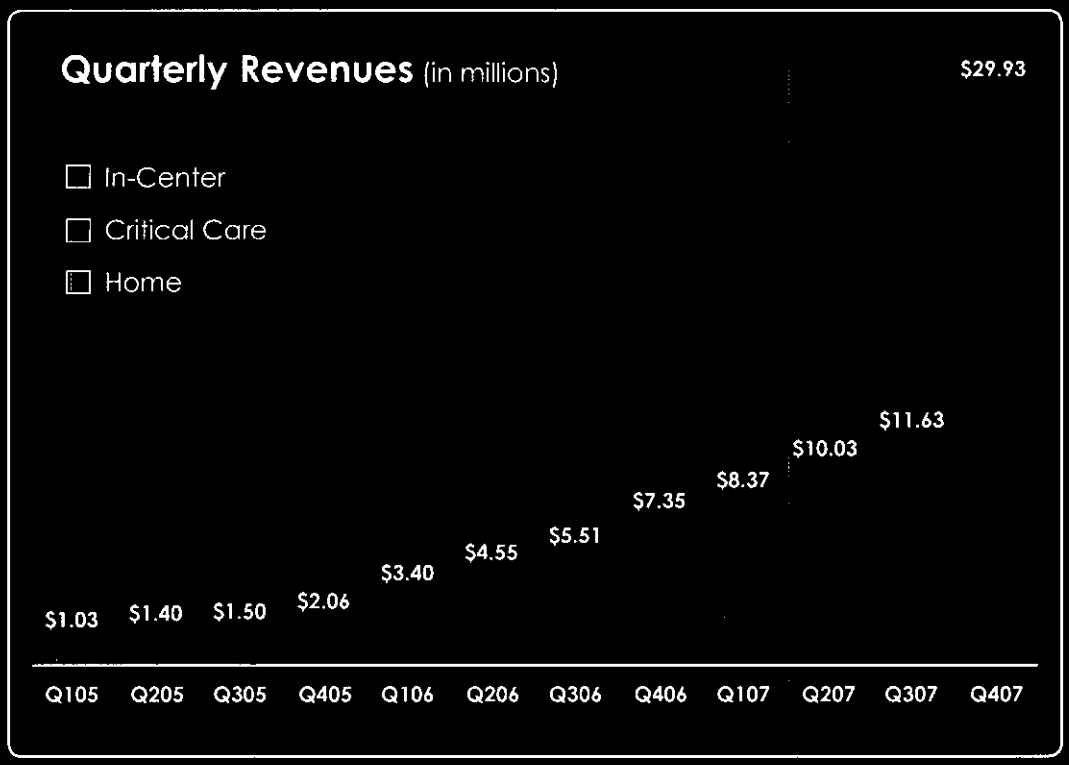
Changing Lives in 3 Dimensions

2007 ANNUAL REPORT
NxStage Medical, Inc.

From its inception, NxStage has been dedicated to improving the lives of people with End Stage Renal Disease (ESRD). Since then, NxStage has made significant progress in changing the way renal care is delivered. In the process, we have achieved new levels of innovation and expanded our market presence.

In 2007, NxStage completed a major, strategic acquisition that dramatically increased our scale and capabilities. We now serve three key dialysis markets: **home, critical care and in-center.**

Each of our markets presents its own dimension of opportunity and challenge. We are committed to overcoming barriers in each of these markets with breakthrough innovation that has been the company's driving force from the beginning.



ACHIEVEMENTS

Achieved In-Center presence. Our acquisition of Medisystems Corporation, a leading manufacturer of hemodialysis blood tubing sets and fistula needles, placed us in a leading role in the U.S. in-center marketplace for dialysis disposables. This market contributed $15.7 million to NxStage sales in the fourth quarter alone. Medisystems' reputation for producing innovative, high-quality products was a key reason we chose to partner with them to assemble the cycler cartridges for our breakthrough NxStage System One.

Continued to expand Home care. We more than doubled the number of home patients using the NxStage System One to perform dialysis at home, ending the year with 2,223 patients prescribed to receive therapy using the System One. We also added 160 new dialysis centers offering our therapy. Significantly, 70% of NxStage home users are also using our innovative PureFlow™ SL, which makes dialysis even simpler by preparing high purity dialysate from ordinary tap water—overcoming another barrier to home dialysis.

Signed strategic agreements with DaVita Inc. for both home therapy and needle supply. We started 2007 with a multi-year national agreement with Davita Inc., the nation's largest independent provider of dialysis services, helping to position NxStage as the definitive U.S. leader in home hemodialysis. In early 2008, we signed a five-year needle supply contract with DaVita. This new agreement extends a long, successful relationship between DaVita and Medisystems, further strengthening our position as a leader in the U.S. in-center hemodialysis disposables market.

Continued growth in Critical Care. We continued to see exciting growth in the use of our NxStage System One in the hospital critical care setting. After just a few short years in this market, the System One accounts for an estimated 20% or more of the installed base of critical care dialysis units, and is in 7 of the top 10 hospitals in the U.S. This success continued to drive revenue which grew by 78% in 2007.

Reduced production costs. In our ongoing effort to reduce expenses and optimize operations, we transitioned manufacturing for some of our System One components and PureFlow disposables to a new facility in Fresnillo, Mexico. We believe this strategic initiative will strengthen our control over both costs and quality as we expand our manufacturing operations to support continued growth.

GOALS FOR 2008

We are excited about the opportunities ahead of us, and are committed to doing the hard work that still needs to be done for us to accomplish our mission. Among our goals for 2008 are:

Continuing to improve operating efficiencies. Throughout 2007, we moved rapidly and deliberately to continue building the infrastructure that will enable us to grow our leadership position in the U.S. renal products marketplace. At the same time, we have begun to realize the benefits of our earlier efforts to improve operating efficiency and reduce product costs. In 2008, we plan to leverage these efforts to further improve our margins, operating costs, reliability and customer satisfaction.

Continued product innovation. Since our inception, NxStage has demonstrated its ability to introduce innovative products designed to address an unmet need in the dialysis marketplace. In 2008, we plan to continue to work to improve the features, reliability, economics, and ease of use of our existing products, as well as to develop new products that will help advance renal care in the years to come.

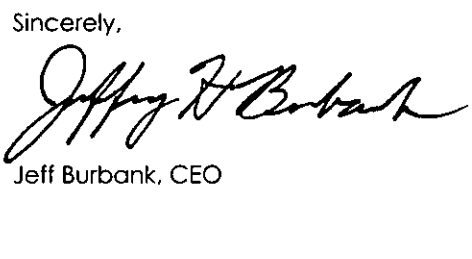
Advocating for progress in reimbursement and building clinical data. Institutional barriers to home and daily dialysis still exist. Key among these is the lack of defined reimbursement for treatments above three times a week and broader recognition of the clinical and economic benefits of daily dialysis. During 2008, NxStage will continue to advocate for improved Medicare reimbursement for daily dialysis, and to build clinical data further demonstrating the benefits of more frequent therapy.

PURE COMMITMENT

As we continue to grow our business, we remain committed to our unique mission: to lead a movement to transform renal care with innovative yet simple solutions that benefit patients, caregivers, and society. We thank our stockholders, patients, employees, and partners for their continued support.

The movement to transform renal care is gaining momentum. And NxStage is helping to lead the way.

Sincerely,



Jeff Burbank, CEO

Freeing patients to live more normal lives means overcoming the limitations of traditional dialysis technology. NxStage is driving that change with solutions that make daily hemodialysis—at home or on the road—a practical alternative for thousands. In 2007, we more than doubled the number of NxStage home care patients, demonstrating our ability to lead and grow this emerging market.

"I've been active all my life and found in-center dialysis was slowing me down. When I found out I could dialyze at home, I knew that was the right approach for me. So I asked my doctor for the NxStage System One. It was not available yet in New Mexico, so I made the decision to fly to Arizona for training. With the NxStage System One, I dialyze on my schedule! So I have time to do the things I really enjoy! Thanks NxStage."

Jim Burnett, Las Cruces, New Mexico

1. Home

Improving the lives of people with ESRD is the driving force behind NxStage innovation. We led development of the home hemodialysis market in the U.S. with our breakthrough System One, the first truly portable hemodialysis system cleared for home use. We believe our expertise in home hemodialysis—gained through more than 1.5 million hours of treatment experience—uniquely positions NxStage for success in the home market.

Innovation: Traditional treatment of patients with ESRD, consisting of in-center hemodialysis three times each week, can be disruptive to patients' health and daily lives. That picture is changing, as our innovative approach to more frequent, home hemodialysis continues to gain traction.

By the end of 2007, there were 2,223 ESRD patients prescribed to receive therapy using the NxStage System One. Home daily dialysis with the System One has been reported to offer enhanced health, control and quality of life—including the freedom to work normal schedules and to travel.

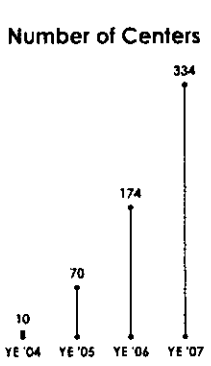
Growth: Home hemodialysis is still in its infancy, with less than 1% market penetration. We estimate that between 35,000 and 50,000 U.S. patients could benefit from home hemodialysis—creating a potential $1 billion market in the U.S. alone. As more clinicians, patients and dialysis centers discover the advantages of NxStage therapy, we expect home care will continue to grow.

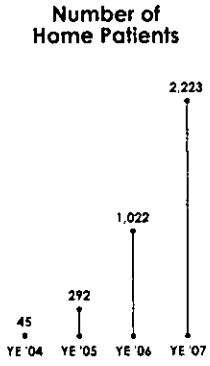
Simplicity: The simplicity of NxStage products, together with responsive NxStage support, makes home therapy a practical alternative for many patients. We complement our System One with our innovative PureFlow™ SL, which simplifies home hemodialysis by preparing high purity dialysate from ordinary tap water—a major advantage for patients and caregivers.

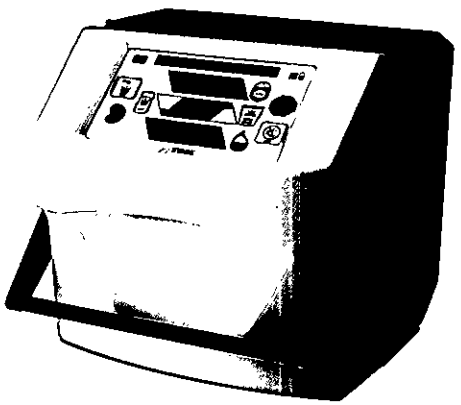
Value: We believe our innovative approach to home hemodialysis offers significant value to all chronic care stakeholders. Patients can realize enhanced health, control and freedom. Providers can realize increased growth and profitability. And payers can realize annual per-patient savings of $10,000 or more through reduced hospital and drug costs.

The Benefits of Daily Home Hemodialysis

In a recent U.S. study, patients reported a recovery of 4-12 hours following traditional thrice-weekly therapy at a dialysis center. This dropped to less than 15 minutes after converting to daily home dialysis using the NxStage System One. Other studies have shown approximately 50% improvements in mortality for patients on daily home hemodialysis.







NxStage System One

Improving renal care also means changing the way hemodialysis is delivered to critical care patients. NxStage is leading the way to a more effective, more efficient approach to critical care therapy that expands treatment options while reducing staff workload. In the process, we are working to create new growth opportunities for NxStage.

"Our own experience with the NxStage System and their volumetric fluid balancing technology has been a positive one. We converted to the NxStage System for our CRRT program at the Hospital of the University of Pennsylvania. This allowed us to do continuous renal replacement therapy that is actually continuous, without anticoagulation in most patients, and with achievement of excellent solute clearance. Acceptance by our nephrologists, dialysis staff, ICU nurses, and critical care physicians has been excellent."

Dr. Jeffrey S. Berns, MD, Hospital of the University of Pennsylvania

2. Critical Care

Our innovative approach to renal care also benefits critical care patients requiring dialysis for treatment of acute renal failure. A growing number of U.S. hospitals have adopted the NxStage System One, which offers clinicians additional treatment options while simplifying dialysis for nursing staff. In just a few years, we have captured an estimated 20% of the U.S. equipment market that employs prolonged, or more intensive therapies, for the treatment of acute kidney failure (defined as the CRRT market). We believe NxStage is strongly positioned to create additional value for our stockholders by further expanding our presence in this market.

Innovation: Many critical care physicians want to administer intensive hemodialysis and hemofiltration therapies, which have been reported to improve outcomes in patients with acute renal failure. The challenge has been delivering that intensive therapy without overwhelming staff or straining hospital budgets. The NxStage System One changes the equation.

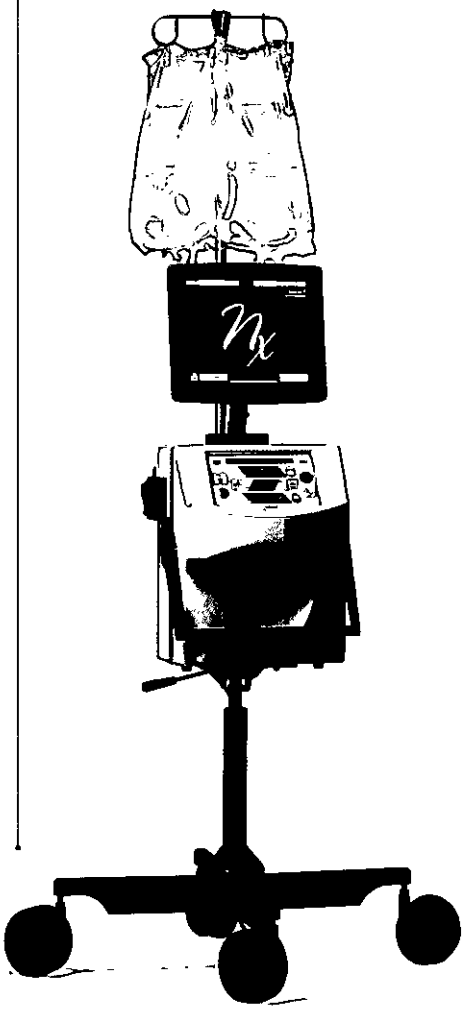
The System One overcomes the limitations of traditional systems, providing flexible, high flows that enable a range of intensive therapies. Our innovative volumetric balancing technology simplifies fluid handling, reducing the burden on critical care staff and hospital resources.

Validation: The flexibility and simplicity of our approach has attracted the attention of leading healthcare providers. In 2007, the NxStage System One was used in 115 hospitals, including 7 of the top 10 renal care hospitals as ranked by *U.S. News & World Report*. In addition, our estimates indicate that NxStage is leading the market in share of new critical care CRRT hemodialysis placements. We believe these facts represent strong validation of NxStage's technology and value.

Simplicity: In addition to treatment flexibility, the simplicity of the NxStage System One has been a key driver of our success in converting top institutions from competing systems. The System One's ease of use helps reduce staff training requirements and frees critical care nurses to focus on patients, instead of their hemodialysis system.

Enabling New Therapy Options

The System One's wide flow rate range and innovative fluid handling allow clinicians to choose the therapy that works best for their patients, while reducing the burden on staff. They can deliver high-dose continuous therapies without increasing the fluid management burden. Or they can deliver gentler therapies that correspond to staff shifts.



NxStage System One

Changing more lives means extending our reach into hemodialysis clinics across the country. With the acquisition of Medisystems Corporation, NxStage has expanded its product portfolio to include innovative consumables that we believe make in-center hemodialysis easier, more efficient and safer for patients and staff alike.

"Never before have bloodlines had such a profound effect on a patient's treatment. We have found that this safe, low volume, airless bloodline positively affects the system pressures so that higher blood flows are possible and higher clearances can follow. We are successfully using Medisystems' new Streamline Airless line to provide our patients with a more efficient treatment while realizing savings from a lower dialysate flow."

Bruce Merriman B.S., Central Florida Kidney Centers, Orlando, FL

3. In-Center

The vast majority of ESRD patients receive hemodialysis three times each week at a dialysis center. With our acquisition in 2007 of Medisystems Corporation, a recognized leader in the U.S. in-center dialysis consumables marketplace, we have expanded our portfolio with established products that are used to treat a significant percentage of U.S. in-center patients every week.

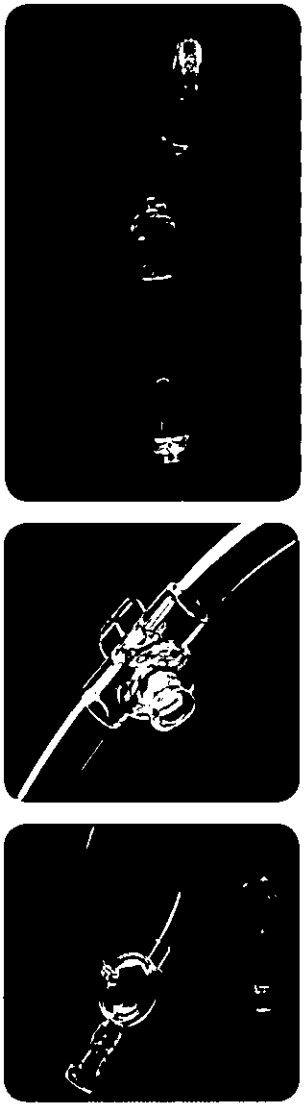
Leadership: Hemodialysis clinics are continually seeking ways to improve efficiency, while enhancing quality of care and patient and staff safety. Medisystems blood tubing sets, fistula needles and buttonhole needles are designed for safety, ease of use and efficiency. Products like our MasterGuard® anti-stick needle protector and FingerShield™ anchor and our Buttonhole™ needle sets, help protect clinic workers from needle sticks and minimize patient discomfort, which has made them the choice of many clinics nationwide. Our products help reduce risk, increase efficiency and make hemodialysis easier on staff and patients alike.

Innovation: Like NxStage, Medisystems has a long tradition of bringing innovation to the marketplace that enables positive change. Our new Streamline blood tubing set uses innovative design and engineering to reduce dialysate volume and waste and increase efficiency. Leveraging the synergies of our combined organizations, we plan to continue to develop and deliver even more innovative products that improve the quality and cost of in-center care.

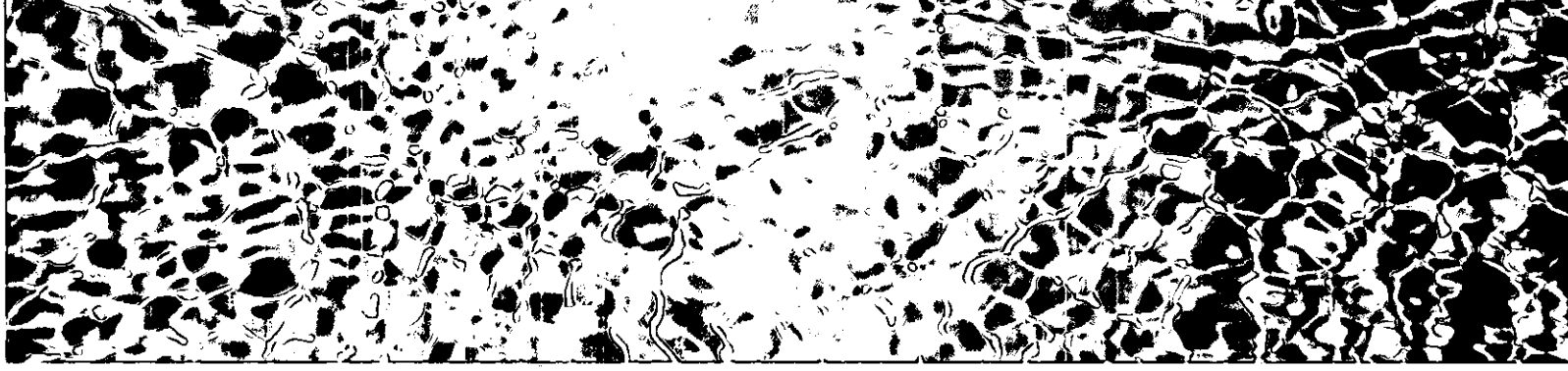
Scale: Our acquisition of Medisystems greatly expands our scale and capabilities, establishing NxStage as a vertically integrated manufacturer and distributor of hemodialysis products. Between our needles and blood tubing sets, millions of Medisystems products are used each and every month. The established technology, manufacturing and operational capabilities behind these products complement those of NxStage, which we believe will enhance our ability to achieve our goal of leadership across all three U.S. renal care product markets.

Streamline Economic Impact

Hemodialysis centers using our new Streamline blood tubing set have realized improved patient therapy, together with improved economics. These centers have increased their patient dialysis dose delivery, while reducing dialysate usage.



Streamline – the only airless blood tubing



Three dimensions. One leader.

In 2007, NxStage made significant progress in our efforts to lead renal care in a beneficial, new direction—at home, in the hospital critical care setting and in the dialysis center. In the process, we have established a solid foundation for growth in all three key renal care markets.

We believe the elements are in place for us to make a significant impact on patients, healthcare providers and payers.

A comprehensive portfolio of innovative hemodialysis products and consumables that are designed to offer significant benefits to patients, healthcare providers and payers alike.

The operational scale and vertical integration to extend our capabilities and improve operational efficiencies.

The knowledge and expertise of renal care professionals with a track record of technology and market leadership, all sharing a common mission.

A commitment to innovation through continuous research and development to ensure our ability to deliver breakthrough solutions that create real value.

Increased acceptance in the marketplace of the benefits of more frequent hemodialysis, which we expect will drive increased adoption of our innovative approach to therapy.

NxSTAGE
Renal Care, Pure and Simple.

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, 2007

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 Act. 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 Act. 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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant was approximately $208.3 million, as of June 29, 2007, based on the last reported sale price of the registrant's common stock on the NASDAQ Global Market on June 29, 2007.

There were 36,775,204 shares of the registrant's common stock issued and outstanding as of the close of business on March 3, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2008 Annual Meeting of Stockholders to be held on May 29, 2008 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.

2007 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; 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, and the impact of possible future changes to reimbursement for chronic dialysis treatments. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words "expect", "anticipate", "intend", "plan", "believe", "seek", "estimate", "potential", "continue", "predict", "may", and similar expressions are intended to 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 end-stage renal disease, or ESRD, and acute kidney failure. Our primary product, the NxStage System One TM , is a small, portable, easy-to-use hemodialysis system designed to provide physicians and patients improved flexibility in how hemodialysis therapy is prescribed and delivered. 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 specifically cleared by the United States Food and Drug Administration, or FDA, for home hemodialysis as well as hospital and clinic-based dialysis. Following our recent acquisition of Medisystems Corporation and certain of its affiliated entities, we also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of 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, which we previously referred to as the chronic market.

ESRD, which affects nearly 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 early in 2007, two of our dialysis chain customers elected to purchase rather than rent System One equipment. 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. As

of December 31, 2007, 2,223 ESRD patients were prescribed to receive therapy using the System One at 334 different dialysis clinics. Substantially all of these patients are treated at home or are in training to treat themselves at home; the remaining patients are doing therapy in a clinic.

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. 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 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. As of December 31, 2007, 115 hospitals were using the System One to deliver acute kidney failure and fluid overload therapy.

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 recently completed acquisition of Medisystems Corporation, or Medisystems, and certain of its affiliated entities, include hemodialysis blood tubing sets, A.V. fistula needles and apheresis needles. Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981, and it has achieved leading positions in the U.S. market for both hemodialysis blood tubing sets and A.V. fistula needles. Our blood tubing set products include the ReadySet High Performance Blood Tubing set, and the Streamline. ReadySet has been on the market since 1993. Streamline is our next generation product designed to provide improved patient outcomes and lower costs to dialysis clinics. Our next generation Streamline product was introduced to the market in 2007 and adoption has been limited to date. 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.

For the year ended December 31, 2007, our revenues were $60.0 million and we incurred a net loss of $58.4 million. As of December 31, 2007, we had total assets of $210.4 million, long term liabilities of $46.1 million and total stockholders' equity of $129.7 million.

Since inception, we have incurred losses every quarter and at December 31, 2007, we had an accumulated deficit of approximately $182.0 million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, although we have recently achieved positive gross margins for our products, in aggregate, as of December 31, 2007 we can not 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 is dependent 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, increasing our reliability, 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.

We will need to sell additional equity or issue debt securities to fund our capital requirements beyond 2008. Any sale of additional equity or issuance of debt securities 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 this 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. Additionally, beginning in February 2009, we will need to begin paying down the principal of the debt we borrowed from Merrill Lynch. To the extent we are unable to obtain additional financing, this obligation to repay debt will only further increase the need to further delay, reduce the scope of, or eliminate one or more aspects of our business, which would likely harm our business.

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.

Recent Developments

Needle Purchase Agreement with DaVita Inc.

On January 6, 2008 we entered into a needle purchase agreement with DaVita pursuant to which DaVita has agreed to purchase the majority of its safety needle requirements from us for five years, subject to certain terms and conditions. The needle purchase agreement expires on January 5, 2013. DaVita has the right to reduce or eliminate its purchase requirements under the agreement following the introduction of a materially improved product (as defined in the agreement) from a third party. If DaVita exercises this right, we may terminate the agreement. The needle purchase agreement provides for liquidated damages in the event DaVita fails to satisfy its purchase requirements or we fail to meet our supply obligations to DaVita.

Merrill Lynch Credit Facility

On November 21, 2007, we obtained a $50.0 million credit and security agreement from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., for a term of 42 months. The credit facility is secured by nearly all our assets, other than intellectual property, and consists of a $30.0 million term loan and a $20.0 million revolving credit facility. We borrowed $25.0 million under the term loan in November 2007, and have the option to borrow the remaining $5 million by May 21, 2008. We expect that we will borrow this amount. We used $4.9 million of the proceeds from the term loan to repay all amounts owed under a term loan dated May 15, 2006 with Silicon Valley Bank. Borrowings under the term loan bear interest equal to LIBOR plus 6% per annum, fixed on November 21 for our first borrowings (at a rate of 10.77% per year) and at the date of borrowing for the remaining $5.0 million still available to be borrowed under the term loan. Interest on the term loan must be paid on a monthly basis. Beginning on February 1, 2009, we must repay principal under the term loan in 29 equal monthly installments. We will also be required to pay a maturity premium of $900,000 at the time of loan payoff. NxStage's borrowing capacity under the revolving credit facility is subject to the satisfaction of certain conditions and calculations of the borrowing amount. There is no guarantee that we will be able to borrow the full amount, or any funds, under the revolving credit facility. Any borrowings under the revolving credit facility will bear interest at LIBOR plus 4.25% per annum There is an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which are charged in the event the revolving credit facility is terminated prior to May 21, 2011 of 4% in year one, 2% in year two, and 1% thereafter.

The credit facility includes covenants that (a) require NxStage to achieve certain minimum net revenue and certain minimum EBITDA targets relating to the acquired Medisystems business, (b) place limitations on NxStage's and our subsidiaries' ability to incur debt, (c) place limitations on NxStage's and our subsidiaries' ability to grant or incur liens, carry out mergers, and make investments and acquisitions, and (d) place limitations on NxStage's and our subsidiaries' ability to pay dividends, make other restricted payments, enter into transactions with affiliates, and amend certain contracts. The credit agreement 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, Merrill Lynch has a

number of remedies, including sale of our assets, control of our cash and cash equivalents, and acceleration of all outstanding indebtedness. Any of these remedies would likely have a material adverse effect on our business.

Medisystems Acquisition

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg under which we agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and Medisystems Services Corporation, 90% of the issued and outstanding shares of Medisystems Europe S.p.A. (the remaining equity of which is held by Medisystems Corporation) and 0.273% of the issued and outstanding equity participation of Medisystems Mexico s. de R.L. de C.V. (the remaining equity of which is held by Medisystems Corporation), which are collectively referred to as the MDS Entities. We refer to our acquisition of the MDS Entities as the Medisystems Acquisition. Mr. Utterberg is a director and significant stockholder of NxStage. The Medisystems Acquisition was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage. In addition, as a result of completion of the Medisystems Acquisition, the supply agreement, dated January 2007, with Medisystems, under which Medisystems agreed to provide cartridges for use with the System One, was terminated. In consideration for the Medisystems Acquisition, we issued Mr. Utterberg 6.5 million shares of our common stock, which we refer to as the Shares. As a result of the Medisystems Acquisition and the issuance of the Shares to Mr. Utterberg, Mr. Utterberg's aggregate ownership of our outstanding common stock increased to approximately 23.2%. In addition, we may be required to issue additional shares of our common stock to Mr. Utterberg. 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. An aggregate of 1.0 million of the shares issued to Mr. Utterberg were placed into escrow to cover potential indemnification claims we may have against him. In connection with the Medisystems Acquisition and as a result of Medisystems Corporation, one of the MDS Entities, becoming a direct or indirect wholly-owned subsidiary of ours, we acquired rights under an existing license agreement between Medisystems and DSU Medical Corporation, a Nevada corporation, which is wholly-owned by Mr. Utterberg, or DSU. We refer to this agreement as the license agreement. Additionally, 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, which we refer to as the consulting agreement.

Under the license agreement, Medisystems received an exclusive, irrevocable, sublicensable, royalty-free, fully paid license to certain DSU patents, or the licensed patents, in exchange for a one-time payment of $2.7 million. The licensed patents fall into two categories, those patents that are used exclusively by the MDS Entities, referred to as the Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, referred to as the Class B patents. Pursuant to the terms of the license agreement, MDS has 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. The license agreement further provides that the rights of Medisystems under the agreement are qualified by certain sublicenses previously granted to third parties. We have agreed that Mr. Utterberg retains the right to the royalty income under one of these sublicenses.

Under the consulting agreement, Mr. Utterberg and DSU will provide consulting, advisory and related services to us for a period of two years following the consummation of the Medisystems Acquisition. In addition, under the terms of the consulting agreement, Mr. Utterberg and DSU have agreed during the term of the agreement not to compete with NxStage during the term of the consulting agreement in the field defined in the consulting agreement and not to encourage or solicit any of our employees, customers or suppliers to alter their relationship with us. The consulting agreement further provides that (1) Mr. Utterberg and DSU assign to us certain inventions and proprietary rights received by him/it during the term of the agreement and (2) we

grant Mr. Utterberg and DSU an exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid license under such assigned inventions and proprietary rights for any purpose outside the inventing field, as defined in the consulting agreement. Under the terms of the consulting agreement, Mr. Utterberg and DSU will receive an aggregate of $200,000 per year, plus expenses, in full consideration for the services and other obligations provided for under the terms of the consulting agreement. The consulting agreement also requires Mr. Utterberg and NxStage to indemnify each other in the event of certain breaches and failures under the agreement and requires that any such indemnification liability be satisfied with 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.

Product Reliability Issue

In the second quarter of 2007, we started to experience an increased incidence of reported dialysate leaks associated with our System One cartridges. Although our cartridges were within our specifications, the reported incidence of leaks was higher than we have historically observed. When the System One was used in accordance with its instructions, these leaks presented no risk to patient health. System One device labeling anticipates the potential for leaks to occur and specifically warns against leaks and alerts users of the need to observe treatments in order to detect leaks. Six patients with reported leaks that were unobserved by these patients or their partners until after their treatments were completed, reported hypotension, or low blood pressure, that was subsequently resolved by a fluid bolus, with no lasting clinical effects. In early August 2007, we sent a letter to our patients and customers informing them of the increased incidence in leaks and reminding them of existing System One labeling alerting users of the potential for leaks and instructing them to observe treatments in order to detect any leaks. We characterized this notification as a voluntary recall. On August 24, 2007, we elected to initiate a second step in our recall actions, and decided to physically recall the affected lots of cartridge inventory being held by home market customers and patients, and replace the affected inventory with newer lots of cartridges at no charge. We instructed patients and customers to destroy all inventory of affected cartridges they have on hand. We have incurred $2.3 million of charges for the recall, which consisted of a $1.5 million write off of inventory and $0.8 million in other costs related to the return or replacement of cartridges and rework of inventory on hand. The $1.5 million write-off provision represented the total value of affected inventory that was then on-hand at the time. As of December 31, 2007, we had approximately $1.1 million of affected inventory related to the original provision remaining on-hand.

Entrada

On March 13, 2007, we entered into a long-term agreement with the Entrada Group, or Entrada, to establish manufacturing and service operations in Mexico, initially for our cycler and PureFlow SL disposables and later for our PureFlow SL hardware. The agreement obligates Entrada to provide us with manufacturing space, support services and a labor force February 28, 2007 through 2012, which term may be extended for additional one-year periods at the mutual agreement of the parties. Either party may terminate the service agreement due to a material breach, generally following a 30-day cure period. The agreement may also be terminated upon the other party's insolvency or due to changed circumstances, including a prolonged labor strike or a change of control of Entrada.

DaVita National Service Provider Agreement

On February 7, 2007, we entered into a National Service Provider Agreement with DaVita, our largest customer. Pursuant to the terms of the agreement, we granted to DaVita certain market rights for the NxStage System One and related supplies for home hemodialysis therapy. We granted DaVita exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the U.S. ESRD patient population, and limited exclusivity in the majority of all other U.S. geographies, subject to DaVita meeting certain requirements, including patient volume commitments and new patient training rates. Under the agreement, we can continue to sell to other clinics in the majority of geographies. If certain minimum patient

numbers or training rates are not achieved, DaVita can lose all or part of its preferred geographic rights. Under the agreement, DaVita committed to purchase all of its existing System One equipment that were currently being rented from NxStage (for a purchase price of approximately $5 million) and to buy a significant percentage of its future System One equipment needs.

The initial term of the agreement extends until December 31, 2009, and DaVita has the option of renewing the agreement for four additional periods of six months if DaVita meets certain patient volume targets.

In connection with the National Service Provider Agreement, on February 7, 2007, we issued and sold to DaVita 2,000,000 shares of our common stock, at a purchase price of $10.00 per share, for an aggregate purchase price of $20.0 million.

Membrana

In January 2007, we entered into a long-term supply agreement with Membrana GmbH, or 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 60-day cure period.

Medisystems Supply Agreement

In January 2007, we entered into a seven-year agreement with Medisystems pursuant to which Medisystems agreed to supply to us no less than 90% of our North American requirements for disposable cartridges for use with the System One. This agreement was terminated in connection with the closing of the Medisystems Acquisition.

Our Products and Services

We sell the System One in the home and critical care markets. Following the Medisystems Acquisition, we also sell blood tubing sets, needles and other extracorporeal products for use primarily in hemodialysis therapy to the in-center market. Sales of the System One, ReadySet and A.V. fistula needles accounted for 94% of our total revenues for the year ended December 31, 2007, with sales of our System One accounting for 74%, sales of ReadySet 14% and sales of A.V. fistula needles 6%.

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.

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 received FDA clearance in March 2006 and was 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 eliminating the need for bagged fluids.

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, as measured in Kt/V.

Streamline

Our latest 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, as measured in Kt/V. 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 clinician's ability to satisfy 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.

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 "the constant-site technique", whereby a fistula needle is inserted in the same place each treatment. Published clinical experience supports that the incidence of pain, hematoma, infection 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.

Transducer Protectors with ViraGuard

Transducer protectors are single-use air filter devices used to protect hemodialysis pressure monitors during treatments. Our transducer protectors include the ViraGuard membrane, designed to maintain the sterility of the fluid pathway and act as a bacterial and viral barrier as well as a unique airflow design, intended to allow for a quick response time with few false alarms.

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.

Access Alert

Vascular access complications are a leading cause of complications during dialysis. To facilitate early identification and intervention for access-related problems, dialysis clinics have instituted routine measurement and trend analysis of access pressures. Medisystems has developed the Access Alert Pressure Measurement Filter for use with our AV fistula needles, designed to measure static intra-access pressure, with no interruption of therapy. These readings can be used to detect venous, mid-graft and arterial inflow stenosis, which is the narrowing of a vein or artery that restricts bloodflow.

Competition

The dialysis therapy market is mature, consolidated and competitive. We compete with suppliers of hemodialysis and peritoneal dialysis devices and certain dialysis device manufacturers that also provide dialysis services. We currently face direct competition in the United States primarily from Fresenius Medical Care AG, or Fresenius, Baxter Healthcare, or Baxter, Gambro AB, or Gambro, B. Braun and others. Fresenius, Baxter and Gambro each have large and well-established dialysis products businesses. Foreign competitors, such as Nipro and JMS, also compete with our newly acquired needle and blood tubing set businesses.

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.

For the home dialysis market, we believe that we compete favorably in terms of product quality and ease of use due to our System One design, portability, drop-in cartridge and use of premixed fluids. We believe we also compete favorably on the basis of clinical flexibility, given the System One's ability to work well in acute and chronic settings and to perform hemofiltration, hemodialysis and ultrafiltration. We believe we compete favorably in terms of cost-effectiveness for clinics. Although our product is priced at a premium compared to some competitive products in the market, we allow clinics to reduce labor costs by offering their patients a home treatment alternative. We compete unfavorably in terms of sales force coverage and branding because we have only recently commenced commercial sales of our System One for home hemodialysis and have a smaller sales force than most of our competitors.

There is presently an increasing interest in the home hemodialysis market from our key competitors. Fresenius and Baxter have each made public statements that they are either contemplating or actively developing new and/or improved systems for home hemodialysis. Fresenius made these statements in relation to their recent acquisition of Renal Solutions, Inc., and Baxter made them in relation to the announcement of a research and development collaboration with DEKA Research & Development Corporation and HHD, LLC. We are unable to predict if or when products from these or other companies may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced. When additional viable products are introduced to the market, it could adversely affect our sales and growth.

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 Medisystems business has been established since the 1980s. We compete unfavorably in terms of sales force coverage, as we rely nearly exclusively on distributors, rather than our own direct sales force.

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. 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 business, 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.

Our primary competitors are large, well-established businesses with significantly more financial and personnel resources and greater commercial infrastructures than we have. 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;
- achieve cost reductions; and
- access the capital needed to support the 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 markets. We have separate marketing and sales efforts dedicated to each market, however, for the in-center market, we rely almost exclusively upon distributors to sell our products rather than a direct sales force. Henry Schein is the primary distributor for our in-center market and our contract with Schein was recently extended through July 2009.

In 2007, sales to DaVita and Schien represented 19.8% and 21.5% of our total revenues, respectively, and 47.7% of Schein's sales of our products in 2007 were derived from sales to DaVita. DaVita and Schien are expected to remain significant customers of ours in 2008. No other single customer represented 10% or more of our revenues in 2007. In 2006, sales to DaVita, Inc. represented 19.4% of our total revenues. No other single customer represented 10% or more of our revenues in 2006. In 2005, sales to Clarian Health Partners represented 10.0% of our total revenues, sales to Renal Care Group represented 12.4% of our total revenues and sales to Wellbound, Inc. represented 10.5% of our total revenues. No other single customer represented 10% or more of our revenues in 2005.

Home

We 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 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, and cannot, sell the System One directly to home patients.

We have a home market direct sales force that calls on dialysis clinics. In addition to specialized sales representatives, we also employ nurses on our home market sales force to serve as clinical educators to support our sales efforts.

Currently, there are approximately 4,500 Medicare-certified dialysis outpatient facilities in the United States. Ownership of these clinics is highly consolidated with DaVita controlling approximately 27% and Fresenius controlling approximately 33%. 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.

In February 2007, we entered into a national service provider agreement with DaVita that grants DaVita certain market rights for the System One and related supplies for home hemodialysis therapy. Under this agreement, we granted DaVita exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the U.S. ESRD patient population, and limited exclusivity in the majority of all other U.S. geographies, subject to DaVita's meeting certain requirements, including patient volume commitments and new patient training rates. We will continue to sell to other clinics in the majority of geographies. The agreement limits, but does not prohibit, the sale by NxStage of the System One for chronic home hemodialysis therapy to any provider that is under common control or management of a parent entity that collectively provides dialysis services to more than 25% of U.S. chronic dialysis patients and that also supplies dialysis products. NxStage is, therefore, limited to some extent in its ability to sell the System One for chronic home hemodialysis therapy to Fresenius. Our national service provider agreement with DaVita extends until December 31, 2009, and DaVita has the option of renewing the agreement for four additional periods of six months if DaVita meets certain patient volume targets.

After renting or selling a System One to a clinic, our clinical educators 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 and other technicians and nurses using the System One, rather than sending our nurses back to the clinic to train each new patient, nurse or technician. 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. As of December 31, 2007, there were 2,223 home hemodialysis patients prescribed to receive therapy using the System One.

In-center

We sell primarily blood tubing sets and needles to customers in the in-center market. In this market, our customers are also 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. Sales through our primary distributor, Schein, accounted for 21.5% of net sales for the year ended December 31, 2007. Our contract with Schein was recently extended through July 2009.

DaVita is also a significant customer for our in-center products. DaVita has an agreement to purchase our blood tubing set products that expires in September 2008, and a separate agreement for needles that expires in January 2013.

We plan production against 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, other than Fresenius clinics. Clinics owned by Fresenius predominantly use Fresenius-manufactured blood tubing sets.

Medisystems has been in the in-center market since 1981.

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 CHF.

We have a critical care direct sales force that calls on hospitals. In addition to specialized sales representatives, we also employ nurses in our critical care sales force to serve as clinical educators to support our sales efforts.

The System One for the critical care market has a list price of $28,000; this price does not include the related disposables required for each treatment. 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. As of December 31, 2007, we had 115 hospitals as critical care customers.

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 NxStage 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 NxStage 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 NxStage 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 approximately $65,000 annually, with dialysis services representing approximately 25% of this cost, while the cost of hospitalizations, drugs and physician fees make up more than 50%. Studies indicate daily therapy may materially reduce overall Medicare costs for the care of chronic dialysis patients, particularly through reduced hospitalization and drug costs.

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. We hope to complete the study and submit our application for a nocturnal indication to the FDA in late 2008 or early 2009.

In addition to the FREEDOM and nocturnal studies, we 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 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 hemodialysis 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 positively 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, 2007, 2006 and 2005, we incurred research and development expenses of $6.3 million, $6.4 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 rights to a number of patents, trademark, copyrights, trade secrets and other intellectual property directly related and important to our business.

As of December 31, 2007, we had 29 issued U.S. and international patents and 48 U.S., international and foreign pending patent applications.

Patent No.	Regime	Filed	Expiration Date	Description
6,254,567	U.S.	2/23/2000	2/26/2019	Addresses fluids requirement by regenerating dialysate
6,554,789	U.S.	2/25/2000	2/14/2017	Panels defined by seals and overlying panels
6,572,576	U.S.	7/7/2001	7/2/2021	Leak detection by flow reversal
6,572,641	U.S.	4/9/2001	4/9/2021	Fluid warmer that removes air
6,579,253	U.S.	2/25/2000	2/14/2017	Balancing chambers are defined by panels of the circuit
6,582,385	U.S.	2/19/1998	2/19/2018	Addresses fluids requirement by purifying waste
6,589,482	U.S.	2/25/2000	2/14/2017	Panels form a combination to mutually displace waste and replacement fluid
6,595,943	U.S.	2/25/2000	2/14/2017	Blood pressure control in filter to optimize throughput
6,638,477	U.S.	2/25/2000	2/14/2017	Divert part of waste stream to control ultrafiltration or rinse
6,638,478	U.S.	2/25/2000	2/14/2017	Mechanically coupled flow assemblies that balance flow of incoming and outgoing fluid streams, respectively
6,649,063	U.S.	7/12/2001	10/7/2021	Using the filter to generate sterile replacement fluid
6,673,314	U.S.	2/25/2000	2/14/2017	Supply notification including third-party notification by network
6,702,561	U.S.	7/12/2001	9/8/2021	Potting distribution channel molded into filter housing
6,743,193	U.S.	7/17/2001	7/17/2021	Hermetic valve design
6,830,553	U.S.	2/25/2000	2/14/2017	Sterile filter in replacement fluid line
6,852,090	U.S.	5/24/2001	12/10/2017	Balancing chambers are defined by circuit portions defined in cooperation with the base
6,872,346	U.S.	3/20/2003	5/14/2023	Manufacturing method for filters using radiant heat to seal filter fibers
6,955,655	U.S.	6/27/2001	10/7/2017	Frequent treatment with simple setup
6,979,309	U.S.	1/7/2002	6/19/2017	New frequent hemofiltration
7,004,924	U.S.	10/19/1998	2/11/2018	Methods, systems, and kits for the extracorporeal processing of blood
7,040,142	U.S.	1/4/2002	2/9/2022	Method and apparatus for leak detection in blood circuits combining external fluid detection and air infiltration detection
7,087,033	U.S.	7/8/2002	8/22/2021	Method and apparatus for leak detection in a fluid line
7,112,273	U.S.	9/26/2003	10/4/2023	Volumetric fluid balance control for extracorporeal blood treatment
7,147,613	U.S.	3/8/2004	8/29/2020	Measurement of fluid pressure in a blood treatment device
7,214,312	U.S.	07/12/2001	07/08/2022	Fluid circuits, systems, and processes for extracorporeal blood
7,226,538	U.S.	07/13/2007	01/21/2022	Fluid processing apparatus
7,267,658	U.S.	02/25/2000	03/06/2021	Renal replacement therapy device for controlling fluid balance treated
7,300,413	U.S.	02/25/2000	05/04/2021	Blood processing machine and system using fluid circuit cartridge
EP969887	EP (UK)	2/5/1998	2/14/2017	Frequent treatment with simple setup

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 Medisystems Acquisition, 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 Medisystems' core products.

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
Universal Connector — MEDIC	US 5071413	12/10/2008
Guarded Winged Needle Assembly: File Wrapper Continuation (FWC)	US 5112311	5/12/2009
Guarded Winged Needle Assembly: FWC-2	US 5266072	11/30/2010
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
Squeeze Clamp for Flexible Tubing	US 6113062	5/20/2018
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 — LocksiteTM	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 in connection with their employment, consulting or advisory relationship 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. Specifically, we assemble, package and label our PureFlow SL disposables within our 35,000 square foot facility in Fresnillo, Mexico. We manufacture components used in our System One cartridge assembly in our 45,000 square foot facility in Lawrence, Massachusetts, and assemble the disposable cartridge, some blood tubing sets, Medics and tranducer protectors in our 118,000 square foot facility in Tijuana, Mexico. We manufacture our dialyzers internally, within our 12,369 square foot facility in Rosdorf, Germany. We outsource the manufacture of premixed dialysate and needles. We rely on internal manufacturing and outsourcing for the System One cycler, PureFlow SL and blood tubing sets.

We have a 32,000 square foot molding facility in Modena, Italy, which molds components used in the products we manufacture ourselves in Tijuana, Mexico, as well as supplies the molded components for finished goods manufactured by Kawasumi Laboratories, Inc., or Kawasumi, as described below.

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 sets expires in March 2009. 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 of 80% of an agreed upon blood tubing sets purchase goal over the term of the agreement. We believe that this minimum purchase commitment is less than our anticipated requirements for blood tubing sets. We are presently negotiating with Kawasumi to determine if this supply agreement for blood tubing sets will be extended beyond March 2009. We can not be certain that this agreement will be renewed or extended on favorable terms, if at all, that 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 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. We have committed to purchase from Kawasumi a minimum of 80% of an agreed upon needle set purchase goal 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 long-term 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 for ten years. 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.

KMC Systems, Inc., or KMC, manufactures the System One cycler for us pursuant to an agreement that obligates KMC to continue to provide product to us at least through mid-2008. This agreement also allows us the option to manufacture for ourselves an increasing portion of cyclers as we deem appropriate over any remaining term, as mutually agreed by the parties. The contract may be terminated upon a material breach, generally following a 30-day cure period. We presently do not intend to seek renewal of this agreement after its termination this year.

We purchase bicarbonate-based premixed dialysate from B. Braun and our lactate-based premixed dialysate from Laboratorios PISA, or PISA. We have a long-term supply agreement with B. Braun that obligates B. Braun to supply the dialysate to us through 2009 in exchange for modest minimum purchase requirements of approximately $100,000 per year. The contract may be terminated upon a material breach, generally following a 30-day cure period. We have entered into a supply agreement with PISA that obligates PISA to supply dialysate to us through 2008 in exchange for annual purchase commitments of approximately $1.0 million. The contract may be terminated upon a material breach, generally following a 30-day cure period. We anticipate seeking to negotiate an extension of our agreement with PISA past December 2008. We can not be certain that this agreement will be renewed or extended on favorable terms, if at all, that we would be able to obtain lactate based bagged premixed dialysate from another third party supplier on favorable terms, if at all, that we would be able to meet our customer demand for bagged premixed dialysate, either through a third party or by manufacturing bagged premixed dialysate ourselves, or some combination thereof, the failure of any of which could impair our business,

We are currently purchasing our PureFlow SL module and chassis from Enercon. We are operating under a short-term supply agreement with Enercon that obligates Enercon to supply this equipment to us through July 2008. There are no minimums or exclusivity clauses associated with this agreement, and the agreement renews on a year to year basis, unless prior written notice is given by either party. The contract may be terminated upon a material breach, generally following a 30-day cure period. We presently do not intend to seek renewal of this agreement with respect to our PureFlow SL module after its termination.

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 23 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 22 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 IV 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 have been submitted to comply with FDA's blood loss policy for routine dialysis treatments. This policy requires 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. Although we have obtained CE marking approval in the EU for our System One, this CE marking is not up to date. Before we would be able to market our current products in the

EU, we would be required to submit additional regulatory documentation. We are not currently marketing the System One in the European Union.

The Medisystems 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. Medisystems maintains six Medical Device Licenses in Canada 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 no other Medisystems products 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 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 there under 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

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 2005 USRDS report, Medicare is the primary payor for approximately 81% of patients using hemodialysis and PD. It is believed that 15% of patients are covered by commercial insurance, with the remaining 4% 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. There is some regional variation in the composite rate, but, the national average for the last three quarters of 2007 was $152 per treatment for independent clinics and $157 per treatment for hospital-based dialysis facilities. This was an increase from approximately $149 per treatment for independent clinics and $154 per treatment for hospital-based dialysis facilities in 2006, due to two recent changes in Medicare reimbursement. As a result of legislation enacted in 2003 and first implemented in 2005, the Centers for Medicare and Medicaid Services, or CMS, shifted a portion of Medicare reimbursement dollars for dialysis from separately billable drugs to the composite rate for dialysis services. This drug add-on to the composite rate is subject to an increase based on the estimated rate of growth of drugs and biologicals. For 2007, an additional 0.5% has been shifted from separately billable drugs to the composite rate. In addition, Congress passed an additional 1.6% increase to the composite rate for treatments received on or after April, 2007. For 2008, CMS again shifted an additional 0.5% from separately billable drugs to the composite rate such that the 2008 national average composite rate is about $153 per treatment for independent clinics and about $158 per treatment for hospital-based dialysis facilities. Depending upon patient case mix, reimbursement may be further improved, based on the case-mix adjustment to the composite rate implemented as a result of the 2003 legislation. 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.

CMS rules limit the number of hemodialysis treatments paid for by Medicare to three per week, unless there is medical justification 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 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.

Employees

As of December 31, 2007, we had 1,399 full-time employees, 3 part-time employees and 63 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 Report 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 substantially all of our efforts to the development of the System One and the related products used with the System One. We commenced marketing the System One and the related disposable products to the critical care market in February 2003. We commenced marketing the System One for chronic hemodialysis treatment in September 2004. Prior to the Medisystems Acquisition, 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 broadens our product offerings, we expect that nearly all of our revenues will be derived from the sale of a limited number of key products primarily applicable to the dialysis business. We expect that in 2008 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 Medisystems' disposable products, including blood tubing sets and needles. To the extent that any of our primary products is not commercially successful or is 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 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 2005, 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. Further, the number of nephrologists and dialysis clinics willing to prescribe home hemodialysis or establish and support home hemodialysis programs is also unknown. 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 willing to establish and support home hemodialysis therapies. We do not know whether the number of home-based dialysis patients will be greater or fewer than the number of patients performing peritoneal dialysis. 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 costs associated with providing more frequent dialysis, market acceptance will likely be impacted 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 significant number of our customers are unable to obtain such additional reimbursement, which will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Finally we are still early in the market launch of the System One for home hemodialysis. We received our home use clearance for the System One from the FDA in June 2005 and we will need to continue to devote significant resources to developing the market. We cannot be certain that this market will develop, how quickly it will develop or how large it will be.

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

We believe that the home hemodialysis market is the largest market opportunity for our System One. In this market, a significant percentage of our home customers rent rather than purchase System One equipment. As a result, we generate, and expect to continue generating in the future, a significant percentage of our revenues and cash flow from the use of System One equipment over time rather than upfront from the sale of System One equipment. This sales model requires significant amounts of working capital to manufacture System One equipment for rental to dialysis clinics. Our agreement with DaVita signed in early 2007 departs from the rental model, which helps us to conserve cash flow. In that agreement, DaVita agreed to purchase all of its System One equipment then being rented from us and to buy a significant percentage of its future System One equipment needs. It is not clear whether we will be able to replicate this sales model with a significant number of other customers in the future. In 2007, only two of our customers, one of which was DaVita, purchased equipment. However, the percentage of our home patients using purchased systems is significant, approximately 47.1%. We have also not yet achieved profitability, which imposes additional requirements for cash.

We will need to sell additional equity or issue debt securities to fund our capital requirements beyond 2008. Any sale of additional equity or issuance of debt securities 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 this 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. Additionally, beginning in February 2009, we will need to begin paying down the principal of the debt we borrowed from Merrill Lynch. To the extent we are unable to obtain additional financing, this obligation to repay debt will only further increase the need to further delay, reduce the scope of, or eliminate one or more aspects of our business, which would likely harm our business.

We have limited operating experience, a history of net losses and an accumulated deficit of $182.0 million at December 31, 2007. We cannot guarantee if, when and the extent that we will become profitable, or that we will be able to maintain profitability once it is achieved.

Since inception, we have incurred losses every quarter and at December 31, 2007, we had an accumulated deficit of approximately $182.0 million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, although we have recently achieved positive gross margins for our products, in aggregate, as of December 31, 2007, we can not provide assurance that our gross margins will remain positive, 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 is dependent 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, increasing our reliability, 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 PureFlow SL module, introduced into the market in July 2006, is a recently implemented design improvement intended to improve our profitability. PureFlow SL is an accessory module to the System One that allows for the preparation of high purity dialysate in the patient's home using ordinary tap water and dialysate concentrate, allowing patients with ESRD to more conveniently and effectively manage their home hemodialysis therapy by eliminating the need for bagged fluids. The gross margin of this product is expected to be more favorable to NxStage than the gross margin on our bagged fluids and is an important part of our strategy to achieve profitability. Since its launch, PureFlow SL penetration has reached approximately 70% of all of our home patients. The product is still early in its commercial launch and we continue to work to improve product reliability, and to introduce PureFlow SL product design enhancements that will improve utilization of disposables and user experience. Any failure to further improve reliability and user experience, and to reduce the utilization of disposables, each of which is critical to achieving improved margins for

PureFlow SL. Failure to further improve reliability will also negatively impact our distribution costs, which would adversely affect our ability to achieve profitability.

In March 2007, we began moving the manufacture of our products from Massachusetts to Mexico. At the end of 2007, we were manufacturing our Pureflow SL disposables and a limited percentage of our Cyclers in Mexico as well as servicing a limited percentage of our Cyclers in Mexico. Our System One cartridge had already been manufactured in Mexico by Medisystems at the time of the Medisystems Acquisition. Our ability to continue to shift manufacturing and servicing to Mexico, in order to take advantage of lower labor costs, is an important part of our strategy to achieve profitability. Any failure or unforeseen difficulties in transitioning additional manufacturing and servicing to Mexico and to maintain or improve product reliability in the process, would adversely affect our ability to achieve profitability.

We entered into a secured credit facility with Merrill Lynch in November 2007, and as of December 31, 2007, we had borrowed $25 million thereunder. We may not be able to borrow the full amount available under that credit facility, and we will need to begin repaying principal on the amounts we have already borrowed under that credit facility in February 2009. Further, if we fail to comply with all terms and covenants under our credit agreement, we may go into default under the credit facility which could trigger, among other things, the acceleration of all of our indebtedness thereunder or the sale of our assets.

On November 21, 2007 we obtained a $50.0 million credit and security agreement from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., for a term of 42 months. The credit facility is secured by nearly all of our assets, other than intellectual property and consists of a $30.0 million term loan and a $20.0 million revolving credit facility. We borrowed $25.0 million under the term loan in November 2007, and have the option to borrow the remaining $5.0 million by May 21, 2008. We expect that we will borrow this amount. We used $4.9 million of the proceeds from the term loan to repay all amounts owed under a term loan dated May 15, 2006 with Silicon Valley Bank. Borrowings under the term loan bear interest equal to LIBOR plus 6% per annum, fixed on November 21 for our first borrowings (at a rate of 10.77% per annum) and at the date of borrowing for the remaining $5.0 million still available to be borrowed under the term loan. Interest on the term loan must be paid on a monthly basis. Beginning on February 1, 2009, we must repay principal under the term loan in 29 equal monthly installments. We will also be required to pay a maturity premium of $900,000 at the time of loan payoff. Our borrowing capacity under the revolving credit facility is subject to the satisfaction of certain conditions and calculation of the borrowing amount. There is no guarantee that we will be able to borrow the full amount, or any funds under the revolving credit facility. Any borrowings under the revolving credit facility will bear interest at LIBOR plus 4.25% per annum. There is an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which are charged in the event the revolving credit facility is terminated prior to May 21, 2011 of 4% in year one, 2% in year two, and 1% thereafter.

The credit facility includes covenants that (a) require us to achieve certain minimum net revenue and certain minimum EBITDA targets relating to the acquired Medisystems business, (b) place limitations on our and our subsidiaries' ability to incur debt, (c) place limitations on our and our subsidiaries' ability to grant or incur liens, carry out mergers, and make investments and acquisitions, and (d) place limitations on our and our subsidiaries' ability to pay dividends, make other restricted payments, enter into transactions with affiliates, and amend certain contracts. The credit agreement 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, Merrill Lynch has a number of remedies, including sale of our assets, control of our cash and cash equivalents, and acceleration of all outstanding indebtedness. Any 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 product lines compete directly against products produced by Fresenius Medical Care AG, Baxter Healthcare, Gambro AB, B. Braun and others, each of which markets 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. Finally, one of our competitors, Gambro AB, has been, until recently, subject to an import hold imposed by the FDA on its acute and chronic dialysis machines. It is not clear what the home and critical care market impact will be now that the import hold is lifted. We believe the overall impact of the import hold has been positive to us, however, we cannot be sure of the magnitude of the impact the import hold has had on revenues.

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 safety, convenience or effectiveness or are offered at lower prices. Fresenius and Baxter have each made public statements that they are either contemplating or actively developing new and/or improved systems for home hemodialysis. Fresenius made these statements in relation to their recent acquisition of Renal Solutions, Inc., and Baxter made them in relation to the announcement of a research and development collaboration with DEKA Research & Development Corporation and HHD, LLC. We are unable to predict if or when products from these or 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.

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

Our System One products still have limited product and brand recognition and have only been used at a limited number of dialysis clinics and hospitals. 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 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 the System One for a number of reasons including:

- the failure by us to demonstrate to patients, operators of dialysis clinics, nephrologists, dialysis nurses and others that our product is equivalent or superior to existing therapy options, or that the cost or risk associated with use of our product is not greater than available alternatives;

- 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 dialysis clinics;
- 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, safer, easier to use or less expensive than ours;
- 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 continued availability of satisfactory reimbursement from healthcare payors, including Medicare.

In addition, the future growth of our business depends, to a lesser degree, upon the successful launch and market acceptance of our latest generation blood tubing set product, Streamline. Streamline is designed to be a high-quality, high-performance blood tubing set that promises to yield valuable savings and improved patient outcomes for those clinics that adopt it for use. Market penetration of this product is quite limited to date, and it is not possible to predict whether and to what extent current and future customers will elect to use this product instead of more established or competitive blood tubing sets. If we are unable to convert customers to the Streamline product and receive more widespread commercial acceptance of this product, our ability to achieve our growth objectives could be impaired.

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 U.S. Congress more than 30 years ago, Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. With over 80% of U.S. ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer's decision to use the System One or our other products and limits the fee for which we can 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 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. 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. In the next two years, Medicare will be 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.

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 to them.

As we continue to commercialize the System One, Streamline and our other products, 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 regulatory, 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 on the product reliability of our System One product, our ability to grow our business and achieve profitability could be impaired.

Our System One is still early in its product launch, and our PureFlow SL module was only introduced during the third quarter of 2006. We continue to experience product reliability issues associated with these products that are higher than we expect long-term, and have led us to incur increased service and distribution costs, as well as increase the size of our field equipment base. This, in turn, negatively impacts our gross margins and increases our working capital requirements. Additionally, product reliability issues can also lead to decreases in customer satisfaction and our ability to grow or maintain our revenues. We continue to work to improve product reliability for these products, and have achieved some improvements to date. If we are unable to continue to improve product reliability of our System One products, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

Most recently, in the second quarter of 2007, we started to experience an increased incidence of reported dialysate leaks associated with our System One cartridges. The reported incidence of leaks was higher than we have historically observed. When the System One was used in accordance with its instructions, these leaks presented no risk to patient health. System One device labeling anticipates the potential for leaks to occur and specifically warns against leaks and alerts users of the need to observe treatments in order to detect leaks. Six patients with reported leaks, that were unobserved by these patients or their partners until after their treatments were completed, reported hypotension, or low blood pressure, resolved by a fluid bolus, with no lasting clinical effect. In early August 2007, we sent a letter to our patients and customers informing them of the increased incidence in leaks and reminding them of existing System One labeling alerting users of the potential for leaks and instructing them to observe treatments in order to detect any leaks. We characterized this notification as a voluntary recall. On August 24, 2007, we elected to initiate a second step in our recall actions, and decided to physically recall the affected lots of cartridge inventory being held by home market customers and patients, and replace the affected inventory with newer lots of cartridges at no charge. We instructed patients and customers to destroy all inventory of affected cartridges they had on hand. As of December 31, 2007, we incurred $2.3 million of charges for the recall, which consisted of a $1.5 million write off of inventory on hand at the time and $0.8 million in other costs related to the return or replacement of cartridges. As of December 31, 2007, we had approximately $1.1 million of affected inventory related to the original provision on hand.

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 the majority of our System One home care business continues to rely upon an equipment 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 barrier would negatively impact our working capital requirements and future profitability.

Our national service provider agreement with DaVita confers certain geographic market rights to DaVita and limits our ability to sell the System One in the home market to Fresenius, both of which may present a barrier to adoption of the System One in the home.

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Fresenius controls approximately 33% of the U.S. dialysis clinics and is the largest worldwide manufacturer of dialysis systems. DaVita controls approximately 27% of the U.S. dialysis clinics, and has entered into a preferred supplier agreement with Gambro pursuant to which Gambro will provide a significant majority of

DaVita's dialysis equipment and supplies for a period of at least 10 years. 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.

Our recent agreement with DaVita confers certain market rights for the System One and related supplies for home hemodialysis therapy. DaVita is granted exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the U.S. ESRD patient population, and limited exclusivity in the majority of all other U.S. geographies, subject to DaVita's meeting certain requirements, including patient volume commitments and new patient training rates. Under the agreement, we can continue to sell to other clinics in the majority of geographies. If certain minimum patient numbers or training rates are not achieved, DaVita can lose all or part of its preferred geographic rights. The agreement further limits, but does not prohibit, the sale by NxStage of the System One for chronic home patient hemodialysis therapy to any provider that is under common control or management of a parent entity that collectively provides dialysis services to more than 25% of U.S. chronic dialysis patients and that also supplies dialysis products. Therefore, our ability to sell the System One for chronic home patient hemodialysis therapy to Fresenius is presently limited.

For the year ended December 31, 2007, 43.8% of our home hemodialysis patients in the home market belonged to DaVita. Although we expect that DaVita will continue to be a significant customer of ours, the agreement imposes no purchase obligations upon DaVita and we cannot be certain whether DaVita will continue to purchase and/or rent the System One from us in the future. We believe that any future decision by DaVita to stop or limit the use of the System One would adversely affect our business, at least in the near term.

We rely heavily upon DaVita as a key customer for our System One and Medisystems 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 Medisystems' products accounted for approximately 41% of Medisystems' revenues in 2007, and NxStage's direct sales to DaVita accounted for approximately 27% of our revenues in 2007. Our contract for Medisystems blood tubing sets and needles with DaVita includes certain minimum order requirements; however, these can be reduced significantly under certain circumstances. Further, DaVita's commitments to purchase Medisystems' blood tubing sets expire in September 2008. We cannot guarantee we will be able to negotiate an extension of this agreement with DaVita on favorable terms, if at all, or the extent to which DaVita will purchase Medisystems' products. NxStage's national service provider agreement with DaVita does not impose minimum purchase requirements, and expires as early as the end of 2009. The partial or complete loss of DaVita as a customer for either 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 can have a significant impact on our revenues, especially in the near term.

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 the most recent USRDS data, in 2004, approximately 17,000 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 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 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. One of our competitors in the critical care market, Gambro AB, has been subject to an FDA import hold that was recently lifted. Although it is unclear what the impact of this import hold has been on our revenues, we expect competition in this market to increase with the reintroduction of Gambro products to the U.S. critical care market.

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

If any of our 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. Although NxStage has not been a party to any such claims, Medisystems and certain of its affiliated entities have been parties to such claims prior to the Medisystems Acquisition. While we maintain insurance, including product and excess liability insurance, claims may be brought against us that could result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product 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 claim brought against us, with or without merit, could result in the increase of our product liability insurance rates 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, 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.

In addition to our operations in Massachusetts, 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 Thai Baht, Euro and Peso. The U.S. dollar has weakened materially against the Thai Baht and Euro over the last five years and may continue to do so. 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 and local regulations that may restrict or impair our ability to conduct our operations.

We currently rely upon 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 March 2009 and its obligation to supply needles expires in February 2011. In the event theses 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, Medisystems has relied upon a third-party manufacturer, Kawasumi Laboratories, Inc. which we refer to as Kawasumi, to manufacture a significant percentage of its blood tubing set products using Medisystems' supplied components. This third party has a strong history of manufacturing high-quality product for Medisystems. Kawasumi's contractual obligation to manufacture blood tubing sets for us expires in March 2009. We are presently negotiating with Kawasumi to determine if this supply agreement for blood tubing sets will be extended beyond March 2009. We can not be certain that this agreement will be renewed or extended on favorable terms, if at all, that 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. In the event this agreement is not renewed or extended upon favorable terms, if at all, if 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 Medisystems' business relies heavily upon third-party distributors.

We sell the majority of our in-center Medisystems' products through three distributors, which collectively accounted for approximately 82% of in-center revenues in 2007, with our primary distributor, Schein, accounting for 66% of Medisystems' in-center revenues in 2007. Schein recently agreed to extend our distribution relationship with Medisystems through July 2009. The contracts with the other two distributors of Medisystems' products are scheduled to expire in October 2008 and July 2009. Our relationship with Schein, in particular, is very significant for our business and any failure to continue this relationship would be harmful to our business, because our current sales force has limited experience selling blood tubing sets or needles.

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.

Medisystems' 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. Medisystems 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 U.S. dialysis services industry, with Fresenius and DaVita collectively controlling approximately 61% of U.S. 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 Medisystems 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 involves 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 Mexico and Thailand. If we misinterpret or violate these laws, or if laws governing our exemption from certain duties changes, we could be subject to significant fines, liabilities or other adverse consequences.

We import into the United States disposable medical supplies from 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.

The inability to successfully integrate the operations and personnel of Medisystems and NxStage, or any significant delay in achieving integration, could have a material adverse effect on our business.

Integrating the operations and personnel of Medisystems and NxStage has required, and continues to require, a significant investment of management's time and effort as well as the investment of capital, particularly with respect to information systems. The continued successful integration of Medisystems and NxStage will require, among other things, coordination of certain manufacturing operations and sales and marketing operations and the integration of Medisystems' operations into our existing organization. The diversion of the attention of our senior management and any difficulties encountered in the process of combining the companies could cause the disruption of, or a loss of momentum in, the activities of our business. The inability to successfully integrate the operations and personnel of Medisystems and NxStage, or any significant delay in achieving integration, could have a material adverse effect on our business and, as a result, on the market price of our common stock.

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

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

Risks Related to the Regulatory Environment

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

Our products are medical devices subject to extensive regulation in the 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. We cannot provide assurance that such clearances or approvals would 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.

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 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 Lawrence, MA U.S. manufacturing facility 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. The FDA has inspected our Lawrence, MA 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 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, 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.

Changes in reimbursement for acute kidney failure could negatively affect the adoption of our critical care products and the level of our future critical care product revenues.

Unlike Medicare reimbursement for ESRD, Medicare only reimburses healthcare providers for acute kidney failure and fluid overload treatment if the patient is otherwise eligible for Medicare, based on age or disability. Medicare and many other third-party payors and private insurers reimburse these treatments provided to hospital inpatients under a traditional 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, may increase the amount reimbursed. For care of these patients to be cost-effective, hospitals

must manage the longer hospitalization stays and significantly more nursing time typically necessary for patients with acute kidney failure and fluid overload. If we are unable to convince hospitals that our System One provides a cost-effective treatment alternative under this diagnosis related group reimbursement system, they may not purchase our product. In addition, changes in Medicare reimbursement rates for hospitals could negatively affect demand for our products and the prices we charge for them.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and foreign countries, there have been legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The federal government and some states have enacted healthcare reform legislation, and further federal and state proposals are likely. We cannot predict the exact form this legislation may take, the probability of passage, or the ultimate effect on us. Our business could be adversely affected by future healthcare reforms or changes in Medicare.

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

Although we have not initiated any marketing efforts in jurisdictions outside of the United States and Canada, we intend in the future to market our products in other markets. In order to market our products in the EU or 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 effect our overall market penetration.

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

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we learn patient names and addresses when we ship our System One supplies to home hemodialysis patients. We may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customer's staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. U.S. Federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. 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. 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. 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.

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.

Although we have not initiated any marketing efforts in jurisdictions outside of the United States and Canada, we intend in the future 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.

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 its products. We also obtain sterilization services from a single supplier. Presently, B. Braun Medizintechnologie GmbH is our only supplier of bicarbonate-based dialysate used with the System One; Membrana GmbH is our only supplier of the fiber used in our filters; PISA is our primary supplier of lactate-based dialysate, and Kawasumi is our only supplier of needles. We also obtain certain other 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 B. Braun, for bicarbonate, and Membrana, for fiber, we are contractually prevented from obtaining an alternative source of supply, except in certain limited instances. 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. Rising oil prices affect both the pricing and availability of this material. Continued 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. Further 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.

MDS 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 MDS Mexico has entered into a collective bargaining agreement with a Union named Mexico Moderno de Trabajadores de la Baja California C.R.O.C. Medisystems has 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 are transitioning manufacturing 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. We are also expanding our manufacturing capacity which requires us to relocate our manufacturing operations to other locations. As such, we and certain of our third party manufacturers, have limited manufacturing experience with certain of our products, including key products such as the PureFlow SL, related disposables and our Streamline. 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, 2007, we had 48 pending patent applications, including foreign, international and U.S. applications, and 29 U.S. and international issued patents. Under our license agreement with DSU Medical Corporation, we also license 99 pending patent applications, including foreign, international and U.S. applications, and 29 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 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;
- 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;
- 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 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 36,771,893 shares of common stock outstanding as of December 31, 2007. 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 367,719 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, 2007, subject to certain conditions, holders of an aggregate of approximately 12,814,221 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, 2007, 7,172,646 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, 2007, 4,094,791 shares were subject to outstanding options, of which 1,963,169 were exercisable and which can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and the restrictions imposed on our affiliates under Rule 144.

Our costs have increased significantly as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as new rules subsequently implemented by the SEC and the NASDAQ Global Market, have imposed various new requirements on public companies, including changes in corporate governance practices. Our management and other personnel now need to devote a substantial amount of time to these new requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2006, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Global Market, SEC or other regulatory authorities.

We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.

We anticipate that we will retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to investors. Investors seeking cash dividends should not invest in our common stock.

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 own, in the aggregate, approximately 48.0% of our outstanding common stock. David S. Utterberg, one of our directors, holds 23.2% 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 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.

Purchase accounting treatment of acquisitions could decrease our net income in the foreseeable future, which could have a material and adverse effect on the market value of our common stock.

Under U.S. generally accepted accounting principals, we account for acquisitions using the purchase method of accounting. Under purchase accounting, we record the consideration issued in connection with the acquisition and the amount of direct transaction costs as the cost of acquiring the company or business. We allocate that cost to the individual assets acquired and liabilities assumed, including various identifiable intangible assets such as acquired technology, acquired trade names and acquired customer relationships based on their respective fair values. Intangible assets generally will be amortized over a three to fifteen year period. Goodwill and certain intangible assets with indefinite lives are not subject to amortization but are subject to at

least an annual impairment analysis, which may result in an impairment charge if the carrying value exceeds their implied fair value. These potential future amortization and impairment charges may significantly reduce net income, if any, and therefore may adversely affect the market value of our common stock.

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 32,000 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 also lease approximately 15,000 square feet of warehousing and manufacturing space in North Andover, Massachusetts on a month-to-month basis. 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***

We held a Special Meeting of Stockholders on October 1, 2007 and our stockholders voted to:

(i) Approve the issuance of 6,500,000 shares of common stock, plus any additional shares of common stock issuable pursuant to a post-closing working capital adjustment, pursuant to the stock purchase agreement, and any additional shares of common stock that we may be required to issue in the future to satisfy any indemnification obligations under the stock purchase agreement between us and Mr. Utterberg or the consulting agreement between us, Mr. Utterberg and DSU, which matter was approved by a vote of 23,415,505 shares voting for, 66,896 shares voting against and 4,213 shares abstaining.

(ii) Amend our 2005 Stock Incentive Plan to increase the number of shares of our common stock that may be issued pursuant to the plan by an additional 3,800,000 shares, of which no more than 1,500,000 shares may be granted as restricted stock, restricted stock units and other stock-based awards, which matter was approved by a vote of 21,431,378 shares voting for, 1,976,893 shares voting against and 78,343 shares abstaining.

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, 2007:

Name	Age	Position
Jeffrey H. Burbank	45	President, Chief Executive Officer
Agustin (Gus) M. Azel	68	Senior Vice President , Manufacturing
Robert S. Brown	49	Senior Vice President, Chief Financial Officer and Treasurer
Winifred L. Swan	43	Senior Vice President, General Counsel and Secretary
Joseph E. Turk, Jr.	40	Senior Vice President, Commercial Operations
Michael J. Webb	41	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. Mr. Burbank is on the Board of the National Kidney Foundation. He holds a B.S. from Lehigh University.

Agustin (Gus) M. Azel has been our Senior Vice President, Manufacturing since October 1, 2007. Prior to joining NxStage's management team, Mr. Azel served as Senior Vice President of Medisystems Corporation since October 2000. Mr. Azel holds a B.S. in Mechanical Engineering from the University of Southwestern Louisiana.

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.

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

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, 2007, 2006 and 2005 and balance sheet data as of December 31, 2007 and 2006 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, 2004 and 2003 and balance sheet data as of December 31, 2005, 2004 and 2003 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,				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	$ 59,964	$ 20,812	$ 5,994	$ 1,885	$ 286
Cost of revenues	65,967	26,121	9,585	3,439	940
Gross deficit	(6,003)	(5,309)	(3,591)	(1,554)	(654)
Operating expenses:					
Selling and marketing	21,589	14,356	7,550	3,334	2,181
Research and development	6,335	6,431	6,305	5,970	4,526
Distribution	13,111	7,093	2,059	495	33
General and administrative	13,046	8,703	4,855	3,604	2,868
Total operating expenses	54,081	36,583	20,769	13,403	9,608
Loss from operations	(60,084)	(41,892)	(24,360)	(14,957)	(10,262)
Other income (expense), net	1,750	2,262	(120)	115	54
Net loss before taxes	(58,334)	(39,630)	(24,480)	(14,842)	(10,208)
Provision for foreign income taxes	62	—	—	—	—
Net loss	$(58,396)	$(39,630)	$(24,480)	$(14,842)	$(10,208)
Net loss per share, basic and diluted	$ (1.86)	$ (1.60)	$ (4.31)	$ (5.81)	$ (4.10)
Weighted-average shares outstanding, basic and diluted	31,426	24,817	5,681	2,556	2,490

	December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash, cash equivalents, short-term investments and marketable securities	$ 34,345	$ 61,802	$ 61,223	$ 18,134	$ 8,881
Working capital	40,655	64,716	62,100	19,205	11,115
Total assets	210,386	101,725	76,575	25,455	13,613
Long-term liabilities	46,134	5,495	2,106	3,006	30
Redeemable convertible preferred stock	—	—	—	75,946	55,946
Accumulated deficit	(182,036)	(123,640)	(84,011)	(59,496)	(44,623)
Total stockholders' equity (deficit)(1)(2)(3)(4)	129,717	83,409	67,354	(57,400)	(43,478)

(1) We closed our initial public offering on November 1, 2005, which resulted in the issuance of 6,325,000 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

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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
2007		
First Quarter	$14.16	$ 8.04
Second Quarter	$14.28	$11.53
Third Quarter	$14.92	$12.00
Fourth Quarter	$15.35	$11.89
2006		
First Quarter	$15.17	$11.50
Second Quarter	$13.33	$ 8.33
Third Quarter	$10.18	$ 6.86
Fourth Quarter	$ 9.80	$ 7.29

Holders

On March 3, 2008, the last reported sale price of our common stock was $5.91 per share. As of March 3, 2008, there were approximately 63 holders of record of our common stock and approximately 5,000 beneficial holders of our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. Our credit agreement with Merrill Lynch restricts our ability to pay dividends.

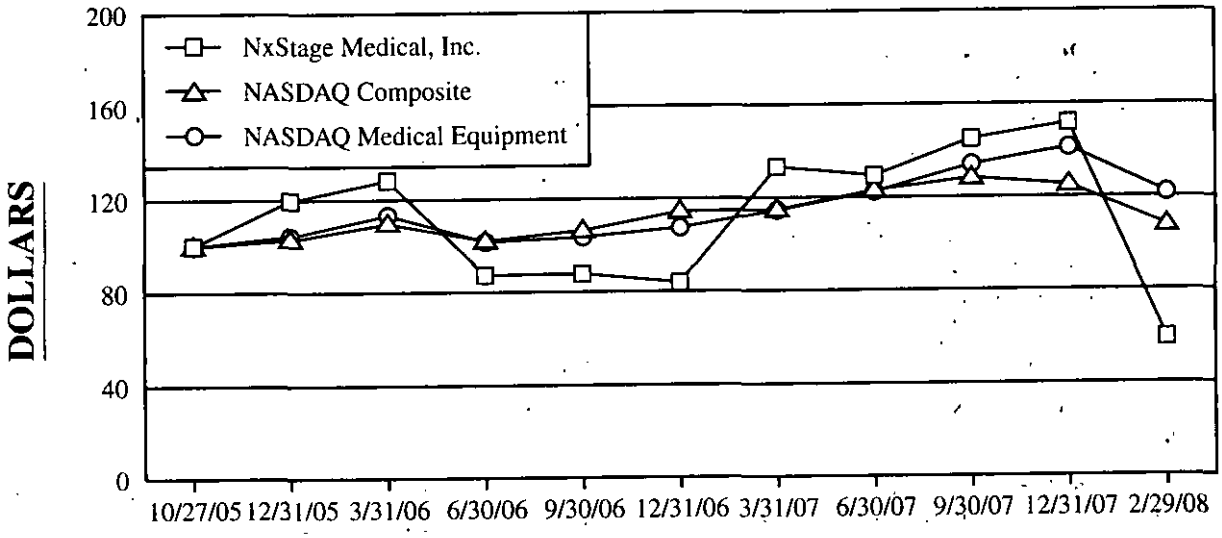
Issuer Purchases of Equity Securities

We made no repurchases of our equity securities during the fourth quarter ended December 31, 2007.

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 February 29, 2008 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, 2007 and 2006, the quarters ended March 31, 2007 and 2006, June 30, 2007 and 2006 and September 30, 2007and 2006.



	10/27/05	12/31/05	3/31/06	6/30/06	9/30/06	12/31/06	3/31/07	6/30/07	9/30/07	12/31/07	2/29/08
NxStage Medical, Inc	100.00	119.60	128.30	87.30	87.70	83.80	133.20	129.30	144.90	151.70	59.2
NASDAQ Composite	100.00	102.70	109.63	102.02	106.39	114.42	114.77	122.99	128.14	125.02	107.57
NASDAQ Medical Equipment	100.00	104.20	113.27	101.63	103.55	107.40	114.59	122.28	133.93	141.09	121.62

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, 2007, 2006 and 2005 and balance sheet data as of December 31, 2007 and 2006 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, 2004 and 2003 and balance sheet data as of December 31, 2005, 2004 and 2003 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,				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	$ 59,964	$ 20,812	$ 5,994	$ 1,885	$ 286
Cost of revenues	65,967	26,121	9,585	3,439	940
Gross deficit	(6,003)	(5,309)	(3,591)	(1,554)	(654)
Operating expenses:					
Selling and marketing	21,589	14,356	7,550	3,334	2,181
Research and development	6,335	6,431	6,305	5,970	4,526
Distribution	13,111	7,093	2,059	495	33
General and administrative	13,046	8,703	4,855	3,604	2,868
Total operating expenses	54,081	36,583	20,769	13,403	9,608
Loss from operations	(60,084)	(41,892)	(24,360)	(14,957)	(10,262)
Other income (expense), net	1,750	2,262	(120)	115	54
Net loss before taxes	(58,334)	(39,630)	(24,480)	(14,842)	(10,208)
Provision for foreign income taxes	62	—	—	—	—
Net loss	$(58,396)	$(39,630)	$(24,480)	$(14,842)	$(10,208)
Net loss per share, basic and diluted	$ (1.86)	$ (1.60)	$ (4.31)	$ (5.81)	$ (4.10)
Weighted-average shares outstanding, basic and diluted	31,426	24,817	5,681	2,556	2,490

	December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash, cash equivalents, short-term investments and marketable securities	$ 34,345	$ 61,802	$ 61,223	$ 18,134	$ 8,881
Working capital	40,655	64,716	62,100	19,205	11,115
Total assets	210,386	101,725	76,575	25,455	13,613
Long-term liabilities	46,134	5,495	2,106	3,006	30
Redeemable convertible preferred stock	—	—	—	75,946	55,946
Accumulated deficit	(182,036)	(123,640)	(84,011)	(59,496)	(44,623)
Total stockholders' equity (deficit)(1)(2)(3)(4)	129,717	83,409	67,354	(57,400)	(43,478)

(1) We closed our initial public offering on November 1, 2005, which resulted in the issuance of 6,325,000 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 12,124,840 shares of common stock.

(2) We closed our follow-on public offering on June 14, 2006, which resulted in the issuance of 6,325,000 shares of common stock at $8.75 per share. Net proceeds from the offering were approximately $51.3 million.

(3) On February 7, 2007, we issued and sold to DaVita 2,000,000 shares of common stock, at a purchase price of $10.00 per share, for an aggregate purchase price of $19.9 million. The price of our common stock on February 7, 2007 was $8.50, resulting in a $3.0 million premium, which was deferred.

(4) On October 1, 2007, we issued 6,500,000 shares of common stock at $12.50 per share to David S. Utterberg in connection with the Medisystems Acquisition.

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

Overview

We are a medical device company that develops, manufactures and markets innovative systems for the treatment of end-stage renal disease, or ESRD, acute kidney failure and fluid overload. Our primary product, the NxStage System One, is a small, portable, easy-to-use hemodialysis system designed to provide physicians and patients improved flexibility in how hemodialysis therapy is prescribed and delivered. In addition to the System One, since October 2007, we also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of ESRD, which we refer to as the in-center market. These product lines were obtained in connection with our Medisystems Acquisition. Although the revenues derived from our Medisystems products are a significant percentage of our current revenues, 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, which we previously referred to as the chronic market.

We distribute our products in three markets: the home, in-center and critical care. We define the home market as the market devoted to the treatment of ESRD patients in the home, the in-center market as the market devoted to in-center hemodialysis, and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. We offer a different configuration of the System One for each of the home and critical care markets. The FDA has cleared both configurations for hemodialysis, hemofiltration and ultrafiltration. We offer primarily needles and blood tubing sets in the in-center market. Our products are predominantly used by our customers to treat patients suffering from ESRD or acute kidney failure and we have separate marketing and sales efforts dedicated to each market, although in the in-center market, nearly all sales 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. At the time of these early marketing efforts, our System One was cleared by the FDA under a general indication statement, allowing physicians to prescribe the System One for hemofiltration, hemodialysis and/or ultrafiltration at the location, time and frequency they considered in the best interests of their patients. Our original indication did not include a specific home clearance, and we were not able to promote the System One for home use at that time. The FDA cleared the System One in June 2005 for hemodialysis in the home.

Our business expanded significantly in late 2007 in connection with our Medisystems Acquisition. With that acquisition, we acquired our needle and blood tubing set product lines for use predominantly in in-center hemodialysis as well as apheresis. The Medisystems business is significantly more mature than our home and critical care businesses. Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981, and it has 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, and the Streamline. ReadySet has been on the market since 1993. Streamline is our next generation product designed to provide improved patient outcomes and lower costs to dialysis clinics. This product is early in its market launch and adoption has been limited to date. Our needle products line includes AV fistula needle sets.

incorporating safety features including PointGuard Anti-Stick Needle Protectors, and MasterGuard technology and ButtonHole needle sets. Our AV Fistula Needle Sets with MasterGuard Anti-Stick Needle Protector were introduced in 1995 and our ButtonHole needle sets were introduced in 2002.

Our customers 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 clinic 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 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.

The manufacture of our products is accomplished through a complementary combination of outsourcing and internal production. Specifically, we assemble, package and label our PureFlow SL disposables within our Fresnillo, Mexico facility. We manufacture components used in our System One cartridge assembly in Lawrence, Massachusetts, and assemble the disposable cartridge, some blood tubing sets, Medics and tranducer protectors in Mexico. We manufacture our dialyzers internally in Rosdorf, Germany. We outsource the manufacture of premixed dialysate and needles. We rely on internal manufacturing and outsourcing for manufacture of our System One cycler, PureFlow SL and blood tubing sets

We market the System One in the home and critical care market through a direct sales force in the United States primarily to dialysis clinics and hospitals. We market our Medisystems products primarily through distributors, although we also have a small dedicated sales force for that business. We have increased the number of sales representatives in our combined sales force from 24 at December 31, 2006 to 33 at December 31, 2007. At present, we believe we have an appropriately sized sales force, although this may change as market conditions warrant.

At December 31, 2007, 2,223 ESRD patients were prescribed to receive therapy using the System One at 334 dialysis clinics, compared to 1,022 ESRD patients at 174 dialysis clinics at December 31, 2006. In addition, at December 31, 2007, 115 hospitals were using the System One for critical care therapy, compared to 77 hospitals at December 31, 2006.

The following table sets forth the amount and percentage of revenues derived from each market for the periods indicated (in thousands):

	Years Ended December 31,					
	2007		2006		2005	
Home	$29,835	49.8%	$12,732	61.2%	$3,164	52.8%
In-Center	15,728	26.2%	—	0.0%	—	0.0%
Critical Care	14,401	24.0%	8,080	38.8%	2,830	47.2%
Total	$59,964		$20,812		$5,994	

Revenues for the in-center market reflected above consisted of MDS Entities revenues for the period from October 1, 2007 (date of Acquisition) through December 31, 2007.

Since inception, we have incurred losses every quarter and at December 31, 2007, we had an accumulated deficit of approximately $182.0 million. We expect to incur increasing operating expenses as we continue to grow our business. We only recently achieved positive gross margins for our products, in aggregate, and we can not 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 is dependent 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,

increasing our reliability, 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.

We will need to sell additional equity or issue debt securities to fund our capital requirements beyond 2008. Any sale of additional equity or issuance of debt securities 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 this 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. Additionally, beginning in February 2009, we will need to begin paying down the principal of the debt we borrowed from Merrill Lynch. To the extent we are unable to obtain additional financing, this obligation to repay debt will only further increase the need to further delay, reduce the scope of, or eliminate one or more aspects of our business, which would likely harm our business.

Statement of Operations Components

Revenues

We derive our revenues from the sale and rental of equipment and the sale of disposable products. In the critical care market, we generally sell the System One and related disposables to hospital customers. In the home market, customers generally 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 in-center market, the majority of revenues are derived from supply and distribution contracts with distributors. We generally recognize revenues when a product has been delivered to our customer, or, in the home market, for those customers that rent the System One, we recognize revenues on a monthly basis in accordance with a contract under which we supply the use of a cycler and the amount of disposables needed to perform a set number of 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, while disposable product revenue is recognized upon delivery.

Our rental contracts with dialysis centers for ESRD home dialysis patients generally include terms providing for the sale of disposable products to accommodate up to 26 treatments per month per patient and the purchase or monthly rental of System One cyclers and, in some instances, our PureFlow SL module. These contracts typically have a term of one year, and are automatically renewed on a month-to-month basis thereafter, subject to a 30 days termination notice. Under these contracts, if home hemodialysis is prescribed, supplies are shipped directly to patient homes and paid for by the treating dialysis clinic. We also include vacation delivery terms, providing for the free shipment of products to a designated vacation destination. 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.

In early 2007, we entered into long-term home market contracts for the System One with three larger dialysis chains, including with DaVita, which was our largest customer in 2007. Each of these agreements has a term of at least three years, and may be cancelled upon a material breach, subject to certain curing rights. These contracts provide the option to purchase as well as rent the System One equipment, and, in the case of the DaVita contract, DaVita has agreed to purchase rather than rent a significant percentage of its future System One equipment needs. In the first quarter of 2007, two of these dialysis chain customers elected to purchase, rather than rent, a significant percentage of their System One equipment currently in use. We expect, at least in the near term, that the majority of our customers will continue to rent the System One in the home market. As of December 31, 2007, we had deferred approximately $19.5 million of revenues related to the sale of equipment in the home market.

Our in-center revenues are highly concentrated in several significant purchasers. Revenues from Schein, our primary distributor, represented approximately 82% of our in-center revenues, as measured from October 1, 2007, the closing date of the Medisystems Acquisition. Revenues from our other two primary distributors over

the same period were 13% of our in-center revenues. Sales to DaVita, through Schein, represent a significant percentage of these revenues. DaVita has contractual purchase commitments under two agreements with Medisystems, one for needles and one for blood tubing sets. DaVita's purchase obligations with respect to needles expire in January 2013, and its purchase obligations with respect to blood tubing sets expire in September 2008. We have no assurance that we will be able to negotiate an extension of these obligations, or that DaVita's purchase obligations under these contracts will not be reduced, as permitted in certain circumstances under the contracts.

Our distribution contracts for our in-center market contain minimum volume commitments with negotiated pricing triggers 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, we offer rebates based on sales to specific end customers and discount incentives for early payment. Our sales revenues are presented net of these rebates, incentives, discounts and returns.

Our agreement with Schein, our primary distributor, will expire in July 2009 and our agreements with the other primary two distributors are scheduled to expire in October 2008 and July 2009.

Our critical care revenues are less concentrated. At December 31, 2007, the System One was used in critical care applications in 115 hospitals, none of which accounted for more than 10% of our critical care revenues. 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. These contracts typically have a term of one year. As our business matures, we are starting to derive a small amount of revenue from the sale of one year service contracts following the expiration of our standard one year warranty period for System One hardware. Similar to our home business, as more System Ones are placed within hospitals, we expect to derive a growing recurring revenue stream from the sale of disposable cartridges for use with our placed System Ones as well as, to a much lesser degree, from the sale of service contracts.

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 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 the products.

We expect the cost of revenues as a percentage of revenues to decline over time for four general reasons. First, we expect to introduce several process and product design changes that have inherently lower cost than our current products Second, we plan to continue to move the manufacture and servicing of certain of our products, including the System One cycler and PureFlow, to lower labor cost markets. Third, we expect to continue to improve product reliability, which would reduce service and distribution costs. Finally, we anticipate that increased sales volume and realization of economies of scale will lead to better purchasing terms and prices and broader options, and efficiencies in manufacturing and supply chain overhead costs, achieving efficient distribution or process. We can not, however, guarantee that our expectations will be achieved with respect to our cost reduction plans.

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 in the operation of our products. 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 market, and as we add additional sales support and marketing personnel.

Research and Development. Research and development expenses consist primarily of salary, benefits and stock-based compensation for research and development personnel, supplies, materials and expenses associated with product design and development, clinical studies, regulatory submissions, reporting and compliance and expenses incurred for outside consultants or firms who furnish services related to these activities. We expect research and development expenses will increase in the foreseeable future as we continue to improve and enhance our core products and expand our clinical activities.

Distribution. Distribution expenses include the freight cost of delivering our products to our customers or our customers' patients, depending on the market and the specific agreement with our customers, and salary, benefits and stock-based compensation for distribution personnel. 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 from customers back to our service center for repair if the product is under warranty, and the related expense of shipping a replacement product to our customers. We expect that distribution expenses will increase at a lower rate than revenues due to expected efficiencies gained from increased business volume, better pricing obtained from carriers following recent price negotiations, the expected customer adoption of our PureFlow SL module, which significantly reduces the weight and quantity of monthly disposable shipments, and improved reliability of System One equipment.

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 from 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. Rent, utilities and depreciation expense are allocated to operating expenses based on personnel and square footage usage. We expect that general and administrative expenses will increase in the near term as we add additional administrative support for our growing business.

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,		
	2007	2006	2005
Revenues	100%	100%	100%
Cost of revenues	110%	126%	160%
Gross deficit	(10)%	(26)%	(60)%
Operating expenses:			
Selling and marketing	36%	69%	126%
Research and development	11%	31%	105%
Distribution	22%	34%	34%
General and administrative	22%	42%	81%
Total operating expenses	91%	176%	346%
Loss from operations	(101)%	(202)%	(406)%
Other income (expense):			
Other income	5%	16%	11%
Other expense	(2)%	(5)%	(13)%
	3%	11%	(2)%
Net loss	(98)%	(191)%	(408)%

Comparison of Years Ended December 31, 2007 and 2006 (in thousands, except percentages)

Revenues

Our revenues for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Increase	Percentage Increase
Revenues	$59,964	$20,812	$39,152	188%

The increase in revenues was attributable to increased sales and rentals of the System One and related disposables of $23.4 million in both the critical care and home markets, primarily as a result of increased sales and marketing efforts as we continue to commercialize the System One, and $15.7 million of in-center sales following the closing of our Medisystems Acquisition on October 1, 2007. The number of home patients prescribed to receive therapy was 2,223 at December 31, 2007 compared to 1,022 at December 31, 2006, an increase of 118%. In addition, we added 160 dialysis clinics in 2007 offering the System One. Revenues in the home market increased to $29.8 million for 2007 compared to $12.7 million in 2006, an increase of 134%, while revenues in the critical care market increased 78% to $14.4 million in 2007, compared to $8.1 million in 2006. Revenues in the in-center market represented $15.7 million for the three months ended December 31, 2007. We do not have comparable results for 2006 because we completed the Medisystems Acquisition on October 1, 2007.

Cost of Revenues and Gross Profit (Deficit)

Our cost of revenues and gross deficit for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Increase	Percentage Increase
Cost of revenues	$65,967	$26,121	$39,846	153%
Gross deficit	$(6,003)	$(5,309)	$ (694)	13%
Gross deficit percentage	(10.0)%	(25.5)%		

The increase in cost of revenues was attributable primarily to our increased revenues from the home and critical care markets, the cost of sales associated with the Medisystems Acquisition a charge of $2.0 million associated with our home cartridge recall in August 2007, and $1.6 million for the write-up of Medisystems inventory to fair value less a reasonable profit on remaining efforts to sell. The increase in product cost of approximately $39.8 million from 2006 to 2007 was due primarily to the Medisystems Acquisition and the increase in revenues attributable to the 2,223 patients and 115 hospitals as of December 31, 2007 compared to 1,022 patients and 77 hospitals as of December 31, 2006. We added 1,201 net patients during the twelve months ended December 31, 2007 to arrive at 2,223 patients compared to 730 net patients added during the twelve months ending December 31, 2006 to arrive at 1,022 patients. In addition, cost of revenues increased during the twelve months ended December 31, 2007 as compared to the same period in 2006 due to a larger employee base that resulted in additional salaries, health benefits and payroll taxes of $2.8 million, increased inbound freight costs of $2.0 million to support our higher production volume, increased service costs of $1.3 million, and the unfavorable impact of the declining dollar $0.4 million. We continue to see incremental improvement in our direct product costs; however, this is currently being partially offset somewhat by an increase in disposable usage per patient and overhead costs due to product reliability issues. We expect that over time as our reliability improves and as we implement further design enhancements, the disposables per patient and overhead support costs will decline.

Selling and Marketing

Our selling and marketing for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Increase	Percentage Increase
Selling and marketing	$21,589	$14,356	$7,233	50%
Selling and marketing as a percentage of revenues	36%	69%		

The primary increase in selling and marketing expense was the result of an increase in headcount and related salary, benefits, payroll taxes and stock-based compensation for selling and marketing personnel from 2006 to 2007. Total headcount for sales and marketing and support personnel increased by 57 employees from December 31, 2006 to December 31, 2007, and represented an increase of $5.7 million in expenses. In addition, travel, field expenses, and supplies increased by $0.5 million, and professional service fees for our scientific advisory board, process improvements, and reimbursement efforts increased by $0.5 million. We anticipate that selling and marketing expenses will continue to increase in absolute dollars as we broaden our marketing initiatives to increase public awareness of the System One in the home market and our other products, particularly Streamline in the in-center market, and as we add additional sales support personnel.

Research and Development

Our research and development for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Decrease	Percentage Decrease
Research and development	$6,335	$6,431	$(96)	(1)%
Research and development as a percentage of revenues	11%	31%		

The slight decrease in research and development expenses during the year ended December 31, 2007 compared to the same period in 2006 was attributable to a shift in spending from research and development efforts associated with PureFlow SL module to an increase in clinical efforts associated with our Freedom study. We expect research and development expenses will increase 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 IDE nocturnal trial, and Freedom study, but we do not expect that research and development expenses will increase as rapidly as other expense categories as we have substantially completed basic development of the System One. We expect research and development expenses to continue to decline as a percentage of revenues.

Distribution

Our distribution expenses for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Increase	Percentage Increase
Distribution	$13,111	$7,093	$6,018	85%
Distribution as a percentage of revenues	22%	34%		

The increase in distribution expenses for the twelve months ended December 31, 2007 compared to the same period in 2006 was due primarily to an increased volume of shipments of disposable products to a growing number of patients in the home market, the delivery of additional product, on an expedited basis due to reliability issues, the delivery of product on an expedited basis due to periodic inventory shortages, and the increased equipment deliveries for the PureFlow SL module. We expect that distribution expenses will increase at a lower rate than revenues due to expected shipping efficiencies gained from increased business volume and density of customers within geographic areas, the reduction of higher cost monthly deliveries associated with bagged fluid due to the lower monthly volumes of disposables on our PureFlow SL module, improved product reliability, and the use of an outsourced logistics provider located in the central part of the continental United States.

General and Administrative

Our general and administrative expenses for 2007 and 2006 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2007	December 31, 2006	Increase	Percentage Increase
General and administrative	$13,046	$8,703	$4,343	50%
General and administrative as a percentage of revenues	22%	42%		

The increase in general and administrative expenses during the twelve months ended December 31, 2007 compared to the same period in 2006 was primarily due to an increase of $2.2 million of professional fees,

$0.7 million for the amortization of intangible assets acquired in the Medisystems Acquisition, $0.4 million of headcount related expenses including salary, benefits, payroll taxes and stock-based compensation, due to increased headcount to support growth of infrastructure, $0.5 million relating to the acquired Medisystems business and $0.5 million of other corporate expenses. The increased professional fees related to increased legal expenses associated with higher contract activity in 2007, increased professional fees associated with acquisition related services for Medisystems, and increased hiring activity for board and senior level positions. We expect that general and administrative expenses will continue to increase in the near term as we add support structure for our growing business.

Other Income and Expense

Interest income is derived primarily from U.S. government securities, certificates of deposit, commercial paper and money market accounts. For the year ended December 31, 2007, interest income decreased by $0.4 million due to decreased cash and investments over the comparable period ending December 31, 2006.

For the year ended December 31, 2007, interest expense increased by $0.1 million over the comparable period ending December 31, 2006 due to our new credit facility. We expect interest expense will increase due to the new credit facility we entered into in November 2007.

Provision for Foreign Income Taxes

The provision for foreign income taxes of $0.1 million relates to our operations of the foreign entities we acquired in the Medisystems Acquisition on October 1, 2007. We expect the expense will increase in 2008 as we will own these foreign entities for a full year.

Comparison of Years Ended December 31, 2006 and 2005 (in thousands, except percentages)

Revenues

Our revenues for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
Revenues	$20,812	$5,994	$14,818	247%

The increase in revenues was attributable to increased sales and rentals of the System One in both the critical care and home markets, primarily as a result of an increase in the number of home patients on therapy resulting from increased sales and marketing efforts. The number of home patients on therapy was 1,022 at December 31, 2006 compared to 292 at December 31, 2005. In addition, we added 104 dialysis clinics in 2006 offering the System One. Revenues in the home market increased to $12.7 million in 2006 from $3.2 million in 2005, an increase of 302%, while revenues in the critical care market increased 186% to $8.1 million in 2006, compared to $2.8 million in 2005. We added an additional 27 hospitals in 2006 that offer the System One.

Cost of Revenues and Gross Deficit

Our cost of revenues and gross deficit for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
Cost of revenues	$26,121	$ 9,585	$16,536	173%
Gross deficit	$ (5,309)	$(3,591)	$ 1,718	48%
Gross deficit percentage	(25.5)%	(59.9)%		

The increase in cost of revenues was attributable primarily to our increased sales volume. For the chronic care market, we added 730 net patients during 2006, which contributed to a $12.9 million increase in cost of revenues. In addition, cost of revenues increased during 2006 because of an increase in manufacturing personnel which resulted in additional salaries, health benefits and payroll taxes of $1.6 million, higher servicing costs of $0.8 million and increased inbound freight costs of $1.1 million to support our higher production volume. The improvement in gross margin during 2006 was attributable to (i) increased sales volume and realization of economies of scale that led to better purchasing terms and prices, and efficiencies in indirect manufacturing overhead costs, (ii) lower labor costs for the manufacture of certain of our products, and (iii) continued improvement in product reliability. In 2006 and 2005 we reduced inventory to net realizable value through charges to cost of revenues.

Selling and Marketing

Our selling and marketing expenses for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
Selling and marketing	$14,356	$7,550	$6,806	90%
Selling and marketing as a percentage of revenues	69%	126%		

The increase in selling and marketing expenses was the result of several factors. Approximately $4.6 million of the increase was due to higher salary and benefits resulting from increased headcount, $0.6 million related to stock-based compensation as a result of the adoption in January 2006 of Statement of Financial Accounting Standards, or SFAS, No. 123R , *"Share-Based Payment"*. The increase in selling and marketing expense was also the result of $1.3 million related to a higher level of sales and marketing activity in both the home and critical care markets. We increased our combined sales force from 20 sales representatives at December 31, 2005 to 24 sales representatives at December 31, 2006.

Research and Development

Our research and development expenses for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
Research and development	$6,431	$6,305	$126	2%
Research and development as a percentage of revenues	31%	105%		

The increase in research and development expenses was attributable to increased salary, benefits and payroll taxes of $0.3 million as a result of increased headcount, approximately $0.1 million of stock-based compensation as a result of the adoption in January 2006 of SFAS No. 123R, offset by a decrease of $0.3 million of development costs associated with our PureFlow SL module which we incurred in 2005 that did not recur in 2006.

Distribution

Our distribution expenses for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
Distribution	$7,093	$2,059	$5,034	244%
Distribution as a percentage of revenues	34%	34%		

The increase in distribution expenses in 2006 was due to increased volume of shipments of disposable products to a growing number of patients in the home market.

General and Administrative

Our general and administrative expenses for 2006 and 2005 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2006	December 31, 2005	Increase	Percentage Increase
General and administrative	$8,703	$4,855	$3,848	79%
General and administrative as a percentage of revenues	42%	81%		

The increase in general and administrative expenses was primarily due to approximately $2.0 million of stock-based compensation as a result of the adoption in January 2006 of SFAS No. 123R, and approximately $1.5 million of legal and administrative expenses incurred as a result of operating as a public company.

Interest Income and Interest Expense

Interest income is derived primarily from U.S. government securities, certificates of deposit, commercial paper and money market accounts. For the year ended December 31, 2006, interest income increased by $2.6 million due to increased cash and investment balances available for investment resulting from our initial public offering and follow-on public offering and, to a lesser degree, higher interest rates.

Interest expense increased during the year ended December 31, 2006 compared to the same period in 2005 due to the early payoff of a debt agreement, which resulted in the early recognition of approximately $0.4 million of interest expense during the second quarter of 2006.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of December 31, 2007, our accumulated deficit was $182.0 million and we had cash and cash equivalents of approximately $34.3 million. On November 21, 2007, we obtained a $50.0 million credit and security agreement from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., for a term of 42 months. The credit facility is secured by nearly all our assets, other than intellectual property and consists of a $30.0 million term loan and a $20.0 million revolving credit facility. We borrowed $25.0 million under the term loan in November 2007, and have the option to borrow the remaining $5 million by May 21, 2008. We expect that we will borrow this amount. We used $4.9 million of the proceeds from the term loan to repay all amounts owed under a term loan dated May 15, 2006 with Silicon Valley Bank. Borrowings under the term loan bear interest equal to LIBOR plus 6% per annum, fixed on November 21 for our first borrowings (at a rate of 10.77% per year) and at the date of borrowing for the remaining $5.0 million still available to be borrowed under the term loan. Interest on the term loan must be paid on a monthly basis. Beginning on February 1, 2009, we must repay principal under the term loan in 29 equal monthly installments. We will also be required to pay a maturity premium of $900,000 at the time of loan payoff. We are accruing the maturity premium as additional

interest over the 42 month term. Our borrowing capacity under the revolving credit facility is subject to satisfaction of certain conditions and calculations of the borrowing amount. There is no guarantee that we will be able to borrow the full amount, or any funds, under the revolving credit facility. Any borrowings under the revolving credit facility will bear interest at LIBOR plus 4.25% per annum There is an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which are charged in the event the revolving credit facility is terminated prior to May 21, 2011 of 4% in year one, 2% in year two, and 1% thereafter.

The credit facility includes covenants that (a) require us to achieve certain minimum net revenue and certain minimum EBITDA targets relating to the acquired Medisystems business, (b) place limitations on our and our subsidiaries' ability to incur debt, (c) place limitations on our and our subsidiaries ability to grant or incur liens, carry out mergers, and make investments and acquisitions, and (d) place limitations on our and our subsidiaries' ability to pay dividends, make other restricted payments, enter into transactions with affiliates, and amend certain contracts. The credit agreement 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, Merrill Lynch has a number of remedies, including sale of our assets, control of our cash and cash equivalents, and acceleration of all outstanding indebtedness. Any of these remedies would likely have a material adverse effect on our business.

On February 7, 2007, we entered into a National Service Provider Agreement with DaVita, our largest customer. Pursuant to the terms of the agreement, we granted to DaVita certain market rights for the NxStage System One and related supplies for home hemodialysis therapy. Under the agreement, DaVita committed to purchase all of its existing System One equipment currently being rented from NxStage (for a purchase price of approximately $5 million) and to buy a significant percentage of its future System One equipment needs. In connection with the National Service Provider Agreement, on February 7, 2007, we issued and sold to DaVita 2,000,000 shares of our common stock at a purchase price of $10.00 per share, for an aggregate purchase price of $20.0 million.

On June 14, 2006, we closed a follow-on public offering in which we received net proceeds, after deducting underwriting discounts, commissions and expenses, of approximately $51.3 million from the sale and issuance of 6,325,000 shares of common stock.

On November 1, 2005, we closed our initial public offering in which we received net proceeds, after deducting underwriting discounts, commissions and expenses, of approximately $56.0 million from the sale and issuance of 6,325,000 shares of common stock. Prior to the initial public offering, we had financed our operations primarily through private sales of redeemable convertible preferred stock resulting in aggregate net proceeds of approximately $91.9 million as of December 31, 2005.

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

	Years Ended December 31,		
	2007	2006	2005
Net cash used in operating activities	$(59,629)	$(53,913)	$(27,348)
Net cash provided by (used in) investing activities	2,539	(14,308)	11,291
Net cash provided by financing activities	40,204	56,778	71,782
Effect of exchange rate changes on cash	172	179	(141)
Net cash flow	$(16,714)	$(11,264)	$ 55,584

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. Significant uses of cash from operations include increases in accounts receivable and increased inventory requirements for production and placements of the System One, offset by increases in accounts payable and accrued expenses. Non-cash transfers from inventory to field equipment for the placement of rental units with our customers represented $32.3 million, $18.6 million and $4.4 million, respectively, during the years ended December 31, 2007, 2006 and 2005.

Net Cash Provided by (Used) in 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. Included in these figures is ($2.7) million of cash, net of acquisition costs, acquired from Medisystems at the close of the transaction on October 1, 2007.

Net Cash Provided by Financing Activities. 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. Net cash provided by financing activities during 2006 included $51.3 million of net proceeds received from the follow-on public offering that closed in June 2006, $1.5 million of proceeds from the exercise of stock options and warrants and net borrowings of $4.0 million. Net cash provided by financing activities during 2005 included $56.5 million of net proceeds received from our initial public offering that closed in November 2005, $16.0 million of net proceeds received from the issuance of redeemable convertible preferred stock and $0.8 million of proceeds from the exercise of stock options and warrants, offset by debt payments of $1.4 million.

We expect to continue to incur net losses for the foreseeable future. We believe we have sufficient cash and cash available through our debt facility to meet our funding requirements through 2008. We expect that our existing resources will be insufficient to satisfy our liquidity requirements beyond 2008, and we will need to sell additional equity, issue debt securities or otherwise obtain additional capital to fund our operations and our growth. Additionally, beginning in February 2009, we will need to begin paying down the principal on the debt we borrowed from Merrill Lynch. Any sale of additional equity or issuance of debt securities 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 this 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.

The following table summarizes our contractual commitments as of December 31, 2007 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(1)	$26,124	$ 54	$19,949	$ 6,121	$ —
Operating leases	7,349	1,809	3,479	2,061	—
Purchase obligations(2)	61,593	42,697	10,712	2,828	5,356
Total	$95,066	$44,560	$34,140	$11,010	$5,356

(1) Includes repayment of 3% maturity premium on term loan of $900,000

(2) 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 the Company's 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 revenues from product sales and services when earned in accordance with Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition* , and Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables.* 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.

Home Market

Prior to 2007, we derived revenue in the home market from short-term rental arrangements with our customers as our principal business model. These rental arrangements, which combine the use of the System One with a specified number of disposable products supplied to customers for a fixed amount per month, are recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to a binding customer purchase order and fixed payment terms. Rental arrangements continue to represent the majority of the arrangements we have with our customers in the home market. Equipment utilized under the rental arrangements is referred to as "Field Equipment".

Beginning in 2007, we entered into long-term customer contracts to sell System One and PureFlow SL equipment along with the right to purchase disposable products and service on a monthly basis. Some of these agreements include other terms such as development efforts, training, market collaborations, limited market exclusivity, and volume discounts. The equipment and related items provided to our customers in these arrangements are considered a multiple-element sales arrangement pursuant to EITF 00-21. When a sales arrangement involves multiple elements, the deliverables included in the arrangement are evaluated to determine whether they represent separate units of accounting. We have determined that we cannot account for the sale of equipment as a separate unit of accounting. Therefore, 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 obligation to supply disposables and service, which is five to seven years. We have 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.

We entered into a national service provider agreement and a stock purchase agreement with DaVita on February 7, 2007. Pursuant to EITF 00-21, we consider these agreements a single arrangement. In connection with the stock purchase agreement, DaVita purchased 2,000,000 shares of our common stock for $10.00 per share, which represented a premium of $1.50 per share, or $3.0 million over the current market price. We have recorded the $3.0 million premium as deferred revenue and will recognize this revenue ratably over seven years, consistent with our equipment service obligation to DaVita. During the twelve months ended December 31, 2007, we recognized revenue of $0.4 million, associated with the $3.0 million premium.

In-Center and Critical Care Market

In the critical care market, sales are structured as direct product sales or as a disposables-based program in which a customer acquires the equipment through the purchase of a specific quantity of disposables over a specific period of time. In the in-center market, sales are structured primarily through supply and distribution contracts with distributors. We recognize revenues at the later of the time of shipment or, if applicable, delivery in accordance with contract terms. Under a disposables-based program, the customer is granted the right to use the equipment for a period of time, during which the customer commits to purchase a minimum number of disposable cartridges or fluids at a price that includes a premium above the otherwise average

selling price of the cartridges or fluids to recover the cost of the equipment and provide for a profit. Upon reaching the contractual minimum purchases, ownership of the equipment transfers to the customer. Revenues under these arrangements are recognized over the term of the arrangement as disposables are delivered. During the reported periods, the majority of our in-center and critical care revenues were derived from supply contracts and direct product sales.

Our contracts 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.

The Company recognizes rebates to customers in its in-center market in accordance with EITF 01-09, *Accounting for Consideration given by a Vendor to a Customer (Including) Reseller of the Vendors Products.* Customer rebates are included as a reduction of sales and trade accounts receivable and are the Company's best estimate of the amount of probable future rebates on current sales.

Inventory Valuation

Inventories are valued at the lower of cost (weighted-average) 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 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 deployed by a patient, and assess whether there are any indicators of impairment for such equipment. During 2007, 2006 and 2005, no such impairment was recognized.

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 and the asset carrying value periodically for reasonableness. Factors considered in determining the reasonableness of the useful life and the asset carrying value include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns, actual equipment disposal rates, our ability to verify the equipment's existence in the field, and the impact of planned design improvements. We believe the five-year useful life to be reasonable as of December 31, 2007.

Accounting for Stock-Based Awards

Until December 31, 2005, we accounted for stock-based employee compensation awards in accordance with Accounting Principles Board, or APB, Opinion No. 25, *"Accounting for Stock Issued to Employees"*, and related interpretations. Accordingly, compensation expense was recorded for stock options awarded to employees and directors to the extent that the option exercise price was less than the fair market value of our common stock on the date of grant, where the number of shares and exercise price were fixed. The difference between the fair value of our common stock and the exercise price of the stock option, if any, was recorded as deferred compensation and was amortized to compensation expense over the vesting period of the underlying stock option. Prior to becoming a public company on October 27, 2005, there had been no public market for our common stock. Absent an objective measure of the fair value of our common stock, the determination of fair value required judgment. Our board of directors periodically estimated the fair value of our common stock in connection with any stock option grants. The fair value of our common stock was estimated based on

factors such as independent valuations, sales of preferred stock, the liquidation preference, dividends, voting rights of the various classes of stock, our financial and operating performance, progress on development goals, the issuance of patents, the value of other companies involved in dialysis, general economic and market conditions and other factors that we believed would reasonably have a significant bearing on the value of our common stock.

Prior to January 1, 2006, we followed the disclosure requirements of Statement of Financial Accounting Standard, or SFAS No. 123, *"Accounting for Stock-Based Compensation"* for stock-based awards granted to employees. All stock-based awards granted to non-employees were accounted for at their fair value in accordance with SFAS No. 123 and related interpretations. For purposes of the pro forma disclosures required by SFAS No. 123, stock options granted subsequent to July 19, 2005, the date of filing our initial registration statement with the SEC, were valued using the Black-Scholes option-pricing model. Prior to July 19, 2005, we used the minimum value method permitted under SFAS No. 123.

We adopted SFAS No. 123R, *"Share-Based Payment"*, on January 1, 2006. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. In addition, SFAS 123R requires the use of the prospective method for any outstanding stock options that were previously valued using the minimum value method. Accordingly, with the adoption of SFAS 123R, we did not recognize the remaining compensation cost for any stock option awards which had previously been valued using the minimum value method. In addition, SFAS 123R prohibits the use of pro forma disclosures for stock option awards valued under the minimum value method (i.e., our pre-July 19, 2005 stock option awards). Stock option awards granted prior to July 19, 2005, the date on which we filed our preliminary prospectus with the SEC, that are subsequently modified, repurchased or cancelled after January 1, 2006 shall be subject to the provisions of SFAS 123R.

We use the modified prospective method under SFAS 123R for any stock options granted after July 19, 2005. The aggregate value of the unvested portion of stock options issued between July 19, 2005 and December 31, 2005 totaled $4.4 million as of December 31, 2005, net of estimated forfeitures. Beginning in 2006, we began recognizing this aggregate value as compensation expense in our consolidated statement of operations ratably over the remaining vesting period.

As a result of adopting SFAS 123R on January 1, 2006, our net loss for the years ended December 31, 2007 and 2006 was $3.2 and $2.4 million, respectively, higher than if we had continued to account for the share-based awards under APB No. 25. Basic and diluted loss per share for the years ended December 31, 2007 and 2006 was $0.09 and $0.10 higher, respectively, than if we had continued to account for share-based awards under APB No. 25. Management continues to evaluate the use of stock-based awards and may consider other forms of equity-based compensation arrangements (such as restricted stock units) or reduce the volume of stock option grants in the future.

Pursuant to SFAS 123R, we reclassified $0.3 million of deferred compensation relating to non-qualified stock options awarded to an executive and a consultant to additional paid-in capital on January 1, 2006.

Prospectively, we use the Black-Scholes option-pricing model to estimate the fair value of stock-based compensation awards on the dates of grant. In accordance with SAB 107, based upon our stage of development and the short period of time that our common stock has been publicly traded on the NASDAQ Global Market, we have used the following assumptions in the Black-Scholes option-pricing model to estimate the fair value of equity-based compensation awards:

Expected Term — the expected term has been determined using the simplified method, as defined in SAB 107, for estimating expected option life of "plain-vanilla" options. Unless otherwise determined by the Board or the Compensation Committee, stock options granted under the 2005 Stock Incentive Plan have a contractual term of seven years, resulting in an expected term of 4.75 years calculated under the simplified method.

Risk-Free Interest Rate — 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.

Volatility — the objective in estimating expected volatility is to ascertain the assumption about expected volatility that marketplace participants would likely use in determining an exchange price for an option. Because we have no options that are traded publicly and because of our limited trading history as a public company, our volatility assumption has been based upon an analysis of the stock volatility experienced by similar companies in the medical device and technology industries, consistent with the methodology used in 2005. For the year ended December 31, 2007, we reached our two year trading anniversary in the fourth quarter and we began to use our historical trading activity and an analysis of similar companies in the medical device and technology industries in order to derive an expected volatility. For the year ended December 31, 2007 we used a volatility rate assumption of 65% to 75%. For the year ended December 31, 2006, we used a volatility rate assumption of 85%

The amount of stock based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock award. We currently expects, based on historical experience, employee growth, and limited trading history, a forfeiture rate of 4% for all awards.

Valuation of Business Combinations

We record tangible and intangible assets acquired and liabilities assumed in recent business combination under the purchase method of accounting. Amounts paid for each acquisition are allocated to the assets acquired and liabilities assumed based on their fair values at the dates of acquisition. We then allocate the purchase price in excess of net tangible assets acquired to identifiable intangible assets based on detailed valuations that use information and assumptions provided by management. We allocate any excess purchase price over the fair value of the net tangible and intangible assets acquired and liabilities assumed to goodwill. We have also used the income approach, as described above, to determine the estimated fair value of certain other identifiable intangibles assets including developed technology, customer relationships and tradenames. Developed technology represents patented and unpatented technology and know-how. Customer relationships represent established relationships with customers, which provides a ready channel for the sale of additional products and services. Tradenames represent acquired product names that we intend to continue to utilize.

Intangibles and Other Long-Lived Assets

Intangible assets resulting from the acquisition of the MDS Entities 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 three months to seven years. Furthermore, periodically we assess whether our 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 projected discounted future operating cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

Goodwill

We account for goodwill in accordance with SFAS No. 142 "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill not be amortized but instead be tested at least annually for impairment, or more frequently when events or changes in circumstances indicate that the assets might be impaired. Management considers our business as a whole to be its reporting unit for purposes of testing for impairment. This impairment test is performed annually during the fourth quarter. A two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill.

Accounting for Income Taxes

We account for federal and state income taxes in accordance with SFAS No. 109, *"Accounting for Income Taxes."* Under the liability method specified by SFAS No. 109, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates.

As of December 31, 2007, we had federal and state net operating loss carryforwards of approximately $172.9 million and $144.8 million, respectively, available to reduce 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 2027, while the state net operating loss carryforwards will expire between 2008 and 2027. We also had combined federal and state research and development credit carryforwards of $4.1 million at December 31, 2007, which begin to expire in 2019 if not utilized. Utilization of the net operating loss carryforwards may be subject to an annual limitation 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 net operating loss carryforwards.

We have $1.6 million of net operating losses resulting from excess tax deductions relating to stock-based compensation. We will realize the benefit of these losses through increases to stockholders' equity in future periods when the losses are utilized to reduce future tax payments.

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 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, 2007 and 2006 to reflect these uncertainties.

In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 48, *"Accounting for Uncertainty in Income Taxes"* ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's financial position or results of operations. Upon adoption of FIN 48 and as of December 30, 2007, the Company had no unrecognized tax benefits recorded.

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.

The Company recognizes interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of December 31, 2007, the Company had no interest and penalty accrual or expense.

Related-Party Transactions

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg under which we agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and Medisystems Services Corporation, 90% of the issued and outstanding shares of Medisystems Europe S.p.A. (the remaining equity of which is held by Medisystems Corporation) and 0.273% of the issued and outstanding equity participation of Medisystems Mexico s. de R.L. de C.V. (the remaining equity of which is held by Medisystems Corporation), which are collectively referred to as the MDS Entities. We refer to our acquisition of the MDS Entities as the Medisystems Acquisition. Mr. Utterberg is a director and significant stockholder of NxStage. The Medisystems Acquisition was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage. In addition, as a result of completion of

the Medisystems Acquisition, the supply agreement, dated January 2007, with Medisystems, under which Medisystems agreed to provide cartridges for use with the System One, was terminated. In consideration for the Medisystems Acquisition, we issued Mr. Utterberg 6.5 million shares of our common stock, which we refer to as the Shares. As a result of the Medisystems Acquisition and the issuance of the Shares to Mr. Utterberg, Mr. Utterberg's aggregate ownership of our outstanding common stock increased to approximately 23.2%. In addition, we may be required to issue additional shares of our common stock to Mr. Utterberg. 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. An aggregate of 1.0 million of the shares issued to Mr. Utterberg were placed into escrow to cover potential indemnification claims we may have against him. In connection with the Medisystems Acquisition and as a result of Medisystems Corporation, one of the MDS Entities, becoming a direct or indirect wholly-owned subsidiary of ours, we acquired rights under an existing license agreement between Medisystems and DSU Medical Corporation, a Nevada corporation, which is wholly-owned by Mr. Utterberg, or DSU. We refer to this agreement as the license agreement. Additionally, 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, which we refer to as the consulting agreement.

Under the license agreement, Medisystems received an exclusive, irrevocable, sublicensable, royalty-free, fully paid license to certain DSU patents, or the licensed patents, in exchange for a one-time payment of $2.7 million. The licensed patents fall into two categories, those patents that are used exclusively by the MDS Entities, referred to as the Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, referred to as the Class B patents. Pursuant to the terms of the license agreement, MDS has 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. The license agreement further provides that the rights of Medisystems under the agreement are qualified by certain sublicenses previously granted to third parties. We have agreed that Mr. Utterberg retains the right to the royalty income under one of these sublicenses.

Under the consulting agreement, Mr. Utterberg and DSU will provide consulting, advisory and related services to us for a period of two years following the consummation of the Medisystems Acquisition. In addition, under the terms of the consulting agreement, Mr. Utterberg and DSU have agreed during the term of the agreement not to compete with NxStage during the term of the consulting agreement in the field defined in the consulting agreement and not to encourage or solicit any of our employees, customers or suppliers to alter their relationship with us. The consulting agreement further provides that (1) Mr. Utterberg and DSU assign to us certain inventions and proprietary rights received by him/it during the term of the agreement and (2) we grant Mr. Utterberg and DSU an exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid license under such assigned inventions and proprietary rights for any purpose outside the inventing field, as defined in the consulting agreement. Under the terms of the consulting agreement, Mr. Utterberg and DSU will receive an aggregate of $200,000 per year, plus expenses, in full consideration for the services and other obligations provided for under the terms of the consulting agreement. The consulting agreement also requires Mr. Utterberg and NxStage to indemnify each other in the event of certain breaches and failures under the agreement and requires that any such indemnification liability be satisfied with 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.

We assumed a $2.8 million liability owed to DSU as a result of the acquisition of the MDS Entities. The amount owed represents consideration owed to DSU by the MDS Entities for the termination of a royalty-bearing sublicense agreement and the establishment of the royalty-free license agreement.

As of December 31, 2007 the Company recorded a receivable for reimbursements of costs related to the acquisition in the amount of $0.4 million from Mr. Utterberg and DSU.

Consistent with the requirements of our Audit Committee Charter, this transaction was reviewed and approved by our Audit Committee, which is comprised solely of independent directors, as well as our Board.

Off-Balance Sheet Arrangements

Since inception we have not engaged in any off-balance sheet financing activities except for leases which are properly classified as operating leases and disclosed in the "Liquidity and Capital Resources" section above.

Recent Accounting Pronouncements

In December 2007, the FASB issued Statement No. 141(R), *Business Combinations* ("Statement 141(R)"), a replacement of FASB Statement No. 141. Statement 141(R) is effective for fiscal years beginning on or after December 15, 2008 and applies to all business combinations. Statement 141(R) 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 current step acquisition model will be eliminated. Additionally, Statement 141(R) changes current practice, in part, as follows: (1) contingent consideration arrangements will be 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, such as legal issues, will generally have to be accounted for in purchase accounting at fair value; and (4) in order to accrue for a restructuring plan in purchase accounting, the requirements in FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, would have to be met at the acquisition date. While there is no expected impact to our consolidated financial statements on the accounting for acquisitions completed prior to December 31, 2008, the adoption of Statement 141(R) on January 1, 2009 could materially change the accounting for business combinations consummated subsequent to that date.

In September 2006, the FASB issued Statement 157, *Fair Value Measurement* ("Statement 157"). Statement 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and establishes a hierarchy that categorizes and prioritizes the sources to be used to estimate fair value. Statement 157 also expands financial statement disclosures about fair value measurements. On February 6, 2008, the FASB issued FASB Staff Position (FSP) 157-b which delays the effective date of Statement 157 for one year for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Statement 157 and FSP 157-b are effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of SFAS No. 157 and FSP 157-b on our consolidated financial statements.

In February 2007, the FASB issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of SFAS 115* ("Statement 159"), which permits but does not require us to measure financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of SFAS No. 159 on our consolidated financial statements.

In December 2007, the Securities and Exchange Commission ("*SEC*") issued Staff Accounting Bulletin No. 110 ("*SAB 110*"). SAB 110 amends and replaces Question 6 of Section D.2 of Topic 14, *Share-Based Payment*. SAB 110 expresses the views of the staff regarding the use of the "simplified" method in developing an estimate of expected term of "plain vanilla" share options in accordance with FASB Statement No. 123(R), *Share Based Payment*. The use of the "simplified" method was scheduled to expire on December 31, 2007. SAB 110 extends the use of the "simplified" method for "plain vanilla" awards in certain situations. We currently use the "simplified" method to estimate the expected term for share option grants as we do not have

enough historical experience to provide a reasonable estimate due to the limited period the Company's equity shares have been publicly traded. We will continue to use the "simplified" method until we have enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110. SAB 110 is effective for options granted after December 31, 2007.

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

Interest Rate Exposure

Our investment portfolio consists primarily of high-grade commercial paper, certificates of deposit and debt obligations of various governmental agencies. 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. Investments are made with a maturity of no more than 180 days. These investments are subject to risk of default, 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 and relatively short effective maturities of the debt instruments, 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.

As of December 31, 2007, we had outstanding debt obligations of $25.2 million. We have a $25.0 million loan with a fixed interest rate equal to 10.77% and a $0.2 million loan with an interest equal to the EURIBOR for 3 months (plus 1.15%) subject to an interest rate swap agreement at rates greater than 4%. When EURIBOR (3 months) plus 1.15% exceeds 4%, interest is calculated on a blended basis, with 50% of the nominal value of the loan subject to a fixed rate of 4%, and the remaining 50% subject to the EURIBOR (3 months) plus 1.15%. As of December 31, 2007, the carrying amount of our debt approximated fair value.

Foreign Currency Exposure

We operate a manufacturing and research facility in Rosdorf, Germany as well as manufacturing facilities in Mexico and Italy. 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, Peso and Thai Baht. 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 since the exposure has not been material to our historical operating results. A 10% movement in the Euro would have had an overall impact to the statement of operations of approximately $1.3 million for 2007, which would have been approximately 1.1% of total annual expenses.

Equity Security Price Risk

As a matter of policy, we do not invest in marketable equity securities; therefore, we do not currently have any direct equity price risk.

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

NXSTAGE MEDICAL, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of NxStage Medical, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share Based Payment.*

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, 2007, 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 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 6, 2008

NXSTAGE MEDICAL, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2007	December 31, 2006
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,245	$ 49,959
Short-term investments	1,100	11,843
Accounts receivable, net	7,990	4,302
Due from affiliate	435	—
Inventory	29,965	10,419
Prepaid expenses and other current assets	2,455	1,014
Total current assets	75,190	77,537
Property and equipment, net	12,146	3,026
Field equipment, net	30,885	20,616
Deferred cost of revenues	14,850	140
Intangible assets, net	33,801	—
Goodwill	41,457	—
Other assets	2,057	406
Total assets	$ 210,386	$ 101,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 21,887	$ 5,917
Accrued expenses	9,820	4,104
Due to affiliates	2,774	—
Current portion of long-term debt	54	2,800
Total current liabilities	34,535	12,821
Deferred revenue	19,530	229
Long-term debt	25,170	4,617
Other long-term liabilities	1,434	649
Total liabilities	80,669	18,316
Commitments and contingencies		
Stockholders' equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; zero shares issued and outstanding as of December 31, 2007 and 2006	—	—
Common stock: par value $0.001, 100,000,000 shares authorized; 36,771,893 and 27,806,543 shares issued and outstanding as of December 31, 2007 and December 31, 2006, respectively	37	28
Additional paid-in capital	311,172	206,848
Accumulated deficit	(182,036)	(123,640)
Accumulated other comprehensive income	544	173
Total stockholders' equity	129,717	83,409
Total liabilities and stockholders' equity	$ 210,386	$ 101,725

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2007	2006	2005
	(In thousands, except per share data)		
Revenues	$ 59,964	$ 20,812	$ 5,994
Cost of revenues	65,967	26,121	9,585
Gross deficit	(6,003)	(5,309)	(3,591)
Operating expenses:			
Selling and marketing	21,589	14,356	7,550
Research and development	6,335	6,431	6,305
Distribution	13,111	7,093	2,059
General and administrative	13,046	8,703	4,855
Total operating expenses	54,081	36,583	20,769
Loss from operations	(60,084)	(41,892)	(24,360)
Other income (expense):			
Other income	2,855	3,235	643
Other expense	(1,105)	(973)	(763)
	1,750	2,262	(120)
Net loss before income taxes	(58,334)	(39,630)	(24,480)
Provision for foreign income taxes	62	—	—
Net loss	$(58,396)	$(39,630)	$(24,480)
Net loss per share, basic and diluted	$ (1.86)	$ (1.60)	$ (4.31)
Weighted-average shares outstanding, basic and diluted	31,426	24,817	5,681

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

	Redeemable convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deferred Compensation	Accumulated Deficit	Other Comprehensive Income (Loss)	Total Comprehensive Income (Loss)
	Shares	Carrying Value	Shares	Amount					
				(In thousands, except share data)					
Balance at December 31, 2004	13,301,415	$ 75,946	2,566,681	$ 3	$ 2,391	$(421)	$ (59,495)	$ 123	
Sale of Series F-1 redeemable convertible preferred stock, net of issuance costs of $34,990	2,197,801	16,000	—	—	—	—	(35)	—	
Conversion of redeemable convertible preferred stock to common stock	(15,499,216)	(91,946)	12,124,840	12	91,933	—	—	—	
Issuance of common stock, net of issuance costs	—	—	6,325,000	6	56,023	—	—	—	
Series D warrant extension	—	—	—	—	478	—	—	—	
Exercise of stock options	—	—	128,729	—	534	—	—	—	
Exercise of warrants	—	—	31,304	—	223	—	—	—	
Stock options issued to nonemployees	—	—	—	—	34	(34)	—	—	
Deferred compensation	—	—	—	—	58	(58)	—	—	
Amortization of deferred compensation	—	—	—	—	—	253	—	—	
Realized gain on marketable securities	—	—	—	—	—	—	—	(24)	(24)
Change in cumulative translation adjustment	—	—	—	—	—	—	—	(171)	(171)
Net loss	—	—	—	—	—	—	(24,779)	—	(24,480)
Total comprehensive loss	—	—	—	—	—	—	—	—	$(24,675)
Balance at December 31, 2005	—	—	21,176,554	21	151,674	(260)	(84,010)	(72)	
Issuance of common stock, net of issuance costs	—	—	6,325,000	7	51,326	—	—	—	
Exercise of stock options	—	—	185,179	—	814	—	—	—	
Exercise of warrants	—	—	78,522	—	503	—	—	—	
Shares issued under employee stock purchase plan	—	—	28,303	—	229	—	—	—	
Shares issued to Directors in lieu of cash	—	—	12,985	—	111	—	—	—	
Stock-based compensation	—	—	—	—	2,451	—	—	—	
Deferred stock compensation adjustment for SFAS No. 123R	—	—	—	—	(260)	260	—	—	
Change in cumulative translation adjustment	—	—	—	—	—	—	—	245	245
Net loss	—	—	—	—	—	—	(39,630)	—	(39,630)
Total comprehensive loss	—	—	—	—	—	—	—	—	$(39,385)
Balance at December 31, 2006	—	—	27,806,543	28	206,848	—	(123,640)	173	
Issuance of common stock, net of issuance costs	—	—	2,000,000	2	16,937	—	—	—	
Exercise of stock options	—	—	392,028	—	2,354	—	—	—	
Exercise of warrants	—	—	21,000	—	—	—	—	—	
Shares issued under employee stock purchase plan	—	—	35,967	—	341	—	—	—	
Shares issued to Directors in lieu of cash	—	—	16,355	—	225	—	—	—	
Stock-based compensation	—	—	—	—	3,224	—	—	—	
Shares issued for Medisystems acquisition	—	—	6,500,000	7	81,243	—	—	—	
Change in cumulative translation adjustment	—	—	—	—	—	—	—	371	371
Net loss	—	—	—	—	—	—	(58,396)	—	(58,396)
Total comprehensive loss	—	—	—	—	—	—	—	—	$(58,025)
Balance at December 31, 2007	—	$ —	36,771,893	$37	$311,172	$ —	$(182,036)	$ 544	

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2007	2006	2005
	(In thousands)		
Cash flows from operating activities:			
Net loss	$(58,396)	$(39,630)	$(24,480)
Adjustments to reconcile net loss to net cash used in operating activities:			
Realized gain on sale of marketable securities	—	—	(24)
Loss on disposal of equipment	126	55	—
Depreciation and amortization	9,277	3,495	1,034
Amortization of inventory step-up	1,520	—	—
Bad debt	122	51	16
Amortization/write-off of debt discount	—	282	141
Stock-based compensation	3,449	2,765	253
Changes in operating assets and liabilities:			
Accounts receivable	(3,597)	(2,985)	(1,004)
Inventory	(41,344)	(23,160)	(5,930)
Prepaid expenses and other current assets	405	(487)	(484)
Accounts payable	10,202	2,846	1,614
Accrued expenses	2,368	2,789	1,391
Deferred rent obligation	(63)	(49)	37
Deferred revenue	16,302	115	88
Net cash used in operating activities	(59,629)	(53,913)	(27,348)
Cash flows from investing activities:			
Purchases of property and equipment	(3,788)	(1,620)	(1,198)
Maturities of short-term investments	30,410	68,836	12,495
Purchases of short-term investments	(19,667)	(80,678)	—
Acquisition costs, net of cash acquired	(2,749)	—	—
Increase in other assets	(1,667)	(846)	(6)
Net cash provided by (used in) investing activities	2,539	(14,308)	11,291
Cash flows from financing activities:			
Net proceeds from issuance of redeemable convertible preferred stock	—	—	15,965
Net proceeds from issuance of common stock	—	51,332	56,508
Net proceeds from private placement sale of common stock	19,939	—	—
Proceeds from stock option and purchase plans	2,695	955	534
Proceeds from exercise of warrants	—	503	223
Proceeds from loans and lines of credit	25,000	8,400	—
Net repayments on loans and lines of credit	(7,430)	(4,412)	(1,448)
Net cash provided by financing activities	40,204	56,778	71,782
Foreign exchange effect on cash and cash equivalents	172	179	(141)
Decrease in cash and cash equivalents	(16,714)	(11,264)	55,584
Cash and cash equivalents, beginning of period	49,959	61,223	5,639
Cash and cash equivalents, end of period	$ 33,245	$ 49,959	$ 61,223
Supplemental Disclosure			
Cash paid for interest	$ 897	$ 963	$ 271
Taxes paid	$ 91	$ —	$ —
Noncash Investing Activities			
Transfers from inventory to field equipment and deferred cost of revenues	$ 32,314	$ 18,598	$ 4,367
Leasehold improvement allowance	$ —	$ —	$ 615
Noncash Financing Activities			
Deferred compensation and paid in capital	$ —	$ —	$ 92
Conversion of preferred stock to common stock	$ —	$ —	$ 91,946
Extension of Series D warrants	$ —	$ —	$ 478

See accompanying notes to these consolidated financial statements.

1. Nature of Operations

NxStage Medical, Inc. (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 (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 clinics. The System One is cleared by the United States Food and Drug Administration (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, and fluids used in conjunction with therapy. Following the recent acquisition of Medisystems Corporation and certain affiliates (the "MDS Entities"), the Company also sells needles and blood tubing sets primarily to the in-center market for the treatment of end-stage renal disease ("ESRD").

As of December 31, 2007, the Company had approximately $34.3 million of cash, cash equivalents and short-term investments. In February 2007, the Company received cash proceeds of $20.0 million from the sale of 2 million shares of its common stock to DaVita. In November 2007, the Company entered into a credit facility with Merrill Lynch Capital consisting of a $30.0 million term loan and a $20.0 million revolving credit facility. The Company drew $25.0 million under the term loan at closing, and may draw the remainder on or before May 21, 2008. 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 that it has sufficient cash to meet its funding requirements through 2008. However, the Company will need to obtain additional financing or capital to meet its needs beyond 2008. There can be no assurance as to the availability of additional financing or the terms upon which additional financing may be available in the future when it is needed. If the Company is unable to obtain additional financing when needed, it may be required to delay, reduce the scope of, or eliminate one or more aspects of its business development activities, which would likely harm the business.

2. Summary of Significant Accounting Policies

(a) 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.

(b) 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.

(c) Revenue Recognition

The Company recognizes revenue from product sales and services when earned in accordance with Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition* , and Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables.* 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.

Home Market

Prior to 2007, the Company derived revenue in the home market from short-term rental arrangements with its customers as its principal business model. These rental arrangements, which combine the use of the System One with a specified number of disposable products supplied to customers for a fixed amount per month, are recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to a binding customer purchase order and fixed payment terms. In the home market, rental arrangements continue to represent the majority of the arrangements the Company has with its customers. Beginning in 2007, the Company entered into long-term customer contracts to sell the System One and PureFlow SL equipment along with the right to purchase disposable products and service on a monthly basis. Some of these agreements include other terms such as development efforts, training, market collaborations, limited market exclusivity and volume discounts. The equipment and related items provided to the Company's customers in these arrangements are considered a multiple-element sales arrangement pursuant to EITF 00-21. When a sales arrangement involves multiple elements, the deliverables included in the arrangement are evaluated to determine whether they represent separate units of accounting. 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 are deferred, and are recognized as revenue on a straight-line basis over the expected term of the Company's obligation to supply disposables and service, which is five to 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. As of December 31, 2007, the Company has deferred approximately $19.5 million of revenue, and $14.9 million of related costs for equipment sales in the home market.

The Company entered into a National Service Provider Agreement and a Stock Purchase Agreement with DaVita, Inc. ("DaVita") on February 7, 2007. Pursuant to EITF 00-21, the Company considers these agreements a single arrangement. In connection with the Stock Purchase Agreement, DaVita purchased 2,000,000 shares of the Company's common stock for $10.00 per share, which represented a premium over the market price on that date of $1.50 per share, or $3.0 million. The Company has recorded the $3.0 million premium as deferred revenue and will recognize this revenue ratably over seven years, consistent with its equipment service obligation to DaVita. During the twelve months ended December 31, 2007, the Company recognized revenue of $0.4 million associated with the $3.0 million premium.

In-Center and Critical Care Market

In the critical care market, the Company structures sales as direct product sales or as a disposables-based program in which a customer acquires the equipment through the purchase of a specific quantity of disposables over a specific period of time. In the in-center market, sales are structured primarily through supply and distribution contracts with distributors. 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. Under a disposables-based program, the customer is granted the right to use the equipment for a period of time, during which the customer commits to purchase a minimum number of disposable cartridges or fluids at a price that includes a premium above the otherwise average selling price of the cartridges or fluids to recover the cost of the equipment and provide for a profit. Upon reaching the contractual minimum purchases, ownership of the equipment transfers to the customer. Revenue under these arrangements is recognized over the term of the arrangement as disposables are delivered. During the reported periods, the majority of our in-center and critical care market revenue is derived from supply contracts and direct product sales.

The Company's contracts 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.

The Company recognizes rebates to customers in its in-center market in accordance with EITF 01-09, *Accounting for Consideration given by a Vendor to a Customer (Including) Reseller of the Vendors Products.* Customer rebates are included as a reduction of sales and trade accounts receivable and are the Company's best estimate of the amount of probable future rebates on current sales. For the three month period ended December 31, 2007, the Company recognized $1.4 million as a reduction of sales in connection with customer rebates. At December 31, 2007, the Company has a $1.0 million reserve against trade accounts receivable for future rebates.

(d) Foreign Currency Translation and Transactions

Assets and liabilities of the Company's foreign operations are translated in accordance with Statement of Financial Accounting Standards ("SFAS") No. 52, *Foreign Currency Translation.* In accordance with SFAS No. 52, 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. The Company's foreign exchange (losses) gains totaled , ($0.7) million, ($0.3) million and $16,000 in 2007, 2006 and 2005, respectively.

(e) 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, certificates of deposit, commercial paper and money market funds. Cash equivalents are stated at cost plus accrued interest, which approximates market value.

The Company accounts for its investments in marketable securities in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* In accordance with SFAS No. 115, the Company has classified all of its short-term investments in marketable securities as held-to-maturity for the years ended December 31, 2007 and 2006. Held-to-maturity securities are carried at amortized cost because the Company has the intent and ability to hold investments to maturity.

Held-to-maturity securities consisted of the following (in thousands):

	Years Ended December 31,	
	2007	2006
U.S. government securities	$ —	$ 5,008
Commercial paper	—	4,896
Certificates of deposit	1,100	1,939
	$1,100	$11,843

At December 31, 2007 and 2006, maturities of held-to-maturity securities were less than one year. At December 31, 2007 and 2006, the estimated fair value of each investment approximated its amortized cost and, therefore, there were no significant unrecognized holding gains or losses.

At December 31, 2007 the Company had $1.4 million in standby letters of credit to guarantee annual VAT refunds in Italy. These amounts are restricted and classified as other assets.

(f) Fair Value of Financial Instruments and Concentration of Credit Risk

Financial instruments consist principally of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and long-term debt. The estimated fair value of these instruments approximates their carrying value due to the short period of time to their maturities. The fair value of the Company's debt is estimated based on the current rates offered to the Company for debt of the same remaining maturities. The carrying amount of long-term debt approximates fair value.

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.

All of the Company's revenues are derived in the United States 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 recently acquired from Medisystems.

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.

The Company reduces gross trade accounts receivable with an allowance for doubtful accounts. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the existing accounts receivable. The Company reviews its allowance for doubtful accounts on a monthly basis and all past due balances are reviewed individually for collectability. Account balances are charged off against the allowance after significant collection efforts have been made and potential for recovery is considered remote. 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, 2007	$63	$122	$111	$ —	$296
December 31, 2006	$12	$ 51	$ —	$ —	$ 63
December 31, 2005	$22	$ 16	$ —	$(26)	$ 12

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

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

Year Ended	Percent of Total Revenue
December 31, 2007	
Customer A	20%
Customer B	22%
December 31, 2006	
Customer A	19%
December 31, 2005	
Customer C	12%
Customer D	11%
Customer E	10%

For the year ended December 31, 2007, no single customer represented greater than 10% of the total accounts receivable. For the year ended December 31, 2006, one customer (Customer A) represented 17% of total accounts receivable.

(g) 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 cost 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 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.

(h) 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. The Company uses other depreciation methods (generally, accelerated depreciation methods) for tax purposes where appropriate. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful lives of the improvements.

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 deployed by a patient, and assesses whether there are any indicators of impairment for such equipment. During 2007, 2006 and 2005, no such impairment was recognized.

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, 2007 represents machinery and equipment under installation.

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. The Company periodically reviews its field equipment's useful life and asset carrying value for reasonableness. Factors considered in determining the reasonableness of the useful life and the asset carrying value include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns, actual equipment disposal rates, our ability to verify the equipment's existence in the field, and the impact of planned design improvements.

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

(i) Intangibles and Other Long Lived Assets

Intangible assets resulting from the acquisition of the MDS Entities 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 projected discounted future operating cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs. The Company recognized $34.5 million of acquired definite-lived intangible assets as a result of the acquisition of the MDS Entities. These definite-lived intangible assets are expected to be amortized over periods ranging from 8 to 14 years with an average life of 12.9 years.

At December 31, 2007 the Company's intangible assets consisted of the following (in thousands), all of which were part of acquiring the MDS Entities:

	December 31, 2007
Bloodline, Needle and Other Patented & Unpatented Technology	$ 6,200
Trade Names	2,300
Customer Relationships	26,000
Intangible assets, gross	34,500
Less: accumulated amortization	(699)
Intangible assets, net	$33,801

The Company recognized $0.7 million of amortization expense for the three months ended December 31, 2007. There was no comparable expense in either 2006 or 2005. The Company will record $2.8 million of amortization expense for each of the years ended December 31, 2008 through 2012 related to the above intangible assets

(j) Goodwill

On October 1, 2007, the Company recorded $41.5 million of goodwill through purchase accounting for the MDS Entities acquisition. The Company accounts for goodwill in accordance with SFAS No. 142 *Goodwill and Other Intangible Assets*. SFAS No. 142 requires that goodwill not be amortized but instead be tested 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 based on product market. A two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, goodwill is impaired and the loss is measured by performing step two. Under step two, the impairment loss is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. The Company believes the factors contributing to a purchase price that results in the recognition of goodwill 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 the MDS Entities and the Company. The goodwill recognized upon acquiring the MDS Entities is not deductible for tax purposes.

(k) Stock-Based Compensation

Until December 31, 2005, the Company accounted for stock-based employee compensation awards in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations. Accordingly, compensation expense was recorded for stock options awarded to employees and directors to the extent that the option exercise price was less than the fair market value of the Company's common stock on the date of grant, where the number of shares and exercise price were fixed. The difference between the fair value of the Company's common stock and the exercise price of the stock option, if any, was recorded as deferred compensation and was amortized to compensation expense over the vesting period of the underlying stock option. All stock-based awards to nonemployees were accounted for at their fair value in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* and related interpretations.

On January 1, 2006, the Company adopted SFAS No. 123R *Share-Based Payment,* using a combination of the prospective and the modified prospective transition methods. Under the prospective method, the Company will not recognize the remaining compensation cost for any stock option awards that had previously been valued using the minimum value method, which was allowed until the Company's initial filing with the Securities and Exchange Commission, (" SEC"), for a public offering of securities (i.e., stock options granted prior to July 19, 2005). Under the modified prospective method, the Company has (a) recognized compensation expense for all share-based payments granted after January 1, 2006 and (b) recognized compensation expense for awards granted to employees between July 19, 2005 and December 31, 2005 that were unvested as of December 31, 2005. The Company recognizes share-based compensation expense using a straight-line method of amortization over the vesting period.

The Company filed a registration statement on Form S-1 for an initial public offering of its common stock on July 19, 2005 and closed the initial public offering on November 1, 2005. Stock options granted prior to July 19, 2005 were valued using the minimum value method, while stock options granted after July 19, 2005 were valued using the Black-Scholes option-pricing model. The minimum value method excludes the impact of stock volatility, whereas the Black-Scholes option-pricing model includes a stock volatility assumption in its calculation. The inclusion of a stock volatility assumption, the principal difference between the two methods, ordinarily yields a higher fair value.

As a result of adopting SFAS 123R on January 1, 2006, the Company's net loss for the year ended December 31, 2007 and 2006 was $3.2 million and $2.4 million higher than if it had continued to account for

share-based compensation under APB No. 25. Basic and diluted loss per share for the year ended December 31, 2007 and 2006 was $0.09 and $0.10, respectively, higher than if the Company had continued to account for share-based compensation under APB No. 25.

Pursuant to SFAS 123R, the Company reclassified $0.3 million of deferred compensation relating to non-qualified stock options awarded to an executive and a consultant to additional paid-in capital on January 1, 2006.

The Company recognized the impact of its share-based payment plans in the consolidated statement of operations for the years ended December 31, 2007 and 2006 under SFAS 123R. The following table presents the captions in which share-based compensation expense is included in the Company's consolidated statement of operations, including share-based compensation recorded in accordance with APB No. 25 (in thousands):

	Years Ended December 31,	
	2007	2006
Cost of revenues	$ 339	$ 72
Selling and marketing	1,140	550
Research and development	221	124
General and administrative	1,749	2,019
	$3,449	$2,765

The weighted-average fair value of options granted during the year ended December 31, 2007 and 2006 was $8.33 and $6.33, 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, 2007	Year Ended December 31, 2006
Expected life	4.75 years(1)	4.75 years(1)
Risk-free interest rate	3.42% - 4.94%(2)	4.35% - 4.88%(2)
Expected stock price volatility	65% to 75%(3)	85%(3)
Expected dividend yield	—	—

(1) The expected term was determined using the simplified method for estimating expected life of "plain-vanilla" options.

(2) 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.

(3) 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 amount of stock based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock award. The Company currently expects, based on historical experience, employee growth, and limited trading history, a forfeiture rate of 4% for all awards.

(l) 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, 2007	$172	$379	$(331)	$220
December 31, 2006	$ 62	$309	$(199)	$172
December 31, 2005	$ 35	$128	$(101)	$ 62

(m) Distribution Expenses

Distribution expenses consist of the costs incurred in shipping products to customers and are charged to operations as incurred. Shipping and handling costs billed to customers are included in revenues and totaled $56,000, $34,000 and $43,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

(n) Research and Development Costs

Research and development costs are charged to operations as incurred.

(o) Income Taxes

The Company accounts for federal and state income taxes in accordance with SFAS No. 109, *"Accounting for Income Taxes"*. Under the liability method specified by SFAS No. 109, a deferred tax asset or liability is determined 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. In June 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation ("FIN") No. 48, *"Accounting for Uncertainty in Income Taxes"* ("FIN 48"), which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with SFAS No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's financial position or results of operations. Upon adoption of FIN 48 and as of December 30, 2007, the Company had no unrecognized tax benefits recorded.

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.

The Company recognizes interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of December 31, 2007, the Company had no interest and penalty accrual or expense.

(p) Net Loss per Share

SFAS No. 128, "Earnings Per Share," requires two presentations of earnings per share, "basic" and "diluted." Basic earnings 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 earnings per share is similar to basic earnings 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 Company has excluded 688,490 incremental shares attributable to outstanding stock options and 2,122 incremental shares attributable to restricted stock and restricted stock units, for the year ended December 31, 2007 (all computed using the treasury stock method) from the computation of diluted earnings per share as their effect would be anti-dilutive. These stock options and restricted stock awards could, however, become dilutive in future periods.

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,		
	2007	2006	2005
Options to purchase common stock	688	262	2,683
Restricted stock units	2	—	—
Warrants to purchase common stock	—	—	170
Redeemable convertible preferred stock	—	—	10,099
Total	690	262	12,952

(q) Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for reporting comprehensive income (loss) and its components in the body of the financial statements. Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in equity, such as foreign currency translation adjustments, that are excluded from results of operations.

At December 31, 2007 and 2006, accumulated other comprehensive income (loss) consists of foreign currency translation adjustments.

(r) Recent Accounting Pronouncements

In December 2007, the FASB issued Statement No. 141(R), *Business Combinations* ("Statement 141(R)"), a replacement of FASB Statement No. 141. Statement 141(R) is effective for fiscal years beginning on or after December 15, 2008 and applies to all business combinations. Statement 141(R) 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 current step acquisition model will be eliminated. Additionally, Statement 141(R) changes current practice, in part, as follows: (1) contingent consideration arrangements will be 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, such as legal issues, will generally have to be accounted for in purchase accounting at fair value; and (4) in order to accrue for a restructuring plan in purchase accounting, the requirements in FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal*

Activities, would have to be met at the acquisition date. While there is no expected impact to our consolidated financial statements on the accounting for acquisitions completed prior to December 31, 2008, the adoption of Statement 141(R) on January 1, 2009 could materially change the accounting for business combinations consummated subsequent to that date.

In September 2006, the FASB issued Statement 157, *Fair Value Measurement* ("Statement 157"). Statement 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and establishes a hierarchy that categorizes and prioritizes the sources to be used to estimate fair value. Statement 157 also expands financial statement disclosures about fair value measurements. On February 6, 2008, the FASB issued FASB Staff Position (FSP) 157-b which delays the effective date of Statement 157 for one year for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Statement 157 and FSP 157-b are effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS No. 157 and FSP 157-b on its consolidated financial statements.

In February 2007, the FASB issued Statement 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an Amendment of SFAS 115* ("Statement 159"), which permits but does not require the Company to measure financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of SFAS No. 159 on its consolidated financial statements.

In December 2007, the Securities and Exchange Commission ("*SEC*") issued Staff Accounting Bulletin No. 110 ("*SAB 110*"). SAB 110 amends and replaces Question 6 of Section D.2 of Topic 14, *Share-Based Payment*. SAB 110 expresses the views of the staff regarding the use of the "simplified" method in developing an estimate of expected term of "plain vanilla" share options in accordance with FASB Statement No. 123(R), *Share Based Payment*. The use of the "simplified" method was scheduled to expire on December 31, 2007. SAB 110 extends the use of the "simplified" method for "plain vanilla" awards in certain situations. The Company currently uses the "simplified" method to estimate the expected term for share option grants as it does not have enough historical experience to provide a reasonable estimate due to the limited period the Company's equity shares have been publicly traded. The Company will continue to use the "simplified" method until it has enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110. SAB 110 is effective for options granted after December 31, 2007.

3. 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 Medisystems Services Corporation, 90% of the issued and outstanding shares of Medisystems Europe S.p.A. (the remaining equity of which is held by Medisystems Corporation) and 0.273% of the issued and outstanding equity participation of Medisystems Mexico s. de R.L. de C.V. (the remaining equity of which is held by Medisystems Corporation), which are collectively referred to as the MDS Entities. Medisystems was a vendor prior to acquisition and Mr. Utterberg is a director and significant stockholder of NxStage. The acquisition was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage.

The MDS Entities design, manufactures, assembles, imports, exports and distributes disposables used in dialysis and related blood treatments and procedures. The acquisition is 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. The assets and liabilities of the MDS Entity are included in the December 31,2007 consolidated balance sheet of the Company and the operating results of the MDS Entity have

been included in the 2007 consolidated statement of operations for the period from October 1, 2007 (date of acquisition) through December 31, 2007. We also entered into consulting and other agreements with Mr. Utterberg or entities owned by him as more fully described in Note 15.

Purchase Price

The Company issued 6.5 million shares of NxStage common stock valued at $12.50 per share, subject to a post closing working capital adjustment, which represents the average trading price of NxStage common stock for five days before and after June 4, 2007, the date the Company announced the signing of a definitive agreement to acquire the MDS Entities. 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.

Allocation of Purchase Price

The acquisition of the MDS Entities has been accounted for using the purchase method of accounting in accordance with SFAS No. 141, *Business Combinations*. Assets acquired and liabilities assumed have been recorded in the accompanying consolidated balance sheet at their estimated fair values as of October 1, 2007. The excess of the purchase price over the aggregate fair values is recorded as goodwill. The following table summarizes the estimated fair value of the assets acquired and liabilities assumed at the date of acquisition (in thousands):

	October 1, 2007
Current assets, excluding inventory	$ 6,213
Inventory	11,922
Property, plant and equipment	6,485
Identifiable intangible assets other than goodwill	34,500
Goodwill	41,457
Other assets	134
Total assets acquired	100,711
Current liabilities	14,537
Long-term liabilities	820
Total liabilities assumed	15,357
Net assets acquired	85,354
Less cash acquired	778
Purchase price, net of acquired cash	$ 84,576

The above purchase price allocation is preliminary and may change as additional information becomes available.

The following table details total purchase consideration and costs of acquiring the MDS Entities (in thousands):

Net book value of the MDS Entities	$ 5,299
Increase in inventory	1,572
Increase to property, plant and equipment	2,526
Identifiable intangible assets	34,500
Goodwill	41,457
Purchase price	$85,354
Purchase Consideration and Costs:	
Fair value of common stock exchanged	$81,250
Estimated closing costs, fees and adjustments	3,643
Estimated severence and relocation costs	461
Total purchase consideration and costs	$85,354

Acquisition-Related Exit Activity Accounted for in Purchase Accounting

As a result of the acquisition, the Company established and approved a plan to integrate the acquired operations of the MDS Entities into the operations of the Company, for which the Company recorded $0.5 million in exit related purchase accounting adjustments in 2007. These purchase accounting adjustments consist of severance for certain MDS Entities employees and relocation benefits for certain MDS Entities employees. The following table summarizes the reserves related to exit activities that have been established through purchase accounting and the related activity that occurred since October 1, 2007 (date of acquisition) (in thousands):

	Severence	Relocation	Total
Balance at 12/31/06	$ —	$ —	$ —
Restructuring expense	301	160	461
Cash payments	—	(21)	(21)
Non-cash utilization	—	—	—
Balance at 12/31/07	$301	$139	$440

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, 2006 The pro forma information presented below does not purport what the actual results would have been had the acquisition occurred on January 1, 2006 (in thousands, except per share amounts):

	December 31, 2007	December 31, 2006
Proforma net revenue	$102,088	$ 78,886
Proforma operating loss	(53,625)	(41,238)
Proforma net loss	(52,269)	(39,143)
Pro forma net loss per share, basic and diluted	$ (1.43)	$ (1.24)

4. Inventory

Inventories at December 31, 2007 and 2006 consist of the following (in thousands):

	December 31, 2007	December 31, 2006
Purchased components	$12,211	$ 2,865
Work in process	1,718	—
Finished goods	16,036	7,554
	$29,965	$10,419

Inventory is shown net of a valuation reserve of approximately $1.8 million and $0.5 million at December 31, 2007 and 2006, respectively. During 2007, the Company recorded a $2.3 million charge for the recall of cartridges in the home market, of which $1.5 million was for the write off of inventory, and $0.8 million 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, 2007, the Company had approximately $1.1 million of affected inventory remaining on-hand. The Company recorded a $1.6 million purchase accounting adjustment to step-up the acquired MDS Entities inventory to fair value less a reasonable profit on remaining sales efforts. During the three months ended December 31, 2007, the Company recognized $1.5 million of the inventory step-up adjustment through cost of sales.

5. 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, 2007	December 31, 2006
Manufacturing equipment and tooling	$ 7,090	$ 2,572
Leasehold improvements	4,341	987
Computer and office equipment	1,651	959
Molds	883	—
Furniture	716	409
Construction-in-process	1,177	438
	15,858	5,365
Less accumulated depreciation and amortization	(3,712)	(2,339)
Property and equipment, net	$12,146	$ 3,026

Depreciation expense for property and equipment was $1.3 million, $0.7 million and $0.5 million in for the years ended December 31, 2007, 2006 and 2005, respectively. Property and equipment includes a $2.5 million purchase accounting adjustment to record the property and equipment acquired as part of the MDS Entities at their fair value. For the three months ended December 31, 2007, the Company recorded $0.1 million of depreciation expense associated with this fair value adjustment.

Field equipment is carried at cost less accumulated depreciation at December 31 2007 and 2006 as follows (in thousands):

	December 31, 2007	December 31, 2006
Field equipment	$39,470	$24,102
Less accumulated depreciation and amortization	(8,585)	(3,486)
Field equipment, net	$30,885	$20,616

Depreciation expense for field equipment was $6.1 million, $2.8 million and $0.6 million for the years ended December 31, 2007, 2006 and 2005, respectively.

6. Accrued Expenses

Accrued expenses at December 31, 2007 and 2006 consist of the following (in thousands):

	December 31, 2007	December 31, 2006
Payroll and related benefits	$3,024	$1,475
Audit, legal and consulting fees	491	372
Inventory purchases	2,533	707
Distribution expenses	1,147	947
Manufacturing related expenses	563	—
General and administrative expenses	496	68
Other	1,566	535
	$9,820	$4,104

7. Financing Arrangements

Debt

On May 15, 2006, the Company entered into an equipment line of credit agreement for the purpose of financing field equipment purchases and placements. The line of credit agreement provides for the availability of up to $20.0 million through December 31, 2007, and borrowings bear interest at the prime rate plus 0.5% (8.75% as of December 31, 2006). Under the line of credit agreement, $10.0 million was available through December 31, 2006 and an additional $10.0 million is available from January 1, 2007 through December 31, 2007. The availability of the line of credit is subject to a number of covenants, including maintaining certain levels of liquidity, adding specified numbers of patients and operating within certain net loss parameters. The Company is also required to maintain operating and/or investment accounts with the lender in an amount at least equal to the outstanding debt obligation. Borrowings are secured by all assets of the Company other than intellectual property and are payable ratably over a three-year period from the date of each borrowing. As of December 31, 2006, the Company had outstanding borrowings of $7.4 million and $1.6 million of borrowing availability under the equipment line of credit. Concurrent with entering into a new credit facility in November 2007, the Company repaid all outstanding borrowings in the aggregate amount of $4.9 million, which included principal and accrued interest and the final interest payment of $30,000. This extinguishment of debt gave rise to early recognition of approximately of $53,000 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 from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., for a term of 42 months. The credit facility is secured by nearly all assets of the Company, other than intellectual

property and consists 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 has the option to borrow the remaining $5.0 million by May 21, 2008. The Company expects that it will borrow this amount. The Company used $4.9 million of the proceeds from the term loan to repay all amounts owed under a term loan dated May 15, 2006 with Silicon Valley Bank. Borrowings under the term loan bear interest equal to LIBOR plus 6% per annum, fixed on November 21 for our first borrowings (at a rate of 10.77% per year) and at the date of borrowing for the remaining $5.0 million still available to be borrowed under the term loan. Interest on the term loan must be paid on a monthly basis. Beginning on February 1, 2009, the Company must repay principal under the term loan in 29 equal monthly installments. The Company will also be required to pay a maturity premium of $900,000 at the time of loan payoff. The Company is accruing the maturity premium as additional interest over the 42 month term. The Company's borrowing capacity under the revolving credit facility is subject to satisfaction of certain conditions and calculations of the borrowing amount. There is no guarantee that the Company will be able to borrow the full amount, or any funds, under the revolving credit facility. Any borrowings under the revolving credit facility will bear interest at LIBOR plus 4.25% per annum. There is an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which are charged in the event the revolving credit facility is terminated prior to May 21, 2011 of 4% in year one, 2% in year two, and 1% thereafter.

The credit facility includes covenants that (a) require the Company to achieve certain minimum net revenue and certain minimum EBITDA targets relating to the acquired Medisystems business, (b) place limitations on the Company's ability to incur debt, (c) place limitations on the Company's ability to grant or incur liens, carry out mergers, and make investments and acquisitions, and (d) place limitations on the Company's ability to pay dividends, make other restricted payments, enter into transactions with affiliates, and amend certain contracts. The credit agreement 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 go into default, Merrill Lynch has a number of remedies, including sale of the Company's assets, control of ash and cash equivalents, and acceleration of all outstanding indebtedness. Any of these remedies would likely have a material adverse effect on the Company's business.

In addition to the Merrill Lynch debt, the Company had one loan outstanding as of December 31, 2007 totaling € 155,000 ($226,000) which expires in September, 2011 and is included in current and long-term debt. The interest on outstanding borrowings is equal to EURIBOR for 3 months (plus 1.15%) subject to an interest rate swap agreement at rates greater than 4%. When EURIBOR (3 months) plus 1.15% exceeds 4%, interest is calculated on a blended basis, with 50% of the nominal value of the loan subject to a fixed rate of 4%, and the remaining 50% subject to the EURIBOR (3 months) plus 1.15%. EURIBOR for 3 months at December 31, 2007 was 4.684%, according to published sources. Interest expense reflects the applied blended interest rate calculation.

Annual maturities of principal under the Company's debt obligations outstanding at December 31, 2007 are as follows (in thousands):

2008	$ 54
2009	9,542
2010	10,407
2011	5,221
	$25,224

8. Long-Term Liabilities

Other long-term liabilities consist of the following (in thousands):

	December 31, 2007	December 31, 2006
Future severence payment under Italian law	$ 830	$ —
Deferred rent	586	649
Lease deposits	18	—
	$1,434	$649

9. Business Segment and Enterprise Wide Disclosures

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, establishes standards for reporting information regarding operating segments in annual financial statements. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

The Company sells products into three markets, home, critical care, and in-center. The critical care market consists of hospitals or facilities that treat patients that have suddenly, and possibly temporarily, lost kidney function. The home market consists of dialysis centers and hospitals that provide treatment options for patients that have end stage renal disease ("ESRD"), and the in-center market consists of the product market for blood tubing sets and needles for hemodialysis and apheresis. Revenues recognized in these markets were as follows (in thousands):

	Years Ended December 31,		
	2007	2006	2005
Home	$29,835	$12,732	$3,164
In-center	15,728	—	—
Critical care	14,401	8,080	2,830
	$59,964	$20,812	$5,994

Revenues for the in-center market reflected consist of MDS Entities sales for the period from October 1, 2007 (date of acquisition) to December 31, 2007. All the Company's revenues are generated in the U.S.

Service revenue relating to extended service contracts in the critical care market totaled approximately $0.2 million and $35,000 for the years ended December 31, 2007 and 2006, respectively.

Long lived tangible assets consist of property and equipment and field equipment. The following table presents total long-lived tangible assets by geographic areas as of December 31, 2007 and 2006, respectively (in thousands):

	December 31, 2007	December 31, 2006
United States	$36,754	$22,777
Europe	3,551	865
Mexico	2,726	—
Total tangible long-lived assets, net	$43,031	$23,642

10. Commitments and Contingencies

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 $1.0 million, $0.5 million and $0.5 million for the years ended December 31, 2007, 2006 and 2005, 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, 2007 under the Company's operating leases are as follows (in thousands):

	Amount
2008	$1,809
2009	1,720
2010	1,759
2011	1,598
2012	463
Thereafter	—
	$7,349

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

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. The agreement may be terminated upon a material breach, generally following a 60-day cure period.

On March 1, 2007, the Company entered into a long-term agreement with the Entrada Group ("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 upon material breach, generally following a 30-day cure period.

As of October 1, 2007 (the acquisition date), the Company has a contract with Kawasumi Laboratories, Inc., a Japanese contract manufacturer. This purchase arrangement is covered by formal contracts expiring in March 2009 for bloodlines and February 2011 for needle sets. Under the terms of the manufacturing agreement, the Company agrees to purchase from this supplier an annual quantity at least equal to 80% of the goals established by both parties for each 12 month period commencing February 1. There have been no losses as a result of this commitment historically, and the Company does not expect any losses over the remaining term of this annual agreement. If the parties cannot agree on new goals for the upcoming year at

least 4 months prior to the start of the contract year, the agreement will be terminated at the conclusion of such contract year.

11. Income Taxes

At December 31, 2007 and 2006, deferred income tax assets and liabilities resulted from 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, 2007	December 31, 2006
Deferred tax assets:		
Net operating loss carryforwards	$ 66,631	$ 46,077
Research and development credits	4,107	3,932
Other	1,965	587
Total deferred tax assets	72,703	50,596
Deferred tax liabilities:		
Depreciation	(3,179)	(1,036)
Deferred tax liability recorded on basis difference of intangible assets acquired as part of Medisystems acquisition	(13,325)	—
Total deferred tax liabilities	(16,504)	(1,036)
Net deferred tax assets before valuation allowance	56,199	49,560
Less: Valuation allowance	(56,199)	(49,560)
Net deferred tax assets	$ —	$ —

As of December 31, 2007, the Company had federal and state net operating loss carryforwards of approximately $172.9 million and $144.8 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 2027 if not utilized, while the state net operating loss carryforwards will expire between 2008 and 2027 if not utilized. The Company also had combined federal and state research and development credit carryforwards of approximately $4.1 million, at December 31, 2007, which begin to expire in 2019 if not utilized. 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 $1.6 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 Company's operating divisions in Mexico (MediMexico) and Italy (Medisystems Europe) that were acquired as part of the Medisystems acquisition are subject to taxation on income in their respective countries. For the year ended December 31, 2007, which covers the period October 1, 2007 through December 31, 2007,

the provision for foreign income taxes for MediMexico was $15,000 and for Medisystems Europe was $47,000.

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

	Years Ended December 31,		
	2007	2006	2005
Federal statutory rate	34.0%	34.0%	34.0%
Research and development credits	0.8%	1.0%	1.7%
Foreign tax	(0.1)%	0.0%	0.0%
Valuation allowance	(33.2)%	(32.3)%	(34.8)%
Other, net	(1.6)%	(2.7)%	(0.9)%
Effective tax rate	(0.1)%	0.0%	0.0%

12. Stock-Based Awards

As of December 31, 2007, the Company has reserved 4,094,791 shares of common stock for issuance upon exercise of stock options and 35,730 shares for issuance under the 2005 Purchase Plan.

Stock Options

The Company maintains the 1999 Stock Option and Grant Plan (the "1999 Plan") under which 4,085,009 shares of common stock were authorized for the granting of incentive stock options ("ISOs") and nonqualified stock options to employees, officers, directors, advisors, and consultants of the Company. Effective upon the closing of the Company's initial public offering, no further grants have been or will be made under the 1999 Plan. ISOs under the 1999 Plan were granted only to employees, while nonqualified stock options under the 1999 Plan were granted to officers, employees, consultants and advisors of the Company. The Company's board of directors (the "Board") determined the option exercise price for incentive and nonqualified stock options and grants, and in no event were the option exercise prices of an incentive stock option less than 100% of the fair market value of common stock at the time of grant, or less than 110% of the fair market value of the common stock in the event that the employee owned 10% or more of the Company's capital stock. In general, all stock options issued under the 1999 Plan expire 10 years from the date of grant and the majority of these grants were exercisable upon the date of grant into restricted common stock, which vests over a period of four years. Prior to the adoption of the 1999 Plan, the Company issued non-qualified options to purchase 55,252 shares of common stock, of which 40,622 shares remain outstanding at December 31, 2007.

In October 2005, the Company adopted the 2005 Stock Incentive Plan (the "2005 Plan"), which became effective upon the closing of the initial public offering. Concurrently, the Company ceased granting stock options and other equity incentive awards under the 1999 Plan and 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 available for grant under the 2005 Plan was increased by 600,000 shares, pursuant to an evergreen provision under the Plan. This evergreen provision of the 2005 Plan was eliminated by the Board in July 2007. In October 2007, the Company amended the 2005 Stock Incentive Plan to increase the number of shares of common stock which may be issued pursuant to the plan by an additional 3,800,000 shares, of which no more than 1,500,000 shares may be granted as restricted stock units. Unless otherwise specified by the Board 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. Stock option grants to directors expire five years from the date of grant and vest 100% on date of grant. At December 31, 2007, options for the purchase of 3,042,125 shares of common stock, of which only

1,477,009 shall be granted as restricted stock units, are available for future grant under the 2005 Plan. The Company settles stock option exercises with newly issued common shares.

During 2007, 2006 and 2005, the Company granted a consultant options to purchase 7,500, 7,500 and 5,849 shares of common stock at an exercise prices of $14.44, $8.15 and $6.84 per share, respectively. The fair value of the 2007, 2006 and 2005 option grants was $8.09, $6.35 and $5.88 per share, respectively, which has been recorded as stock-based compensation and is being recognized ratably over the awards' vesting period. Further, these stock options will be marked to market over their vesting period based upon changes in fair value of the award. During 2005, 47,579 shares were exercised by the consultant at a weighted average exercise price of $4.24 per share.

The fair value of options granted to consultants is estimated on the date of grant and at each remeasurement date using the Black-Scholes option-pricing model. The following assumptions were used for grants made in 2007, 2006 and 2005: dividend yield of zero percent for each year; expected volatility of 65%, 85%, and 85% ; risk free interest rates ranging from 3.42 to 4.68 percent; and expected life ranging from 5 to 10 years. Stock-based compensation expense related to stock options granted to consultants was $21,000, $0.1 million and $0.2 million for 2007, 2006 and 2005, respectively, and is included in general and administrative expenses in the accompanying consolidated statements of operations.

With the exception of one stock option award, which was granted in 2006, all stock option awards granted to employees during 2007, 2006 and 2005 were made at exercise prices equal to or greater than the then fair value of the Company's common stock. The Company granted 208,962 stock options to a newly hired executive officer (the "Executive") on October 25, 2004 with an exercise price of $4.10 per share, which was lower than the fair value at the date of grant of $5.47 per share. The intrinsic value of $1.37 per option is being recognized as compensation expense over the four-year vesting period. The Executive's stock option award was modified in March 2006 as a result of Internal Revenue Code Section 409A. In connection with the modification, the Executive's exercise price was changed to its fair market value on date of grant, $5.47 per share, in exchange for $0.1 million in cash paid in January 2007 and 13,027 shares of restricted stock that began vesting on January 1, 2007. The modification resulted in $0.1 million in stock-based compensation expense in 2007 and additional compensation expense of $0.1 million in 2006, respectively.

During 2007, the Company entered into a restricted stock agreement with one executive pursuant to which 22,991 shares were granted with a restriction period of four years at a market price of $14.98. The fair market value of the shares was measured on the date of grant and is being amortized to expense over the respective vesting periods. During the year ended December 31, 2007, stock-based compensation relating to these shares charged to operations was $14,350. During 2006, the Company entered into restricted stock agreements with three executives pursuant to which 30,449 shares were granted with restriction periods of three months to four years at market prices ranging from $8.92 to $13.05. The fair market value of the shares was measured on the date of grant and is being amortized to expense over the respective vesting periods. During the year ended December 31, 2007 and 2006, stock-based compensation relating to these shares charged to operations was $0.1 million and $0.1 million, respectively. At December 31, 2007 and 2006, the weighted-average grant date fair value and weighted-average remaining contractual life for outstanding shares of restricted stock was $13.14 and $11.40 and 4.3 years and 4.1 years, respectively.

For stock option grants between July 1, 2004 and the Company's initial public offering that closed on November 1, 2005, the Company determined the fair value of its common stock based on a number of factors including independent valuation analyses as well as the prices for recent issuances of preferred stock. The Company believes that the methodologies and approaches used were consistent with the recommendations in the Technical Practice Aid of American Institute of Certified Public Accountants, or AICPA, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation."

A summary of the Company's stock option activity under all plans is as follows:

	2007		2006		2005	
Fixed Options	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	3,068,430	$ 7.00	2,683,286	$6.22	1,690,556	$3.97
Granted	1,526,916	$14.16	754,642	$9.25	1,217,970	$9.02
Exercised	(390,278)	$ 6.03	(177,757)	$4.08	(128,729)	$4.14
Forfeited or expired	(110,277)	$ 8.06	(191,741)	$8.96	(96,511)	$5.03
Outstanding at end of year	4,094,791	$ 9.65	3,068,430	$7.00	2,683,286	$6.22
Vested at end of year	1,873,734	$ 6.67	1,705,007		1,249,030	
Exercisable at end of year	1,963,169	$ 6.69	1,959,785		1,448,571	

The aggregate intrinsic value at December 31, 2007 was $22.3 million for stock options outstanding, $15.9 million for stock options vested and $16.7 million for stock options exercisable. The intrinsic value for stock options outstanding, vested and exercisable is calculated based on the exercise price of the underlying awards and the market price of the Company's common stock as of December 31, 2007, excluding out-of-the-money awards. The total intrinsic value of options exercised during the year ended December 31, 2007 and 2006 was $3.6 million and $0.8 million, respectively. The total fair value of shares vested during the year ended December 31, 2007 and 2006 was $3.1 million and $4.9 million, respectively.

The following table summarizes information about stock options outstanding at December 31, 2007:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.34 to $0.55	91,417	1.4 years	$ 0.36	91,417	$ 0.36
$1.37	2,924	2.4 years	$ 1.37	2,924	$ 1.37
$2.74 to $4.10	726,079	4.1 years	$ 3.89	726,079	$ 3.89
$5.47 to $6.84	354,133	6.8 years	$ 6.37	354,133	$ 6.37
$7.90 to $9.27	1,095,321	5.5 years	$ 8.51	431,258	$ 8.51
$9.63 to $11.19	106,267	5.4 years	$10.70	92,095	$10.78
$11.78 to $13.65	695,641	6.0 years	$12.91	252,467	$12.52
$14.20 to $15.22	1,023,009	6.9 years	$14.63	12,796	$14.98
$0.34 to $15.22	4,094,791	5.7 years	$ 9.65	1,963,169	$ 6.69

The following table summarizes the status of the Company's non-vested stock options:

Fixed Options	Shares	Fair Value
Nonvested at December 31, 2005	1,434,256	$ 7.89
Granted	754,642	$ 9.25
Vested	(633,734)	$ 7.76
Forfeited	(191,741)	$ 8.96
Nonvested at December 31, 2006	1,363,423	$ 8.54
Granted	1,526,916	$14.16
Vested	(559,005)	$ 9.58
Forfeited	(110,277)	$ 8.06
Nonvested at December 31, 2007	2,221,057	$12.17

Certain outstanding stock option awards are subject to an early exercise provision. Upon exercise, the award was initially subject to a repurchase right in favor of the Company. The repurchase right terminated upon the closing of the Company's initial public offering.

As of December 31, 2007, approximately $14.5 million of unrecognized stock compensation cost related to nonvested awards (net of estimated forfeitures) is expected to be recognized over a weighted-average period of 3.2 years.

Employee Stock Purchase 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. Each six-month offering period begins in January or 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.

The weighted-average fair value of stock purchase rights granted as part of the Company's 2005 Purchase Plan during the year ended December 31, 2007 and 2006 was $2.60 and $2.30 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, 2007	Year Ended December 31, 2006
Expected life	6 months	6 months
Risk-free interest rate	4.90% - 4.94%	4.42% - 5.11%
Expected stock price volatility	61.7% - 75%	50.9% - 67.0%
Expected dividend yield	—	—

There were 35,967, 28,303, and 0 shares issued under the ESPP Plan for the years ended December 31, 2007, 2006, and 2005, respectively. As of December 31, 2007, the maximum number of shares available for future issuance under the 2005 Purchase Plan is 35,730.

The Company recognized share-based compensation expense relating to the 2005 Purchase Plan of $0.1 million for the year ended December 31, 2007 and 2006, respectively.

13. Employee Benefit Plan

The Company has a 401(k) retirement plan (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 $0.8 million, $0.6 million and $0.4 million to the 401(k) Plan during the years ended December 31, 2007, 2006 and 2005, respectively.

14. Stockholders' Equity

Common and Preferred Stock

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 MDS Entities acquisition as discussed in Note 3.

On February 7, 2007, the Company issued and sold to DaVita 2,000,000 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 will be recognized ratably to revenue over a term of 7 years as discussed in Note 2.

On June 14, 2006, the Company completed a follow-on public offering of 6,325,000 shares of its common stock at a price of $8.75 per share and with aggregate net proceeds of approximately $51.3 million.

On November 1, 2005, the Company completed its initial public offering of 6,325,000 shares of its common stock at a price of $10.00 per share and with aggregate net proceeds of approximately $56.0 million. In connection with the initial public offering, all shares of all series of the Company's outstanding preferred stock were automatically converted into an aggregate of 12,124,840 shares of common stock.

Warrants

During 2007, 73,460 of outstanding warrants to purchase shares of common stock were exercised, resulting in the issuance of 21,000 shares of common stock. There are no warrants to purchase shares of common stock outstanding at December 31, 2007.

At December 31, 2006, warrants to purchase a total of 73,460 shares of common stock were outstanding. These warrants have a weighted average exercise price of $8.17 per share and expire in December 2011. During the year ended December 31, 2006, certain warrant holder's exercised warrants to purchase 78,522 shares of the Company's common stock for aggregate proceeds of approximately $0.5 million. During the year ended December 31, 2005, certain warrant holder's exercised warrants to purchase 31,304 shares of the Company's common stock for aggregate proceeds of approximately $0.2 million.

Four of the Company's significant shareholders invested in the Company's initial public offering. Three of these shareholders held warrants to purchase Series D Preferred Stock, which were due to expire on November 22, 2005, during the six month lock-up period required by the underwriting agreement entered into in connection with the initial public offering. In November 2005, the Company offered to extend the exercise period of the warrants held by these three investors through May 31, 2006. Two of these investors with warrants for a total of 80,968 shares accepted the Company's offer to extend the exercise period. The extension of the warrants had no net effect on the financial position or results of operations of the Company. The fair value on date of modification was calculated at $0.5 million and has been accounted for within the additional paid-in capital account, as both an increase to the cost of the initial public offering, offset by a corresponding credit to reflect the value of the warrant extension.

15. Related-Party Transactions

As discussed in Note 3, on June 4, 2007, the Company entered into a stock purchase agreement with David S. Utterberg under which the Company agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and Medisystems Services Corporation, 90% of the issued and outstanding shares of Medisystems Europe S.p.A. (the remaining equity of which is held by Medisystems Corporation) and 0.273% of the issued and outstanding equity participation of Medisystems Mexico s. de R.L. de C.V. (the remaining equity of which is held by Medisystems Corporation), which are collectively referred to as the MDS Entities. The Company refers to its acquisition of the MDS Entities as the Medisystems Acquisition. Mr. Utterberg is a director and significant stockholder of NxStage. The Medisystems Acquisition was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage. In addition, as a result of completion of the Medisystems Acquisition, the supply agreement, dated January 2007, with Medisystems, under which Medisystems agreed to provide cartridges for use with the System One, was terminated with no resultant gain or loss recognized. In consideration for the Medisystems Acquisition, the Company issued Mr. Utterberg 6.5 million shares of our common stock, which the Company refers to as the Shares. As a result of the Medisystems Acquisition and the issuance of the Shares to Mr. Utterberg, Mr. Utterberg's aggregate ownership of outstanding common stock increased to approximately 23.2%. In addition, the Company may be required to issue additional shares of common stock to Mr. Utterberg since, 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. An aggregate of 1.0 million of the shares issued to Mr. Utterberg were placed into escrow to cover potential indemnification claims the Company may have against Mr. Utterberg. In connection with the Medisystems Acquisition and as a result of Medisystems Corporation, one of the MDS Entities, becoming a direct or indirect wholly-owned subsidiary of the Company, acquired rights under an existing license agreement between Medisystems and DSU Medical Corporation, a Nevada corporation, which is wholly-owned by Mr. Utterberg, or DSU. The Company refers to this agreement as the license agreement. Additionally, 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, which the Company refers to as the consulting agreement.

Under the license agreement, Medisystems received an exclusive, irrevocable, sublicensable, royalty-free, fully paid license to certain DSU patents, or the licensed patents, in exchange for a one-time payment of $2.7 million. The licensed patents fall into two categories, those patents that are used exclusively by the MDS Entities, referred to as the Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, referred to as the Class B patents. Pursuant to the terms of the license agreement, MDS has 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. The license agreement further provides that the rights of Medisystems under the agreement are qualified by certain sublicenses previously granted to third parties. The Company has agreed that Mr. Utterberg retains the right to the royalty income under one of these sublicenses.

Under the consulting agreement, Mr. Utterberg and DSU will provide consulting, advisory and related services to us for a period of two years following the consummation of the Medisystems Acquisition. In addition, under the terms of the consulting agreement, Mr. Utterberg and DSU have agreed during the term of the agreement not to compete with NxStage during the term of the consulting agreement in the field defined in the consulting agreement and not to encourage or solicit any of our employees, customers or suppliers to alter their relationship with us. The consulting agreement further provides that (1) Mr. Utterberg and DSU

assign to us certain inventions and proprietary rights received by him/it during the term of the agreement and (2) the Company grants Mr. Utterberg and DSU an exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid license under such assigned inventions and proprietary rights for any purpose outside the inventing field, as defined in the consulting agreement. Under the terms of the consulting agreement, Mr. Utterberg and DSU will receive an aggregate of $200,000 per year, plus expenses, in full consideration for the services and other obligations provided for under the terms of the consulting agreement. The consulting agreement also requires Mr. Utterberg and NxStage to indemnify each other in the event of certain breaches and failures under the agreement and requires that any such indemnification liability be satisfied with shares of our 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 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 Company assumed a $2.8 million liability owed to DSU as a result of the acquisition of the MDS Entities. The amount owed represents consideration owed to DSU by the MDS Entities for the termination of a royalty-bearing sublicense agreement and the establishment of the royalty-free license agreement.

As of December 31, 2007 the Company recorded a receivable for reimbursements of costs related to the acquisition in the amount of $0.4 million from Mr. Utterberg and DSU.

16. Subsequent Event

On January 6, 2008, the Company entered into a needle purchase agreement (the "Agreement") with DaVita, pursuant to which DaVita has agreed to purchase the majority of its safety needle requirements from the Company for five years, subject to certain terms and conditions. The term of the Agreement expires on January 5, 2013. Either party may terminate the Agreement upon a substantial breach of the terms thereof that remains uncured. Additionally, either party may terminate the Agreement if any proceeding under the bankruptcy or insolvency laws is brought against the other party, a receiver is appointed for the other party, the other party makes an assignment for the benefit of creditors, or the other party dissolves. DaVita may also terminate the Agreement (i) upon our continued failure to supply safety needles, or (ii) if we deliver defective safety needles to DaVita for a continued period of time. DaVita has the right to reduce or eliminate its purchase requirements under the Agreement following the introduction of a materially improved product (as defined in the Agreement) from a third party. If DaVita exercises this right, we may terminate the Agreement. The Agreement provides for liquidated damages in the event DaVita fails to satisfy its purchase requirements or the Company fails to meet its supply obligations to DaVita.

17. Quarterly Financial Data (Unaudited)

The following table sets forth selected quarterly information (unaudited, in thousands):

	Year Ended December 31, 2007			
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
Revenues	$ 8,374	$ 10,031	$ 11,625	$ 29,934
Gross profit (deficit)	(1,544)	(1,480)	(3,536)	557
Net loss	(11,993)	(12,882)	(16,124)	(17,397)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.43)	$ (0.54)	$ (0.47)

	Year Ended December 31, 2006			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
Revenues	$ 3,401	$ 4,546	$ 5,512	$ 7,353
Gross deficit	(1,457)	(1,457)	(1,108)	(1,287)
Net loss	(9,255)	(10,388)	(9,576)	(10,411)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.46)	$ (0.34)	$ (0.37)

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, 2007. 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, 2007, 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.

Management's report on NxStage's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and the independent registered public accounting firm's related audit report are included in Item 8 of this Form 10-K and are incorporated herein by reference.

No change in NxStage's internal control over financial reporting occurred during the fiscal year ended December 31, 2007 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 the financial statements.

Management has evaluated the effectiveness of its internal control over financial reporting as of December 31, 2007, 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.

Our evaluation of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of the MDS Entities, a business we acquired during the year ended December 31, 2007 and which is included in our 2007 consolidated financial statements and constituted approximately $21.2 million and $7.3 million of total and net assets, respectively, as of December 31, 2007 and $15.7 million and $2.0 million of revenues and net income, respectively, for the period from the date of acquisition through December 31, 2007.

Based on such evaluation, we have concluded that NxStage's internal control over financial reporting is effective as of December 31, 2007.

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, 2007, 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.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of the MDS Entities, a business acquired by NxStage Medical, Inc. during the year-ended December 31, 2007, which is included in the 2007 consolidated financial statements of NxStage Medical, Inc. and constituted approximately $21,233,0000 and $7,345,000 of total and net assets, respectively, as of December 31, 2007 and $15,728,000 and $2,025,000 of revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of NxStage Medical, Inc. also did not include an evaluation of the internal control over financial reporting of the MDS Entities.

In our opinion, NxStage Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, 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, 2007 and 2006, and the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007 of NxStage Medical, Inc. and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 6, 2008

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

None.

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 2008 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":

Report of Independent Registered Public Accounting Firm 75
Consolidated Balance Sheets 76
Consolidated Statements of Operations 77
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) 78
Consolidated Statements of Cash Flows 79
Notes to Consolidated Financial Statements 80

(b) *Exhibits*

The exhibits listed in the Exhibit Index immediately preceding the exhibits are incorporated herein by referenced 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 7, 2008

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 7, 2008
/s/ Robert S. Brown Robert S. Brown	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	March 7, 2008
/s/ Philippe O. Chambon Philippe O. Chambon, M.D., Ph.D.	Chairman of the Board of Directors	March 5, 2008
/s/ Daniel A. Giannini Daniel A. Giannini	Director	March 5, 2008
/s/ Craig W. Moore Craig W. Moore	Director	March 5, 2008
/s/ Reid S. Perper Reid S. Perper	Director	March 7, 2008
/s/ Peter P. Phildius Peter P. Phildius	Director	March 5, 2008
/s/ David S. Utterberg David S. Utterberg	Director	March 5, 2008

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
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				
10.6#	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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
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
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.				
10.38	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†	Consulting Agreement, dated October 1, 2007, by and between the Registrant, DSU Medical Corporation and David S. Utterberg	10-Q	10.1	11/7/2007	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-14 or 15d-14, 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-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
*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, 2007 (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 7, 2008

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, 2007 (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 7, 2008

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, 2007 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 7, 2008

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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, 2007 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 7, 2008

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request

Corporate Information

Board of Directors

Philippe O. Chambon, MD, PhD,
Chairman and Managing Director
NLV Partners, LLC

Jeffrey H. Burbank
President and Chief Executive Officer
NxStage Medical, Inc.

Daniel A. Giannini
Retired Partner
PricewaterhouseCoopers LLP

Craig W. Moore
Retired; Former Chairman and Chief Executive Officer
Everest Healthcare Services Corporation

Reid S. Perper
Managing Director
Healthcare Investment Partners, LLC

Peter P. Phildius
Chairman and Chief Executive Officer
Avitar, Inc

David S. Utterberg
President and Chief Executive Officer
Lifestream Medical Corporation

Corporate Officers

Jeffrey H. Burbank
President and Chief Executive Officer

Agustin M. Azel
Senior Vice President, Manufacturing

Robert S. Brown
Senior Vice President and
Chief Financial Officer

Thomas F. Shea
Senior Vice President, Operations

Winifred L. Swan
Senior Vice President, Secretary and
General Counsel

Joseph E. Turk, Jr.
Senior Vice President,
Commercial Operations

Michael J. Webb
Senior Vice President of Quality,
Regulatory and Clinical Affairs

Corporate Headquarters
NxStage Medical, Inc.
439 South Union Street, 5th Floor
Lawrence, MA 01843
978-687-4700
www.nxstage.com

Transfer Agent
Inquiries concerning the transfer or exchange of shares, lost stock certificates, duplicate mailings or changes of address should be addressed to the Company's Transfer Agent at:
Computershare Trust Company, N.A.
P.O. Box 43078
Providence, RI 02940-3078
781-575-3100
www.computershare.com

Independent Registered Accountants
Ernst & Young LLP
200 Clarendon Street
Boston, MA 02116

Annual Meeting
The Annual Meeting of Stockholders will be held on Thursday, May 29, 2008 at 10:00 a.m. at the offices of WilmerHale, 60 State Street, Boston, MA 02109

Market for NxStage Medical, Inc Stock
Nasdaq Global Market
Common Stock: NXTM

Investor Information
Copies of our annual reports on Form 10-K, proxy statements, quarterly reports on Form 10-Q, and current reports on Form 8-K are available to stockholders upon request without charge. Please visit our website at www.nxstage.com or send requests to:
NxStage Medical, Inc
439 S. Union Street, 5th Floor
Lawrence, MA 01843
ATTN: Investor Relations
Phone: (978) 687-4700
Fax: (978) 687-4805
E-mail: info@nxstage.com

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 in-center, home, and critical care dialysis markets, the development and commercialization of our products, the development of new products, our leadership position in any of our markets, expected improvements in operating efficiencies, our ability to obtain additional capital, expectations with respect to clinical findings, our ability to achieve profitable operations, and possible future changes to reimbursement for home daily dialysis treatments. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words "expect", "anticipate", "intend", "plan", "believe", "seek", "estimate", "potential", "continue", "predict", "may", and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, the risks identified in our annual report on Form 10-K and our other filings with the Securities and Exchange Commission. We assume no obligation to update any forward-looking information contained in this annual report.

Design: RainCastle Communications
www.raincastle.com

NxSTAGE
Renal Care, Pure and Simple.

END

www.nxstage.com

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Lawrence, MA 01843
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