home hemodialysis market, or home market, for the treatment of ESRD.

ESRD, which affects over 500,000 people in the United States, 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 United States 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 there is an unmet need for a hemodialysis system that allows more frequent and easily administered therapy at home and have designed our system to address this and other kidney replacement markets.

Measuring 15x15x18 inches, 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 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. Given its compact size and lack of infrastructure requirements, the System One is portable, allowing patients freedom to travel. We believe these features provide patients and their physicians new treatment options for ESRD.

We market the System One to dialysis clinics for chronic hemodialysis treatment, providing clinics with improved access to a developing market, the home hemodialysis market, and the ability to expand their patient base by adding home-based patients without adding clinic infrastructure. The clinics in turn provide the System One to ESRD 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. Typically, our customers rent the System One equipment on a month to month basis, although a number of our customers have elected to purchase rather than rent System One equipment. DaVita Inc., or DaVita, our largest customer in the home market, purchases rather than rents a significant percentage of its System One equipment. Clinics

receive reimbursement from Medicare, private insurance and patients for dialysis treatments. We commenced marketing the System One for chronic hemodialysis treatment in September 2004.

We are not responsible for, and do not provide patient training. We provide training to dialysis clinic staff, who in turn, train home hemodialysis patients and their partners. Training takes place at the clinic primarily during the patient's prescribed, often daily, two to three hour treatment sessions. Patient training, which typically takes two to three weeks, includes basic instruction on ESRD, operation of the System One and insertion by the patient or their partner of needles into the patient's vascular access site. Clinics provide testing to patients and their partners at the conclusion of training to verify skills and an understanding of System One operation. Training sessions are presently reimbursed by Medicare, and there may be a co-payment requirement to the patient associated with this training.

Medicare reimburses the same amount per treatment for home and in-center hemodialysis treatments, up to three treatments per week. Payment for more than three treatments per week is available with appropriate medical justification. The adoption of our System One for more frequent therapy for ESRD would likely be slowed if Medicare is reluctant or refuses to pay for these additional treatments.

We also market the System One in the critical care market 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 United States each year. The System One provides an effective, simple-to-operate alternative to dialysis systems currently used in the hospital to treat these acute conditions. We commenced marketing the System One to the critical care market in February 2003.

In addition to the System One, we also sell a line of extracorporeal disposable products for use primarily in in-center dialysis treatments for patients with ESRD. These products, which we obtained in connection with our acquisition of Medisystems Corporation and certain affiliated entities, collectively the MDS Entities, include hemodialysis blood tubing sets, A.V. fistula needles and apheresis needles. The MDS Entities have been selling products to dialysis centers for the treatment of ESRD since 1981, and have achieved leading positions in the U.S. market for both hemodialysis blood tubing sets and AV fistula needles. Our blood tubing set products include the ReadySet High Performance Blood Tubing set, or ReadySet, and the Streamline Airless Blood Tubing set, or Streamline. ReadySet has been on the market since 1993. Streamline, our next generation 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 needle sets incorporating safety features, first introduced in 1995, including PointGuard Anti-Stick Needle Protectors and MasterGuard technology, and ButtonHole needle sets, first introduced in 2002.

We report the results of our operations in two segments: the System One segment and the In-Center segment. The business we acquired in connection with our acquisition of the MDS Entities constitutes the operations of the In-Center segment. This acquisition was not completed until October 1, 2007, and therefore, we did not realize In-Center segment revenues until the fourth quarter of 2007. 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 equipment and the sale of disposable products in the home and critical care markets. We define the home market as the market devoted to the treatment of ESRD patients in the home and the critical care market as the market 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 needles and blood tubing sets primarily used for in-center dialysis treatments.

For the year ended December 31, 2009, our revenues were $148.7 million and we incurred a net loss of $43.5 million. As of December 31, 2009, we had cash and cash equivalents of $21.7 million, total assets of $197.0 million, long term liabilities of $78.3 million and total stockholders' equity of $89.4 million.

Since inception, we have incurred losses every quarter, and at December 31, 2009, we had an accumulated deficit of approximately $276.7 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins 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. Our ability to become profitable depends principally upon implementing design and process improvements to lower the costs of manufacturing our products, obtaining better purchasing terms and prices, growing revenues, increasing reliability of our products, improving our field equipment utilization, achieving efficiencies in manufacturing and supply chain overhead costs, achieving efficiencies in the distribution of our products and achieving a sufficient scale of operations.

We have experienced negative operating margins and cash flows from operations and expect to continue to incur net losses in the foreseeable future. We believe, based on current projections, that we have the required resources to fund operating requirements through 2010 and beyond. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of complementary businesses, services or technologies.

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 439 South Union Street, Fifth Floor, 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.

Recent Events

On March 10, 2010, we entered into a Loan and Security Agreement, the Agreement, with Silicon Valley Bank, SVB, for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the Agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our Agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. We did not draw any amounts under the Agreement at closing, but may do so in the future to fund working capital and operating requirements.

In May 2009, we entered into a five year exclusive distribution agreement with Kimal plc, or Kimal, a distributor of medical device technology across the United Kingdom and international healthcare markets, for the promotion, sale, delivery and service of the System One and certain of our other products in the United Kingdom and Ireland. The agreement marked our first international expansion for the System One outside of the United States and Canada. Under the terms of the agreement, the System One and PureFlow SL dialysate preparation system will be available to dialysis centers and hospitals throughout the United Kingdom and Ireland exclusively through Kimal, which also has the option to make our blood tubing sets and needles available to their customers in these regions. Since signing this agreement with Kimal, we have continued to expand internationally, recently announcing a distribution agreement with Nordic Medcom AB for Sweden, Denmark and Finland and Dirinco in the Netherlands.

In June 2009, we entered into a five year distribution agreement with Gambro Renal Products, Inc., or Gambro, pursuant to which we agreed to supply blood tubing sets, including our ReadySet and the Streamline product lines, to Gambro. Gambro, in turn, agreed to exclusively supply the blood tubing sets to DaVita for use with specific dialysis machines, subject to certain conditions.

In May 2009, we entered into a series of agreements with Asahi Kasei Kuraray Medical Co., Ltd., or Asahi, a medical supply company headquartered in Japan. The agreements are multi-faceted and include a term loan and security agreement, or term loan, pursuant to which Asahi agreed to provide us with $40.0 million of debt financing. The term loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of our assets. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions. We used $30.0 million of the proceeds to pay off the entire debt obligation, including prepayment and other transaction fees, owed under our credit and security agreement with General Electric Capital Corporation. We intend to use the remaining proceeds for operating purposes.

Our Products and Services

We sell the System One in the home and critical care markets. Since our acquisition of the MDS Entities, which was completed on October 1, 2007, we also sell blood tubing sets, needles and other extracorporeal products for use primarily in hemodialysis therapy to the in-center market.

The System One

Our primary product, the NxStage System One, is a small, portable, easy-to-use hemodialysis system, which incorporates multiple design technologies and design features. Sales of the System One and related disposables accounted for approximately 58%, 52%, and 74% of our total sales for the years ended December 31, 2009, 2008 and 2007, 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, which we received FDA clearance for in March 2006 and made available to our customers beginning in July 2006. 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.

For the home hemodialysis market, the System One is designed to make home treatment and more frequent treatment easier and more practical. Although most studies have not been performed using our product, clinical studies suggest that therapy administered five to six times per week, commonly referred to as daily therapy, better mimics the natural functioning of the human kidney and can lead to improved clinical outcomes, including reduction in hypertension, improved anemia status, reduced reliance on pharmaceuticals, improved nutritional status, reduced hospitalizations and overall improvement in quality of life. Published literature also supports the clinical and quality of life benefits associated with home dialysis therapy.

For the critical care market, our System One is designed to offer clinicians an alternative that simplifies the delivery of acute kidney replacement therapy and makes longer or continuous critical care therapies easier to deliver. The ability of our system to perform hemofiltration and/or isolated ultrafiltration, for which the System One is also FDA cleared, is advantageous, as many clinicians choose to prescribe hemofiltration for patients with acute kidney failure.

ReadySet

The ReadySet High Performance Blood Tubing Set, which was introduced for use in hemodialysis in 1993, features a pump segment material designed to deliver reliable, accurate flows throughout the treatment. The blood tubing is designed to be easy to handle and to enable relatively fast priming, or removal of air from the dialysate solution. These technological advances are intended to optimize dose delivery. Sales of ReadySet accounted for approximately 19%, 24% and 14% of our total sales for the years ended December 31, 2009, 2008 and 2007, respectively.

Streamline

Our next generation blood tubing set product is Streamline. Streamline features an efficient and airless design intended to result in superior clinical and economic performance. It 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, thereby intended to facilitate a clinician's ability to satisfy Occupational Safety and Health Administration, or OSHA, anti-stick requirements.

AV Fistula and Apheresis Needles with MasterGuard Anti-Stick Needle Protectors

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. Sales of AV fistula and apheresis needles accounted for approximately 14%, 18% and 6% of our total sales for the years ended December 31, 2009, 2008 and 2007, respectively.

ButtonHole Needle Set

As an alternative to our AV fistula needles with MasterGuard, we also offer ButtonHole needles for hemodialysis therapies. 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 designed to reduce the risk of accidental needle sticks.

Medic

The Medic needle/connector device was engineered to help reduce the risk of accidental needle sticks, as required by OSHA. Medic can be used with any standard syringe, and is used in hemodialysis procedures with catheters, AV fistula needles, blood tubing sets and dialysis priming sets. For apheresis procedures, Medic is designed to easily access drug vials and blood collection tubes.

Competition

The dialysis therapy market is mature, consolidated and competitive. Our System One in the critical care market competes against Gambro AB, Fresenius Medical Care AG, Baxter Healthcare, B. Braun and others. Our System One in the home market is currently the only system specifically indicated for use in the home market in the United States. Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter Healthcare, 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 offers products that have been in use for a longer time than our System One, and in some instances many of our Medisystems products, 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.

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.

We presently have the only product specifically cleared for home hemodialysis therapy in the United States.

There is, however, presently an increasing interest in the home hemodialysis market from our key competitors. Baxter has announced a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it hopes to commence clinical studies of DEKA's new home hemodialysis system in 2010. We are unable to predict when, if ever, this product, or products from other companies, may attain regulatory clearance and enter the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it could adversely affect our sales and growth.

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. As with the home market, we believe we also compete favorably on the basis of clinical flexibility, given the System One's ability to perform hemofiltration, hemodialysis and ultrafiltration. However, the fact that we are not indicated for hemodiafiltration may be perceived by some clinicians as a disadvantage of our system over others. We believe we compete favorably in terms of cost-effectiveness for hospitals that perform continuous renal replacement therapies, or CRRT. For those hospitals that do not perform CRRT or other types of prolonged therapies, we compete unfavorably in terms of cost-effectiveness. We compete unfavorably in terms of sales force coverage and branding, because we have a smaller sales force than most of our competitors. In the fluid overload market, which is a very 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.

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 the MDS Entities have 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 us. We believe our ability to compete successfully will depend largely on our ability to:

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

- access the capital needed to support our business.

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.

Sales and Marketing

We sell our products in three markets: home, in-center, and critical care. Substantially all our revenue is generated from sales to external customers in the United States, with a small amount of revenues resulting from international sales through distributors. 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 to serve as clinical educators to support our sales efforts. Our marketing and 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. Henry Schein, Inc., or Henry Schein, is the primary distributor for our in-center market. In 2009, sales to DaVita and Henry Schein represented 22% and 28% of our total revenues, respectively, and nearly half of In-center segment sales in 2009 were derived from sales to DaVita. DaVita and Henry Schein are expected to remain significant customers of ours in 2010. No other single customer represented 10% or more of our revenues in 2009. In 2008, sales to DaVita and Henry Schein represented 18% and 39% of our total revenues, respectively, and half of Henry Schein's sales of our products in 2008 were derived from sales to DaVita. No other single customer represented 10% or more of our revenues in 2008. In 2007, sales to DaVita and Henry Schein represented 20% and 22% of our total revenues, respectively, and half of Henry Schein's sales of our products in 2007 were derived from sales to DaVita. No other single customer represented 10% or more of our revenues in 2007. Sales to DaVita are primarily in the System One segment and sales to Henry Schein are in the In-center segment.

Home

We rent or sell the System One to customers in the home market. In this market, our customers are independent dialysis clinics as well as dialysis clinics that are part of national or regional chains. Since 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.

Currently, there are nearly 5,000 Medicare-certified dialysis outpatient facilities in the United States. Ownership of these clinics is highly consolidated with DaVita and Fresenius each controlling approximately 30% of U.S. dialysis patients. Smaller chains and independent clinics and hospitals represent the approximately 40% of remaining clinics. Our customers include independent clinics as well as large and smaller chains.

DaVita is our largest customer in the home market. In February 2007, we entered into a national service provider agreement with DaVita that conferred to DaVita certain market rights for the System One and related supplies for home hemodialysis therapy. Under the agreement, DaVita was granted exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the United States ESRD patient population, and limited exclusivity in the majority of all other United States geographies, subject to DaVita's meeting certain requirements, including the achievement of certain patient numbers and training rates. The agreement further limited, but did not prohibit, the sale by NxStage of the System One for chronic home patient hemodialysis therapy to Fresenius. Per the agreement, DaVita no longer has any preferred geographic market or exclusivity rights, and as of December 31, 2009, the initial term of our national service provider agreement with DaVita expired. While we negotiate a new agreement with DaVita for the home market, we continue to restrict our activities in a limited subset of geographic markets where DaVita

previously held preferred market rights. However, we can provide no assurance that we will enter into a new agreement with DaVita or what the terms, including exclusivity provisions, of a new agreement with DaVita would be. Our national service provider agreement with DaVita contemplates ongoing sales of products following December 31, 2009. We expect that DaVita will continue to be our largest customer for the foreseeable future. The change in DaVita's exclusivity rights does give us the opportunity to expand in certain markets and with other providers, including Fresenius. We have a low, but growing, volume of sales to Fresenius of our System One in the home market, and have been able to expand at certain other providers, but we have no assurance that this will continue. It is too early to predict what effect the change in DaVita's exclusivity rights will have on our growth in the home market.

After renting or selling a System One to a clinic, our clinical educators generally train the clinic's nurses and dialysis technicians on the proper use of the system using proprietary training materials. We then rely on the trained technicians and nurses to train home patients, their partners and other technicians and nurses using the System One. This approach also allows the clinic and physician to select, train and support the dialysis patients that will use our system, much the same way as they manage their patients who are on home peritoneal dialysis therapy.

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.

Critical Care

We sell the System One to customers in the critical care market. The System One cycler is based on the same technology platform used in the home market, but includes an additional display module, called OneView, that is designed to facilitate easier medical record charting and troubleshooting. In the critical care market, because both acute kidney failure and fluid overload are typically treated in hospital intensive care units, our customers are hospitals. We are specifically focusing our sales efforts in the critical care market on those large institutions that we believe are most dedicated to increased and improved dialysis therapy for patients with acute kidney failure and believe in ultrafiltration as an earlier-stage treatment option for fluid overload associated with multiple diseases, including congestive heart failure, CHF.

After selling or placing a System One in a hospital, our clinical educators train the hospital's intensive care unit, or ICU, and acute dialysis nurses on the proper use of the system using 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 began promoting our System One product for use in the critical care market in February 2003.

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 chains. The majority of our sales in this market are made through distributors, in order to leverage national networks, shipping efficiencies and existing customer relationships. Our distribution agreement with Henry Schein, our primary distributor for the In-center segment, originally scheduled to expire in July 2009, has been extended on a non exclusive basis while the parties work to negotiate a new agreement.

DaVita is also a significant customer for our In-center segment products. DaVita contractually committed to purchase our needles through January 2013. Under our recently signed Gambro agreement, Gambro has contractually committed to exclusively supply our blood tubing sets in the United States to DaVita through July 2014. Gambro's long term product supply agreement with DaVita entered into in connection with the sale of Gambro's United States dialysis clinic business to DaVita, obligates DaVita to purchase a significant majority of its product requirements from Gambro.

We plan our manufacturing and distribution activities based on distributor purchase orders. Finished goods are shipped directly to distributor warehouses. Our customer and clinic services team markets the tubing sets

and/or blood access devices under the Medisystems brand name. To support blood tubing set and needle sales, our clinic services personnel regularly visit or call clinic operators.

International

Historically, nearly all of our product sales occurred in the United States, with limited sales experience in Canada. In 2009, we signed our first international distribution agreement for the sale of our System One outside of the United States and Canada. In May 2009, we entered into a five year exclusive distribution agreement with Kimal plc, or Kimal, a distributor of medical device technology across the United Kingdom and international healthcare markets, for the promotion, sale, delivery and service of the System One and certain of our other products in the United Kingdom and Ireland. Since signing this agreement with Kimal, we have continued to expand internationally, recently announcing a five year exclusive distribution agreement with Nordic Medcom AB for the promotion, sale, delivery and service of the System One and certain of our other products in Finland, Denmark and Sweden and a five year distribution agreement with Dirinco for the promotion, sale, delivery and service of the System One and certain of our other products in the Netherlands. Our experience selling internationally has been very limited to date, and international sales of our products were immaterial in 2009.

Customer Support Services

We primarily use a depot service model for equipment servicing and repair for the home market. If a device malfunctions and requires repair, we arrange for a replacement device to be shipped to the site of care, whether it is a patient's home, clinic or hospital, 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, clinic or hospital can quickly and easily set up the new machine. In addition, we ship monthly supplies via common carrier and courier services directly to home patients, dialysis clinics and hospitals.

In addition to depot service, the critical care market also demands field service calls for cycler servicing and repair. The nature of the hospital environment, coupled with the practices of other ICU dialysis equipment suppliers, frequently necessitates on-site support for our systems installed in this environment.

We maintain telephone service coverage 24-hours a day, seven days a week, to respond to technical questions raised by patients, clinics and hospitals concerning all of our products, including the System One, needles and blood tubing sets.

Clinical Experience and Results

Over 100 published articles have reported on the benefits of daily dialysis therapy. Although most of these publications were based on studies that did not use our product, the literature strongly supports that daily hemodialysis therapy can lead to improved clinical outcomes, including reduction in hypertension, improved anemia status, reduced reliance on pharmaceuticals, improved nutritional status, reduced hospitalizations and overall improvement in quality of life.

In late 2005, 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 benefits and cost savings 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, which will enroll up to 500 Medicare patients in up to 70 clinical centers. Enrollment is ongoing. The study will compare Medicare patients using the System One with a matched cohort of patients from the United States 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.

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 $70,000 annually, with dialysis services representing approximately 25% of this cost, while the cost of hospitalizations, drugs and physician fees make up nearly 60%. Studies indicate daily therapy may materially reduce overall Medicare costs for the care of chronic dialysis patients, particularly through reduced hospitalization and drug costs.

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 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, and a reduction in anti-hypertensive medications.

More recently, we announced FDA approval of an investigational device exemption, or IDE, study intended to support a home nocturnal indication for the System One, which started in the first quarter of 2008. We recently completed the IDE study and submitted the associated 510(k) to the FDA.

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 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-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. 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, 2009, 2008 and 2007, we incurred research and development expenses of $9.8 million, $8.9 million and $6.3 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 or have licensed rights to a number of patents, trademark, copyrights, trade secrets and other intellectual property directly related and important to our business both in the United States and abroad. We also have domestic and foreign pending patent applications.

As of December 31, 2009, we had 44 issued U.S. and international patents, 1 issued European Union, or EU, industrial design registration and 44 U.S., international and foreign pending patent applications.

Patent No.	Regime	Description	Issued	Expiration Date
6,254,567	US	Flow-Through Peritoneal Dialyzer System and Methods with on-line Dialysis Solution Regeneration	7/3/2001	2/26/2019
6,554,789	US	Layered Fluid Circuit Assemblies and Methods for Making Them	4/29/2003	2/14/2017
6,572,641	US	Devices for Warming Fluid and Methods of use	6/3/2003	4/9/2021
6,572,576	US	Method and ApparatUS for Leak Detection In A Fluid Line	6/3/2003	7/2/2021
6,579,253	US	Fluid Processing Systems and Methods using Extracorporeal Fluid Flow Panels Oriented within a Cartridge	6/17/2003	2/14/2017
6,582,385	US	Hemofiltration System Including Ultrafiltrate Purification and Re-Infusion System	6/24/2003	2/19/2018
6,589,482	US	Extracorporeal Circuits for Performing Hemofiltration Employing Pressure Sensing Without an Air Interface	7/8/2003	2/14/2017
6,595,943	US	Systems and Methods for Controlling Blood Flow and Waste Fluid Removal During Hemofiltration	7/22/2003	2/14/2017
6,638,477	US	Fluid Replacement Systems and Methods for use in Hemofiltration	10/28/2003	2/14/2017
6,638,478	US	Synchronized Volumetric Fluid Balancing Systems and Methods	10/28/2003	2/14/2017
6,649,063	US	Method for Performing Renal Replacement Therapy Including Producing Sterile Replacement Fluid in a Renal Replacement Therapy Unit	11/18/2003	10/7/2021
6,673,314	US	Interactive Systems and Methods for Supporting Hemofiltration Therapies	1/6/2004	2/14/2017
6,702,561	US	Devices and Methods for Potting a Filter for Blood Processing	3/9/2004	9/8/2021
6,743,193	US	Hermetic Flow Selector Valve	6/1/2004	7/17/2021
6,830,553	US	Blood Treatment Systems and Methods That Maintain Sterile Extracorporeal	12/14/2004	2/14/2017
6,852,090	US	Fluid Processing Systems and Methods using Extracorporeal Fluid Flow	2/8/2005	12/10/2017
6,872,346	US	Method and Apparatus for Manufacturing Filters	3/29/2005	5/14/2023
6,955,655	US	Hemofiltration System	10/18/2005	10/7/2017
6,979,309	US	Systems and Methods for Performing Blood Processing and/or Fluid Exchange Procedures	12/27/2005	6/19/2017
7,004,924	US	Methods, Systems, and Kits for The Extracorporeal Processing of Blood	2/28/2006	2/11/2018
7,040,142	US	Method and Apparatus for Leak Detection in Blood Circuits Combining External Fluid Detection and Air Infiltration Detection	5/9/2006	2/9/2022
7,087,033	US	Method and Apparatus for Leak Detection In A Fluid Line	8/8/2006	8/22/2021
7,112,273	US	Volumetric Fluid Balance Control for Extracorporeal Blood Treatment	9/26/2006	10/4/2023
7,147,613	US	Measurement of Fluid Pressure in a Blood Treatment Device	12/12/2006	8/29/2020

Patent No.	Regime	Description	Issued	Expiration Date
7,214,312	US	Fluid Circuits, Systems, and Processes for Extracorporeal Blood Processing	5/8/2007	7/8/2022
7,226,538	US	Fluid Processing Apparatus	6/5/2007	1/21/2022
7,267,658	US	Renal Replacement Therapy Device for Controlling Fluid Balance of Treated Patient	9/11/2007	3/6/2021
7,300,413	US	Blood Processing Machine and System using Fluid Circuit Cartridge	11/27/2007	5/4/2021
7,338,460	US	Blood Processing Machine Fluid Circuit Cartridge	3/4/2008	6/9/2018
7,337,674	US	Pressure Detector for Fluid Circuits	3/4/2008	6/14/2024
7,347,849	US	Modular Medical Treatment Replaceable Component	3/25/2008	6/30/2018
7,419,597	US	Fluid, Circuits, Systems, and Processes for Extracorporeal Blood Processing	9/2/2008	7/12/2021
7,470,265	US	Dual Access Spike for Infusate Bags	12/30/2008	1/11/2024
7,473,238	US	Hemofiltration Systems and Methods That Maintain Sterile Extracorporeal Processing Conditions	1/6/2009	8/11/2020
7,544,300	US	Batch Filtration System for Preparation of Sterile Fluid for Renal Replacement Therapy	6/9/2009	1/7/2024
7,588,684	US	Systems and Methods for Handling Air and/or Flushing Fluids in a Fluid Circuit	9/15/2009	7/13/2021
602004021672.0	DE	Preparing Replacement Fluid	6/24/2009	11/29/2020
1592494	EP	Batch Filtration System for Preparation of Sterile Replacement Fluid for Renal Therapy	6/24/2009	1/7/2024
0969887	GB	Hemofiltration System	11/16/2005	2/5/2018
1592494	GB	Preparing Replacement Fluid	6/24/2009	1/7/2024
4118233	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
000023148-0001	EU*	Blood Treatment Machine and Parts thereof	4/1/2003	4/1/2028

* EU industrial design registration

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.

In connection with the acquisition of the MDS Entities on October 1, 2007, we also acquired exclusive license rights to a portfolio of patents. The licensed patents fall into two categories: those that are used exclusively by the MDS Entities, which we refer to as Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, which we refer to as the Class B patents. Pursuant to the terms of our license agreement with DSU Medical Corporation, we have a license to (1) the Class A patents, to practice in all fields for any purpose and (2) the Class B patents, solely with respect to certain defined products for use in the treatment of extracorporeal fluid treatments and/or renal insufficiency treatments. This license agreement further provides that our rights under the agreement are qualified by certain sublicenses previously granted to third parties. We have agreed that Mr. Utterberg will retain the right to royalty income under one of these sublicenses.

The following table lists all of the issued patents licensed by us under the license agreement that are fundamental to the manufacture and sale of the core products we sell to customers in the in-center market.

Subject Matter	Patent Number	Patent Expiration
Pump Segment Having Connected, Parallel Branch Line	US 5360395	11/1/2011
Pump Segment Having Connected, Parallel Branch Line: Continuation	US 6440095	5/5/2017
Blood Set Priming Method & Apparatus	US 5895368	9/23/2016
Blood Set Priming Method & Apparatus: Div.	US 6290665	3/11/2018
Reversing Flow Blood Processing System	US 6177409	6/10/2018
New Reverso	US 6695807	1/18/2022
Turbo Cap for Blood Processing	US 6517508	11/3/2019
Measuring Vascular Access Pressure — Access Alert	US 6346084	1/10/2020
Guarded Winged Needle Assembly (Method): Div. Of Continuation	US 5433703	7/18/2012
Easy Use Needle Protector Sheath	US 5704924	1/11/2016
European Guarded Winged Needle Assembly	EUR 436646	8/31/2011
European Guarded Winged Needle Assembly: Divisional	EUR 558162	1/9/2010
Japan Easy Use Needle Protector Sheath	JP 3809563	12/20/2016
Luer Connector with Integral Closure	US 5385372	1/31/2012
Squeeze Clamp for Flexible Tubing	US 6089527	10/3/2017
Divisional Squeeze Clamp for Flexible Tubing	US 6196519	9/15/2019
Canada Squeeze Clamp for Flexible Tubing	CN 2308052	9/22/2018
Injection Site for Male Luer — Locksite™	US 7025744	10/4/2022

In addition to the issued patents and pending patent applications owned by us and the issued patents and patent applications licensed to us, in the United States 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 outsource the manufacture of premixed dialysate, needles, some blood tubing sets, and some components.

We have single-source suppliers of components, but in most instances there are alternative sources of supply available. Where obtaining a second source is more difficult, we have tried to establish supply agreements that better protect our continuity of supply. These agreements, currently in place with several key suppliers, are intended to establish commitments to supply product. We do not have supply agreements in place with all of our single-source suppliers.

We have certain agreements that grant certain suppliers exclusive or semi-exclusive supply rights. We contract for the manufacture of the majority of our finished goods of ReadySet blood tubing sets and all our needles from Kawasumi, headquartered in Tokyo, Japan, with manufacturing facilities in Thailand. The current agreement with Kawasumi for the manufacture of blood tubing extends through January 2011, which term can be automatically extended for additional one year periods, unless either party provides sufficient notice of termination. Under the terms of this agreement, we supply Kawasumi with molded component parts and Kawasumi in turn uses these components to manufacture finished goods blood tubing sets, which are then purchased by us. We have committed to purchase from Kawasumi a minimum quantity of blood tubing sets over the term of the agreement. We believe that this minimum purchase commitment is less than our anticipated requirements for blood tubing sets.

We also have an agreement with Kawasumi for the manufacture of needle sets. Virtually all of these needle sets rely on our patented guarded needle set technology. In February 2007, we agreed with Kawasumi to extend their needle set supply agreement through February 2011, with opportunities to extend the term beyond that date. We have committed to purchase from Kawasumi a minimum quantity of needle sets over the three-year extended term of the contract. We believe that this minimum purchase commitment is less than our anticipated requirements for needles.

In January 2007, we entered into a supply agreement with Membrana pursuant to which Membrana has agreed to supply, on an exclusive basis for a period of ten years, the capillary membranes that we use in the filters used with the System One. Membrana has agreed to pricing reductions based on volumes ordered and we have agreed to purchase a base amount of membranes per year. The agreement may be terminated upon a material breach, generally following a sixty-day cure period.

We purchase bicarbonate-based premixed dialysate from B. Braun Medizintechnologie GmbH, or B. Braun, and our lactate-based premixed dialysate from Laboratorios PISA, or PISA. We have a supply agreement with B. Braun that obligates B. Braun to supply the dialysate to us for an indefinite period until either party provides twelve months notice of termination in exchange for a minimum purchase commitment, which we believe is less than our anticipated requirements. The contract may be terminated upon a material breach, generally following a 30-day cure period. Our supply agreement with PISA extends through 2011. This contract may be terminated upon a material breach, generally following a 30-day cure period.

Government Regulation

Food and Drug Administration

In the United States, our products are subject to regulation by the FDA, which regulates our products as medical devices. The FDA regulates the 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 prior 510(k) clearance or pre-market approval from the FDA before they may be commercially distributed in the United States. Submissions to obtain 510(k) clearance and pre-market approval must be accompanied by a user fee, unless exempt. In addition, the FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

The FDA classifies medical devices into one of three classes: Class I, Class II or Class III — depending on the FDA's assessment of the degree of risk associated with the device and the controls it deems necessary

to reasonably ensure the device's safety and effectiveness. The FDA has deemed our System One to be a Class II medical device and we have marketed it as such in the United States.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls, which include compliance with facility registration and product listing requirements, reporting of adverse events, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Class II devices are also subject to these same general controls, as well as any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidelines. Pre-market review and clearance by the FDA for Class II devices is accomplished through the 510(k) pre-market notification procedure, unless the device is exempt. When 510(k) clearance is required, a manufacturer must submit a pre-market notification to the FDA demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 and for which the FDA has not yet required premarket approval; a device which has been reclassified from Class III to Class II or I; or 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. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or possibly a pre-market approval. Class III devices are devices for which insufficient information exists that general or special controls will provide reasonable assurance of safety and effectiveness, and the devices are life-sustaining, life-supporting, or implantable, or of substantial importance in preventing the impairment of human health, or present a potential, unreasonable risk of illness or injury. Class III devices requiring an approved pre-market approval application to be marketed are devices that were regulated as new drugs prior to May 28, 1976, devices not found substantially equivalent to devices marketed prior to May 28, 1976 and Class III pre-amendment devices, which are devices introduced in the U.S. market prior to May 28, 1976, that by regulation require pre-market approval.

FDA Regulatory Clearance Status

We currently have all of the regulatory clearances required to market the System One in the United States 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. To date we have received a total of 25 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 24 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 apherisis, 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. 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 "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.

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 significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the pre-market approval process. Pre-market approval 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:

- 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;
- 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; and
- recalls and notices of correction or removal.

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 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 adultered 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 three times. In our first inspection, one observation was made, but was rectified during the inspection, requiring no further response from us. Our last two inspections, including our most recent inspection in March 2006, resulted in no observations. Medisystems has been inspected by the FDA on eight 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

Clearance or approval of our products by regulatory authorities comparable to the FDA 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 consuming and expensive. We have not

sought approval for our products outside of the United States, Canada and the European Union, or EU. We cannot provide assurance that we will be able to obtain regulatory approvals in any other markets.

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 obtained CE marking approval in the EU for our System One.

Our blood tubing sets, AV fistula needles, apheresis needles, dialysis priming sets, transducer protectors, Reverso, and Medic 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 brandname for these products. We have received CE marking in the EU for AV fistula needles, apheresis needles, Medic and its Reverso product. At this time none of our other products sold to customers in the in-center market have been approved for CE marking.

Fraud and Abuse Laws

Anti-Kickback Statutes

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under a federal healthcare program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, 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 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 one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Arrangements that implicate the Anti-Kickback Law, and that do not fall within a safe harbor, are analyzed by the OIG on a case-by-case basis.

Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of 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.

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 submission of false claims. 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 United States 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, or, in several states, 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.

Privacy and Security

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, or PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates, as such term is defined by HIPAA, which, among other things, obligate the business associates to safeguard the covered entity's PHI against improper use and disclosure. While not directly regulated by HIPAA, a business associate may face significant contractual liability pursuant to such an agreement if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. In the course of our business operations, we have entered into several business associate agreements with certain of our customers that are also covered entities. Pursuant to the terms of these business associate agreements, we have agreed, 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 prohibited disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. Accordingly, we incur compliance related costs in meeting HIPAA-related obligations under business associate agreements to which we are a party. Moreover, if we fail to meet our contractual obligations under such agreements, we may incur significant liability.

In addition, HIPAA's criminal provisions could potentially be applied to a non-covered entity that aided and abetted the violation of, or conspired to violate HIPAA, although we are unable at this time to determine conclusively whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. Also, many state laws regulate the use and disclosure of health information, and are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA. Finally, in the event we change our business model and become a HIPAA covered entity, we would be directly subject to HIPAA, its rules and its civil and criminal penalties.

Reimbursement

Home and In-Center Care 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 rent or sell our System One to dialysis clinics and sell our needles and blood tubing sets to dialysis clinics. These clinics are, in turn, reimbursed by Medicare, Medicaid and private insurers. According to the 2009 USRDS Annual Data Report, Medicare is the primary payor for approximately 75% of prevalent dialysis patients using hemodialysis and peritoneal dialysis. The report also indicates that approximately 15% of patients are covered by commercial insurance, with the remaining 10% of patients classified by the USRDS as "other" or "unknown." Certain centers have reported that the NxStage daily home dialysis therapy attracts a higher percentage of commercial insurance patients than other forms of dialysis.

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. For patients eligible for Medicare based solely on ESRD, generally patients under age 65, Medicare eligibility begins three months after the month in which the patient begins dialysis treatments. During this three-month waiting period either Medicaid, private insurance or the patient is responsible for payment for dialysis services. Medicare generally waives this waiting period for individuals who participate in a self-care 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 composite rate for dialysis services reimbursed based on the composite rate 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 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 in recent years 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 composite rate, leaving the secondary insurance or the patient responsible for the remaining 20%. The Medicare composite rate is set by Congress and is intended to cover virtually all costs associated with each dialysis treatment, excluding physician services and certain separately billable drugs and laboratory services. While there is some regional variation in the Medicare allowable rate, the national average for 2010 is $155 per treatment for both independent and hospital-based dialysis facilities. Depending upon patient case mix, reimbursement may be further improved, based on a case-mix adjustment to the composite rate. Under the case-mix adjustment, Medicare now pays more for larger patients and those under the age of 65. This may be beneficial to our customers, as to date our patient population has tended to be younger and larger than the ESRD national average. As a result of the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA legislation, Centers for Medicare and Medicaid Services, or CMS, has announced that, in 2011, it will implement a new "bundled" payment for dialysis treatment. Proposed rules have been released by CMS and the public comment period concluded on December 16, 2009. Final rules will likely be published in 2010. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

CMS rules limit the number of hemodialysis treatments paid for by Medicare to three per week, unless there is medical justification provided by the patient's physician, for the additional treatments. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis. A clinic's decision as to how much it is willing to spend on home daily 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.

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.

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 diagnosis related group, or DRG, system. Under this system, reimbursement is determined based on a patient's primary diagnosis and is intended to cover all 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.

Our Employees

As of December 31, 2009, we had 1,509 full-time employees, 4 part-time employees and 22 seasonal or temporary employees. From time to time we also employ independent contractors to support our engineering, marketing, sales, clinical and administrative organizations.

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 450 Fifth Street, N.W., Washington, D.C. 20549. In addition, our SEC filings are available to the public on the SEC's website (www.sec.gov).

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 rental or sale of our 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 acquisition of the MDS Entities 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 2010 and in the foreseeable future, we will continue 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 acquired in the Medisystems Acquisition, 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 hemodialysis 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 hemodialysis market. However this market is presently very small and adoption of the 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 United States Renal Data System, or USRDS, the number of patients receiving peritoneal dialysis was approximately 26,000 in 2006, representing approximately 8% of all patients receiving dialysis treatment for ESRD in the United States. Very few ESRD patients receive hemodialysis treatment outside of the clinic setting. Because the adoption of home hemodialysis has been limited to date, the number of patients who desire to, and are capable of, administering their own 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-based 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 therapies.

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered five or more 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 supply costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for Medicare patients by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. Presently, we understand that a number of our customers are unable to obtain such additional reimbursement, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times per week. Both of these facts will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to grow our revenue in the future. As a result of 2008 MIPPA legislation, CMS has announced that, in 2011, it will implement a new "bundled" payment for dialysis treatment. Proposed rules have been released by CMS and the public comment period concluded on December 16, 2009. Final rules will likely be published in 2010. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

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. In 2008, CMS

released new Conditions for Coverage applicable to our customers. These Conditions for Coverage impose 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.

We require significant capital to build our business, and financing may not be available to us on reasonable terms, if at all.

We have experienced negative operating margins and cash flows from operations and we expect to continue to incur net losses in the foreseeable future. In addition, our System One home market relies heavily upon a rental sales model whereby approximately half of our sales to customers in the home market include the rental rather than the purchase of System One equipment. This sales model requires significant amounts of working capital to manufacture System One equipment for rental to dialysis clinics. A number of our home market customers, including DaVita, have purchased System One equipment, with certain customers committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. There can, however, be no assurance that we will be able to expand the percentage of our equipment placements that are purchased rather than rented.

We believe, based on current projections, that we have the required resources to fund operating requirements through 2010 and beyond. Future capital requirements will depend on many factors including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing activities and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of complementary businesses, services or technologies. There is no assurance that additional debt or equity capital will be available to us on favorable terms, if at all.

If we sell additional equity or issue debt securities to fund future capital requirements, it will likely result in dilution to our stockholders, and we cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to us, or at all. If we are unable to obtain additional financing when needed, we may be required to delay, reduce the scope of, or eliminate one or more aspects of our business development activities, which would likely harm our business.

We have limited operating experience, a history of net losses and an accumulated deficit of $276.7 million at December 31, 2009. 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 losses every quarter and, at December 31, 2009, we had an accumulated deficit of approximately $276.7 million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, while we have achieved positive gross margins for our products, in the aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins will continue to 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. Our ability to become profitable depends principally upon implementing design and process improvements to lower our costs of manufacturing our products, accessing lower labor cost markets for the manufacture of our products, growing revenue, increasing the reliability of our products, improving our field equipment utilization, achieving efficiencies in manufacturing and supply chain overhead costs, achieving efficient distribution of our products, achieving a sufficient scale of operations and obtaining better purchasing terms and prices.

Our customers in the System One and In-Center segment 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 more than 60% of United States dialysis patients. Additionally, DaVita has certain dialysis supply purchase obligations to Gambro under a long-term preferred supplier agreement. Each of Fresenius and DaVita may choose to offer their dialysis patients only the dialysis equipment manufactured by them or their affiliates, to offer the equipment they contractually agreed to offer or to otherwise limit access to the equipment manufactured by competitors. With less than 40% of United States dialysis patients cared for by independent dialysis clinics, our market adoption, at least within the United States, will be more constrained without the presence of one or both of DaVita and Fresenius as customers for our System One and In-Center products.

DaVita is our most significant customer for both of the System One and In-Center segments. February 2007, we entered into a national service provider agreement with DaVita that conferred to DaVita certain market rights for the System One and related supplies for home hemodialysis therapy. Under the agreement, DaVita was granted exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the United States ESRD patient population, and limited exclusivity in the majority of all other United States geographies, subject to DaVita's meeting certain requirements, including the achievement of certain patient numbers and training rates. The agreement further limited, but did not prohibit, the sale by NxStage of the System One for chronic home patient hemodialysis therapy to Fresenius. Per the agreement, DaVita no longer has any preferred geographic market or exclusivity rights, and as of December 31, 2009, the initial term of our national service provider agreement with DaVita expired. While we negotiate a new agreement with DaVita for the home market, we continue to restrict our activities in a limited subset of geographic markets where DaVita previously held preferred market rights. However, we can provide no assurance that we will enter into a new agreement with DaVita or what the terms, including exclusivity provisions, of a new agreement with DaVita would be. Our national service provider agreement with DaVita contemplates ongoing sales of products following December 31, 2009. We expect that DaVita will continue to be our largest customer for the foreseeable future. The change in DaVita's exclusivity rights does give us the opportunity to expand in certain markets and with other providers, including Fresenius. We have a low, but growing, volume of sales to Fresenius of our System One in the home market, and have been able to expand at certain other providers, but we have no assurance that this will continue. It is too early to predict what effect the change in DaVita's exclusivity rights will have on our growth in the home market.

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 nearly half of In-Center segment revenues for the year ended December 31, 2009, and direct sales to DaVita accounted for approximately 38% of our System One segment revenues for the year ended December 31, 2009, and half of our home hemodialysis patients. The initial term of our national service provider agreement with DaVita expired on December 31, 2009. We cannot guarantee we will be able to negotiate a new agreement with DaVita on favorable terms, if at all, or the extent to which DaVita will purchase our products. 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 contract for needles with DaVita, expiring in December 2013, includes certain minimum order requirements; however, these can be reduced significantly under certain circumstances. Our contract for blood tubing sets with DaVita expired in September 2009. However, in June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines to DaVita. 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. Further, given the significance of DaVita as a customer, any change in DaVita's ordering or clinical practices could have a significant impact on our revenues, especially in the near term.

We entered into a $40.0 million term loan and security agreement with Asahi in May 2009. We are obligated to pay 50% of the interest on the first day of November and May, beginning on November 1, 2009, and repay the remaining interest and principal upon maturity in May 2013. If we fail to comply with all terms under this agreement, we may go into default, which could trigger, among other things, the acceleration of all of our indebtedness thereunder or the sale of our assets.

In May 2009, we entered into a $40.0 million term loan, with Asahi. The four year term loan bears interest at 8% annually, payable on the first day of November and May beginning on November 1, 2009, with 50% of the interest deferred to maturity. The term loan is secured by substantially all of our assets.

The term loan and security agreement includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Any of these remedies would likely have a material adverse effect on our business.

We entered into a two year Loan and Security Agreement, the Agreement, dated as of March 10, 2010, with Silicon Valley Bank, SVB. The terms of our Agreement may restrict our current and future operations, which could affect our ability to respond to changes in our business and to manage our operations.

On March 10, 2010, we entered into an Agreement with SVB for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the Agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our Agreement with SVB. 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 on the Agreement. However, were we to draw on the Agreement, 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 in the critical care market competes against Gambro AB, Fresenius Medical Care AG, Baxter Healthcare, B. Braun and others. Our System One in the home market is currently the only system specifically indicated for use in the home market in the United States. Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter Healthcare, 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 offers products that have been in use for a longer time than our System One, and in some instances many of our Medisystems products, 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. Baxter has announced a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it hopes to commence clinical studies of DEKA's new home hemodialysis system in 2010. We are unable to predict when, if ever, this product, or products from other companies, 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 market, it would adversely affect our sales and growth. 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 or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological 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.

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 four distinct constituencies involved in the choice of dialysis therapy, namely operators of dialysis clinics, nephrologists, dialysis nurses and patients, 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 recently adopted 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, including Medicare and any negative impact of the "bundle" payment method to be implemented by CMS in 2011.

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.

The world's financial markets are currently experiencing significant turmoil, resulting in reductions in available credit, increased costs of credit, increased volatility in security prices, rating downgrades of investments and reduced valuations of securities generally. These events have materially and adversely impacted the availability of financing to a wide variety of businesses and the resulting uncertainty has led to reductions in capital investments, overall spending levels and future product plans and sales projections. In general, we believe demand for our products in the home and in-center market will not be substantially affected by the current market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, revenues in the in-center market could be impacted by changes in sales volumes and inventory management policies of our distributors and end customers. Finally, the impact of tightened credit markets on hospitals could continue to impair the manner and pace in which we sell equipment in the critical care market or delay equipment placements. Hospitals 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.

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.

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our products. As a result of legislation passed by the United States Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the United States for ESRD. With approximately 75% of United States 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 rent or sell 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 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 the 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 on a case-by-case basis, based on documentation provided by our customers. If daily 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 authorized 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. We understand that a number of our customers are unable to obtain additional reimbursement for more frequent therapy, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times a week. Both of these factors will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to more predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to our revenue growth in the future. Additionally, any adverse changes in the rate paid by Medicare for ESRD treatments in general would likely negatively affect demand for our products in the home market and the prices we charge for them. As a result of 2008 MIPPA legislation, CMS has announced that, in 2011, it will implement a new "bundled" payment for dialysis treatment. Proposed rules have been released by CMS and the public comment period concluded on December 16, 2009. Final rules will likely be published in 2010. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

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

As the commercial launch of the System One and Streamline continues, 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 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.

If we are unable to improve the reliability of our System One product or maintain strong product reliability for our other products, our ability to maintain or grow our business and achieve profitability could be impaired.

We have not yet achieved our long term reliability objectives for our System One and PureFlow SL hardware, and as a result we continue to incur increased service and distribution costs. This, in turn, negatively impacts our gross margins and increased our working capital requirements. Additionally, 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. We continue to work to improve product reliability for all products, and have achieved some improvements to date. If we are unable to continue to improve product reliability of our System One, PureFlow SL products and Streamline products, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

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

Because a significant percentage of our System One home care business continues to rely upon an equipment and service rental model, our ability to manage System One equipment is important to minimizing our working capital requirements. 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 2007, approximately 17,500 patients received kidney transplants in the United States. 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 or other solutions for renal replacement may also limit the market for our products.

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 associated with, among other conditions, congestive heart failure. 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 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. One of our competitors in the critical care market, Gambro AB, had been subject to an FDA import hold that was lifted in late 2007. Since the import hold has lifted, competition from Gambro has increased, which could impair our performance in the future in the critical care market.

We could be subject to costly and damaging product and professional liability claims and may not be able to maintain sufficient liability insurance to cover claims against us.

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. Claims of this nature may also adversely affect our reputation, which could damage our position in the market. While we maintain insurance, including professional liability, product and excess liability 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, due to the recent tightening of global credit and the disruption in the financial markets, there may be a disruption in our insurance coverage or delay or disruption in the payment of claims by our insurance providers. Our insurance policies also have various exclusions, and we may be subject to a product or professional liability 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 our insurance.

Any product liability or professional liability claim brought against us, with or without merit, could result in the increase of our product liability or professional liability insurance rates, respectively, or the inability to secure additional insurance coverage in the future. A product liability claim, whether meritorious or not, could 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 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. To the extent we fail to control our exchange rate risk, our 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 associated with sourcing and shipping goods internationally, difficulty managing operations in multiple locations, local regulations that may restrict or impair our ability to conduct our operations, and health issues, such as pandemic disease risk including the swine flu virus, which could disrupt our manufacturing and logistical and import activities.

We currently rely upon Kawasumi, a third-party manufacturer, to manufacture a significant percentage of our blood tubing set products using our supplied components and all of our needles. Kawasumi's contractual obligation to manufacture blood tubing sets expires in January 2011, with opportunities for extension, and its obligation to supply needles expires in February 2011, with opportunities to extend the term beyond that date. In the event these agreements are not renewed or extended upon favorable terms, if at all, or in the event we are unable to sufficiently expand our manufacturing capabilities, or obtain alternative third party supply prior to the expiration of these agreements, our growth and ability to meet customer demand would be impaired.

Historically, we have relied upon a third-party manufacturer, Kawasumi, to manufacture a significant percentage of our blood tubing set products using our supplied components. Kawasumi has a strong history of manufacturing high-quality product for us. In May 2008, we negotiated a new agreement with Kawasumi with an initial term that extended their obligation to supply blood tubing sets to us through January 31, 2010. The agreement was later extended through January 2011, with further opportunities for extension. We cannot be certain that after the expiration of this agreement we would be able to manufacture independently the volume of products currently manufactured by Kawasumi, and therefore, whether we would have sufficient capacity to meet all of our customer demand, that we would be able to manufacture products at the same cost at which we currently purchase products from Kawasumi or that we could find a third party to supply blood tubing sets on favorable terms, if at all, the failure of any of which could impair our business. We also depend solely on Kawasumi for all of our finished goods needles. Kawasumi's obligation to supply needles to us expires in February 2011, with opportunities to extend the term beyond that date. In the event this agreement is not renewed or extended on favorable terms, if at all, and we are unable to manufacture comparable needles for ourselves prior to the contract expiration, or if we are unable to obtain comparable needles from another third party on favorable terms, if at all, the revenues and profitability of our business will be impaired.

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

We sell the majority of our In-Center products through distributors, which collectively accounted for substantially all of In-Center revenues for the year ended December 31, 2009, with our primary distributor, Henry Schein, accounting for approximately 66% of In-Center revenues for the year ended December 31, 2009. Our distribution agreement with Henry Schein, originally scheduled to expire in July 2009, has been extended on a non exclusive basis while the parties seek to negotiate a new agreement. There is, however no assurance that a new agreement will be signed on favorable terms, if at all. In June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines, to DaVita. During the third quarter of 2009 we began selling blood tubing sets to Gambro. Sales to Gambro represented approximately 14% of our In-Center segment revenues for the year ended December 31, 2009. 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 blood tubing set business through Streamline or 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 business to competitors in the dialysis industry.

Our blood tubing set business has historically been a commodities business. Prior to the Medisystems Acquisition, Medisystems competed favorably and gained share through the development of a high quality, low-cost, standardized blood tubing set, which could be used on several different dialysis machines. Our products continue to compete favorably in the dialysis blood tubing set business, but are increasingly subject to pricing pressures, especially given recent market consolidation in the United States dialysis services industry, with Fresenius and DaVita collectively controlling approximately 60% of United States dialysis services business. Unless we can successfully demonstrate to customers the differentiating features of the Streamline product 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 business to competitors in the dialysis industry.

The activities of our business involve the import of finished goods into the United States from foreign countries, subject to customs inspections and duties, and the export of components and certain other products from other countries into Germany, Mexico and Thailand. 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 United States disposable medical supplies from Germany, Thailand and Mexico. We also import into the United States disposable medical components from China, Germany and Italy and export components and assemblies into Mexico, Thailand and Italy. The import and export of these items are subject to extensive laws and regulations with which we will 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 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 Generalised 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. Pandemics, could also impair our ability to import or export goods internationally.

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 President and Chief Executive Officer.

We have filed a resale registration statement covering shares of our common stock that we recently sold in a private placement. If the holders of these shares are unable to sell the shares under the registration statement, we may be obligated to pay them damages, which could harm our financial condition.

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.

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 United States, and in foreign markets we may wish to enter. To market a medical device in the United States, 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 clearances 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 for our products. Presently, we are pursuing a nocturnal indication for the System One under an IDE study started in the first quarter of 2008. We recently completed the IDE study and have submitted the associated 510(k). We cannot provide assurance that this or other clearances or approvals will be forthcoming, or, if forthcoming, what the timing and expense of obtaining such clearances or approvals might be. 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 510k regulation has not changed, it is under review and based on comments made by FDA in public forums, changes are likely. In the mean time, it should be expected that the requirements to demonstrate substantial equivalence, in order to support a 510k clearance, will be more comprehensive.

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.

Even if we obtain the necessary FDA 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. 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;
- 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.

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 would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and 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. The FDA enforces its QSRs through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. Our Corporate office located in Lawrence, Massachusetts U.S. has previously had three FDA QSR inspections. The first resulted in one observation, which was rectified during the inspection

and required no further response from us. Our last two inspections, including our most recent inspection in March 2006, resulted in no observations. Medisystems has been inspected by the FDA on eight 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.

We cannot provide assurance that any 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 United States, 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.

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 for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. 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. Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform and a number of bills have been proposed in Congress. A leading proposal includes an excise tax on the medical device industry that would be payable based on revenue, not income. In addition, recent legislation and many of these proposed bills include funding to assess the comparative effectiveness of medical devices. It is unclear what impact the excise tax proposal or the comparative effectiveness analysis would have on our financial results. The ultimate content or timing of any future healthcare reform legislation, and its impact on medical device companies such as us, is impossible to predict, although the impact should be less than what may be seen in other healthcare contexts due to the fact that the vast majority of ESRD patients already are covered under a federal health care program. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

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

Historically, we have not sold or marketed the System One outside the United States and Canada. In May 2009, we announced our first international distribution agreement for the System One with Kimal, granting Kimal distribution rights for the System One as well as Streamline and ButtonHole needles in the United Kingdom and Ireland. In February 2010, we announced another international distribution agreement for the System One with Nordic Medcom, granting Nordic Medcom distribution rights for the System One as well as Streamline and ButtonHole needles in Finland, Sweden and Denmark. We are currently assessing other international markets for the System One as well. Our In-Center products are presently sold in the United States 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 and Europe. 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 testing. 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 any market outside the United States, which

could negatively affect our overall market penetration. Additionally, any loss of foreign regulatory approvals, for any reason, could negatively affect 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. United States 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. At this time, we are not a HIPAA covered entity and consequently are not directly subject to HIPAA. However, we have entered into several business associate agreements with covered entities that contain commitments to protect the privacy and security of patients' health information and, in some instances, require that we indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability and/or our reputation and business could be harmed. In addition, conduct by a person that is not a covered entity could potentially be prosecuted under aiding and abetting or conspiracy laws if there is an improper disclosure or misuse of patient information.

Many state laws apply to the use and disclosure of health information, which could affect the manner in which we conduct our business. Such laws are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA. Such state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

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 Medicare/Medicaid anti-kickback laws, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. In addition, several states require us to report and disclose the value, nature, purpose and particular recipient of any fee, payment, subsidy or economic benefit which we may from time to time provide to certain physicians or health care providers. These 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 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 one of our sales representatives were to offer an inappropriate inducement to purchase our products to a customer, we could be subject to a claim under the Medicare/Medicaid anti-kickback laws or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable state anti-kickback laws, or healthcare provider sunshine laws.

Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments from 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 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, 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 billing and 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 concerning the benefits of daily therapy. Anti-kickback and 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.

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

To date, our marketing efforts have been confined nearly exclusively to the United States. We have had limited activities in Canada with our System One, and in certain other jurisdictions with our In-Center products sold through distributors. In May 2009, we announced an international distribution agreement with Kimal, whereby we would commence promotion and sales of our System One, as well as Streamline and ButtonHole needles, in the United Kingdom and Ireland. In February 2010, we announced an international distribution agreement with Nordic Medcom, whereby we would commence promotion and sales of our System One, as well as Streamline and ButtonHole needles, in Finland, Sweden and Denmark. We may, in the future, seek to market our products in other markets. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. 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 United States, 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 United States Foreign Corrupt Practices Act could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act which generally prohibits United States 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. While we have policies and procedures in place to prevent noncompliance, we can make no assurance that our employees or other agents will not engage in prohibited conduct under the Foreign Corrupt Practices Act 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 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, 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

We obtain some of our raw materials or components from a single source or a limited group of suppliers. We also obtain sterilization services from a single supplier. 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 on a number of single-source suppliers for some of the raw materials and components we use in our products. We also obtain sterilization services from a single supplier. Membrana GmbH is our sole supplier of the fiber used in our filters for System One products. Kawasumi is our only supplier of needles. We also obtain certain other products and components from other single source suppliers or a limited group of suppliers. Our dependence on single source suppliers of components, subassemblies and finished goods 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.

Finding alternative sources for these components and subassemblies would be difficult in many cases and may entail a significant amount of time and disruption. In the case of Membrana, for fiber, we are contractually prevented from obtaining an alternative source of supply for our System One products. In the case of other suppliers, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our System One or other products and, potentially, further FDA clearance or approval of any modification, thereby causing further costs and delays.

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.

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, therefore, 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 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.

Certain of our products are recently developed and we have recently transitioned the manufacturing of certain of these products to new locations. We, and certain of our third-party manufacturers, have limited manufacturing experience with these products.

We continue to develop new products and make improvements to existing products. As such, we and certain of our third-party manufacturers, have limited manufacturing experience with certain of our products. We are, therefore, more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature.

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 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.

As of December 31, 2009, we had 44 pending patent applications, including foreign, international and U.S. applications, and 44 U.S. and international issued patents plus 1 European Union, or EU, industrial design registraion. Under our license agreement with DSU Medical Corporation, we also license approximately 30 pending patent applications, including foreign, international and U.S. applications, and approximately 98 U.S. and international issued patents. We cannot specify which of these 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 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 United States 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 United States. 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.

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 and positive cash flow 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;
- 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 daily 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;
- 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;
- 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 shares of common stock, the market price of our common stock could decline significantly. We have 46,795,859 shares of common stock outstanding as of December 31, 2009. 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 467,959 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.

At December 31, 2009, subject to certain conditions, holders of an aggregate of approximately 24,280,888 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 following the expiration of the lock-up agreements, they can sell those shares in the public market.

As of December 31, 2009, 11,435,552 shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan and outstanding stock options. As of December 31, 2009,

6,850,050 shares were subject to outstanding options, of which 4,034,447 were exercisable and can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144.

Our executive officers, directors and current and principal stockholders own a large percentage of our voting common stock and could limit new stockholders' influence on corporate decisions or could delay or prevent a change in corporate control.

Our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially hold, in the aggregate, approximately 65% of our outstanding common stock. David S. Utterberg, one of our directors, holds approximately 18% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in control of our company;
- entrenching our management and/or Board;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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;
- 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***

We are headquartered in Lawrence, Massachusetts, where we lease approximately 45,000 square feet under a lease expiring in 2012. We have manufacturing facilities consisting of a 118,000 square foot facility in Tijuana, Mexico with a lease expiring in 2011, a 36,300 square foot facility in Modena, Italy with a lease expiring in 2012, a 35,000 square foot facility through our relationship with Entrada with a lease expiring in 2012, and a 12,369 square foot facility in Rosdorf, Germany with a term expiring in 2011. We believe that our existing facilities are adequate for our current needs and that suitable additional or alternative space will be available at such time as it becomes needed on commercially reasonable terms. In addition to these facilities we lease a number of small offices for administrative purposes.

Item 3. ***Legal Proceedings***

From time to time we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4. ***Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2009.

EXECUTIVE OFFICERS OF THE REGISTRANT

Executive Officers

The following is a list of names, ages and background of our executive officers as of December 31, 2009:

Name	Age	Position
Jeffrey H. Burbank	47	President, Chief Executive Officer
Robert S. Brown	51	Senior Vice President, Chief Financial Officer and Treasurer
Tom Shea	47	Senior Vice President, Manufacturing Operations
Winifred L. Swan	45	Senior Vice President, General Counsel and Secretary
Joseph E. Turk, Jr.	42	Senior Vice President, Commercial Operations
Michael J. Webb	43	Senior Vice President of Quality, Regulatory and Clinical Affairs

Jeffrey H. Burbank has been our President and Chief Executive Officer and a director of the Company since December 1998. Prior to joining NxStage, Mr. Burbank was a founder and the CEO of Vasca, Inc., a medical device company that developed and marketed a new blood access device for dialysis patients. Mr. Burbank also served in roles of increasing responsibility in areas of manufacturing, and sales and marketing at Gambro, a leading dialysis products company. He holds a B.S. from Lehigh University.

Robert S. Brown has been our Senior Vice President, Chief Financial Officer and Treasurer since November 2006. Prior to joining NxStage, Mr. Brown held several leadership positions in Boston Scientific's financial group including Vice President, Corporate Analysis & Control from 2005 until he joined us in 2006, where he and his team were responsible for Boston Scientific's financial, compliance and operational audits and reported directly to the Audit Committee of the Board of Directors. Mr. Brown also served as Vice President, International from 1999 through 2004, where he was responsible for the financial functions of

Boston Scientific's international division in over forty countries. Previous experience also includes financial reporting and special projects at United Technologies and public accounting and consulting at Deloitte & Touche. He holds a B.B.A. degree in Accounting from the University of Toledo and an M.B.A. from the University of Michigan, and is a certified public accountant.

Tom Shea has been our Senior Vice President of Manufacturing Operations since March 2008. Prior to joining NxStage, he held several leadership positions at Jabil Incorporated, a $12 billion Tier I contract manufacturer. Most recently, Tom served as Jabil's Global Business Unit Manager, supporting clients in the aerospace, defense and telecommunications industries. In this capacity, he developed and implemented global operations, logistics and pricing strategies for his sector. He previously served as Operations Manager at Jabil where he had full plant profit and loss responsibility for their Massachusetts facility. Mr. Shea earned his M.B.A. at The University of Massachusetts and his B.S. in Production and Operations Management at Bryant University.

Winifred L. Swan has been our Senior Vice President since January 2005 and our Vice President and General Counsel since November 2000. From July 1995 to November 2000, Ms. Swan was Senior Corporate Counsel at Boston Scientific Corporation. She holds a B.A., cum laude , in Economics and Public Policy from Duke University and a J.D., cum laude and Order of the Coif , from the University of Pennsylvania Law School.

Joseph E. Turk, Jr. has been our Senior Vice President, Commercial Operations since January 2005 and our Vice President, Sales and Marketing since May 2000. From August 1998 to May 2000, Mr. Turk was employed at Boston Scientific Corporation as Director of New Business Development. Mr. Turk holds an A.B. degree in Economics from Wabash College and an M.B.A. in Marketing and Finance from Northwestern University's Kellogg School of Management.

Michael J. Webb has been our Senior Vice President of Quality, Regulatory and Clinical Affairs since August 2007, Vice President of Disposables Operations from January 2007 through August 2007, Vice President of Quality Assurance and Regulatory Affairs from July 2002 through January 2007, and our Vice President of Operations from July 2001 through July 2002. Prior to joining NxStage, Mr. Webb was Vice President of Operations for Mosaic Technologies, a developer of gene-based diagnostic products. Other previous positions include Director of Operations for TFX Medical and Director of Disposables Manufacturing and Logistics for Haemonetics Corporation. Mr. Webb received a B.S. degree in Industrial and Management Engineering and his M.B.A. in Manufacturing Management from Rensselaer Polytechnic Institute.

PART II

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

Market Information

Our common stock has been quoted on the NASDAQ Global Market under the symbol "NXTM" since July 1, 2006 and prior to that was quoted on the NASDAQ National Market since October 27, 2005. Prior to that time, there was no public market for our stock. The following table sets forth, for the periods indicated, the high and low intraday sale prices of our common stock.

	High	Low
2009		
First Quarter	$ 3.98	$2.11
Second Quarter	$ 5.90	$1.93
Third Quarter	$ 7.04	$4.64
Fourth Quarter	$ 8.43	$5.39
2008		
First Quarter	$14.97	$3.70
Second Quarter	$ 6.74	$3.84
Third Quarter	$ 4.57	$3.10
Fourth Quarter	$ 5.01	$2.10

Holders

On March 9, 2010, the last reported sale price of our common stock was $10.13 per share. As of March 9, 2010, there were approximately 77 holders of record of our common stock and approximately 3,400 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 agreements with Asahi and SVB restrict our ability to pay dividends.

Issuer Purchases of Equity Securities

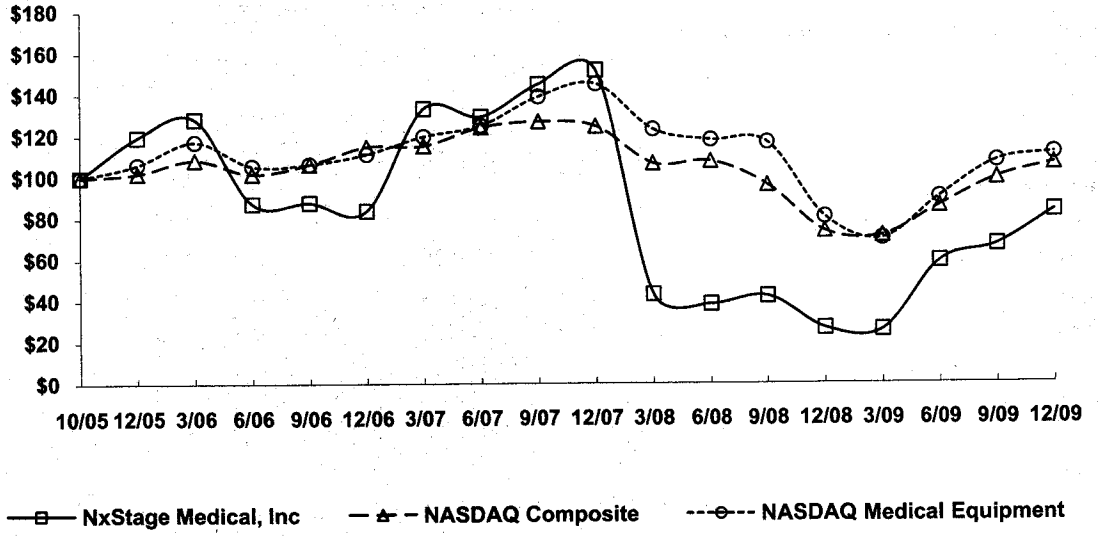
We made no repurchases of our equity securities during the year ended December 31, 2009.

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.

The comparative stock performance graph below compares the cumulative stockholder return on our common stock for the period from the first day that our common stock was publicly traded, October 27, 2005, through December 31, 2009 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 October 27, 2005 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 years ended December 31, 2009 and 2008, the quarters ended March 31, 2009 and 2008, June 30, 2009 and 2008 and September 30, 2009 and 2008.

COMPARISON OF 50 MONTH CUMULATIVE TOTAL RETURN*
Among NxStage Medical, Inc, The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index



* $100 invested on 10/27/05 in stock or 9/30/05 in index, including reinvestment of dividends. Fiscal year ending December 31.

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 operations data for the years ended December 31, 2009, 2008 and 2007 and balance sheet data as of December 31, 2009 and 2008 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 operations data for the years ended December 31, 2006 and 2005 and balance sheet data as of December 31, 2007, 2006 and 2005 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,				
	2009	2008	2007	2006	2005
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	$148,676	$128,763	$ 59,964	$ 20,812	$ 5,994
Cost of revenues	111,812	108,387	65,967	26,121	9,585
Gross profit (deficit)	36,864	20,376	(6,003)	(5,309)	(3,591)
Operating expenses:					
Selling and marketing	30,047	27,965	21,589	14,356	7,550
Research and development	9,814	8,890	6,335	6,431	6,305
Distribution	13,918	14,267	13,111	7,093	2,059
General and administrative	19,532	19,239	13,046	8,703	4,855
Total operating expenses	73,311	70,361	54,081	36,583	20,769
Loss from operations	(36,447)	(49,985)	(60,084)	(41,892)	(24,360)
Other income (expense), net	(6,755)	(852)	1,750	2,262	(120)
Net loss before taxes	(43,202)	(50,837)	(58,334)	(39,630)	(24,480)
Provision for income taxes	265	374	62	—	—
Net loss	$(43,467)	$(51,211)	$(58,396)	$(39,630)	$(24,480)
Net loss per share, basic and diluted	$ (0.93)	$ (1.23)	$ (1.86)	$ (1.60)	$ (4.31)
Weighted-average shares outstanding, basic and diluted	46,627	41,803	31,426	24,817	5,681

	December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 21,720	$ 26,642	$ 34,345	$ 61,802	$ 61,223
Working capital	36,037	34,362	40,655	64,716	62,100
Total assets	196,978	212,066	210,386	101,725	76,575
Long-term liabilities	78,267	52,580	46,134	5,495	2,106
Accumulated deficit	(276,714)	(233,247)	(182,036)	(123,640)	(84,011)
Total stockholders' equity(1)(2)(3)(4)(5)	89,446	122,447	129,717	83,409	67,354

(1) In May 2008, we issued and sold approximately 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.

(2) On October 1, 2007, we issued 6.5 million shares of common stock at $12.50 per share in connection with the Medisystems Acquisition.

(3) On February 7, 2007, we issued and sold to DaVita 2.0 million shares of common stock at a purchase price of $10.00 per share, for net proceeds of $19.9 million.

(4) We closed our follow-on public offering on June 14, 2006, which resulted in the issuance of 6.3 million shares of common stock at $8.75 per share. Net proceeds from the offering were approximately $51.3 million.

(5) We closed our initial public offering on November 1, 2005, which resulted in the issuance of 6.3 million shares of common stock at $10.00 per share. Net proceeds from the offering were approximately $56.5 million. All shares of all series of our outstanding preferred stock were converted into common stock upon the closing of our initial public offering and resulted in the issuance of 12.1 million shares of common stock.

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

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 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 centers. Given its design, the System One is particularly well-suited for home hemodialysis and more frequent, or "daily," dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared by the United States Food and Drug Administration, or FDA, for home hemodialysis as well as hospital and clinic-based dialysis. We also sell needles and blood tubing sets primarily to dialysis centers for the treatment of end-stage renal disease, or ESRD. We believe our largest future product market opportunity is for our System One used in the home hemodialysis market, or home market, for the treatment of ESRD.

We report the results of our operations in two segments: the System One segment and the In-Center segment. We distribute our products in three markets: the home, critical care and in-center. Within the System One segment, we offer a similar technology platform of the System One for the home and critical care markets with different features. The FDA has cleared the System One for hemodialysis, hemofiltration and ultrafiltration. We offer primarily needles and blood tubing sets in the In-Center segment. Our products are predominantly used by our customers to treat patients suffering from ESRD or acute kidney failure. We have marketing and sales efforts dedicated to each market, although nearly all sales in the In-Center segment are made through distributors.

We received clearance from the FDA in July 2003 to market the System One for treatment of renal failure and fluid overload using hemodialysis as well as hemofiltration and ultrafiltration. In the first quarter of 2003, we initiated sales of the System One in the critical care market to hospitals and medical centers in the United States. In late 2003, we initiated sales of the System One for the treatment of patients with ESRD. The FDA cleared the System One in June 2005 for hemodialysis in the home. Presently, we are pursuing a nocturnal indication for the System One under an IDE study started in the first quarter of 2008. We recently completed the IDE study and have submitted the associated 510(k).

Our business expanded significantly in late 2007 in connection with the October 1, 2007 acquisition of Medisystems Corporation and certain affiliated entities, which we refer to as the Medisystems Acquisition. With that acquisition, we acquired our needle and blood tubing set product lines for use predominantly in hemodialysis performed in-center as well as apheresis, which constitutes our In-center segment. The In-Center segment is significantly more mature than our System One segment. Medisystems Corporation and certain affiliated entities, which we refer to collectively as the MDS Entities, have been selling products to dialysis centers for the treatment of ESRD since 1981, and they have achieved leading positions in the United States

market for both blood tubing sets and needles. Our blood tubing set products include the ReadySet High Performance Blood Tubing set, or ReadySet, and the Streamline Airless Blood Tubing set, or Streamline. ReadySet has been on the market since 1993. Streamline is our next generation blood tubing product designed to provide improved patient outcomes and lower costs to dialysis centers. This product is early in its market launch and adoption has been somewhat limited to date, but growing. Our needle product line includes AV fistula needle sets incorporating safety features including MasterGuard Anti-Stick Needle Protectors and MasterGuard technology and ButtonHole needle sets. Our AV fistula needle sets with MasterGuard Anti-Stick Needle Protector were commercially introduced in 1995 and our ButtonHole needle sets were commercially introduced in 2002.

Our customers, which include dialysis centers and hospitals, receive reimbursement for the dialysis treatments provided with our products typically from Medicare and, to a lesser degree, from private insurers. Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. Reimbursement claims for dialysis therapy using the System One or our blood tubing sets and needles are typically submitted by the dialysis center or hospital to Medicare and other third-party payors using established billing codes for dialysis treatment or, in the critical care setting, based on the patient's primary diagnosis. Medicare presently limits reimbursement for chronic hemodialysis to three treatments per week, absent a finding of medical justification. Because most of our System One home dialysis patients are treated more than three times a week, expanding Medicare reimbursement over time to more predictably cover more frequent therapy may be critical to the market penetration of the System One in the home market and to our revenue growth in the future. As a result of the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA legislation, Centers for Medicare and Medicaid Services, or CMS, has announced that, in 2011, it will implement a new "bundled" payment for dialysis treatment. Proposed rules have been released by CMS and the public comment period concluded on December 16, 2009. Final rules will likely be published in 2010. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

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 outsource the manufacture of premixed dialysate, needles, some blood tubing sets, and some components.

In our System One segment, we market the System One in the home and critical care markets through a direct sales force in the United States primarily to dialysis centers, for ESRD hemodialysis patients, and hospitals. In our In-Center segment, we market our blood tubing and needle products primarily through distributors, although we also have a small dedicated sales force for that business. Nearly all In-Center sales are made to customers in the United States, with very limited amounts sold internationally through distributors. In May 2009, we announced our first international distribution agreement for the System One with Kimal. To date, substantially all System One segment revenues have been derived from sales within the United States. Under our agreement with Kimal, we began selling the System One in the United Kingdom and Ireland this year, and expect to sell Streamline and ButtonHole needles through Kimal in those territories in the future. Since signing this agreement with Kimal, we have continued to expand internationally, recently announcing a five year exclusive distribution agreement with Nordic Medcom AB for the promotion, sale, delivery and service of the System One and certain of our other products in Finland, Denmark and Sweden and a five year distribution agreement with Dirinco for the promotion, sale, delivery and service of the System One and certain of our other products in the Netherlands.

Since inception, we have incurred losses every quarter, and at December 31, 2009, we had an accumulated deficit of approximately $276.7 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins 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. Our ability to become profitable depends principally upon implementing design and process improvements to lower the costs of manufacturing our products, obtaining better purchasing terms and prices, growing revenue, increasing reliability of our products, improving our field equipment utilization, achieving

efficiencies in manufacturing and supply chain overhead costs, achieving efficiencies in the distribution of our products and achieving a sufficient scale of operations.

We have experienced negative operating margins and cash flows from operations and expect to continue to incur net losses in the foreseeable future. We believe, based on current projections, that we have the required resources to fund operating requirements through 2010 and beyond. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of complementary businesses, services or technologies.

Statement of Operations 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 rent or purchase 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, the majority of revenues are derived from supply and distribution contracts with distributors.

In the home market, for those customers that rent the System One, we recognize revenues on a monthly basis in accordance with customer contracts under which we supply the use of hardware and disposables needed to perform dialysis therapy sessions during a month. For customers that purchase the System One in the home market, we recognize revenue from the equipment sale ratably over the expected service obligation period and recognize disposable product revenue upon delivery.

Our contracts with dialysis centers 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 some instances, our PureFlow SL hardware. The terms of these contracts vary, and are automatically 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 an insignificant amount of revenues from the sale of ancillary products, such as extra lengths of tubing. Over time, as more home patients are treated with the System One and more systems are placed in patient homes that provide for the purchase or rental of the machine and the purchase of the related disposables, we expect this recurring revenue stream to continue to grow. A number of our home market customers, including DaVita, have purchased System One equipment, with certain customers committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. There can, however, be no assurance that we will be able to expand the percentage of our equipment placements that are purchased rather than rented.

Our critical care 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. We recognize revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms. These contracts typically have a term of one year. We expect, at least in the near term, as hospitals face continued pressure to reduce capital spending, increasingly more of our sales will include the rental rather than the sale of our System One hardware than we have experienced in the past. We derive a small amount of revenue 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 this market, we have implemented 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 not offered for the home market within our System One segment. 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. Similar to our home market, as more System One equipment is placed within hospitals, we expect to derive a growing recurring revenue stream from the sale of disposable cartridges and fluids for use with our placed System One equipment as well as, to a much lesser degree, from the sale of service and bio-medical training contracts.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Revenues from Henry Schein, our primary distributor, represented approximately 66% of our In-Center segment revenues during 2009 and approximately 80% during 2008 and 2007. During the third quarter of 2009, we began selling blood tubing sets to Gambro. Revenues from our other significant distributors, including Gambro, over each of the same periods were 31%, 20% and 10% of our In-Center segment revenues, respectively. Sales to DaVita, through Henry Schein and Gambro represent a significant percentage of these revenues. DaVita has contractual purchase commitments under two agreements: one for blood tubing sets and one for needles. DaVita's purchase obligations with respect to needles will expire under an agreement with us in January 2013. Under our recently signed Gambro agreement, Gambro has contractually committed to exclusively supply our blood tubing sets in the United States to DaVita through July 2014. Gambro's long term product supply agreement with DaVita entered into in connection with the sale of Gambro's United States dialysis clinic business to DaVita, obligates DaVita to purchase a significant majority of its product requirements from Gambro. Our In-Center segment revenues are subject to fluctuation as a result of changes in sales volumes and variations in inventory management policies of our distributors and end users. We regularly monitor the amount of inventory held by distributors to ensure it is not excessive when compared to end user demand.

Some of the distribution contracts for our In-Center segment offer rebates based on sales to specific end customers and discount incentives for early payment. Our revenues are presented net of these rebates, incentives, discounts and returns. As of December 31, 2009, we had $1.5 million reserved against trade accounts receivable for future sales incentives. We recorded $8.6 million, $7.3 million and $1.7 million during 2009, 2008 and 2007, respectively, as a reduction of sales in connection with sales incentives.

Our distribution agreement with Henry Schein, our primary distributor for the In-Center segment, originally scheduled to expire in July 2009, has been extended on a non exclusive basis while the parties work to negotiate a new agreement. If we are unable to negotiate a renewal, we will need to seek alternative distribution relationships or to sell our In-Center segment products directly to end users. Our agreements with two other distributors for the In-Center segment are scheduled to expire in July 2011 and February 2012, respectively. Our blood tubing set distribution agreement with Gambro expires in July 2014.

DaVita continues to be our most significant customer for both segments. We have long-term purchase agreements directly or indirectly covering product sales to DaVita in the In-Center segment, however, the initial term of our long-term agreement with DaVita for the purchase of the System One in the home market expired on December 31, 2009. We are currently working with DaVita to negotiate the terms of a new agreement for the home market, however, there can be no assurance that we will enter into a new agreement for the home market with DaVita or regarding the terms of any such agreement. Our February 7, 2007 agreement with DaVita contemplates ongoing sales of products following December 31, 2009. The loss of any of this business, at least in the near term, would have an adverse effect on our business.

Cost of Revenues

Cost of revenues consists primarily of direct product costs, including material and labor required to manufacture our products, service of System One equipment that we rent and sell to customers and production overhead. It also includes the cost of inspecting, servicing and repairing System One equipment prior to sale or during the warranty period and related stock-based compensation. 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.

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 we do not 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.

Results of Operations

The following table presents, for the periods indicated, information expressed as a percentage of revenues. This information has been derived from our consolidated statements of operations included elsewhere in this Annual Report on Form 10-K. You should not draw any conclusions about our future results from the results of operations for any period.

	Years Ended December 31,		
	2009	2008	2007
Revenues	100%	100%	100%
Cost of revenues	75%	84%	110%
Gross profit (deficit)	25%	16%	(10)%
Operating expenses:			
Selling and marketing	20%	22%	36%
Research and development	7%	7%	11%
Distribution	9%	11%	22%
General and administrative	13%	15%	22%
Total operating expenses	49%	55%	91%
Loss from operations	(24)%	(39)%	(101)%
Other income (expense):			
Interest income	0%	0%	5%
Interest expense	(5)%	(3)%	(2)%
Change in fair value of financial instruments	0%	2%	0%
	(5)%	(1)%	3%
Provision for income taxes	0%	0%	0%
Net loss	(29)%	(40)%	(98)%

Comparison of Years Ended December 31, 2009 and 2008

Revenues

Our revenues for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2009		2008	
System One segment				
Home	$ 63,461	43%	$ 48,319	38%
Critical Care	22,340	15%	18,554	14%
Total System One segment	85,801	58%	66,873	52%
In-Center segment	62,875	42%	61,890	48%
Total	$148,676	100%	$128,763	100%

The increase in revenues was attributable to increased sales and rentals of the System One and related disposables in both the home and critical care markets, primarily as a result of the growing number of patients using the System One as we continue to penetrate the market place, and an increase in sales of blood tubing sets in our In-Center segment.

In the home market, revenues increased $15.1 million, or 31%, in 2009 compared to 2008 as a result of an increase in the number of patients prescribed to use and centers offering the System One. During 2009 we increased the average number of patients at existing centers and the number of total centers offering the System One. Critical care market revenues increased $3.8 million, or 20%, in 2009 compared to 2008, primarily as a result of sales of additional System One units, the growth of our installed base of units and the associated sales of disposables due to our efforts to continue to penetrate the market. Future demand for our products in both the home and critical care markets is expected to remain strong due to the life-sustaining, non-elective nature of dialysis therapy. Revenues in the home market are expected to continue to increase as we further penetrate the market place and as we expand internationally. However, in the critical care market, we expect, at least in the short-term, to see a continuation of a conservative capital spending environment as hospitals face pressure to reduce capital spending.

In-Center segment revenues increased $1.0 million, or 2%, in 2009 compared to 2008. The increase in revenues was due to higher sales volumes of our blood tubing sets including Streamline, our newest blood tubing set product line. We expect future demand will be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users.

Cost of Revenues and Gross Profit

Our cost of revenues for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2009	December 31, 2008	Change	Percentage Change
System One segment	$ 64,538	$ 57,913	$ 6,625	11%
In-Center segment	47,274	50,474	(3,200)	(6)%
Total Cost of revenue	$111,812	$108,387	$ 3,425	3%

Gross profit for the System One segment increased $12.3 million, or 137%, from $9.0 million for 2008 to $21.3 million for 2009. The increase in gross profit was a result of increased revenues, improvements in reliability and equipment utilization and lower overall costs of manufacturing as we continue to realize the benefits of leveraging our manufacturing infrastructure, certain cost saving initiatives such as the transition of manufacturing and equipment service to lower cost labor markets, and improvements in product design and reliability.

Gross profit for the In-Center segment increased $4.2 million, or 37%, from $11.4 million for 2008 to $15.6 million for 2009. The increase in gross profit was due to lower manufacturing costs resulting from the benefits of certain manufacturing process improvements and product design improvements.

We expect the cost of revenues as a percentage of revenues to continue to decline over time for three general reasons. First, we expect to introduce additional process improvements and product design changes that have inherently lower cost than our current products. Second, we expect to continue to improve product reliability, which would reduce service costs. Finally, we anticipate that increased volume and realization of economies of scale will lead to better purchasing terms and prices and efficiencies in manufacturing and supply chain overhead costs. We cannot, however, guarantee that we will achieve our expected cost reduction plans.

Selling and Marketing

Our selling and marketing expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	December 31, 2009	December 31, 2008	Change	Percentage Change
System One segment	$26,144	$24,491	$1,653	7%
In-Center segment	3,903	3,474	429	12%
Total Selling and marketing	$30,047	$27,965	$2,082	7%

The increase in selling and marketing expenses was primarily the result of increased personnel and personnel-related costs, including non-cash stock-based compensation expense due to expanded sales and marketing and customer service functions. We anticipate that selling and marketing expenses will continue to increase as we broaden our marketing initiatives to increase public awareness of the System One in the home market and other products, particularly Streamline, in the In-center segment, and as we add additional sales support and marketing personnel, but decrease as a percent of revenues as we continue to leverage our existing infrastructure.

Research and Development

Our research and development expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2009	December 31, 2008	Change	Percentage Change
Research and development	$9,814	$8,890	$924	10%

The increase in research and development expenses was primarily a result of increased personnel and personnel-related costs, including non-cash stock-based compensation expense, due to increased headcount. Additionally, clinical trials expenses have increased due to increased patient enrollment in our nocturnal IDE and FREEDOM studies. We expect research and development expenses will increase in absolute dollars but remain relatively constant as a percentage of revenues in the foreseeable future as we seek to further enhance our System One and related products, and their reliability, and with the increased activity associated with our FREEDOM study.

Distribution

Our distribution expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2009	December 31, 2008	Change	Percentage Change
System One segment	$12,564	$12,631	$ (67)	(1)%
In-Center segment	1,354	1,636	(282)	(17)%
Total Distribution	$13,918	$14,267	$(349)	(2)%

The decrease in distribution expenses was primarily a result of better pricing obtained from carriers and shipping efficiencies. Distribution expenses for the System One segment remained relatively consistent year over year but decreased as a percentage of revenues from 19% during 2008 to 15% during 2009, due primarily to better pricing obtained from carriers, shipping efficiencies and improved reliability of our System One and PureFlow SL hardware. Distribution expenses for the In-center segment decreased due to shipping efficiencies. We expect that distribution expenses will continue to increase at a lower rate than revenues due to expected efficiencies gained from increased business volume, better pricing obtained from carriers, increased volume, customer adoption of our PureFlow SL hardware, which significantly reduces the weight and quantity of monthly disposable shipments, and improved reliability of System One equipment. We cannot predict the estimated impact, if any, of fuel costs on future distribution costs.

General and Administrative

Our general and administrative expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2009	December 31, 2008	Increase	Percentage Increase
General and administrative	$19,532	$19,239	$293	2%

General and administrative expenses increased year over year but decreased as a percentage of revenue from 15% during 2008 to 13% during 2009 due to our continued initiative to leverage our overhead structure. The increase in general and administrative expenses was primarily a result of increased personnel and personnel related costs, including non-cash stock-based compensation expense, offset by a decreases in external services expense resulting from cost savings measures. We expect that general and administrative expenses will remain relatively flat in the near term as we continue to leverage our existing infrastructure.

Other Income and Expense

Interest income decreased $0.5 million in 2009 compared to 2008 due to lower interest rates on investments. Interest income is derived primarily from investments in money market funds.

Interest expense increased $2.9 million in 2009 compared to 2008 due primarily to prepayment and other transaction fees of $2.0 million incurred during 2009 to pay off the entire debt obligation owed under our credit and security agreement with General Electric Capital Corporation and an increase in outstanding borrowings.

The change in fair value of the warrants issued on May 22, 2008 and August 1, 2008 in connection with the private placement resulted in the recognition of a $3.2 million gain and the change in fair value of the obligation entered into on May 22, 2008 in connection with the second tranche resulted in the recognition of a $0.7 million loss during 2008. The obligation relating to the second tranche was settled on August 1, 2008 and the fair value on settlement of $0.6 million was recorded in equity. The exercise price of the warrants was fixed at $5.50 per share on December 31, 2008 based on the Company's ability to achieve over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, beginning January 1, 2009, the warrants were classified in equity and thereafter, no longer result in the recognition of changes in fair value in earnings.

Provision for Foreign Income Taxes

The provision for income taxes of $0.3 million in 2009 and $0.4 million in 2008 relates to the profitable operations of certain of our foreign entities.

Comparison of Years Ended December 31, 2008 and 2007

Revenues

Our revenues for 2008 and 2007 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2008		2007	
System One segment				
Home	$ 48,319	38%	$29,835	50%
Critical Care	18,554	14%	14,401	24%
Total System One segment	66,873	52%	44,236	74%
In-Center segment	61,890	48%	15,728	26%
Total	$128,763	100%	$59,964	100%

The increase in revenues was attributable to the addition of the In-Center segment as a result of the Medisystems Acquisition on October 1, 2007 and increased sales and rentals of the System One and related disposables in both the critical care and home markets, primarily as a result of increased patient count as we continued to penetrate the marketplace.

In the home market, revenues increased $18.5 million, or 62%, in 2008 compared to 2007 as a result of an increase in the number of patients using and centers offering the System One. Critical care market revenue increased $4.2 million, or 29%, in 2008 compared to 2007 as a result of sales of additional System One units, the growth of our installed base of units and the associated sales of disposables due to our efforts to continue to penetrate the market.

Revenues in the In-Center segment were $61.9 million during 2008 versus and $15.7 million during 2007. We completed the Medisystems Acquisition on October 1, 2007 and therefore the 2007 and 2008 results are not comparable.

Cost of Revenues and Gross Profit (Deficit)

Our cost of revenues for 2008 and 2007 were as follows (in thousands, except percentages):

	December 31, 2008	December 31, 2007	Change	Percentage Change
System One segment	$ 57,913	$53,108	$ 4,805	9%
In-Center segment	50,474	12,859	37,615	293%
Total Cost of revenue	$108,387	$65,967	$42,420	64%

The increase in total cost of revenues was attributable primarily to increased sales volume in the home and critical care markets and the addition of the In-Center segment as a result of the Medisystems Acquisition. Gross margin increased to 16% in 2008 compared to a deficit of 10% in 2007. The improvement in gross margin was a result of the Medisystems Acquisition, manufacturing cost improvements to the System One equipment and disposables and the leveraging of our manufacturing overhead. Additionally, we incurred a one time inventory charge of $2.0 million relating to a voluntary recall of our chronic cartridges during 2007.

Selling and Marketing

Our selling and marketing expenses for 2008 and 2007 were as follows (in thousands, except percentages):

	December 31, 2008	December 31, 2007	Change	Percentage Change
System One segment	$24,491	$20,797	$3,694	18%
In-Center segment	3,474	792	2,682	339%
Total Selling and marketing	$27,965	$21,589	$6,376	30%

The increase in selling and marketing expense was primarily the result of the increase in salary, benefits, payroll taxes and stock-based compensation for the additional selling and marketing personnel and the addition of the In-Center segment as a result of the Medisystems Acquisition.

Research and Development

Our research and development expenses for 2008 and 2007 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2008	December 31, 2007	Change	Percentage Change
Research and development	$8,890	$6,335	$2,555	40%

The increase in research and development expense was primarily the result of an increase in headcount and related salary, benefits, payroll taxes and stock-based compensation for research and development personnel from 2007 to 2008 and increased clinical trials expenses.

Distribution

Our distribution expenses for 2008 and 2007 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2008	December 31, 2007	Change	Percentage Change
System One segment	$12,631	$12,909	$ (278)	(2)%
In-Center segment	1,636	202	1,434	710%
Total Distribution	$14,267	$13,111	$1,156	9%

Distribution expense was 11% of revenue in 2008 compared to 22% in 2007. The decreased cost of distribution as a percentage of revenue was due to lower cost of distribution for the In-Center segment as well as improved shipping rates resulting from our efforts to successfully negotiate better shipping terms, better product reliability resulting in fewer expedited shipments and reduction in cost of shipping bagged fluids as we converted more patients to our PureFlow SL products.

General and Administrative

Our general and administrative expenses for 2008 and 2007 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2008	December 31, 2007	Change	Percentage Change
General and administrative	$19,239	$13,046	$6,193	47%

The increase in general and administrative expenses in 2008 compared to 2007 was primarily due to $2.8 million of amortization of intangible assets acquired in the Medisystems Acquisition and an increase in headcount and associated infrastructure costs of $2.8 million and professional services including legal, tax and audit fees of $0.5 million.

General and administrative expenses as a percentage of revenue decreased to 15% in 2008 compared to 22% in 2007. The decrease was due to our continued initiative to leverage our overhead structure.

Other Income and Expense

Interest income decreased $2.4 million, or 83%, in 2008 compared to 2007 due to decreased cash and investments which were used to fund operations and lower interest rates on investments. Interest income is derived primarily from investments in money market funds.

Interest expense increased $2.8 million, or 251%, in 2008 compared to 2007 due to an increase in outstanding borrowings. Interest expense was derived primarily from borrowings under our credit and security agreement with General Electric Capital Corporation that we entered into in November 2007.

The change in fair value of the warrants issued on May 22, 2008 and August 1, 2008 in connection with the private placement resulted in the recognition of a $3.2 million gain and the change in fair value of the obligation entered into on May 22, 2008 in connection with the second tranche resulted in the recognition of a $0.7 million loss during 2008. The obligation relating to the second tranche was settled on August 1, 2008 and the fair value on settlement of $0.6 million was recorded in equity. The exercise price of the warrants was fixed at $5.50 per share on December 31, 2008 based on the Company's ability to achieve over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, beginning January 1, 2009, the

warrants were classified in equity and thereafter, no longer result in the recognition of changes in fair value in earnings.

Provision for Foreign Income Taxes

The provision for income taxes of $0.4 million in 2008 and $0.1 million in 2007 relates to the profitable operations of certain of our foreign entities acquired in the Medisystems Acquisition on October 1, 2007.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of December 31, 2009, our accumulated deficit was $276.7 million and we had cash and cash equivalents of approximately $21.7 million.

Our primary ongoing cash requirements will be to fund operating activities, product development and debt service. Our primary sources of liquidity are cash on hand and ongoing revenues. A number of our home market customers, including DaVita, have purchased System One equipment, with certain customers committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. There can, however, be no assurance that we will be able to expand the percentage of our equipment placements that are purchased rather than rented. At December 31, 2009, we had $21.7 million of cash and cash equivalents and working capital of $36.0 million. A significant factor affecting the management of our ongoing cash requirements is our ability to execute upon cost reduction initiatives to lower product cost. We have the flexibility under our term loan with Asahi to seek up to $40.0 million in additional debt at market interest rates to fund our growth objectives. On March 10, 2010, we entered into a Loan and Security Agreement, the Agreement, with Silicon Valley Bank, SVB, for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the Agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our Agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. We did not draw any amounts under the Agreement at closing, but may do so in the future to fund working capital and operating requirements.

In May 2009, we entered into a series of agreements with Asahi. The agreements are multi-faceted and include a term loan in which Asahi agreed to provide us with $40.0 million of debt financing. The term loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of our assets. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions. We used $30.0 million of the proceeds to pay off the entire debt obligation, including prepayment and other transaction fees, owed under our credit and security agreement with General Electric Capital Corporation. We intend to use the remaining proceeds for operating purposes. In connection with entering into the loan and security agreement with SVB, we amended the term loan and security agreement with Asahi to provide for secondary liens on the SVB collateral.

The term loan agreement with Asahi includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Any of these remedies would likely have a material adverse effect on our business.

On May 22, 2008, we entered into a $43 million private placement agreement to sell an aggregate of 9.6 million shares of our common stock at a price of $4.50 per share and warrants to purchase 1.9 million shares of our common stock at an exercise price of $5.50 per share. The exercise price of the warrants was fixed at $5.50 per share on December 31, 2008 based on the Company's ability to achieve over 3,100 ESRD patients prescribed to receive therapy using the System One. The warrants have a term of 5 years and expire on May 28, 2013 and August 1, 2013 for the first and second tranches respectively. The warrants also contain a net share settlement feature that is available to investors once the underlying shares are registered. Additional provisions require the Company, 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.

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 $1.6 million as other long-term liabilities at December 31, 2009 for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2009, 2008 or 2007.

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

	Years Ended December 31,		
	2009	2008	2007
Net cash used in operating activities	$(13,157)	$(53,222)	$(59,629)
Net cash (used in) provided by investing activities	(2,065)	(457)	2,539
Net cash provided by financing activities	10,031	47,575	40,204
Foreign exchange effect on cash and cash equivalents	269	(499)	172
Net cash flow	$ (4,922)	$ (6,603)	$(16,714)

Net Cash Used in Operating Activities. For each of the periods above, net cash used in operating activities was attributable primarily to net losses after adjustment for non-cash charges, such as depreciation, amortization and stock-based compensation expense. Net cash used in operating activities decreased by $40.1 million and $6.4 million during the twelve months ended December 31, 2009 and 2008, respectively. The decrease in net cash used in operating activities during both periods were primarily due to a decrease in our net loss after adjustments for non-cash charges, as we continue to reduce product costs, and a decrease in inventory purchases for the production and placement of System One and PureFlow SL hardware as a result of reduced costs and improved reliability. The decrease in net cash used in operating activities during 2008 was offset by an increase in cash used for accounts payable due to timing of vendor payments. Deferred revenues increased $5.1 million, $10.1 million and $16.3 million during the years ended December 31, 2009, 2008 and 2007, respectively. The increase in deferred revenues was primarily a result of purchases of System One equipment by certain customers, including DaVita, offset by the amortization of $6.0 million, $4.3 million and $0.7 million during 2009, 2008 and 2007, respectively, of deferred revenues into revenues. Non-cash transfers from inventory to field equipment for the placement of rental units with our customers represented $10.3 million, $21.8 million and $17.6 million, respectively, during the years ended December 31, 2009, 2008 and 2007. The decrease is primarily due to lower equipment costs, improved equipment reliability and our continued effort to improve equipment utilization. Non-cash transfers from field equipment to deferred costs of sales for sales of units to customers represented $7.4 million, $12.8 million and $14.7 million during the years ended December 31, 2009, 2008 and 2007, respectively.

Net Cash (Used in) Provided by Investing Activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, primarily for research and development, information technology, manufacturing operations and capital improvements to our facilities. During 2007, net cash provided by investing activities included $10.7 million of proceeds from short-term investments and $2.7 million of costs to acquire Medisystems.

Net Cash Provided by Financing Activities. Net cash provided by financing activities decreased by $37.5 million during 2009 and increased by $7.4 million during the twelve months ended December 31, 2008.

Net cash provided by financing activities during 2009 included $40.0 million of borrowings under our term loan with Asahi offset by $0.1 million in fees paid in connection with the Asahi debt issuance, $30.0 million in repayments of borrowings under our credit and security agreement with GE and a $0.5 million amendment fee paid in connection with the March 16, 2009 amendment to our credit and security agreement with GE. Net cash provided by financing activities during 2008 included $5.0 million of additional borrowings under our credit and security agreement with GE and $42.3 million net proceeds from the sale of 9.6 million shares of our common stock and warrants to purchase 1.9 million shares of our common stock. Net cash provided by financing activities during 2007 included $19.9 million of net proceeds received from the sale to DaVita of our common stock, $2.7 million of proceeds from the exercise of stock options and warrants and net borrowings of $17.6 million.

We have experienced negative operating margins and cash flows from operations and expect to continue to incur net losses in the foreseeable future. We believe, based on current projections, that we have the required resources to fund operating requirements through 2010 and beyond. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of, complementary businesses, services or technologies.

Contractual Obligations

The following table summarizes our contractual commitments as of December 31, 2009 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
Debt obligations	$ 53,355	$ 1,732	$51,623	$ —	$ —
Operating leases	3,910	1,759	2,146	5	—
Purchase obligations	50,388	27,822	17,814	3,168	1,584
Total	$107,653	$31,313	$71,583	$3,173	$1,584

Long-term debt obligations include the aggregate outstanding principle amount under our $40.0 million term loan with Asahi and related deferred interest and estimated interest payments.

Our purchase obligations include purchase commitments for System One components, primarily for equipment, blood tubing sets, needles, and fluids pursuant to contractual agreements with several of our suppliers. Certain of these commitments may be extended and/or canceled at our option.

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 accounting principles generally accepted in the United States, or 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.

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. 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 whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

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 refunds can be made. If a reasonable estimate of future returns or refunds 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.

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 PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

Under the rental arrangements, which combine the use of the System One and PureFlow SL hardware with a specified number of disposable products supplied to customers for a fixed price per month, 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.

For customers that purchase the System One and PureFlow SL hardware, we must determine whether (a) the equipment has stand-alone value and (b) the fair value of the undelivered items, typically the disposables and, in some instances service, can be determined. If either criteria is not met, which is generally the case, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and 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. If both criteria are met, then the items are accounted for separately as delivered.

In the critical care market, we structure sales of the System One as direct product sales. We recognize revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

Our contracts for the System One in the critical care market provide for training, technical support and 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 revenue is recognized ratably over the warranty period.

In-Center Segment

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. 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 cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

In addition to contractually determined volume discounts, in many agreements we offer rebates based on sales to specific end customers and discount incentives for early payment. Discounts and incentives 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.

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 an estimated forecast of product demand for each of our existing product configurations. 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 capitalize field equipment at cost and amortize field equipment through cost of revenues using the straight-line method over an estimated useful life of five years. We review the estimated useful life of five years periodically for reasonableness. Factors considered in determining the reasonableness of the useful life include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns and the impact of planned design improvements. We also review field 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.

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 on a straight-line basis 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 restricted stock programs, we make assumptions principally related to the number of awards that are expected to vest.

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. Furthermore, 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. 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. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

Goodwill

We assess goodwill for impairment annually in the fourth quarter and whenever events or circumstances indicate an impairment may exist. Goodwill may be considered impaired if we determine that the carrying value of our reporting unit, including goodwill, exceeds the reporting unit's fair value. 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. We estimate reporting unit fair value using a discounted cash flow approach which requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. Our annual impairment testing indicated no significant risk of impairment based upon changes in value that are reasonably likely to occur. However, changes in these estimates and assumptions could materially affect the estimated fair values of reporting units.

Accounting for Income Taxes

We record the tax effect of transactions when such transactions are recorded in our consolidated statement of operations, with deferred taxes provided for items that are recognized in different periods for financial statement and tax reporting purposes. Due to uncertainty surrounding the realization of deferred tax assets through future taxable income, we have provided a full valuation allowance and no benefit has been recognized for the net operating loss carryforward and other deferred tax assets. Accordingly, a valuation allowance for the full amount of the deferred tax asset has been established as of December 31, 2009 and 2008 to reflect these uncertainties.

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. 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. If our 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 file federal, state and foreign tax returns. We have accumulated significant losses since our inception in 1998. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

Related-Party Transactions

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg, a director and significant stockholder, under which we agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and certain affiliated entities, which we refer to as the MDS Entities, in exchange for the issuance of 6.5 million shares of our common stock. We may be required to issue additional shares of common stock to Mr. Utterberg because, pursuant to the terms of the stock purchase agreement, Mr. Utterberg and we have agreed to indemnify each other in the event of certain breaches or failures, and any such indemnification amounts must be paid in shares of our common stock, valued at the time of payment. However, we will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of our common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. The stock purchase agreement provided that an aggregate of one million shares would be held back in escrow to secure any indemnification obligations of Mr. Utterberg for a period of two years. All shares have been released from escrow, consistent with the terms of the escrow agreement entered into between the parties. In connection with the acquisition of the MDS Entities we assumed a $2.8 million liability owed to DSU Medical Corporation, or DSU, a Nevada corporation, which is wholly-owned by Mr. Utterberg. We paid the liability during 2008. As a condition to the parties' obligations to consummate the Medisystems Acquisition, Mr. Utterberg and DSU

entered into a consulting agreement with us, dated October 1, 2007. We paid Mr. Utterberg and DSU $150,000, $200,000 and $50,000 during 2009, 2008 and 2007, respectively, in consideration for services performed under this agreement. Finally, in connection with the Medisystems Acquisition, we also agreed that if Mr. Utterberg is no longer a director of NxStage, our Board of Directors will nominate for election to our Board of Directors any director nominee proposed by Mr. Utterberg, subject to certain conditions.

On May 22, 2008, we entered into Securities Purchase Agreements relating to a private placement of shares of our common stock and warrants to purchase shares of our common stock. The private placement took place in two closings, on May 28, 2008 and August 1, 2008, and raised $25.0 million and $18.0 million, respectively, in gross proceeds. Participants in the private placement consisted of unaffiliated and affiliated accredited institutional investors. One of these investors, the Sprout Group, is affiliated with one of our Board members, Dr. Philippe O. Chambon. The Sprout Group purchased 1.0 million shares and warrants to purchase 0.2 million shares of our common stock at a price similar to that of unaffiliated investors. Under applicable rules of the NASDAQ Global Market, the second closing of the private placement, which included all shares issued to the Sprout Group and other affiliated accredited institutional investors, was subject to stockholder approval, which was obtained at a special meeting on July 31, 2008.

We entered into a Securities Purchase Agreement with OrbiMed Advisors, LLC, or OrbiMed, in connection with the private placement which required that we appoint one individual nominated by OrbiMed to our Board of Directors upon the earlier of the second closing of the private placement or sixty days after the first closing of the private placement. The appointment of Mr. Jonathan Silverstein, a general partner of OrbiMed, on July 23, 2008, to the Board satisfied this requirement. OrbiMed purchased an aggregate of 5.6 million shares and warrants to purchase 1.1 million shares of our common stock in connection with the private placement at a price similar to that of unaffiliated investors.

Recent Accounting Pronouncements

Effective January 1, 2009, we adopted a new accounting standard update regarding business combinations. As codified under Accounting Standards Codification, or ASC, 805, this update provides that, upon initially obtaining control, an acquirer shall recognize 100 percent of the fair values of acquired assets, including goodwill and assumed liabilities, with only limited exceptions, even if the acquirer has not acquired 100 percent of its target. As a consequence, the step acquisition model will be eliminated. Additionally, it changes current practice, in part, as follows: (1) contingent consideration arrangements will be recorded at their estimated fair valued at the acquisition date and included on that basis in the purchase price consideration; (2) transaction costs will be expensed as incurred, rather than capitalized as part of the purchase price; (3) pre-acquisition contingencies will generally have to be accounted for in purchase accounting at fair value to the extent that such value can be objectively determined; (4) in-process research and development will be capitalized and either amortized over the life of the product or written off if the project is abandoned or impaired; (5) changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense; and (6) restructuring costs generally will be expensed in periods subsequent to the acquisition date.

Since this accounting update is applicable to future acquisitions completed after January 1, 2009 and we have not had any business combinations subsequent to January 1, 2009 to date, the adoption of this update did not have an impact on our consolidated financial statements. This accounting update also amended accounting for uncertainty in income taxes such that adjustments made to valuation allowances on deferred taxes and acquired tax contingencies associated with acquisitions that closed prior to the effective date of ASC 805 would also follow the provisions of this update. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in purchase accounting will be recognized in current period income tax expense.

Effective January 1, 2009, we adopted an accounting standard update as codified under ASC 815 that requires the application of a two-step approach in evaluating whether an equity-linked financial instrument (or embedded feature) is indexed to a company's own stock, including evaluating the instrument's contingent

exercise and settlement provisions, and must be applied to all instruments outstanding on the date of adoption. The adoption of this update did not have an impact our consolidated financial statements.

Effective April 1, 2009, we adopted an accounting standard update as codified under ASC 820-10-65 which provides guidelines for making fair value measurements more consistent and provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed this guidance is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of this update did not have an impact on our consolidated financial statements.

Effective April 1, 2009, we adopted a new accounting standard update as codified under ASC 825. This update requires expanded disclosures about the fair value of financial instruments in interim as well as in annual financial statements and also requires those disclosures in all interim financial statements. The adoption of this standard has resulted in the enhanced disclosure of the fair values attributable to debt instruments within this annual report. Since this update addresses disclosure requirements, the adoption of this update did not impact our financial position, results of operations or cash flows.

Effective April 1, 2009, we adopted an accounting standard update as codified under ASC 320-10-65, which provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event related to debt securities and to more effectively communicate when an other-than-temporary impairment event has occurred. The adoption of this update did not have an impact on our consolidated financial statements.

Effective June 30, 2009, we adopted a new accounting standard for subsequent events as codified in ASC 855-10. The update provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The adoption of this standard did not impact our financial position, results of operations or cash flows.

Effective July 1, 2009, we adopted *The "FASB Accounting Standards Codification" and the Hierarchy of Generally Accepted Accounting Principles,* or ASC 105. This standard establishes only two levels of generally accepted accounting principles in the United States, or GAAP, authoritative and nonauthoritative. The Financial Accounting Standards Board, or FASB, ASC became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became nonauthoritative. We began using the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it did not have any impact on our consolidated financial statements.

In June 2009, the FASB issued the following new accounting standard which has not yet been integrated into the Codification, Statement of Financial Accounting Standards No. 166, *Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140,* or SFAS 166. Accordingly, SFAS 166 will remain authoritative until integrated. SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, SFAS 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. SFAS 166 is effective for transfer of financial assets occurring on or after January 1, 2010. We have not determined the effect the adoption of SFAS 166 will have on our financial statements, but the effect will be limited to future transactions.

In August 2009, the FASB issued Update No. 2009-05, which amends ASC 820 to provide further guidance on how to measure the fair value of a liability, an area where practitioners have been seeking further guidance. It primarily does three things: 1) sets forth the types of valuation techniques to be used to value a

liability when a quoted price in an active market for the identical liability is not available, 2) clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability and 3) clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. The update became effective during our fourth quarter of 2009. The adoption of this update did not impact our consolidated financial statements.

In September 2009, the FASB issued Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-13. It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. The update will be effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. We are currently assessing the future impact of this new accounting update to our consolidated financial statements.

In September 2009, the FASB issued Update No. 2009-14, *Certain Revenue Arrangements That Include Software Elements — a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-14. It amends ASC 985-605 such that tangible products, containing both software and non-software components that function together to deliver the tangible product's essential functionality, are no longer within the scope of ASC 985-605. It also amends the determination of how arrangement consideration should be allocated to deliverables in a multiple-deliverable revenue arrangement. This ASU will become effective for us for revenue arrangements entered into or materially modified on or after April 1, 2011. Earlier application is permitted with required transition disclosures based on the period of adoption. The adoption of this update will not have an impact on our consolidated financial statements as we have concluded the software component of our tangible products to be incidental.

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

Interest Rate Exposure

Our investment portfolio consists primarily of 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 investments are subject to changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. Due to the conservative nature of our investments, we believe interest rate risk is mitigated. 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 Exposure

We operate a manufacturing and research facility in Germany as well as manufacturing facilities in Italy and Mexico. 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 United States from foreign companies and have agreed to pay them in currencies other than the U.S. dollar, including the Euro and Peso. We also have contracts with key suppliers that expose us to foreign currency risks. As a result, our expenses and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses increase when translated into U.S. dollars. Although it is possible to do so and we may in the future, we do not currently hedge our foreign currency transactions since the exposure has not been material to our historical operating results. A 10% movement in the Euro and Peso would have an overall impact to the statement of operations of approximately $2.0 million for 2009, which would have been approximately 1.0% of total annual expenses.

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

NXSTAGE MEDICAL, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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. as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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. at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young, LLP

Boston, Massachusetts
March 12, 2010

NXSTAGE MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2009	December 31, 2008
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,720	$ 26,642
Accounts receivable, net	14,238	11,886
Inventory	28,117	30,862
Prepaid expenses and other current assets	1,227	2,011
Total current assets	65,302	71,401
Property and equipment, net	10,336	12,254
Field equipment, net	21,726	30,445
Deferred cost of revenues	27,799	23,711
Intangible assets, net	28,208	31,004
Goodwill	42,698	42,698
Other assets	909	553
Total assets	$ 196,978	$ 212,066
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 19,827	$ 17,183
Accrued expenses	9,377	10,746
Current portion of long-term debt	61	9,110
Total current liabilities	29,265	37,039
Deferred revenue	38,490	29,634
Long-term debt	37,854	21,054
Other long-term liabilities	1,923	1,892
Total liabilities	107,532	89,619
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of December 31, 2009 and 2008	—	—
Common stock: par value $0.001, 100,000,000 shares authorized; 46,795,859 and 46,548,585 shares issued and outstanding as of December 31, 2009 and 2008, respectively	47	47
Additional paid-in capital	365,548	355,266
Accumulated deficit	(276,714)	(233,247)
Accumulated other comprehensive income	565	381
Total stockholders' equity	89,446	122,447
Total liabilities and stockholders' equity	$ 196,978	$ 212,066

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2009	2008	2007
	(In thousands, except per share data)		
Revenues	$148,676	$128,763	$ 59,964
Cost of revenues	111,812	108,387	65,967
Gross profit (deficit)	36,864	20,376	(6,003)
Operating expenses:			
Selling and marketing	30,047	27,965	21,589
Research and development	9,814	8,890	6,335
Distribution	13,918	14,267	13,111
General and administrative	19,532	19,239	13,046
Total operating expenses	73,311	70,361	54,081
Loss from operations	(36,447)	(49,985)	(60,084)
Other (expense) income:			
Interest income	35	489	2,855
Interest expense	(6,790)	(3,877)	(1,105)
Change in fair value of financial instruments	—	2,536	—
	(6,755)	(852)	1,750
Net loss before income taxes	(43,202)	(50,837)	(58,334)
Provision for income taxes	265	374	62
Net loss	$(43,467)	$(51,211)	$(58,396)
Net loss per share, basic and diluted	$ (0.93)	$ (1.23)	$ (1.86)
Weighted-average shares outstanding, basic and diluted	46,627	41,803	31,426

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In	Accumulated	Other Comprehensive Income	Total Stockholders'
	Shares	Amount	Capital	Deficit	(Loss)	Equity
			(In thousands, except share data)			
Balance at December 31, 2006	27,806,543	$28	$206,848	$(123,640)	$ 173	$ 83,409
Comprehensive income (loss):						
Net loss	—	—	—	(58,396)	—	(58,396)
Foreign currency translation adjustment	—	—	—	—	371	371
Total comprehensive income (loss)	—	—	—	—	—	(58,025)
Issuance of common stock, net of issuance costs	2,000,000	2	16,937	—	—	16,939
Exercise of stock options	392,028	—	2,354	—	—	2,354
Exercise of warrants	21,000	—	—	—	—	—
Shares issued under employee stock purchase and incentive plan	35,967	—	341	—	—	341
Shares issued to Directors in lieu of cash	16,355	—	225	—	—	225
Stock-based compensation expense	—	—	3,224	—	—	3,224
Shares issued for Medisystems acquisition	6,500,000	7	81,243	—	—	81,250
Balance at December 31, 2007	36,771,893	37	311,172	(182,036)	544	129,717
Comprehensive income (loss):						
Net loss	—	—	—	(51,211)	—	(51,211)
Foreign currency translation adjustment	—	—	—	—	(163)	(163)
Total comprehensive (loss)	—	—	—	—	—	(51,374)
Issuance of common stock, net of issuance costs	9,555,556	10	37,880	—	—	37,890
Exercise of stock options	71,547	—	103	—	—	103
Shares issued under employee stock purchase and incentive plan	95,102	—	377	—	—	377
Shares issued to Directors in lieu of cash	54,487	—	220	—	—	220
Stock-based compensation expense		—	5,514	—	—	5,514
Balance at December 31, 2008	46,548,585	47	355,266	(233,247)	381	122,447
Comprehensive income (loss):						
Net loss	—	—	—	(43,467)	—	(43,467)
Foreign currency translation adjustment	—	—	—	—	184	184
Total comprehensive (loss)	—	—	—	—	—	(43,283)
Reclassificaion warrant liability to equity	—	—	1,858	—	—	1,858
Exercise of stock options	86,927	—	270	—	—	270
Shares issued under employee stock purchase and incentive plan	116,799	—	403	—	—	403
Shares issued to Directors in lieu of cash	43,548	—	196	—	—	196
Stock-based compensation expense		—	7,555	—	—	7,555
Balance at December 31, 2009	46,795,859	$47	$365,548	$(276,714)	$ 565	$ 89,446

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2009	2008	2007
	(In thousands)		
Cash flows from operating activities:			
Net loss	$(43,467)	$(51,211)	$(58,396)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	20,778	19,201	9,277
Amortization of inventory step-up	—	52	1,520
Stock-based compensation	9,226	5,842	3,449
Change in fair value of financial instruments	—	(2,536)	—
Other	2,690	1,038	248
Changes in operating assets and liabilities:			
Accounts receivable	(2,208)	(4,761)	(3,597)
Inventory	(9,209)	(23,431)	(41,344)
Prepaid expenses and other current assets	1,513	747	405
Accounts payable	2,568	(4,626)	10,202
Accrued expenses and other liabilities	(119)	(3,641)	2,305
Deferred revenue	5,071	10,104	16,302
Net cash used in operating activities	(13,157)	(53,222)	(59,629)
Cash flows from investing activities:			
Purchases of property and equipment	(1,725)	(3,037)	(3,788)
Maturities of short-term investments	—	1,100	30,410
Purchases of short-term investments	—	—	(19,667)
Acquisition costs, net of cash acquired	—	—	(2,749)
(Increase) decrease in other assets	(340)	1,480	(1,667)
Net cash (used in) provided by investing activities	(2,065)	(457)	2,539
Cash flows from financing activities:			
Issuance of common stock	—	42,284	19,939
Proceeds from stock option and purchase plans	673	372	2,695
Proceeds from loans and lines of credit	39,895	5,000	25,000
Net repayments on loans and lines of credit	(30,537)	(81)	(7,430)
Net cash provided by financing activities	10,031	47,575	40,204
Foreign exchange effect on cash and cash equivalents	269	(499)	172
Decrease in cash and cash equivalents	(4,922)	(6,603)	(16,714)
Cash and cash equivalents, beginning of year	26,642	33,245	49,959
Cash and cash equivalents, end of year	$ 21,720	$ 26,642	$ 33,245
Supplemental Disclosures			
Cash paid for interest	$ 4,749	$ 3,308	$ 897
Cash paid for taxes	$ 401	$ 641	$ 91
Noncash Investing Activities			
Transfers from inventory to field equipment and deferred cost of revenues	$ 10,315	$ 21,833	$ 17,602
Transfers from field equipment to deferred cost of revenues	$ 7,358	$ 12,759	$ 14,712

See accompanying notes to these consolidated financial statements.

1. Nature of Operations

NxStage Medical, Inc., or the Company, is 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. The Company's primary product, the NxStage 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 centers. The System One is cleared by the United States Food and Drug Administration, or the FDA, and sold commercially in the United States for the treatment of acute and chronic kidney failure and fluid overload. The System One consists of an electromechanical medical device (cycler), a disposable blood tubing set and a dialyzer (filter) pre-mounted in a disposable, single-use cartridge. Dialysate used in conjunction with this system in the home is most frequently prepared using the Company's PureFlow SL hardware and premixed concentrate bags. The Company also sells needles and blood tubing to dialysis centers for the treatment of end-stage renal disease, or ESRD.

The Company has experienced negative operating margins and cash flows from operations and it expects to continue to incur net losses in the foreseeable future. The Company believes, based on current projections, that it has the required resources to fund operating requirements through 2010 and beyond. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of, complementary businesses, services or technologies.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made to prior years' financial statements to conform to the 2009 presentation.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with generally accepted accounting principles in the United States requires 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

The Company recognizes 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. The Company's 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 whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

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 refunds can be made. If a reasonable estimate of future returns or refunds cannot be made, the Company recognizes 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.

System One Segment

The Company derives its 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 PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

Under the rental arrangements, which combine the use of the System One and PureFlow SL hardware with a specified number of disposable products supplied to customers for a fixed price per month, 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.

For customers that purchase the System One and PureFlow SL hardware, the Company must determine whether (a) the equipment has stand-alone value and (b) the fair value of the undelivered items, typically the disposables and, in some instances service, can be determined. If either criteria is not met, which is generally the case, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and recognized as revenue on a straight-line basis over the expected term of the Company's 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. If both criteria are met, then the items are accounted for separately as delivered.

In the critical care market, the Company structures sales of the System One primarily as direct product sales. The Company recognizes revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

The Company's contracts for the System One in the critical care market provide for training, technical support and warranty services to its customers. The Company recognizes training and technical support revenue when the related services are performed. In the case of extended warranty, the revenue is recognized ratably over the warranty period.

In-Center Segment

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. Some of the Company's distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

In addition to contractually determined volume discounts, in many agreements the Company offers rebates based on sales to specific end customers and discount incentives for early payment. Discounts and sales incentives are recorded as a reduction of revenues and trade accounts receivable, based on the Company's best estimate of the amount of probable future rebate or discount on current sales.

Foreign Currency Translation and Transactions

Assets and liabilities of the Company's 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 operations and totaled $0.3 million, $0.1 million and $0.7 million in 2009, 2008 and 2007, respectively.

Cash, Cash Equivalents, Marketable Securities and Restricted Cash

The Company considers all highly-liquid investments purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents include amounts invested in federal agency securities, commercial paper and money market funds. Cash equivalents are stated at cost plus accrued interest, which approximates market value.

The Company had $0.6 million and $0.2 million of restricted cash classified as other assets at December 31, 2009 and 2008, respectively. These amounts relate primarily to standby letters of credit to guarantee annual VAT refunds in Italy.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. Management believes that the financial institutions that hold the Company's cash are financially sound and, accordingly, minimal credit risk exists with respect to these balances.

Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company makes substantial sales. One customer represented 19% of accounts receivable at December 31, 2009. Two customers represented 26% and 10% of accounts receivable at December 31, 2008. To reduce risk, the Company routinely assesses the financial strength of its customers and closely monitors their amounts due and, as a result of its assessment, believes that its accounts receivable credit risk exposure is limited. Historically, the Company has not experienced any significant credit losses related to an individual customer or group of customers in any particular industry or geographic area. The Company maintains an allowance for doubtful accounts based on an analysis of historical losses from uncollectible accounts 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 operations.

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

Year Ended	Balance at Beginning of Year	Provision	Other(1)	Write-offs	Balance at End of Year
December 31, 2009	$918	—		$193	$725
December 31, 2008	$296	$694	—	$ 72	$918
December 31, 2007	$ 63	$122	$111	—	$296

(1) Amount represents allowance for doubtful accounts assumed in the Medisystems acquisition.

The Company uses and is dependent upon a number of single source suppliers of components, subassemblies and finished goods. The Company is dependent on the ability of its 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 could have a material adverse effect on the Company. The Company believes that its relationships with its suppliers are satisfactory.

Fair Value Measures

Effective January 1, 2008, the Company adopted a newly issued accounting standard for fair value measures for financial assets and liabilities. Effective January 1, 2009 the Company adopted a newly issued accounting standard for fair value measurements for all non financial assets and non financial liabilities not recognized or disclosed at fair value in the financials statements on a recurring basis. The adoption of the accounting standard for these assets and liabilities did not have an impact on the Company's financial position or results of operations; however, this standard may impact us in subsequent periods and require additional disclosure.

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 the Company has 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.

Inventory

Inventory is stated at the lower of cost, determined using the first-in first out method (FIFO), or market (net realizable value). The Company regularly reviews its inventory quantities on hand and related costs and records a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. The Company also reviews its inventory value to determine if it reflects the 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.

Property and Equipment and Field Equipment

Property and equipment and field equipment are recorded at cost. Depreciation is provided over the estimated useful lives of the related assets using the straight-line method for financial statement purposes. Repairs and maintenance are expensed as incurred. Expenditures that increase the value or productive capacity of assets are capitalized. 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 either included in operations or, most frequently, deferred and recognized in operations on a straight-line basis over the same period as the related revenue.

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, 2009 and 2008 represents machinery and equipment under installation.

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 the Company that are swapped for cyclers that need repairs or maintenance by the Company while being rented or owned by a patient. The Company continually monitors 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 assesses whether there are any indicators of impairment for such equipment. During 2009, 2008 and 2007, no such impairment was recognized.

The Company periodically reviews its field equipment's useful life for reasonableness. Factors considered in determining the reasonableness of the useful life include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns and the impact of planned design improvements. The Company also reviews its field equipment carrying value for reasonableness. The Company considers factors such as actual equipment disposals and the ability to verify the equipment's existence in the field to identify lost equipment. Write-downs for lost equipment are included in distribution expenses. The estimated service lives of property and equipment and field equipment are as follows:

	Estimated Useful Life
Manufacturing equipment and tooling	5 to 6 years
Molds	4 years
Leasehold improvements	Lesser of 5 years or lease term
Computer and office equipment	3 years
Furniture	5 to 7 years
Field equipment	5 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. Furthermore, periodically the Company assesses whether long-lived assets including intangible assets, should be 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. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, the Company may be required to record additional impairment charges. During 2009, 2008 and 2007, 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.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of Medisystems Corporation and certain affiliated entities, which the Company refers to as the MDS Entities. The Company believes the factors contributing to the goodwill that resulted from acquiring the MDS Entities include (but are not limited to), increased manufacturing capacity and efficiency, securing long-term rights to certain technology and brand names and strengthening long-term customer relationships common to both the MDS Entities and the Company. The Company tests goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets might be impaired. This impairment test is performed annually during the fourth quarter at the reporting unit level. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. When testing goodwill for impairment the Company primarily looks to the fair value of the System One segment, as a majority of the goodwill relates to the system one segment. Reporting unit fair value is estimated using a discounted cash flow approach which requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. During 2009, 2008 and 2007, no such impairment was recognized. The goodwill recognized upon acquiring the MDS Entities is not deductible for tax purposes.

Stock-Based Compensation

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense on a straight-line basis 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 performance based restricted stock units, the Company recognizes expense using the graded vesting methodology based on the number of shares expected to vest after assessing the probability that certain performance criteria will be met. Compensation expense associated with these performance based restricted stock units is adjusted quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date the results are determined.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock options and quoted market prices of the Company's common stock to estimate fair value of restricted stock units. The expected term is estimated using the simplified method, as defined in Staff Accounting Bulletin No. 107. 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 option term. Because the Company has no options that are traded publicly and because of its limited trading history as a public company, the stock volatility assumption is based on an analysis of the Company's historical volatility and the volatility of the common stock of comparable companies in the medical device and technology industries. The dividend yield of zero is based upon the fact that the Company has not historically granted cash dividends, and does not expect to issue dividends in the foreseeable future.

Warranty Costs

For a period of one year following the delivery of products to its critical care customers, the Company provides for product repair or replacement if it is determined that there is a defect in material or manufacture of the product. For sales into the critical care market, the Company accrues estimated warranty costs at the time of shipment based on contractual rights and historical experience. Warranty expense is included in cost of revenues in the consolidated statement of operations. Following is a rollforward of the Company's warranty accrual:

Year Ended	Balance at Beginning of Year	Provision	Usage	Balance at End of Year
December 31, 2009	$235	$331	$(361)	$205
December 31, 2008	$220	$366	$(351)	$235
December 31, 2007	$172	$379	$(331)	$220

Distribution Expenses

Distribution expenses consist of costs incurred in shipping product to and from customers and are charged to operations as incurred. Shipping and handling costs billed to customers are included in revenues and totaled $0.2 million in 2009, $0.2 million in 2008 and $0.1 million in 2007.

Research and Development Costs

Research and development costs are charged to operations as incurred.

Income Taxes

The Company records the tax effect of transactions when such transactions are recorded in its consolidated statement of operations. The Company records 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. The Company's 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.

The Company periodically assesses its exposures related to its provisions for income taxes and accrues for contingencies that may result in potential tax obligations. On January 1, 2007, the Company adopted a newly issued accounting standard on accounting for uncertain tax positions. The adoption of this standard did not have a material impact on the Company's financial position or results of operations. Upon adoption, the Company had no unrecognized tax benefits recorded and had no interest and penalty accrual or expense. The Company recognizes interest and penalties for uncertain tax positions in income tax expense.

The Company files federal, state and foreign tax returns. The Company has accumulated significant losses since its inception in 1998. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of the Company's tax years remain open to examination by the major taxing jurisdictions to which the Company is subject.

Comprehensive Loss

The Company has chosen to disclose comprehensive (loss), which consists of net loss and other comprehensive income (loss), in the consolidated statement of changes in stockholders' equity. Other comprehensive income (loss) primarily includes foreign currency translation adjustments that are excluded from results of operations.

Subsequent Events

Events occurring subsequent to December 31, 2009 have been evaluated for potential recognition or disclosure in the Company's financial statements.

Recent Accounting Pronouncements

Effective January 1, 2009, the Company adopted a new accounting standard update regarding business combinations. As codified under Accounting Standards Codification, or ASC, 805, this update provides that, upon initially obtaining control, an acquirer shall recognize 100 percent of the fair values of acquired assets, including goodwill and assumed liabilities, with only limited exceptions, even if the acquirer has not acquired 100 percent of its target. As a consequence, the step acquisition model will be eliminated. Additionally, it changes current practice, in part, as follows: (1) contingent consideration arrangements will be recorded at their estimated fair value at the acquisition date and included on that basis in the purchase price consideration; (2) transaction costs will be expensed as incurred, rather than capitalized as part of the purchase price; (3) pre-acquisition contingencies will generally have to be accounted for in purchase accounting at fair value to the extent that such value can be objectively determined; (4) in-process research and development will be capitalized and either amortized over the life of the product or written off if the project is abandoned or impaired; (5) changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense; and (6) restructuring costs generally will be expensed in periods subsequent to the acquisition date.

Since this accounting update is applicable to future acquisitions completed after January 1, 2009 and the Company has not had any business combinations subsequent to January 1, 2009 to date, the adoption of this update did not have an impact on the Company's consolidated financial statements. This accounting update also amended accounting for uncertainty in income taxes such that adjustments made to valuation allowances on deferred taxes and acquired tax contingencies associated with acquisitions that closed prior to the effective date of ASC 805 would also follow the provisions of this update. Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in purchase accounting will be recognized in current period income tax expense.

Effective January 1, 2009, the Company adopted an accounting standard update as codified under ASC 815 that requires the application of a two-step approach in evaluating whether an equity-linked financial

instrument (or embedded feature) is indexed to a company's own stock, including evaluating the instrument's contingent exercise and settlement provisions, and must be applied to all instruments outstanding on the date of adoption. The adoption of this update did not have an impact the Company's consolidated financial statements.

Effective April 1, 2009, the Company adopted an accounting standard update as codified under ASC 820-10-65 which provides guidelines for making fair value measurements more consistent and provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed this guidance is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of this update did not have an impact the Company's consolidated financial statements.

Effective April 1, 2009, the Company adopted a new accounting standard update as codified under ASC 825. This update requires expanded disclosures about the fair value of financial instruments in interim as well as in annual financial statements and also requires those disclosures in all interim financial statements. The adoption of this standard has resulted in the enhanced disclosure of the fair values attributable to debt instruments within this annual report. Since this update addresses disclosure requirements, the adoption of this update did not impact the Company's financial position, results of operations or cash flows.

Effective April 1, 2009, the Company adopted an accounting standard update as codified under ASC 320-10-65, which provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event related to debt securities and to more effectively communicate when an other-than-temporary impairment event has occurred. The adoption of this update did not have an impact on the Company's consolidated financial statements.

Effective June 30, 2009, the Company adopted a new accounting standard for subsequent events as codified in ASC 855-10. The update provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The adoption of this standard did not impact the Company's financial position, results of operations or cash flows.

Effective July 1, 2009, the Company adopted *The "FASB Accounting Standards Codification" and the Hierarchy of Generally Accepted Accounting Principles,* or ASC 105. This standard establishes only two levels of generally accepted accounting principles in the United States, or GAAP, authoritative and nonauthoritative. The Financial Accounting Standards Board, or FASB, ASC became the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification became nonauthoritative. The Company began using the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it did not have any impact on the Company's consolidated financial statements.

In June 2009, the FASB issued the following new accounting standard which has not yet been integrated into the Codification, Statement of Financial Accounting Standards No. 166, *Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140*, or SFAS 166. Accordingly, SFAS 166 will remain authoritative until integrated. SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, SFAS 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities

that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. SFAS 166 is effective for transfer of financial assets occurring on or after January 1, 2010. The Company has not determined the effect the adoption of SFAS 166 will have on its financial statements, but the effect will be limited to future transactions.

In August 2009, the FASB issued Update No. 2009-05, which amends ASC 820 to provide further guidance on how to measure the fair value of a liability, an area where practitioners have been seeking further guidance. It primarily does three things: 1) sets forth the types of valuation techniques to be used to value a liability when a quoted price in an active market for the identical liability is not available, 2) clarifies that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustment to other inputs relating to the existence of a restriction that prevents the transfer of the liability and 3) clarifies that both a quoted price in an active market for the identical liability at the measurement date and the quoted price for the identical liability when traded as an asset in an active market when no adjustments to the quoted price of the asset are required are Level 1 fair value measurements. The update became effective during the Company's fourth quarter of 2009. The adoption of this update did not impact its consolidated financial statements.

In September 2009, the FASB issued Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-13. It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The revised guidance primarily provides two significant changes: 1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and 2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. The update will be effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The Company is currently assessing the future impact of this new accounting update to its consolidated financial statements.

In September 2009, the FASB issued Update No. 2009-14, *Certain Revenue Arrangements That Include Software Elements — a consensus of the FASB Emerging Issues Task Force*, or ASU 2009-14. It amends ASC 985-605 such that tangible products, containing both software and non-software components that function together to deliver the tangible product's essential functionality, are no longer within the scope of ASC 985-605. It also amends the determination of how arrangement consideration should be allocated to deliverables in a multiple-deliverable revenue arrangement. This ASU will become effective for the Company for revenue arrangements entered into or materially modified on or after April 1, 2011. Earlier application is permitted with required transition disclosures based on the period of adoption. The adoption of this update will not have an impact on the Company's consolidated financial statements as the Company has concluded the software component of its tangible products to be incidental.

3. Significant Revenue Contracts

National Service Provider Agreement and Stock Purchase Agreement with DaVita

In February 2007, the Company entered into a National Service Provider Agreement and a Stock Purchase Agreement with DaVita, a significant customer, which the Company considers to be a single arrangement.

In connection with the National Service Provider Agreement, the Company agreed to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The National Service Provider Agreement included other terms such as development efforts, training,

market collaborations, limited market exclusivity and volume discounts. Per the agreement, DaVita no longer has any preferred geographic market or exclusivity rights, and as of December 31, 2009 the initial term of the National Service Provider Agreement with DaVita expired, and the parties continue to operate under the agreement. The sale of equipment and other items included in the arrangement were considered to be multiple-element sales arrangements pursuant to ASC 605, *Revenue Recognition*. The Company has determined that it cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under this arrangement were deferred and recognized as revenue on a straight-line basis over the expected term of the Company's obligation to supply disposables and service pursuant to the agreement, which is seven years. The Company has deferred both the unrecognized revenue and direct costs relating to the delivered equipment, which costs are being amortized over the same period as the related revenue.

In connection with the Stock Purchase Agreement, DaVita purchased 2.0 million shares of the Company's common stock for $10.00 per share, which on the date of the purchase represented a premium over the market price of $1.50 per share, or $3.0 million. The Company has recorded the $3.0 million premium as deferred revenue and is recognizing this revenue ratably over seven years, consistent with its equipment service obligation to DaVita.

Asahi Strategic Business Alliance

In May 2009, the Company entered into a series of agreements with Asahi Kasei Kuraray Medical, or Asahi, a leading medical supply company headquartered in Japan which the company considers to be a single arrangement. The signed agreements between the Company and Asahi are multi-faceted and include a Term Loan and Security Agreement, or Loan Agreement, Technology and Trademark License Agreement, or License Agreement, a Dialyzer Production Agreement, a Supply and Purchase Agreement and a Collaboration Agreement.

Under the terms of the Loan Agreement, Asahi agreed to provide the Company with $40.0 million of debt financing. The four year loan bears interest at 8% annually, with 50% of the interest deferred to maturity. The Company estimated the fair value of the loan at issuance using quoted prices for similar debt instruments, level 2 measurements within the fair value hierarchy. The fair value of the loan of $36.3 million was recorded by the Company, net of a $3.7 million discount. The discount will be amortized ratably over the term of the loan into interest expense. In accordance with the terms of the License Agreement, the Company granted Asahi a royalty-free license to its Streamline blood tubing set technology and production technology to make and sell the Company's current dialyzer design. The Company estimated the fair value of the license using an income approach, namely the relief from royalty approach, which requires assumptions related to future cash flows, assumed royalty rates and a discount rate, level 3 measurements within the fair value hierarchy. The fair value of the license of $3.7 million was recorded as deferred revenue and will be recognized as revenue over the estimated life of the underlying patents, of six to seven years. The deferral of the consideration allocated to the license represents a noncash operating activity.

Under the terms of the Dialyzer Production Agreement in which the Company agreed to manufacturer dialyzers for Asahi, the Company will recognize revenue from product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

Kimal Strategic Business Alliance

In March 2009, the Company signed a five year exclusive distribution agreement with Kimal plc, or Kimal. Pursuant to the agreement, the Company will sell Kimal the NxStage System One and certain other products for use or resale in the UK and Ireland.

The Company has determined that it cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under this arrangement are deferred and recognized as revenue on a straight-line basis over the longer of the economic life of the equipment or the expected term of the Company's obligation to supply disposables pursuant to the agreement, which is five years. The Company has deferred both the unrecognized revenue and direct costs relating to the delivered equipment, which costs are being amortized over the same period as the related revenue.

4. Business Combination

On June 4, 2007, the Company entered into a stock purchase agreement with David S. Utterberg under which it agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and certain affiliated entities, collectively the MDS Entities. The acquisition was part of the Company's strategy to expand the business on a commercial, operational and financial scale as well as enhance the Company's ability to execute operationally. Medisystems was a vendor prior to acquisition and Mr. Utterberg is a director and significant stockholder of the Company. The acquisition was completed on October 1, 2007 and the operating results of the MDS Entities have been included in the consolidated statements of operations since the acquisition date. The acquisition of the MDS Entities was accounted for using the purchase method of accounting and the aggregate purchase price was approximately $85.4 million, which consisted of stock valued at approximately $81.3 million, transaction costs of $3.6 million, and a charge of $0.5 million for acquisition-related exit activities. The issuance of stock in connection with the acquisition represents a noncash investing activity.

Acquisition-Related Exit Activity Accounted for in Purchase Accounting

As a result of the Company's acquisition of the MDS Entities on October 1, 2007, the Company established and approved a plan to integrate the acquired operations of the MDS Entities into the operations of the Company. The following table summarizes the reserves related to exit activities that the Company has established and the related activity (in thousands):

	Severence	Relocation	Total
Balance at 12/31/07	$ 301	$ 139	$ 440
Restructuring expense	145	149	294
Cash payments	(445)	(281)	(726)
Balance at 12/31/08	1	7	8
Cash payments	(1)	(7)	(8)
Balance at 12/31/09	$ —	$ —	$ —

Unaudited Pro-Forma Results

The following unaudited pro forma financial information gives effect to the acquisition as if it had been completed on January 1, 2007. The pro forma information presented below does not purport what the actual results would have been had the acquisition occurred on January 1, 2007 (in thousands, except per share amounts):

	December 31, 2007
Proforma net revenue	$102,088
Proforma operating loss	(53,625)
Proforma net loss	(52,269)
Pro forma net loss per share, basic and diluted	$ (1.43)

5. Inventory

Inventories include material, labor and overhead, and are stated at lower of cost (first-in, first-out) or market. The components of inventories are as follows (in thousands):

	December 31, 2009	December 31, 2008
Purchased components	$14,214	$15,296
Work in process	1,640	1,402
Finished goods	12,263	14,164
	$28,117	$30,862

During 2007, the Company recorded a $2.0 million charge for the recall of cartridges in the home market, of which $1.2 million was for the write off of inventory, and $0.8 million was for other costs related to the replacement of cartridges and rework of inventory. The $1.5 million provision represents the total value of inventory that was affected by the home market cartridge recall. As of December 31, 2008, the Company had none of the affected inventory remaining on-hand.

6. Property and Equipment and Field Equipment

Property and equipment are carried at cost less accumulated depreciation. A summary of the components of property and equipment are as follows (in thousands):

	December 31, 2009	December 31, 2008
Manufacturing equipment and tooling	$ 9,804	$ 8,620
Leasehold improvements	4,846	4,696
Computer and office equipment	2,283	2,190
Molds	1,803	893
Furniture	471	445
Construction-in-process	1,619	2,491
	20,826	19,335
Less accumulated depreciation	(10,490)	(7,081)
Property and equipment, net	$ 10,336	$12,254

Depreciation expense for property and equipment was $3.4 million, $3.0 million and $1.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

Field equipment is carried at cost less accumulated depreciation at December 31, 2009 and 2008 as follows (in thousands):

	December 31, 2009	December 31, 2008
Field equipment	$ 48,381	$ 47,989
Less accumulated depreciation	(26,655)	(17,544)
Field equipment, net	$ 21,726	$ 30,445

Depreciation expense for field equipment was $9.8 million, $9.0 million and $6.1 million for the years ended December 31, 2009, 2008 and 2007, respectively.

7. Goodwill and Intangible Assets

During the third quarter of 2008, the Company finalized the purchase price allocation for the Medisystems Acquisition. During 2008, the Company increased severance and relocation accruals by $0.1 million, recorded an additional $0.1 million in accruals for certain pre-acquisition contingencies and recorded adjustments to the fair value of certain other assets and liabilities acquired in the MDS Acquisition of $1.0 million all of which resulted in an increase to goodwill of $1.2 million. The increase in goodwill represents a noncash investing activity.

Intangible assets consisted of the following (in thousands):

	December 31, 2009		December 31, 2008		Estimated Useful Life
	Cost	Accumulated Amortization	Cost	Accumulated Amortization	
Bloodline, needle and other patented and unpatented technology	$ 6,200	$(1,744)	$ 6,200	$ (970)	8 years
Trade names	2,300	(370)	2,300	(205)	14 years
Customer relationships	26,000	(4,178)	26,000	(2,321)	14 years
Intangible assets, gross	$34,500	$(6,292)	$34,500	$(3,496)	

The Company recognized amortization expense of $2.8 million during both 2009 and 2008 and $0.7 million during 2007. The Company will record $2.8 million of amortization expense for each of the years ending December 31, 2010 through 2014 and $14.2 million in the aggregate thereafter related to the above intangible assets.

8. Net Loss per Share

Basic loss per share is computed by dividing income 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 shares had been issued.

The following potential common stock equivalents were not included in the computation of diluted net loss per share as their effect would have been anti-dilutive (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Options to purchase common stock	584	275	688
Restricted stock units	888	—	2
Total	1,472	275	690

9. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2009	December 31, 2008
Payroll and related benefits	$4,433	$ 3,052
Distribution expenses	1,616	1,423
Warrant liability	—	1,857
Other	3,328	4,414
	$9,377	$10,746

10. Debt

On May 15, 2006, the Company entered into an equipment line of credit agreement with Silicon Valley Bank for the purpose of financing field equipment purchases and placements. The line of credit agreement provided for the availability of up to $20.0 million through December 31, 2007, and borrowings bore interest at the prime rate plus 0.5% (8.75% as of December 31, 2006). Concurrent with entering into a new credit facility in November 2007, the Company repaid all outstanding borrowings under this agreement in the aggregate amount of $4.9 million, which included principal and accrued interest and the final interest payment. This extinguishment of debt gave rise to early recognition of approximately of $0.1 million of interest expense for the year ended December 31, 2007.

On November 21, 2007, the Company obtained a $50.0 million credit and security agreement with a term of 42 months from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., which was subsequently acquired by General Electric Capital or (GE). The credit facility consisted of a $30.0 million term loan and a $20.0 million revolving credit facility. The Company borrowed $25.0 million under the term loan in November 2007 and borrowed the remaining $5.0 million under the term loan on March 25, 2008. The Company used $4.9 million of the proceeds from the term loan to repay all amounts owed under the term loan with Silicon Valley Bank. On March 16, 2009, the Company amended its credit and security agreement with GE. The amendment postponed principal payments under the term loan for three months from April through June 2009, and modified certain covenants and the interest rate on the term loan and revolving credit facility. In connection with this amendment, the Company also granted the facility lenders a security interest in all of the Company's intellectual property, increasing the collateral securing this facility to include nearly all the assets of the Company. Borrowings under the term loan, as amended in March 2009, bore interest at a rate of 11.12% per annum. Interest on the term loan was payable on a monthly basis. The Company was also required to pay a maturity premium of $0.9 million at the time of loan payoff. The Company accrued the maturity premium as additional interest over the term. Any borrowings under the revolving credit facility bore interest at LIBOR plus 6.5% per annum with a LIBOR floor of 4.0%. The revolving credit facility of the loan included an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which would be charged in the event the revolving credit facility was terminated prior to May 21, 2011. The Company paid a $0.5 million amendment fee in connection with the March 2009 amendment of its credit and security agreement with GE. Concurrent with entering into the term loan with Asahi, the Company terminated the GE credit and security agreement and repaid all outstanding borrowings owed under its credit and security agreement with GE, including prepayment and other transactions fees.

In June 2009, the Company closed a $40.0 million term loan and security agreement with Asahi. Borrowings bear interest at a rate of 8% per annum payable in arrears on November 1st and May 1st, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of the Company's assets. The

term loan may be prepaid, without penalty, at the Company's option. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of the Company's common stock, with the number of shares to be determined based upon the average closing stock price of the Company's common stock during the thirty business days preceding the maturity date. Under no circumstance would the Company be obligated to issue more than 10% of the number of its shares of common stock outstanding on the maturity date to Asahi in satisfaction of this obligation; provided that the Company and Asahi may mutually agree, in each of its own sole discretion, to increase the 10% limitation up to 20%. The term loan and security agreement with Asahi includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event the Company fails to satisfy the covenants, or otherwise goes into default, Asahi has a number of remedies, including sale of the Company's assets and acceleration of all outstanding indebtedness.

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 will be recorded ratably to interest expense over the term of the agreement, through May 31, 2013. The Company used $30.0 million of the proceeds from the term loan and security agreement to pay off the Company's debt obligation owed under its credit and security agreement with GE, including $2.0 million of prepayment and other transactions fees which were recorded to interest expense during the three months ended June 30, 2009.

In addition to the $40.0 million term loan, the Company had one Euro denominated loan outstanding of $0.1 million and $0.2 million at December 31, 2009 and 2008, respectively, which expires in September 2011, and is included in current and long-term debt.

Annual maturities of principal under the Company's debt obligations outstanding at December 31, 2009, gross of a $3.1 million discount, are as follows (in thousands):

2010	$ 61
2011	47
2012	—
2013(1)	40,938
	$41,046

(1) Amount includes $938 thousand of deferred interest related to the Asahi term loan

11. Business Segment and Geographic Information

After an evaluation of the business activities regularly reviewed by the Company's chief operating decision-maker for which separate discrete financial information is available, management determined that the Company has two reporting segments, System One and In-Center. Beginning in the first quarter of 2009, the Company allocated previously unallocated cost of revenues to its System One and In-Center segments. Prior year segment information has been changed to conform to the current presentation.

The accounting policies of the reportable segments are the same as those described in Note 2, "Summary of Significant Accounting Policies." The profitability measure employed by the Company and its chief operating decision maker for making decisions about allocating resources to segments and assessing segment performance is segment (loss) profit, which consists of sales, less cost of sales, selling and marketing and distribution expenses.

The Company's management measures are designed to assess performance of these operating segments excluding certain items. As a result, certain corporate expenses are excluded from the segment operating

performance measures, including research and development expenses and general and administrative expenses, as they are managed centrally.

Within the System One segment, the Company derives revenue 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 in the home, 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, the Company sells a similar technology platform of the System One with different features. Some of the Company's largest customers in the home market provide outsourced renal dialysis services to some of the Company's customers in the critical care market. Sales of product to both markets are made through dedicated sales forces and products are distributed directly to the customer, or the patient.

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

The Company's reportable segments consist of the following (in thousands):

	System One	In-Center	Unallocated	Total
Year Ended December 31, 2009				
Revenues from external customers	$ 85,801	$62,875	$ —	$148,676
Segment (loss) profit	(17,444)	10,343	(29,346)	(36,447)
Segment assets	74,534	17,346	105,098	196,978
Year Ended December 31, 2008				
Revenues from external customers	$ 66,873	$61,890	$ —	$128,763
Segment (loss) profit	(23,092)	10,075	(36,968)	(49,985)
Segment assets	78,956	17,948	115,162	212,066
Year Ended December 31, 2007				
Revenues from external customers	$ 44,236	$15,728	$ —	$ 59,964
Segment (loss) profit	(31,664)	2,376	(30,796)	(60,084)
Segment assets	71,072	12,618	126,696	210,386

Substantially all of the Company's 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 United States.

The following table summarizes the number of customers who individually comprise greater than 10% of total revenue:

	Years Ended December 31,		
	2009	2008	2007
Customer A	22%	18%	20%
Customer B	28%	39%	22%

Sales to Customer A are primarily in the System One segment and sales to Customer B are to one of the Company's significant distributors in the In-Center segment. Half of all Customer B sales are to Customer A.

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

	December 31, 2009	December 31, 2008
Total segment assets	$ 91,880	$ 96,904
Corporate assets:		
Cash and cash equivalents	21,720	26,642
Property and equipment, net	10,336	12,254
Intangible assets, net	28,208	31,004
Goodwill	42,698	42,698
Prepaid and other assets	2,136	2,564
Total assets	$196,978	$212,066

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

	December 31, 2009	December 31, 2008	December 31, 2007
United States	$25,922	$35,924	$36,754
Europe	5,290	5,679	5,142
Mexico	850	1,096	1,135
	$32,062	$42,699	$43,031

12. Commitments and Contingencies

The Company enters into arrangements to purchase inventory requiring minimum purchase commitments in the ordinary course of business.

As of October 1, 2007, in connection with the Medisystems Acquisition, the Company, through its wholly-owned subsidiary, Medisystems Corporation, assumed a supply and distribution agreement with Kawasumi, a Japanese contract manufacturer. This agreement covers blood tubing sets and needle sets for the In-Center segment, and has certain minimum purchase commitments. On May 6, 2008, the Company through its wholly-owned subsidiary, Medisystems Corporation, entered into a new supply and distribution agreement with Kawasumi covering only blood tubing sets. Pursuant to the terms of the agreement, Kawasumi agreed to continue to manufacture and supply blood tubing sets to the Company through an initial term ending January 31, 2010. In exchange for Kawasumi's commitment to supply blood tubing sets, and Kawasumi's agreement not to sell blood tubing sets to any other entity in the United States, the Company agreed to purchase certain minimum quantities of blood tubing sets. This agreement amends, but does not replace, the prior supply and distribution agreement entered into between Medisystems Corporation and Kawasumi. The prior agreement originally covered the supply of needles as well as blood tubing sets. The new agreement supersedes the prior agreement with respect to the supply of blood tubing sets while the prior agreement continued to be in effect with respect to needles supplied by Kawasumi. Kawasumi's obligation under the prior agreement to supply needles expires in February 2011, with opportunities to extend the term beyond that date.

On March 1, 2007, the Company entered into a long-term agreement with the Entrada Group, or Entrada, to establish manufacturing and service operations in Mexico, initially for its cycler and PureFlow SL disposables and later for its PureFlow SL hardware. The agreement obligates Entrada to provide the Company with manufacturing space, support services and a labor force through 2012. Subject to certain exceptions, the Company is obligated for facility fees through the term of the agreement which approximate $0.2 million

annually. The agreement may be terminated by either party upon material breach, generally following a 30-day cure period, or upon the insolvency of the other party.

In January 2007, the Company 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, the Company has 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 60-day cure period, or upon the insolvency of the other party.

The Company maintains its corporate headquarters in a leased building located in Lawrence, Massachusetts and maintains its manufacturing operations in Mexico, Germany, and Italy. During 2005, the Company renewed its lease agreement at its headquarters through 2012. The lease agreement contains a provision for future rent increases, requires the Company to pay executory costs (real estate taxes, operating expenses and common utilities) and provides for a renewal option of five years. The Company's leased manufacturing facilities are subject to lease agreements with termination dates beginning in 2011. 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, net of sublease income, was $1.7 million, $1.8 million and $1.0 million for the years ended December 31, 2009, 2008 and 2007, respectively. The lease agreement for the Company's headquarters included a tenant improvement allowance paid by the landlord of $0.6 million, which has been recorded as both a leasehold improvement and a deferred rent obligation. All of the Company's leases are accounted for as operating leases.

The future minimum rental payments as of December 31, 2009 under the Company's operating leases are as follows (in thousands):

2010	$1,759
2011	1,588
2012	558
2013	5
	$3,910

13. Income Taxes

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 comprised of the following (in thousands):

	December 31, 2009	December 31, 2008
Deferred tax assets:		
Net operating loss carryforwards	$ 95,610	$ 83,904
Research and development credits	5,271	4,743
Other	6,843	3,259
Total deferred tax assets	107,724	91,906
Deferred tax liabilities:		
Depreciation	(4,938)	(4,156)
Deferred tax liability recorded on basis difference of intangible assets acquired as part of Medisystems acquisition	(11,048)	(12,143)
Total deferred tax liabilities	(15,986)	(16,299)
Net deferred tax assets before valuation allowance	91,738	75,607
Less: Valuation allowance	(91,738)	(75,607)
Net deferred tax assets	$ —	$ —

As of December 31, 2009, the Company had federal, state and foreign net operating loss carryforwards of approximately $248.0 million, $209.0 million and $0.2 million, respectively, available to offset future taxable income, if any. Substantially all net losses are in the United States. The federal net operating loss carryforwards will expire between 2019 and 2029 if not utilized, while the state net operating loss carryforwards will expire between 2010 and 2029 if not utilized. The Company also had federal and state research and development credit carryforwards of $3.8 million and $2.2 million, which begin to expire in 2019 if not utilized. During 2009, the deferred tax valuation allowance increased by approximately $15.7 million, primarily as the result of increases to net operating losses and credits. A full valuation allowance has been recorded in the accompanying consolidated financial statements to offset the Company's deferred tax assets because the future realizability of such assets is uncertain. 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.

The Company has $4.8 million of net operating losses resulting from excess tax deductions relating to stock-based compensation. The Company will realize the benefit of these losses through increases to stockholders' equity in future periods when and if the losses are utilized to reduce future tax payments.

The provision for income taxes of $0.3 million, $0.4 million and $0.1 million in 2009, 2008 and 2007, respectively, relates to the profitable operations 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,		
	2009	2008	2007
Federal statutory rate	34.0%	34.0%	34.0%
State income tax, net of federal tax benefit	4.9%	0.0%	0.0%
Valuation allowance	(38.5)%	(34.2)%	(33.2)%
Other, net	(1.0)%	(0.5)%	(0.9)%
Effective tax rate	(0.6)%	(0.7)%	(0.1)%

The Company has $0.1 million of unrecognized tax benefits at December 31, 2009 that would, if recognized, affect its effective tax rate. The Company does not anticipate a significant change in the amount of these unrecognized tax benefits over the next twelve months. Since the Company is in a loss carryforward position, the Company is generally subject to US federal, state, local and foreign income tax examinations by tax authorities for all years for which a loss carryforward is available.

14. Stock Plans and Stock-Based Compensation

Stock Incentive Plans

The Company maintains the 2005 Stock Incentive Plan (the "2005 Plan") that governs awards to both employees and non-employees. The 2005 Plan replaces and supersedes the 1999 Stock Option and Grant Plan (the "1999 Plan"), except that awards granted under the 1999 Plan remain in effect pursuant to their original terms. Upon adoption of the 2005 Plan 971,495 shares, which were then still available for grant under the 1999 Plan, were transferred and became available for grant under the 2005 Plan. In January 2007, the number of shares authorized for grant under the 2005 Plan was increased by 600,000 shares, pursuant to an evergreen provision under the Plan which was subsequently eliminated by the Board in July 2007. In October 2007, the Company's shareholders approved an amendment to the 2005 Plan that increased the number of authorized shares by an additional 3,800,000 shares, of which no more than 1,500,000 shares may be granted as restricted stock units. In May 2009, the Company's shareholders approved an amendment to the 2005 Plan that increased the number of authorized shares by an additional 4,100,000 shares and provided that each share issued under a restricted stock or restricted stock unit award after May 28, 2009 will reduce the number of total shares available for grant by 1.23 shares.

Unless otherwise specified by the Company's 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.

At December 31, 2009, options for the purchase of 4,137,211 shares of common stock are available for future grant under the 2005 Plan. The Company settles stock option exercises and restricted stock unit vesting with newly issued common shares. As of December 31, 2009, the Company has reserved 6,850,050 shares of common stock for issuance upon settlement of awards.

In March 2009, the Company committed to grant up to 1,591,250 restricted stock units to certain employees and executive officers based on the Company's financial performance for the year ending December 31, 2009. The grants vest over a remaining requisite service period of two years. Further, in March 2009, the Company approved its 2009 corporate bonus plan. Payout under the 2009 bonus plan will be based on the Company's financial performance for the year ending December 31, 2009 and will be paid primarily in

shares of the Company's common stock. The estimated payout under the 2009 bonus plan was recognized as compensation expense during 2009 and has been classified as a liability on the Company's consolidated balance sheet. The terms of both awards are governed by the 2009 Plan.

The Company's 2005 Employee Stock Purchase Plan (the "2005 Purchase Plan") authorizes the issuance of up to 100,000 shares of common stock to participating employees through a series of periodic offerings. In May 2009 and June 2008, the Company amended the 2005 Purchase Plan to include an additional 500,000 and 50,000 shares, respectively. 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 the Company's common stock on the NASDAQ Global Market on the day the offering terminates, unless otherwise determined by the Board or Compensation Committee. As of December 31, 2009, the maximum number of shares available for future issuance under the 2005 Purchase Plan is 396,488.

Stock Options

A summary of the status of stock options granted under all of the Company's plans at December 31, 2009, and changes during the year then ended, is as follows:

Stock Options	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (In thousands)	Weighted Average Remaining Contractual Life (In years)
Outstanding at beginning of year	5,437,097	$8.38		
Granted	1,755,430	$2.45		
Exercised	(86,927)	$3.10		
Forfeited or expired	(255,550)	$9.87		
Outstanding at end of year	6,850,050	$6.87	$19,315	4.62
Fully vested and exercisable	4,034,447	$7.55	$ 8,821	3.98
Fully vested, exercisable and expected to vest	6,568,490	$6.91	$18,266	4.33

The aggregate intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was $0.3 million, $0.2 million and $3.6 million, respectively. The intrinsic value for stock options is calculated based on the market price of the Company's common stock as of December 31, 2009, less the exercise price of the underlying awards, excluding out-of-the-money awards. The total fair value of options that vested during the years ended December 31, 2009, 2008 and 2007 was $6.0 million, $5.7 million and $4.5 million, respectively.

The weighted-average fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was $1.33, $2.85 and $8.33 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:

	Year Ended December 31, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007
Expected life (in years)	4.75	4.75	4.75
Risk-free interest rate	1.71% - 2.58%	2.40% - 3.70%	3.42% - 4.94%
Expected stock price volatility	65% to 75%	67%	65% to 75%
Expected dividend yield	—	—	—

Restricted Stock Units

The total fair value of restricted stock units that vested was $0.1 million during each of the years ended December 31, 2009, 2008 and 2007. The weighted-average fair value of restricted stock units granted during the years ended December 31, 2009 and 2007 was $2.11 and $14.98 per unit, respectively. The following table summarizes the status of the unvested restricted stock units:

	Shares	Weighted Average Grant-date Fair Value	Aggregate Intrinsic Value (In thousands)	Weighted Average Remaining Contractual Life (In years)
Nonvested at December 31, 2008	21,777	$13.45		
Granted	1,213,734	$ 2.11		
Vested	(8,947)	$12.81		
Nonvested at December 31, 2009	1,226,564	$ 2.23	$10,242	6.2

Employee Stock Purchase Plan

The weighted-average fair value of stock purchase rights granted as part of the 2005 Purchase Plan during the years ended December 31, 2009, 2008 and 2007 was $0.97, $0.87 and $2.60 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:

	Year Ended December 31, 2009	Year Ended December 31, 2008	Year Ended December 31, 2007
Expected life (in months)	6	6	6
Risk-free interest rate	0.18% - 0.33%	1.6% - 3.4%	4.90%
Expected stock price volatility	65%	65% - 67%	65% to 75%
Expected dividend yield	—	—	—

There were 103,551, 85,691 and 35,967 shares issued under the 2005 Purchase Plan for the years ended December 31, 2009, 2008 and 2007, respectively, which resulted in share-based compensation expense of $0.1 million for each of the years ended December 31, 2009, 2008 and 2007.

Stock-based Compensation Expense

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

	Years Ended December 31,		
	2009	2008	2007
Cost of revenues	$1,593	$1,053	$ 339
Selling and marketing	3,507	2,247	1,140
Research and development	774	520	221
General and administrative	3,352	2,022	1,749
Total stock-based compensation expense	$9,226	$5,842	$3,449

As of December 31, 2009, approximately $10.4 million of unrecognized stock compensation cost related to nonvested stock option and restricted stock unit awards (net of estimated forfeitures) is expected to be recognized over a weighted-average period of 2.0 years.

Other Compensation Plans

The Company maintains 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, the Company obtains an annual actuarial valuation of the benefit plans. The Company has recorded a liability of $1.6 million and $1.4 million at December 31, 2009 and 2008, respectively, as other long-term liabilities for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2009, 2008 or 2007.

15. Employee Benefit Plan

The Company has 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. The Company contributes 100% of the first 3% of the employee's contribution and 50% of the next 2% of the employee's contribution. The Company contributed $1.0 million, $0.9 million and $0.8 million to the 401(k) Plan during the years ended December 31, 2009, 2008 and 2007, respectively.

16. Stockholders' Equity

On May 22, 2008, the Company entered into a $43.0 million private placement agreement to sell an aggregate of 9.6 million shares of its common stock at a price of $4.50 per share and warrants to purchase 1.9 million shares of its common stock at an exercise price of $5.50 per share. The first tranche of the financing, consisting of approximately 5.6 million newly-issued and unregistered shares of common stock and warrants to purchase 1.1 million shares of the Company's common stock, closed on May 28, 2008 for aggregate gross proceeds of $25.0 million to certain accredited investors managed by a single advisor, OrbiMed Advisors LLC. The Company agreed to close, subject to stockholder approval, the second tranche under the same terms to certain existing investors, some of whom are affiliates of the Company and include a member of the Company's board of directors. Cash to purchase the second tranche of the financing was placed in escrow on May 28, 2008 until such time as the Company obtained stockholder approval. On July 31, 2008, at a special meeting of its stockholders, the Company obtained approval for, and subsequently issued and sold on August 1, 2008, an additional 4.0 million shares of common stock and warrants exercisable for 0.8 million shares of the Company's common stock in exchange for aggregate gross proceeds of $18.0 million. The proceeds from both tranches of the financing, net of transaction costs, were approximately $42.3 million.

The Company is required to register the common stock and the common stock issuable upon exercise of the warrants with the Securities and Exchange Commission, which was done 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, the Company 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.

The exercise price of the warrants to purchase shares of the Company's common stock issued in connection with this private placement was fixed at $5.50 per share on December 31, 2008 based on the Company's achievement of over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, the fair value of these warrants of $1.9 million at December 31, 2008 was reclassified from a current liability to equity on January 1, 2009. The reclassification on January 1, 2009 represents a noncash financing activity. The warrants have a term of 5 years and expire on May 28, 2013 and August 1, 2013 for the first and second tranches, respectively. The warrants also contain a net share settlement feature that is available to investors once the underlying shares are registered. Additional provisions require the Company, 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.

The fair value of the warrants at issuance was $3.3 million for the warrants issued on May 28, 2008 and $1.8 million for the warrants issued on August 1, 2008. The Company recognized a $3.2 million gain in other expense, net during 2008 related to changes in fair value of outstanding warrants. These amounts were determined using the Black-Scholes option pricing model and calculated using the following assumptions: 67% volatility; expected term of 5 years; 1.6% — 3.4% risk-free interest rate; and 0% dividend. The fair value of the warrants issued in connection with the private placement represents a noncash financing activity.

The Company's obligation, entered into on May 22, 2008, to issue 4.0 million shares of common stock and warrants to purchase 0.8 million shares of common stock in the second tranche met the definition of a derivative instrument under ASC 815. The fair value of the derivative instrument upon issuance on May 22, 2008 was $1.3 million. The fair value of the derivative instrument upon settlement on August 1, 2008 was $0.6 million and was recorded in equity as a reduction of the total proceeds received from the transaction. These amounts were determined using the Black-Scholes option pricing model and calculated using the following assumptions: 76% volatility; expected term of 32 to 71 days; 1.9% risk-free interest rate; and 0% dividend. The Company recognized a loss of $0.7 million in other expense, net during 2008 related to changes in fair value of this derivative instrument. The fair value of the derivative instrument issued in connection with the private placement represents a noncash financing activity.

On October 1, 2007, the Company issued 6.5 million shares of its common stock at a price of $12.50 per share in connection with the acquisition of the MDS Entities.

On February 7, 2007, the Company issued and sold to DaVita 2.0 million shares of common stock at a purchase price of $10.00 per share, for an aggregate purchase price of $19.9 million, net of issuance costs. The price of the Company's common stock on February 7, 2007 was $8.50 per share, resulting in a $3.0 million premium, which was deferred and is being recognized ratably to revenue over a term of seven years.

17. Related-Party Transactions

On June 4, 2007, the Company entered into a stock purchase agreement with David S. Utterberg, a director and significant stockholder of the Company, under which the Company agreed to purchase from Mr. Utterberg the issued and outstanding shares of the MDS Entities, in exchange for the issuance of 6.5 million shares of the Company's common stock. The Company may be required to issue additional shares of common stock to Mr. Utterberg because, pursuant to the terms of the stock purchase agreement, Mr. Utterberg and the Company have agreed to indemnify each other in the event of certain breaches or failures, and any such indemnification amounts must be paid in shares of the Company's common stock, valued at the time of payment. However, the Company will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of the Company's common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. The stock purchase agreement provided that an aggregate of one million shares would be held back in escrow to secure any indemnification obligations of Mr. Utterberg for a period of two years. All shares have been released from escrow, consistent with the terms of the escrow agreement entered into between the parties. In connection with the acquisition of the MDS Entities the Company assumed a $2.8 million liability owed to DSU Medical Corporation, or DSU, a Nevada corporation, which is wholly-owned by Mr. Utterberg. The Company paid the liability during 2008. As a condition to the parties' obligations to consummate the Medisystems Acquisition, Mr. Utterberg and DSU entered into a consulting agreement with the Company, dated October 1, 2007. The Company paid Mr. Utterberg and DSU $150,000, $200,000 and $50,000 during 2009, 2008 and 2007, respectively, in consideration for services performed under this agreement. Finally, in connection with the Medisystems Acquisition, the Company also agreed that if Mr. Utterberg is no longer a director of NxStage, the Company's Board of Directors will nominate for election

to the Company's Board of Directors any director nominee proposed by Mr. Utterberg, subject to certain conditions.

On May 22, 2008, the Company entered into Securities Purchase Agreements relating to a private placement of shares of its common stock and warrants to purchase shares of its common stock. The private placement took place in two closings, on May 28, 2008 and August 1, 2008, and raised $25.0 million and $18.0 million, respectively, in gross proceeds. Participants in the private placement consisted of unaffiliated and affiliated accredited institutional investors. One of these investors, the Sprout Group, is affiliated with one of the Company's Board members, Dr. Philippe O. Chambon. The Sprout Group purchased 1.0 million shares and warrants to purchase 0.2 million shares of the Company's common stock at a price similar to that of unaffiliated investors. Under applicable rules of the NASDAQ Global Market, the second closing of the private placement, which included all shares issued to the Sprout Group and other affiliated accredited institutional investors, was subject to stockholder approval, which was obtained at a special meeting on July 31, 2008.

The Company entered into a Securities Purchase Agreement with OrbiMed Advisors, LLC, or OrbiMed, in connection with the private placement which required that the Company appoint one individual nominated by OrbiMed to the Company's Board of Directors upon the earlier of the second closing of the private placement or sixty days after the first closing of the private placement. The appointment of Mr. Jonathan Silverstein, a general partner of OrbiMed, on July 23, 2008, to the Board satisfied this requirement. OrbiMed purchased an aggregate of 5.6 million shares and warrants to purchase 1.1 million shares of the Company's common stock in connection with the private placement at a price similar to that of unaffiliated investors.

18. Fair Value Measurements

At December 31, 2009, the Company had $12.8 million in money market funds, included in cash and cash equivalents, measured at fair value on a recurring basis utilizing quoted prices (unadjusted) in active markets of identical assets, also referred to as level 1 inputs.

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

The carrying amount of the Company's long-term debt approximates fair value at December 31, 2009. The fair value of the Company's long-term debt was estimated using inputs derived principally from market observable data, including current rates offering to the Company for debt of the same or similar remaining maturities. Within the hierarchy of fair value measurements, these are level 2 inputs.

19. Subsequent Events

On March 10, 2010, the Company entered into a Loan and Security Agreement, the Agreement, with Silicon Valley Bank, SVB, for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of the Company's assets. In connection with this Agreement, the Company amended the term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of the Company's assets for so long as the Agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, the Company has agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the Agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. The Company did not draw any amounts under the Agreement at closing, but may do so in the future to fund working capital and operating requirements.

20. Quarterly Financial Data (Unaudited)

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

	Year Ended December 31, 2009			
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
Revenues	$ 33,735	$ 36,398	$ 38,033	$40,510
Gross profit	7,055	8,817	9,545	11,447
Net loss	(12,228)	(12,515)	(10,047)	(8,677)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.27)	$ (0.22)	$ (0.19)

	Year Ended December 31, 2008			
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
Revenues	$ 31,005	$ 31,616	$ 30,466	$35,676
Gross profit	4,018	4,415	4,782	7,161
Net loss	(13,944)	(12,534)	(14,970)	(9,763)
Net loss per common share, basic and diluted	$ (0.38)	$ (0.32)	$ (0.33)	$ (0.21)

(1) Net loss includes changes in fair value of financial instruments of $2.1 million gain, $1.8 million loss, $2.3 million gain during the quarters ending June 30, 2008, September 30, 2008 and December 31, 2008, respectively.

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

Not applicable.

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, 2009. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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. 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 NxStage's disclosure controls and procedures as of December 31, 2009, our chief executive officer and chief financial officer concluded that, as of such date, NxStage's disclosure controls and procedures were effective at the reasonable assurance level.

No change in NxStage's internal control over financial reporting occurred during the fiscal quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, NxStage's 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.

Management has evaluated the effectiveness of its internal control over financial reporting as of December 31, 2009, 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, 2009.

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited NxStage Medical, Inc's internal control over financial reporting as of December 31, 2009, 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.'s 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. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, 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. as of December 31, 2009 and 2008, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009, and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 12, 2010

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

On March 10, 2010, the Company entered into a Loan and Security Agreement, the Agreement, with Silicon Valley Bank, SVB, for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of the Company's assets. In connection with this Agreement, the Company amended the term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of the Company's assets for so long as the Agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, the Company has agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the Agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. The Company did not draw any amounts under the Agreement at closing, but may do so in the future to fund working capital and operating requirements.

PART III

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

The information required by Part III, Items 10-14 of this report is incorporated by reference from our definitive proxy statement for our 2010 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 Officer and Director Compensation," "Certain Relationships and Related Transactions, and Director Independence," "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, 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.

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
March 12, 2010

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	March 12, 2010
/s/ Robert S. Brown Robert S. Brown	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	March 12, 2010
/s/ Philippe O. Chambon Philippe O. Chambon, M.D., Ph.D.	Chairman of the Board of Directors	March 12, 2010
/s/ Daniel A. Giannini Daniel A. Giannini	Director	March 12, 2010
/s/ Craig W. Moore Craig W. Moore	Director	March 12, 2010
/s/ Reid Perper Reid Perper	Director	March 12, 2010
/s/ Earl R. Lewis Earl R. Lewis	Director	March 12, 2010
/s/ Jonathan Silverstein Jonathan Silverstein	Director	March 12, 2010
/s/ David S. Utterberg David S. Utterberg	Director	March 12, 2010

EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			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
9.1	Form of Voting Agreement, dated as of May 22, 2008 and a schedule of signatories thereto	8-K	9.1	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 S-1/A 10-K	10.3 10.22 10.5	11/7/2007 10/20/2005 3/16/2007	000-51567 333-126711 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 17, 2005 between the Registrant and Philip R. Licari	S-1/A	10.13	10/20/2005	333-126711
10.8#	Employment Agreement dated October 18, 2005 between the Registrant and Joseph E. Turk, Jr.	S-1/A	10.15	10/20/2005	333-126711
10.9#	Employment Agreement dated October 18, 2005 between the Registrant and Winifred L. Swan	S-1/A	10.16	10/20/2005	333-126711
10.10#	Employment Agreement dated November 27, 2006 between Registrant and Robert S. Brown	10-K	10.10	3/16/2007	000-51567
10.11#	Restricted Stock Agreement Granted Under 2005 Stock Incentive Plan dated March 24, 2006 between the Registrant and Philip R. Licari	10-Q	10.4	5/5/2006	000-51567
10.12#	Amendment to Non-Qualified Stock Option Agreement dated March 24, 2006 between the Registrant and Philip R. Licari	10-Q	10.5	5/5/2006	000-51567
10.13#	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
10.14#	Summary of 2006 Executive Compensation and 2006 Corporate Bonus Plan	S-1	10.25	5/17/2006	333-134187
10.15#	Director Compensation Policy	10-Q	10.2	5/5/2006	000-51567

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.16	Loan and Security Agreement dated December 23, 2004 by and between the Registrant and Lighthouse Capital Partners V, L.P.	S-1	10.4	7/19/2005	333-126711
10.17	Second Promissory Note made December 29, 2004 by Registrant in favor of Lighthouse Capital Partners V, L.P.	S-1	10.5	7/19/2005	333-126711
10.18	Warrant to Purchase Series F Preferred Stock dated December 23, 2004 issued to Lighthouse Capital Partners IV, L.P.	S-1	10.6	7/19/2005	333-126711
10.19	Warrant to Purchase Series F Preferred Stock dated December 23, 2004 issued to Lighthouse Capital Partners V, L.P.	S-1	10.7	7/19/2005	333-126711
10.20	Warrant to Purchase Series E Preferred Stock dated September 26, 2002 issued to Comerica Bank	S-1	10.8	7/19/2005	333-126711
10.21	Credit and Security Agreement, dated as of November 21, 2007, by and among the Registrant, EIR Medical, Inc., Medisystems Services Corporation, and Medisystems Corporation, as Borrowers, and Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as Lender, Administrative Agent, Sole Lead Arranger and Sole Bookrunner	8-K	10.1	11/28/2007	000-51567
10.22	Loan and Security Agreement dated as of May 15, 2006 between the Silicon Valley Bank and the Registrant	S-1	10.24	5/17/2006	333-126711
10.23	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	10.10	7/19/2005	333-126711
10.24	Commercial Tenancy-At-Will Agreement dated March 14, 2005 between the Registrant and Osgood St., LLC, as amended by Modification to Tenancy-At-Will Agreement	S-1	10.11	7/19/2005	333-126711
10.25†	Supply Agreement dated as of October 26, 2004 between the Registrant and B. Braun Medizintechnologie GmbH	S-1	10.17	7/19/2005	333-126711
10.26†	Supply Agreement dated October 1, 2004 between the Registrant, EIR Medical, Inc. and Membrana GmbH	S-1	10.18	7/19/2005	333-126711
10.27†	Production Agreement dated as of June 27, 2005 between the Registrant and KMC Systems, Inc.	S-1	10.19	7/19/2005	333-126711
10.28†	Supply Agreement dated as of January 5, 2007 between the Registrant and Membrana GmbH	10-K	10.27	3/16/2007	000-51567
10.29†	National Service Provider Agreement dated as of February 7, 2007 between the Registrant and DaVita Inc.	10-K	10.29	3/16/2007	000-51567
10.30†	Supply Agreement dated March 27, 2006 between the Registrant and Laboratorios PISA S.A. de C.V.	10-Q	10.01	5/5/2006	000-51567

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.31†	Extracorporeal Disposables Distribution Agreement, dated July 25, 2007, by and between Medisystems Corporation and Henry Schein	10-Q	10.4	11/7/2007	000-51567
10.32†	Supply and Distribution Agreement, dated February 1, 2001. by and between Medisystems Corporation and Kawasumi Laboratories, Inc.	10-Q	10.6	11/7/2007	000-51567
10.33	Stock Purchase Agreement dated as of February 7, 2007 between the Registrant and DaVita Inc.	10-K	10.31	3/16/2007	000-51567
10.34	Registration Rights Agreement dated as of February 7, 2007 between the Registrant and DaVita Inc.	10-K	10.32	3/16/2007	000-51567
10.35	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	10.9	7/19/2005	333-126711
10.36†	Agreement, dated December 22, 2003, by and between Medisystems Corporation and DaVita, Inc.	10-Q	10.5	11/7/2007	000-51567
10.37†	Needle Purchase Agreement, dated January 6, 2008, by and between the Registrant and DaVita, Inc.	10-K	10.37	3/7/2008	000-51567
10.38	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	10.6	5/9/2007	000-51567
10.39†	License Agreement, dated June 1, 2007, by and between Medisystems Corporation and DSU Medical Corporation	10-Q	10.2	11/7/2007	000-51567
10.40	Stock Purchase Agreement, dated June 4, 2007, by and between the Registrant and David S. Utterberg.	10-Q	10.1	8/9/2007	000-51567
10.41	Escrow Agreement, dated October 1, 2007, by and between the Registrant, David S. Utterberg and Computershare Trust Company	8-K	10.1	10/4/2007	000-51567
10.42†	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
10.43	Amendment No. 4, dated as of March 16, 2009, to the Credit and Security Agreement, dated November 21, 2007, by and among the Registrant, EIR Medical, Inc., Medisystems Services Corporation and Medisystems Corporation, as Borrowers and GE Business Financial Service Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), individually as a Lender and as Administrative Agent	10-K	10.44	3/16/2009	000-51567
10.44†	Supply Agreement, dated April 10, 2009, by and between the Registrant and Laboratorios PiSA	10-Q/A	10.45	10/19/2009	000-51567

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.45†	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
10.46†	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 Medimexico s. de R.L. de C.V., NxStage Verwaltungs GmbH, NxStage GmbH & Co. KG and Medisystems Europe S.p.A., as Guarontors and Asahi Kasei Kuraray Medical, Co., Ltd., as the Lender	10-Q	10.47	8/7/2009	000-51567
10.47†	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
*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				
*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				

* 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.

EXHIBIT 31.1

**CERTIFICATION PURSUANT TO RULE 13A-14(A)/15D-14(A),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey H. Burbank, certify that:

1. I have reviewed this Annual Report on Form 10-K of NxStage Medical, Inc. for the fiscal year ended December 31, 2009 (this "report");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Jeffrey H. Burbank

Jeffrey H. Burbank
President and Chief Executive Officer

Date: March 12, 2010

EXHIBIT 31.2

**CERTIFICATION PURSUANT TO RULE 13A-14(A)/15D-14(A),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert S. Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K of NxStage Medical, Inc. for the fiscal year ended December 31, 2009 (this "report");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Robert S. Brown

Robert S. Brown
Chief Financial Officer and Senior Vice President

Date: March 12, 2010

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of NxStage Medical, Inc. (the "Company") for the year ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Jeffrey H. Burbank, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey H. Burbank

Jeffrey H. Burbank
President and Chief Executive Officer

Date: March 12, 2010

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of NxStage Medical, Inc. (the "Company") for the year ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Robert S. Brown, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert S. Brown

Robert S. Brown
Chief Financial Officer and Senior Vice President

Date: March 12, 2010

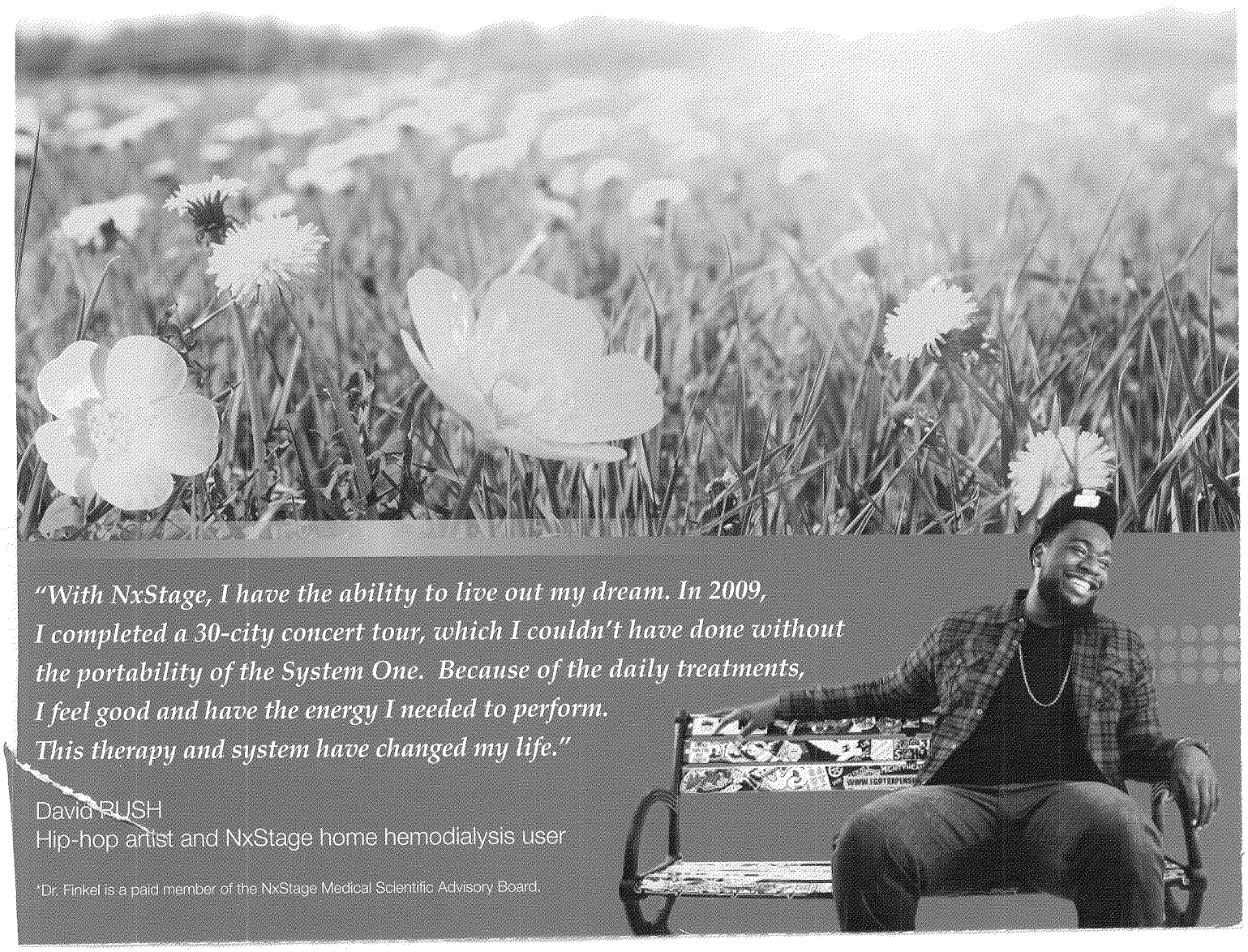
NOTES

"When it came time to replace our CRRT devices, both types of machines we evaluated were capable of high volume and high blood flows. But we chose NxStage because our nurses do the CVVH and they liked 3 things about it: 1) it's volume controlled, not weight-based; 2) the user interface is easy to understand; 3) the great customer service we get from NxStage."

Kevin Finkel, MD, FACP, Nephrology
Memorial Herman-Texas Medical Center*

"While NxStage has been known as an innovator in home dialysis, their new Streamline® sets bring innovation to our in-center dialysis business as well. We conducted a thorough evaluation in several of our centers with the Streamline sets and found that they not only improved patient clearances and reduced costs, but also were the preferred set by staff."

Dean Weiland, COO of Renal Advantage Inc.



"With NxStage, I have the ability to live out my dream. In 2009, I completed a 30-city concert tour, which I couldn't have done without the portability of the System One. Because of the daily treatments, I feel good and have the energy I needed to perform. This therapy and system have changed my life."

David RUSH
Hip-hop artist and NxStage home hemodialysis user

*Dr. Finkel is a paid member of the NxStage Medical Scientific Advisory Board.

NxSTAGE®

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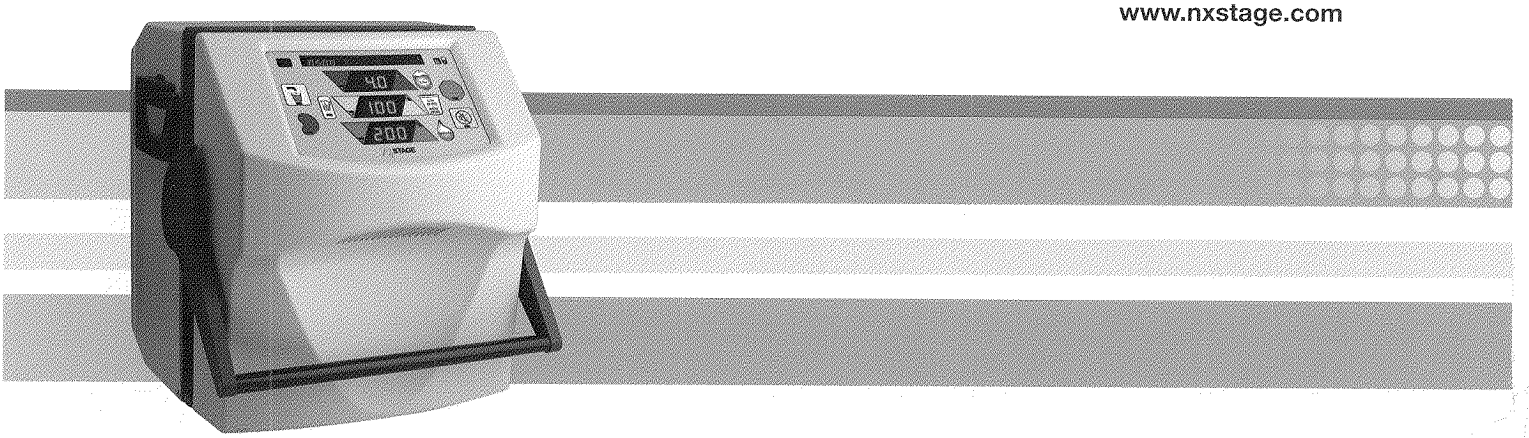
1-866-NxStage (1-866-697-8243)
www.nxstage.com



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CAUTION: Federal law restricts these devices to sale by or on the order of a physician. APM460 Rev. A