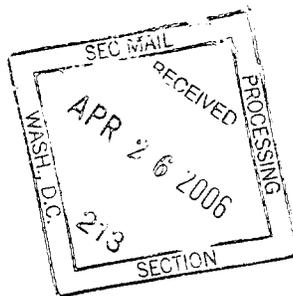
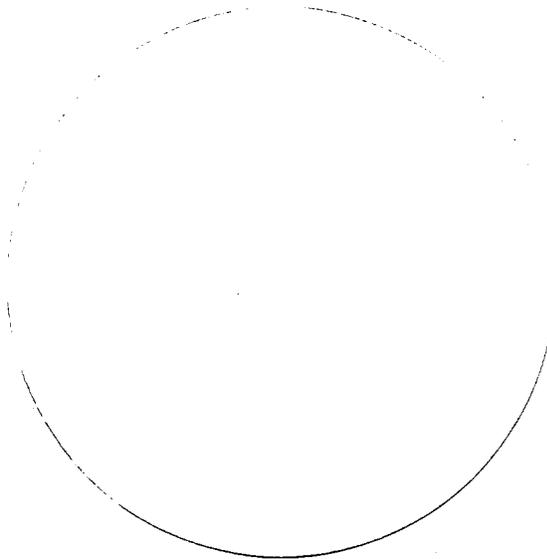




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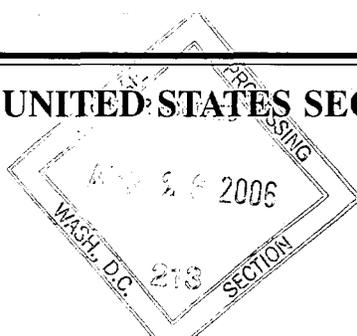
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549



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, 2005

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

(State of Incorporation)

04-3454702

(I.R.S. Employer Identification No.)

439 S. Union St., 5th Floor, Lawrence, MA

(Address of Principal Executive Offices)

01843

(Zip Code)

Registrant's Telephone Number, Including Area Code:

(978) 687-4700

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

None

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

Common Stock, \$0.001 par value

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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act: (Check One):

Large accelerated filer Accelerated filer Non-accelerated filer

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

The aggregate market value of common stock held by non-affiliates of the registrant was approximately \$125.0 million, as of October 27, 2005, based on the price at which common equity was last sold by the registrant.

There were 21,182,072 shares of the registrant's common stock issued and outstanding as of the close of business on February 27, 2006.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2006 Annual Meeting of Stockholders to be held on May 30, 2006 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.
2005 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 chronic and critical care dialysis markets in general and the home hemodialysis market in particular, the development and commercialization of our products, the adequacy of our funding and our ability to obtain additional funding, the timing of when we might achieve profitable operations, 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 recent and 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 in Item 1A (Risk Factors), "Management's Discussion and Analysis of Financial Condition and Results of Operation", 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 operation 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 systems for the treatment of end-stage renal disease, or ESRD, and acute kidney failure. 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. 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. We believe the largest market opportunity for our product is the home hemodialysis market for the treatment of ESRD.

ESRD, which affects approximately 453,000 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. Over 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, 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 or preparation between treatments 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 typically bill the clinic for the rental of the machine and purchase of the related disposable cartridges and treatment fluids. 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, 2005, 292 ESRD patients were using the System One at 70 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. Training is provided by the patient's dialysis clinic and 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 partners 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 are no costs to the patient associated with this training.

Medicare reimburses the same amount 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 could 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 associated with multiple diseases, including congestive heart failure, or CHF. 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, 2005, 50 hospitals were using the System One to deliver acute kidney failure and fluid overload therapy.

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.

Our Products and Services

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 is comprised of 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, integrated treatment cartridge that loads simply and easily into the cycler. The cartridge incorporates a proprietary disposable volumetric fluid management system and includes a pre-attached dialyzer. This fully disposable design eliminates any contact between the dialysis machine and the dialysate, thereby avoiding complex disinfection requirements associated with traditional systems.
- *Premixed Dialysate.* The System One uses high-purity, premixed dialysate for hemodialysis applications. The volume of fluids used varies with treatment options and prescription, but typical weekly volumes are similar to the amount of dialysate used by a patient on peritoneal dialysis, or PD, therapy. Currently, we supply all of our premixed dialysate in four and one-half and five liter bags. In March 2005, we received FDA clearance for a proprietary dialysate preparation module, which allows for on-site preparation of premixed dialysate. We submitted an application for FDA clearance of the next generation of our dialysate preparation module in February 2006. We hope to make this product available to our customers during the third calendar quarter of 2006.

For the ESRD market, the System One, which is specifically FDA cleared for hemodialysis use in the home, is designed to make home treatment and more frequent treatment easier and more practical. Although not performed using our product, 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 improved quality of life as patients feel better. Other published literature also supports the clinical and quality of life benefits associated with home dialysis therapy. We believe traditional equipment cannot satisfy the demand for home

and more frequent treatment due to its complexity, lack of portability, size and infrastructure requirements. The costs of delivering more frequent therapy in center, as well as clinic scheduling limitations, present further obstacles to the broader adoption of more frequent therapy, and we believe the System One addresses many of the barriers to more frequent and home 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. Because of its small size, portability and lack of infrastructure requirements, our system can be easily moved between patient rooms, set up and taken down. It can also be easily moved from the intensive care unit, or ICU, to the cardiac care unit, or CCU, or telemetry floor to treat patients with fluid overload. Our use of volumetric balancing rather than scales eliminates the frequent nursing interventions required by existing ICU dialysis systems. The ability of our system to perform hemofiltration, for which the System One is also FDA cleared in addition to hemodialysis, is advantageous, as many clinicians choose to prescribe this therapy for patients with acute kidney failure.

Competition

Chronic Care

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, Gambro, Baxter and Aksys. Fresenius, Gambro and Baxter each have large and well-established dialysis products businesses and Aksys markets a competitive product specifically designed for more frequent use in the home. In addition, DaVita 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.

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.

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 bagged, 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 to 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 chronic kidney failure and have a smaller sales force than most of our competitors.

Our primary competitors are large, well-established businesses with significantly more financial and personnel resources than us. They also have significantly 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 the System One, and any products we may develop in the future, 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.

Critical Care

We believe that competition in the critical care market will be affected by system functionality, ease-of-use, reliability, portability and infrastructure requirements. In the fluid overload market, we believe competition will be further affected by physicians' willingness to adopt ultrafiltration as a viable treatment alternative to pharmaceutical therapy. In the critical care market, we face direct competition from Gambro, Baxter, B. Braun, Fresenius and CHF Solutions.

In the fluid overload market, drug therapy is currently the most common and preferred treatment. To date, ultrafiltration has not been broadly adopted and, if the medical community does not accept ultrafiltration as clinically useful, cost-effective and safe, we will not be able to successfully compete against existing pharmaceutical therapies. Our ability to successfully market the System One for the treatment of fluid overload associated with multiple diseases, including CHF, could also be adversely affected by pharmacological and technological advances in preventing or treating fluid overload.

Sales and Marketing

We sell our products in two markets: the chronic market and the critical care market. We have separate marketing and sales efforts dedicated to each market. 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. In 2004, sales to Clarian Health Partners represented 13.1% of our total revenues, sales to University of Chicago represented 12.4% of our total revenues and sales to Wellbound, Inc. represented 11.5% of our total revenues. No other single customer represented 10% or more of our revenues in 2004.

Chronic Care

In the chronic care 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 chronic care patients.

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

Currently, there are approximately 4,400 dialysis clinics in the United States. Ownership of these clinics is highly consolidated with DaVita controlling approximately 28%, and Fresenius controlling approximately 35% on a pro forma basis assuming the completion of its pending acquisition of Renal Care Group and the completion of the recently announced sale of approximately 100 clinics to the National Renal Institutes, and independent clinics and hospitals represent the approximately 37% of remaining clinics. Because the chronic market is highly concentrated with some vertically integrated suppliers, it is possible, with a relatively small sales force, for us to target and market to only those clinics that we believe would be interested in our system. Our customers include independent clinics as well as large chains.

After renting or selling a System One to a clinic, our sales representatives and 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 sales representatives and 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. As of December 31, 2005, there were 292 patients with chronic ESRD using the System One.

Critical Care

In the critical care market, because both acute kidney failure and fluid overload are typically treated in hospital intensive care units, our customers are hospitals. We are specifically focusing our sales efforts in the critical care market on those large institutions that we believe are most dedicated to increased and improved dialysis therapy for patients with acute kidney failure and believe in ultrafiltration as an earlier stage treatment option for fluid overload associated with multiple diseases, including congestive heart failure.

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 sales representatives and clinical educators train the hospital's ICU 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 representatives and 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, 2005, we had 50 hospitals as critical care customers.

Customer Support Services

We use a depot service model for equipment servicing and repair for the chronic care 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 defective system. This shipment is done by common carrier, and, as there are no special installation requirements, the patient, clinic or hospital can set up the new machine in a matter of minutes. In addition, we ship monthly supplies via common carrier and courier services directly to chronic care 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 clinical 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 our System One product. In addition, due to the intense nature of the needs of patients with acute kidney failure and fluid overload, our critical care sales representatives and technical specialists are personally available to answer questions 24 hours a day, seven days a week. We generally do not handle clinical questions or issues from patients, but instead refer them to their physician or dialysis clinic.

Billing

In the chronic care market, we typically rent the System One, and sell the related disposables, to the dialysis clinics, and bill the clinics monthly for each system and all disposables used by their patients. In the

critical care market, we rent or sell our systems, and sell all related disposables, to hospitals and bill the hospitals directly. The clinics and hospitals then bill their treated patients' insurance providers, usually Medicare, for the treatment provided.

Clinical Experience and Results

Over one hundred published articles have reported on the benefits of daily dialysis therapy. Although 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 improved quality of life as patients feel better.

Recently, we announced the first enrollment of a patient in our post-market FREEDOM study (Following Rehabilitation, Economics, and Everyday Dialysis Outcome Measurements) 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 over what is expected to be a two-year period. It will compare Medicare patients using the NxStage System One with a matched cohort of patients from the 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 \$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%. It is believed daily therapy may materially reduce overall Medicare costs for the care of chronic dialysis patients, particularly through reduced hospitalization and drug costs.

In addition to the FREEDOM study, we conducted 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 investigational device exemption, or IDE. We are currently conducting 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. Our development team has skills across the range of technologies required to develop and maintain dialysis systems. 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 positively supplement our

existing product offerings and intend to continue to actively pursue opportunities for the research and development of complementary products.

For the years ended December 31, 2005, 2004 and 2003, we incurred total research and development expenses of \$6.3 million, \$6.0 million and \$4.5 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, 2005, we had 20 issued U.S. and international patents and 66 U.S., international and foreign pending patent applications.

<u>Patent No.</u>	<u>Regime</u>	<u>Filed</u>	<u>20 Yrs+Priority</u>	<u>Description</u>
6,254,567	US	2/23/2000	2/21/2019	Addresses fluids requirement by regenerating dialysate
6,554,789	US	2/25/2000	2/9/2017	Panels defined by seals and overlying panels
6,572,576	US	7/7/2001	7/2/2021	Leak detection by flow reversal
6,572,641	US	4/9/2001	4/4/2021	Fluid warmer that removes air
6,579,253	US	2/25/2000	2/9/2017	Balancing chambers are defined by panels of the circuit
6,582,385	US	2/19/1998	2/14/2018	Addresses fluids requirement by purifying waste
6,589,482	US	2/25/2000	2/9/2017	Panels form a combination to mutually displace waste and replacement fluid
6,595,943	US	2/25/2000	2/9/2017	Blood pressure control in filter to optimize throughput
6,638,477	US	2/25/2000	2/9/2017	Divert part of waste stream to control ultrafiltration or rinse
6,638,478	US	2/25/2000	2/9/2017	Mechanically coupled flow assemblies that balance flow of incoming and outgoing fluid streams, respectively
6,649,063	US	7/12/2001	7/7/2021	Using the filter to generate sterile replacement fluid
6,673,314	US	2/25/2000	2/9/2017	Supply notification including third-party notification by network
6,702,561	US	7/12/2001	7/7/2021	Potting distribution channel molded into filter housing
6,743,193	US	7/17/2001	7/12/2021	Hermetic valve design
6,830,553	US	2/25/2000	2/9/2017	Sterile filter in replacement fluid line
6,852,090	US	5/24/2001	2/9/2017	Balancing chambers are defined by circuit portions defined in cooperation with the base
6,872,346	US	3/20/2003	3/15/2023	Manufacturing method for filters using radiant heat to seal filter fibers
6,955,655	US	6/27/2001	2/9/2017	Frequent treatment with simple setup
6,979,309	US	1/7/2002	2/9/2017	New frequent hemofiltration
EP969887	EP (UK)	8/15/1999	2/9/2017	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 addition to our patents and pending patent applications in the United States and selected non-U.S. markets, we use trade secrets and proprietary know-how in our products. Any of our trade secrets, know-how or other technology not protected by a patent could be disclosed to, or independently developed by, a competitor.

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 disposable cartridges for the critical care market within our 45,000 square foot facility in Lawrence, Massachusetts. We also manufacture our dialyzers internally, within our 5,000 square foot facility in Rosdorf, Germany. We outsource the manufacture of our premixed dialysate and the System One cyclers, cartridges for the chronic care market and sterilization of our disposable cartridges.

The manufacturing process for our disposable cartridges for the critical care market includes the inspection, assembly, testing, packaging, and sterilization of components that have been manufactured to our specifications by various suppliers. 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 not made commitments to suppliers as exclusive providers of a particular product except KMC Systems, Inc., the outsourced manufacturer of the System One cycler. We have an agreement with KMC that provides us a committed supply in exchange for limited exclusivity, which expires upon our receipt of a specified number of cyclers. We expect this exclusivity requirement to expire in late 2006. Thereafter, the agreement may be renewed on a non-exclusive basis for additional one-year terms. The contract may be terminated upon a material breach, generally following a 30-day cure period. We may terminate the exclusivity provision earlier if KMC fails to supply our product requirements for two consecutive months.

We purchase bicarbonate-based premixed dialysate from B. Braun and our lactate-based premixed dialysate from B. Braun and other sources. 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 also purchase lactate-based premixed dialysate from Laboratorios PISA. We are negotiating a long-term supply agreement with PISA, which we expect to finalize shortly, that will obligate PISA to supply dialysate to us through 2008 in exchange for modest volume commitments. The contract may be terminated upon a material breach, generally following a 30-day cure period.

We expect to purchase our dialysate preparation module from Enercon. We are negotiating a short-term supply agreement with Enercon, which we expect to finalize shortly, that will obligate Enercon to supply this equipment to us for the next 12 months. There are no minimums 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 are currently negotiating a long-term supply agreement with Medisystems for our disposable cartridge. David Utterberg, a director and significant stockholder of NxStage, is the sole stockholder and chief executive officer of Medisystems. We are currently purchasing components and chronic disposable cartridges from Medisystems under purchase orders. We cannot be certain that we will enter into an agreement with Medisystems.

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. 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 Class I or Class II device or a Class III device that has been on the market on or prior to May 28, 1976, for which the FDA has not required pre-market application approval. 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 found by FDA to be not substantially equivalent to a legally marketed device or those devices that the FDA deems to pose the greatest risk, such as life-supporting or implantable devices. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a pre-market approval application.

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 chronic 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. Most recently, in June 2005, we received FDA clearance specifically allowing us to promote home hemodialysis using the System One. We have received a total of 20 product clearances from the FDA since our inception in December 1998. We continue to seek opportunities for product improvements and feature enhancements, which will, from time to time, require FDA clearance before market launch.

FDA Clearance Procedures

510(k) Clearance Pathway. When we are required to obtain a 510(k) clearance for a device, which we wish to market, we must submit a pre-market notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 (or to a pre-1976 class III device for which the FDA has not yet called for the submission of pre-market approval applications). 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, 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 overseeing the clinical trial. If FDA fails to respond to an IDE application within 30 days of receipt, the application is deemed approved, but institutional review board, or 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 submitting 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 follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- 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. As of December 31, 2005, we submitted 67 MDRs. Most of these have been submitted to comply with FDA's blood loss policy for routine dialysis treatments. This policy requires manufactures to file MDR reports related to routine dialysis treatments if the blood loss is greater than 20cc.

FDA Inspections. We have registered with the FDA as a medical device manufacturer. Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA, 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;
- 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 twice inspected our facility and quality systems. In our first inspection, one observation was made, but was rectified during the inspection, requiring no further response from us. The second inspection resulted in no observations. We cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facility.

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 the commencement of marketing of 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. We cannot provide assurance that we will be able to obtain regulatory approvals in any other markets.

The System One cyclor and related cartridges are regulated as medical devices in Canada under the Canadian Medical Device Regulations and in the European Union, or EU, under the Medical Device Directive. We have received four product licenses from Canada; and our System One is covered by a recently obtained Canadian license. 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 any products in Canada or in the European Union.

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, some enforcement officials have argued that 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, has 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 Law, 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 thereunder require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information, or PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates, as such term is defined by HIPAA, which, among other things, obligate the business associates to safeguard the covered entity's PHI against improper use and disclosure. While not directly regulated by HIPAA, a business associate may face significant contractual liability pursuant to such an agreement if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. In the course of our business operations, we have entered into several business associate agreements with certain of our customers that are also covered entities. Pursuant to the terms of these business associate agreements, we have agreed, among other things, not to use or further disclose the covered entity's PHI except as permitted or required by the agreements or as required by law, to use reasonable safeguards to prevent prohibited disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. Accordingly, we incur compliance related costs in meeting HIPAA-related obligations under business associates 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

Chronic 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; these clinics are, in turn, reimbursed by Medicare, Medicaid and private insurers.

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 a 30-month waiting period that follows the establishment of Medicare eligibility or entitlement based on ESRD. During the waiting 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 coordination period, Medicare will make payments up to the applicable composite rate for dialysis services reimbursed through 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 waiting period. Under current rules, Medicare is also the primary payor for ESRD patients during the 30-month coordination period under certain circumstances. Medicare remains the primary payor when an individual becomes eligible for Medicare on the basis of ESRD if, (a) the individual was already age 65 or over or was eligible for Medicare based on disability and (b) 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 is currently approximately \$155 per treatment. This is an increase from approximately \$132 per treatment in 2004, due to two recent changes in Medicare reimbursement. First, in 2005 and 2006, the Center 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. Second, Congress recently passed an additional 1.6% increase to the composite rate for 2006. Depending upon patient case mix, reimbursement may be further improved, based on the case-mix adjustment to the composite rate implemented as part of the Medicare Modernization Act in April 2005. Under the case-mix adjustment, Medicare now pays more for younger and larger patients. 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 a 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 more for dialysis services than Medicare.

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, 2005, NxStage had 153 full-time employees, three part-time employees and 20 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 Report 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 through our website (www.nxstage.com) under the "Investor Information" caption free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to the rules of the SEC. We are not including the information contained on our website as part of, or incorporating it by reference into, this report. You may read and copy materials that we have filed with the SEC at the SEC's public reference room located at 100 F. Street, N.E., Room 1580, Washington, D.C. 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 substantially all of our future revenues from the rental or sale of our System One and the sale of our related disposable products used with the System One.

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. We expect that the rental or sale of the System One and the sale of related products will account for substantially all of our revenues for the foreseeable future. Most of our related products cannot be used with any other dialysis systems and, therefore, we will derive little or no revenues from related products unless we sell or otherwise place the System One. To the extent that the System One is not a successful product or is withdrawn from the market for any reason, we do not have other products in development that could replace revenues from the System One.

We cannot accurately predict the size of the home hemodialysis market, and it may be smaller or slower to develop than we expect.

Although home hemodialysis treatment options are available, adoption 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 25,000 in 2002, 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; USRDS data indicates approximately 1,200 patients were receiving home-based hemodialysis in 2002. 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. Our long-term growth will depend on the number of patients who adopt home-based hemodialysis and how quickly they adopt it, and 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 or how many peritoneal dialysis patients will switch to home-based hemodialysis. We received our home use clearance for the System One from the FDA in June 2005 and we will need 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 chronic market is the largest market opportunity for our System One hemodialysis system. We typically bill the dialysis clinic for the rental of the equipment and the sale of the related disposable cartridges and treatment fluids. As a result, we expect that we will generate revenues and cash flow from the use of the cyclers over time rather than upfront from the sale of the cyclers, and we will need significant amounts of working capital to manufacture cyclers for rental to dialysis clinics.

We only recently began marketing our System One to dialysis clinics for the treatment of ESRD, and we have not achieved widespread market acceptance of our product. We may not be able to generate sufficient revenues and cash flow to meet our capital needs. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities. Any sale of additional equity or debt securities may result in additional 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, we may be required to delay, reduce the scope of, or eliminate one or more aspects of our business strategy, which could harm the growth of our business.

We have limited operating experience, a history of net losses and an accumulated deficit of \$84.0 million at December 31, 2005. 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, 2005, we had an accumulated deficit of approximately \$(84.0) million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, in the ESRD market, the cost of manufacturing the System One and related disposables currently exceeds the market price. We cannot provide assurance that we will be able to lower the cost of manufacturing the System One and related disposables below the current chronic market price, 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 in part upon achieving a sufficient scale of operations, obtaining improved purchasing terms and the implementation of design and process improvements to lower our costs of manufacturing our products.

Our dialysate preparation module, which we hope to introduce in the chronic market during the third calendar quarter of 2006, is an important part of our cost reduction plans. Any delay in our plans to introduce that product, or any failure to gain rapid market acceptance of that product, will impair our ability to achieve profitability. We submitted an application for clearance of our next generation of the dialysate preparation module to the FDA in February 2006. We cannot be certain that the FDA will clear our submission on a timely basis or that a delay in the market introduction of this product will not occur. We also cannot be certain that we will be able to gain rapid market acceptance of this product after FDA clearance is obtained.

We only recently began marketing our System One hemodialysis system to dialysis clinics for the treatment of ESRD, and our success will depend on our ability to achieve market acceptance of our System One.

We only recently began marketing our System One for the treatment of ESRD. Our products have limited product and brand recognition and have only been used at a limited number of dialysis clinics and hospitals. In the ESRD market, we will 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 will 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.

Current Medicare reimbursement rates limit the price at which we can market the System One, and adverse changes to reimbursement could affect the adoption of the System One.

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our System One. 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 and limits the fee for which we can rent the System One and sell the related disposable cartridges and treatment fluids. 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 may be slowed.

Although changes to the composite rate have been relatively infrequent, changes in Medicare reimbursement rates could negatively affect demand for our products and the prices we charge for them.

As we evolve from a company primarily involved in the development of dialysis products into one that is also involved in the commercialization of those products, we may have difficulty managing our growth and expanding our operations successfully.

As the commercial launch of the System One 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 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.

We compete against other dialysis equipment manufacturers with much greater financial resources and better established products and customer relationships, which may make it difficult for us to penetrate the market and achieve significant sales of our products.

Our System One competes directly against equipment produced by Fresenius Medical Care AG, Baxter Healthcare Corporation, Gambro AB, and others, each of which markets one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. In addition, Aksys, Ltd. sells a hemodialysis machine, which is also specifically cleared by the FDA for home use. Each of our competitors offers products that have been in use for a longer time than our products and are more widely recognized by physicians, patients and providers. Most of our 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, in the case of Fresenius, own and operate a chain of dialysis clinics. Most of these companies manufacture additional complementary products enabling them to offer a bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our 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 than our System One. 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 two largest dialysis clinic chains in the United States are affiliated with, or have contractual arrangements with, other dialysis equipment manufacturers, which may present a barrier to adoption of the System One at these chains.

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Fresenius controls approximately 35% of the U.S. dialysis clinics, on a pro forma basis assuming the completion of its pending acquisition of Renal Care Group and the completion of the recently announced sale of 100 clinics to National Renal Institutes. Fresenius is also the largest worldwide manufacturer of dialysis systems. DaVita controls approximately 28% 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 to patients in their dialysis clinics 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. We are presently renting the System One to several DaVita dialysis clinics. We cannot be sure that DaVita will continue to rent the System One from us or that any future decision by DaVita to stop using the System One would not adversely affect our business.

If kidney transplantation becomes a viable treatment option for more patients with ESRD, the market for our System One 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 2002 approximately 15,700 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 System One.

If we are unable to convince hospitals and healthcare providers of the benefits of our products for the treatment of acute kidney failure and fluid overload, we may not be successful in penetrating 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 and ease of operation.

Fluid overload resulting from congestive heart failure is most often treated with a variety of drugs rather than with ultrafiltration because ultrafiltration is a less well-known, less studied treatment option and as a result, there is a lack of clinical evidence to support its effectiveness. Because the System One would be used to deliver ultrafiltration, we will need to convince hospitals, healthcare providers and third-party payors that ultrafiltration using the System One is as effective and cost-efficient as existing treatments for fluid overload resulting from congestive heart failure.

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

If our System One 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. As is the case with a number of other medical device companies, it is likely that product liability claims will be brought against us. Since their introduction into the market, our products have been subject to two voluntary recalls and one voluntary product withdrawal. Our first voluntary recall occurred in February 2001 in Canada and related to a software glitch that we detected in our predecessor system, which could have increased the likelihood of a clotted filter during treatment. There were no patient injuries associated with this recall, and the software glitch was remedied with a subsequent software release. The second voluntary recall occurred in April 2004 in the United States relating to pinhole-sized dialysate leaks in our cartridge. The leaks were readily observable and required a cartridge replacement to continue treatment. There were no patient injuries associated with this recall; we subsequently switched suppliers and instituted additional testing requirements to minimize the chance for pinhole-sized leaks in our cartridges. The voluntary market withdrawal occurred in the United States in May 2002 when we suspended sales of our predecessor system while we addressed issues involving limited instances of contaminated hemofiltration fluids compounded by a pharmacy and supplied by a third-party. Six patients exposed to contaminated fluids reported fevers and/or chills, with no lasting clinical effect. We subsequently modified our cartridge to allow for an additional filter to remove contaminants from fluids used with our product. Our products may be subject to further recalls or withdrawals, which could increase the likelihood of product liability claims. We have also received several reports of operator error from both patients in the home hemodialysis setting and nurses in the critical care setting. Instances of operator error could also increase the likelihood of product liability claims.

Although we maintain insurance, including product liability insurance, we cannot provide assurance that any claim that may be brought against us will not 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 have had limited sales, marketing, customer service and distribution experience. We need to expand our sales and marketing, customer service and distribution infrastructures to be successful in penetrating the dialysis market.

We currently market and sell the System One through our own sales force, and we have had limited experience in sales, marketing and distribution of dialysis products. As of December 31, 2005, we had 65 employees in our sales, marketing and distribution organization, including 20 direct sales representatives. We plan to expand our sales, marketing, customer service and distribution infrastructures. We cannot provide assurance that we will be able to attract experienced personnel to our early-stage company and build an adequate sales and marketing, customer service and distribution staff or that the cost will not be prohibitive.

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 Lawrence, Massachusetts, we operate a manufacturing facility in Rosdorf, Germany and we 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. These risks include fluctuations in foreign currency exchange rates that may increase the U.S. dollar cost of the disposables we purchase from foreign third-party suppliers, 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.

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 System One and related products, including the disposables required for its use, are all 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 the System One. 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 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 technological change 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 the System One 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 substantially equivalent 510(k) decision. Also, PMA products require approval supplements for any change that affects safety and effectiveness before the modified device may be marketed. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our products, which will have a negative effect on our revenues growth.

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

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

- untitled letters, warning letters, fines, injunctions and civil penalties;
- administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;
- customer notification, or orders for repair, replacement or refund;
- voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to review pre-market notification or pre-market approval submissions;
- rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and
- criminal prosecution.

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

Complex medical devices, such as the System One, 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. A recall involving the System One could be particularly harmful to our business and financial results, because the System One is our only product.

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 U.S. manufacturing facility has previously had two FDA QSR inspections. The first resulted in one observation, which was rectified during the inspection and required no further response from us. The second inspection resulted in no observations. 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, recalling of 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 treatment for ESRD could affect the adoption of our System One and the level of our future product revenues.

In the United States, all patients who suffer from ESRD, regardless of age, are eligible for coverage under Medicare, after a requisite waiting period if other insurance is available. As a result, more than 80% of patients with ESRD are covered by Medicare. Although we rent and sell our products to hospitals, dialysis centers and other healthcare providers and not directly to patients, the reimbursement rate for ESRD treatments is an important factor in a potential customer's decision to purchase the System One. The dialysis centers that purchase our product rely on adequate third-party payor coverage and reimbursement to maintain their ESRD facilities. There is some regional variation in the composite rate for dialysis services, but the national average rate is currently approximately \$155 per treatment, which is intended to cover most items and services related to the treatment of ESRD, but does not include payment for physician services or separately billable laboratory services or drugs. Although Congress has periodically adjusted the composite rate, changes have been infrequent. Changes in Medicare reimbursement rates could negatively affect demand for our products and the prices we charge for them.

Most ESRD patients who use our product for dialysis therapy in the home treat themselves six times per week. CMS rules, however, limit the number of hemodialysis treatments paid for by Medicare to three a 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. 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.

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 diagnosis related 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.

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, and the ultimate effect on NxStage. 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 European Union 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 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 System One operations 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 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 NxStage. 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 System One 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 the System One 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 depend on the services of our senior executives and certain key engineering, scientific, clinical and marketing personnel, the loss of whom could negatively affect our business.

Our success depends upon the skills, experience and efforts of our senior executives and other key personnel, including our chief executive officer, certain members of our engineering staff, our marketing executives and managers and our clinical educators. Much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. We have

agreements with all of our executive officers that contain non-competition provisions that may prevent a former employee of ours from working for a competitor for a period of time; however, these clauses may not be enforceable, or enforceable only in part, or the company may choose not to seek enforcement. We do not maintain "key man" life insurance on any of our senior executives, other than our chief executive officer.

We obtain some of the components, subassemblies and completed products included in the System One from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenues.

We depend on single source suppliers for some of the components and subassemblies we use in the System One. KMC Systems, Inc. is our only contract manufacturer of the System One cyclor; 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 a primary supplier of lactate-based dialysate and Medisystems Corporation is our primary supplier of tubing and certain other components used in the System One disposable cartridge, and will soon be our sole supplier of chronic disposable cartridges. We also obtain certain other components included in the System One from other single source suppliers or a limited group of suppliers. Medisystems is a related party to NxStage. David Utterberg, the chief executive officer and sole stockholder of Medisystems, is a member of our board of directors and as of December 31, 2005, held approximately 9.3% of our common stock. 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, or an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation, or cause customers to switch 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 weekly 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 some cases, 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 and, potentially, further FDA clearance or approval of any modification, thereby causing further costs and delays.

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

We purchase components and subassemblies from third-party suppliers, including some of our 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 to us 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 these suppliers. If we inaccurately forecast demand for components or subassemblies, our ability to manufacture and commercialize the System One 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.

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 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, 2005, we had 66 pending patent applications, including foreign, international and U.S. applications, and 20 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 Ownership

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;
- 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.

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 53% of our outstanding common stock. As a result, these stockholders, if acting together, will have the ability to determine the outcome of all 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.

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 21,176,554 shares of common stock outstanding as of December 31, 2005. 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 211,766 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. Approximately 14,692,000 shares, or 69.4%, of our outstanding shares are currently restricted as a result of securities laws or lock-up agreements. In connection with our initial public offering of common stock, officers, directors and a substantial majority of our other stockholders agreed, with exceptions, not to sell or transfer any common stock until April 24, 2006, subject to extension by up to an additional 34 days by Merrill Lynch, Pierce, Fenner & Smith Incorporated. Upon expiration or termination of these lock-up agreements, approximately 2,900,000 shares of common stock will be freely tradeable.

Subject to certain conditions, holders of an aggregate of approximately 13,401,000 shares of common stock have rights with respect to the registration of these shares of common stock with the 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, 2005, 2,683,286 shares were subject to outstanding options, of which 1,448,571 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 National 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 National 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.

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 also lease approximately 24,000 square feet of warehousing and manufacturing space in North Andover, Massachusetts and 5,000 square feet of manufacturing and office space in Rosdorf, Germany, under leases expiring in 2012 and 2006, respectively. 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.

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

The information contained in the Section "Submission of Matters to a Vote of Security Holders" of the Company's Quarterly Report on Form 10-Q for the Third Quarter of 2005, and filed with the SEC in December 2005, is incorporated in this Annual Report or Form 10-K by reference.

EXECUTIVE OFFICERS OF THE REGISTRANT

Executive Officers

The following is a list of names, ages and background of our current executive officers:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Jeffrey H. Burbank	43	President, Chief Executive Officer
David N. Gill	51	Senior Vice President, Chief Financial Officer and Treasurer
Philip R. Licari	47	Senior Vice President and Chief Operating Officer
Winifred L. Swan	41	Senior Vice President, General Counsel and Secretary
Joseph E. Turk, Jr.	38	Senior Vice President, Commercial Operations

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; he is currently a director of Vasca. Mr. Burbank is on the Board of the National Kidney Foundation. He holds a B.S. from Lehigh University.

David N. Gill has been our Senior Vice President, Chief Financial Officer and Treasurer since July 2005. He served as Senior Vice President and Chief Financial Officer of CTI Molecular Imaging, Inc., a publicly-traded medical equipment company, from January 2002 to May 2005, before its sale. Previously, he served from February 2000 to March 2001 as Chief Financial Officer and Director, and from January 2001 to August

2001 as President, Chief Operating Officer, and Director, of Interland, Inc., a publicly-traded telecom-related company, before its sale. Mr. Gill served from July 1996 to February 2000 as Chief Financial Officer and from February 1997 to February 2000 as Chief Operating Officer of Novoste Corporation, a publicly-traded medical device company. He holds a B.S. degree, *cum laude*, in Accounting from Wake Forest University and an M.B.A. degree, with honors, from Emory University, and was formerly a certified public accountant.

Philip R. Licari has been our Senior Vice President since January 2005 and our Vice President and Chief Operating Officer since October 2004. From August 1996 to October 2004, Mr. Licari was employed at Boston Scientific Corporation, a worldwide developer, manufacturer and marketer of medical devices, where he held vice president positions in Global Supply Chain, Clinical Operations, and Corporate Sales/National Accounts. Mr. Licari earned a B.S. in Biomedical Engineering from Tufts University and an M.B.A. in finance from the University of Chicago Graduate School of Business.

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.

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 National Market under the symbol "NXTM" since October 27, 2005. Prior to that time, there was no public market for our stock. The high and low sales prices for our common stock during the fourth quarter ended December 31, 2005 were \$14.20 and \$9.10, respectively.

Holders

On February 27, 2006, the last reported sale price of our common stock was \$14.52 per share. As of February 17, 2006, there were approximately 117 holders of record of our common stock and approximately 1,500 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes, as of December 31, 2005, the number of outstanding warrants and options issued under our equity compensation plans and the number of awards available for future issuance under these plans:

<u>Plan Category</u>	<u>(a)</u> <u>Number of Securities</u> <u>to be Issued Upon</u> <u>Exercise of</u> <u>Outstanding Options,</u> <u>Warrants and Rights</u>	<u>(b)</u> <u>Weighted-Average</u> <u>Exercise Price of</u> <u>Outstanding Options,</u> <u>Warrants and Rights</u>	<u>(c)</u> <u>Number of Securities</u> <u>Remaining Available for</u> <u>Future Issuance Under</u> <u>Equity Compensation</u> <u>Plans, Excluding</u> <u>Securities Reflected</u> <u>in Column (a)(1)</u>
Equity compensation plans approved by security holders	2,855,607	\$6.31	767,001
Equity compensation plans not approved by security holders	<u>—</u>	<u>—</u>	<u>—</u>
Total	<u><u>2,855,607</u></u>	<u><u>\$6.31</u></u>	<u><u>767,001</u></u>

(1) Column (c) represents 717,001 shares that are available for issuance under our 2005 Stock Incentive Plan and 50,000 shares that are available for issuance under our 2005 Employee Stock Purchase Plan as of December 31, 2005. The number of shares available for grant under the 2005 Stock Incentive Plan will be increased annually beginning in 2007 by the least of (i) 600,000 shares, or (ii) 3% of the then outstanding shares of our common stock, or (iii) a number determined by the board of directors.

Use of Proceeds

We registered shares of our common stock in connection with our initial public offering under the Securities Act of 1933, as amended. The Registration Statement on Form S-1 (File No. 333-126711) filed in connection with our initial public offering was declared effective by the SEC on October 27, 2005. The offering commenced on October 27, 2005 and did not terminate before any securities were sold. We sold 5,500,000 shares of our registered common stock in the initial public offering and an additional 825,000 shares of our registered common stock in connection with the underwriters' exercise of their over-allotment option. The underwriters of the offering were Merrill Lynch, Pierce, Fenner & Smith Incorporated, Thomas Weisel Partners LLC, William Blair & Company and JMP Securities LLC.

All 6,325,000 shares of our common stock registered in the offering were sold at the initial public offering price of \$10 per share. The aggregate purchase price of the offering was \$63,250,000. The net offering proceeds received by us, after deducting expenses incurred in connection with the offering was approximately \$56.5 million. These expenses consisted of direct payments of:

- i. (a) \$4.4 million in underwriters discounts, fees and commissions,,
- ii. (b) \$1.6 million in legal, accounting and printing fees, and
- iii. (c) \$0.7 million in miscellaneous expenses.

No payments for such expenses were directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We closed our initial public offering on November 1, 2005, and we have invested the aggregate net proceeds in short-term investment-grade securities and money market accounts.

We currently estimate that of the net proceeds from the initial public offering, we will spend approximately \$24.5 million to finance working capital needs, including investment in System One field equipment and in sales and marketing programs, including hiring additional personnel; approximately \$30.0 million to fund continuing operations and approximately \$2.0 million to expand our manufacturing

capabilities. We have not yet used the proceeds of the offering, but have instead used working capital in existence prior to the initial public offering to fund our ongoing operations. We expect to use the net proceeds of the offering beginning in 2006.

Issuer Purchases of Equity Securities

We made no repurchases of our equity securities during the fourth quarter ended December 31, 2005.

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, 2005, 2004 and 2003 and balance sheet data as of December 31, 2005 and 2004 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, 2002 and 2001 and balance sheet data as of December 31, 2003, 2002 and 2001 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,				
	2005	2004	2003	2002	2001
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues.....	\$ 5,994	\$ 1,885	\$ 286	\$ 30	\$ —
Cost of revenues	9,585	3,439	940	404	—
Gross profit (deficit).....	<u>(3,591)</u>	<u>(1,554)</u>	<u>(654)</u>	<u>(374)</u>	<u>—</u>
Operating expenses:					
Research and development	6,305	5,970	4,526	5,913	7,669
Selling and marketing	7,550	3,334	2,181	2,286	1,908
Distribution	2,059	495	33	6	—
General and administrative.....	4,855	3,604	2,868	2,554	2,219
Total operating expenses.....	<u>20,769</u>	<u>13,403</u>	<u>9,608</u>	<u>10,759</u>	<u>11,796</u>
Loss from operations	(24,360)	(14,957)	(10,262)	(11,133)	(11,796)
Other income (expense), net.....	<u>(120)</u>	<u>115</u>	<u>54</u>	<u>153</u>	<u>(447)</u>
Net loss.....	<u>\$(24,480)</u>	<u>\$(14,842)</u>	<u>\$(10,208)</u>	<u>\$(10,980)</u>	<u>\$(12,243)</u>
Net loss per share, basic and diluted.....	<u>\$ (4.31)</u>	<u>\$ (5.81)</u>	<u>\$ (4.10)</u>	<u>\$ (4.66)</u>	<u>\$ (5.63)</u>
Weighted-average shares outstanding, basic and diluted.....	<u>5,681</u>	<u>2,556</u>	<u>2,490</u>	<u>2,356</u>	<u>2,176</u>
Balance Sheet Data(1):					
Cash, cash equivalents and marketable securities	\$ 61,223	\$ 18,134	\$ 8,881	\$ 4,028	\$ 17,640
Working capital	62,100	19,205	11,115	5,235	16,329
Total assets	76,431	25,455	13,613	7,983	19,306
Long-term liabilities	2,106	3,006	30	146	282
Redeemable convertible preferred stock	—	75,946	55,946	40,006	40,006
Accumulated deficit	(84,011)	(59,496)	(44,623)	(34,368)	(23,388)
Total stockholders' equity (deficit).....	67,354	(57,400)	(43,478)	(33,271)	(22,427)

(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.

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 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. We believe the largest market opportunity for our product is the home hemodialysis market for the treatment of ESRD.

From our inception in 1998 until 2002 our operations consisted primarily of start-up activities, including designing and developing the System One, recruiting personnel and raising capital. Historically, research and development costs have been our single largest operating expense. However, with the launch of the System One in the home chronic market, selling and marketing costs have become our largest operating expense in 2005 as we continue to expand our United States sales force to penetrate our markets and grow revenues.

Our overall strategy since inception has been to (a) design and develop new products for the treatment of kidney failure, (b) establish that the products are safe, effective and cleared for use in the United States, (c) further enhance the product design through field experience from a limited number of customers, (d) establish reliable manufacturing and sources of supply, (e) execute a market launch in both the chronic and critical care markets and establish the System One as a preferred system for the treatment of kidney failure, (f) obtain the capital necessary to finance our working capital needs and build our business and (g) achieve profitability. The evolution of NxStage, and the allocation of our resources since we were founded, reflects this plan. We believe we have largely completed steps (a) through (d), and we plan to continue to pursue the other strategic objectives described above.

We sell our products in two markets: the chronic market and the critical care market. We define the chronic market as the market devoted to the treatment of patients with ESRD 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 market. The FDA has cleared both configurations for hemodialysis, hemofiltration and ultrafiltration. Our products may be used by our customers to treat patients suffering from either condition, although the site of care, the method of delivering care and the duration of care are sufficiently different that we have separate marketing and sales efforts dedicated to each market.

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 in the chronic market and commenced full commercial introduction in the chronic market in September 2004 in the United States. 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 indication did not include a specific home clearance, and we were not able to promote the System One for home use at that time. In order to be able to specifically promote the System One for home use, the FDA required that we conduct a clinical study, referred to as an investigational device exemption study, or IDE, comparing center-based and home-based therapy with the System One. After submitting the results of that study to the FDA, together with an application for a specific home indication for the System One, the FDA cleared our System One in June 2005 for hemodialysis in the home.

Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. Reimbursement claims for the System One therapy 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. Expanding Medicare reimbursement over time to cover more frequent therapy may be critical to our market penetration and revenue growth in the future.

Our System One is produced through internal and outsourced manufacturing. We purchase many of the components and subassemblies included in the System One from third-party manufacturers, some of which are single source suppliers. In addition to outsourcing with third-party manufacturers, we assemble, package and label disposable cartridges in our leased facility in Lawrence, Massachusetts. In August 2002, we organized EIR Medical, Inc., a Massachusetts corporation and wholly-owned subsidiary of NxStage. EIR Medical is the sole manufacturer of the dialyzer filter that is a component of the disposable cartridges used with the System One. Since its organization, EIR Medical has conducted its manufacturing in Rosdorf, Germany through a branch operation. In recognition of our growing presence in Germany, we recently organized NxStage GmbH & Co. KG, a wholly-owned German subsidiary of EIR Medical. We contributed the German branch of EIR Medical to NxStage GmbH & Co. KG effective January 1, 2006.

We market the System One through a direct sales force in the United States primarily to dialysis clinics and hospitals. We only recently began a broad commercial introduction of our System One and we expect revenues to continue to increase in the near future. Our revenues were \$6.0 million in 2005, a 218% increase from revenues of \$1.9 million in 2004. We have increased our combined sales force from 6 sales representatives as of December 31, 2004, to 20 sales representatives as of December 31, 2005, and we plan to add additional sales and marketing personnel as needed in 2006. As of December 31, 2005, 292 ESRD patients were using the System One at 70 dialysis clinics, compared to 45 ESRD patients at 10 dialysis clinics as of December 31, 2004. In addition, as of December 31, 2005, 50 hospitals were using the System One for critical care therapy, compared to 20 hospitals as of December 31, 2004.

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

	Years Ended December 31,					
	2005		2004		2003	
Critical care	\$2,829,960	47.2%	\$1,332,053	70.7%	\$268,576	93.9%
Chronic	3,163,779	52.8%	552,516	29.3%	17,378	6.1%
Total	<u>\$5,993,739</u>	100%	<u>\$1,884,569</u>	100%	<u>\$285,954</u>	100%

For the year ended December 31, 2005, we generated a net loss of \$(24.5) million, bringing our accumulated deficit balance to \$(84.0) million. We have not been profitable since inception, and we expect to incur net losses for the foreseeable future as we expand our sales efforts and grow our operations. Our goal is to increase our sales volume and revenues to gain scale of operation and to drive product cost reductions, which we believe, when combined with other design improvements, will allow us to reach profitability. We expect our revenues in the chronic market to grow faster than those in the critical care market and believe they will continue to represent the majority of our revenues.

Statement of Operations Components

Revenues

Our products consist of the NxStage System One cyclor, an electromechanical device used to circulate the patient's blood during therapy; a single-use, disposable cartridge, which contains a preattached dialyzer, and dialysate fluid used in our therapy. We sell our products in two markets: the chronic market and the critical care market. We define the chronic market as the market devoted to the treatment of ESRD patients in the home and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. We offer a different configuration of the System One for each market. The FDA has cleared both configurations for hemodialysis, hemofiltration and ultrafiltration. Our products may be

used by our customers to treat patients suffering from either condition, although the site of care, the method of delivering care and the duration of care are sufficiently different that we have separate marketing and sales efforts dedicated to each market.

We derive our revenues from the sale and rental of equipment and the sale of the related disposable cartridges and treatment fluids. In the critical care market, we generally sell the cyclers and disposables to hospital customers. In the chronic market, customers generally rent the machine and then purchase the related disposable cartridges and treatment fluids based on a specific patient prescription. We generally recognize revenues when a product has been delivered to our customer, or, in the chronic market, 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. Our contracts with dialysis centers for ESRD patients include purchase and rental terms providing for the sale of cartridges and fluids to accommodate up to 26 treatments a month per patient and the monthly rental of System One cyclers. These contracts typically have a term of one year and are cancelable at any time by the dialysis clinic with 30 days' notice. Under the contract, 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. We do not currently derive any revenues from service contracts. Over time, as more chronic patients are treated with the System One and more systems are placed in patient homes under monthly agreements that provide for the rental of the machine and the purchase of the related disposable cartridges and treatment fluids, we expect that a recurring revenue stream will become a meaningful component of our revenues.

Cost of Revenues

Cost of revenues consists primarily of direct product costs, including material and labor required to manufacture our products, depreciation and maintenance of System One cyclers that we rent to customers, production overhead and the cost of purchasing system components from vendors which we then resell to our customers. It also includes the cost of inspecting, servicing and repairing equipment prior to sale or during the warranty period. The cost of our products depends on several factors, including the efficiency of our manufacturing operations, the cost at which we can obtain products from third party suppliers, and the design of the products.

We are currently operating at negative gross profit as we are building a base of recurring revenues. We expect the cost of revenues as a percentage of revenues to decline over time for two general reasons: first, we anticipate that increased sales volume will lead to efficiencies in purchases, production and reduced material costs. Second, we have plans to introduce several process and product design changes that have inherently lower cost than our current products. We expect that over time unit cost of revenues will become less than unit revenues as we build the scale of our operations.

Operating Expenses

Research and Development. Research and development expenses consist primarily of salary and benefits 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 continue to increase in the foreseeable future as we seek to further enhance our System One and related products, but not as rapidly as other expense categories as we have substantially completed basic development of the System One.

Selling and Marketing. Selling and marketing expenses consist primarily of salary and benefits 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 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 the System One. We anticipate that selling and marketing expenses will

continue to increase as we broaden our marketing initiatives, particularly in the chronic market, to increase public awareness of the System One, as we add additional sales and marketing personnel and due to variable compensation plans tied to future sales growth.

Distribution. Distribution expenses include the cost of delivering our products to our customers, or our customers' patients, depending on the market and the specific agreement with our customers. 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 to our service center for repair if the product is under warranty, and the related expense of shipping a replacement product back to our customers. We expect that distribution expenses will increase at a lower rate than revenues, due to expected efficiencies from increased sales and rental volume and the use of outsourced logistics providers.

General and Administrative. General and administrative expenses consist primarily of salary and benefits for executive management, legal, including fees to outside legal counsel, finance and accounting, including fees for our annual audit and tax services, and general expenses to operate the business, including insurance and other corporate-related expenses. Rent and utilities are included in general and administrative expense and 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 support structure for our growing business and as a result of becoming a public company.

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.

	<u>Years Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Revenues	100%	100%	100%
Cost of revenues	<u>160</u>	<u>183</u>	<u>329</u>
Gross profit (deficit)	<u>(60)</u>	<u>(83)</u>	<u>(229)</u>
Operating expenses:			
Research and development	105	317	1583
Selling and marketing	126	177	763
Distribution	34	26	11
General and administrative	<u>81</u>	<u>191</u>	<u>1003</u>
Total operating expenses	<u>346</u>	<u>711</u>	<u>3360</u>
Loss from operations	<u>(406)</u>	<u>(794)</u>	<u>(3589)</u>
Other income (expense):			
Interest income	11	7	51
Interest expense	<u>(13)</u>	<u>(1)</u>	<u>(32)</u>
	<u>(2)</u>	<u>6</u>	<u>19</u>
Net loss	<u>(408)%</u>	<u>(788)%</u>	<u>(3570)%</u>

Comparison of Years Ended December 31, 2005 and 2004

Revenues

Our revenues for 2005 and 2004 were as follows:

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
Revenues	<u>\$5,994</u>	<u>\$1,885</u>	<u>\$4,109</u>	218%

The increase in revenues was attributable to increased sales and rentals of the System One in both the chronic and critical care markets, primarily as a result of increased sales and marketing efforts as we continue our commercial launch of the System One. Revenues in the chronic market increased to \$3.2 million in 2005 from \$0.6 million in 2004, an increase of 473%, while revenues in the critical care market increased 112% to \$2.8 million in 2005, compared to \$1.3 million in 2004.

Cost of Revenues and Gross Profit (Deficit)

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
Cost of revenues	<u>\$ 9,585</u>	<u>\$ 3,439</u>	<u>\$6,146</u>	179%
Gross profit (deficit)	<u>\$(3,591)</u>	<u>\$(1,554)</u>	<u>\$2,037</u>	131%
Gross profit percentage	<u>(59.9)%</u>	<u>(82.4)%</u>		

The increase in cost of revenues was attributable to our increased revenues. Contributing to the 2005 negative gross margin was a lower of cost or market valuation allowance in the amount of \$0.3 million relating to disposable cartridge and fluid inventory designated for the chronic market, as well as service costs of approximately \$0.5 million to upgrade 100 older cyclers to meet the specifications of our current product generation. We are currently operating at negative gross profit as we are building a base of recurring revenues. We expect the cost of revenues as a percentage of revenues to decline over time as increased sales volume should lead to efficiencies in production, better purchasing terms and reduced material costs, and as we introduce product design changes to lower the manufacturing cost of our current products. We expect that over time unit cost of revenues will become less than unit revenues as we build the scale of our operations.

Research and Development

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
Research and development	<u>\$6,305</u>	<u>\$5,970</u>	<u>\$335</u>	6%
Research and development as a percentage of revenues	<u>105%</u>	<u>317%</u>		

The increase in research and development expenses was attributable to increased salary and benefits of approximately \$840,000 as a result of increased headcount and development costs associated with our dialysate preparation module, or DPM, partially offset by a decrease of approximately \$520,000 in clinical trial expenses due to the completion of the IDE home trial for System One in 2004. We expect research and development expenses will continue to increase in the foreseeable future as we seek to further enhance our System One and related products, but not 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.

Selling and Marketing

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
Selling and marketing	<u>\$7,550</u>	<u>\$3,334</u>	<u>\$4,216</u>	126%
Selling and marketing as a percentage of revenues	<u>126%</u>	<u>177%</u>		

The increase in selling and marketing expenses was the result of several factors. Approximately \$2.7 million of the increase was due to higher salary and benefits resulting from increased headcount, approximately \$0.8 million of the increase related to higher travel expenses and the balance of the increase was due to a generally higher level of sales and marketing activity in both the chronic and critical care markets. We increased our sales force from six sales representatives as of December 31, 2004, to 20 sales representatives as of December 31, 2005. We anticipate that selling and marketing expenses will continue to increase in absolute dollars as we broaden our marketing initiatives, particularly in the chronic market, to increase public awareness of the System One and as we add additional sales and marketing personnel.

Distribution

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
Distribution	<u>\$2,059</u>	<u>\$495</u>	<u>\$1,564</u>	316%
Distribution as a percentage of revenues	<u>34%</u>	<u>26%</u>		

The increase in distribution expenses was due to increased volume of shipments of disposable products to a growing number of patients in the chronic market. We expect that distribution expenses will increase at a lower rate than revenues due to expected efficiencies from increased business volume and the use of an outsourced logistics provider located in the central part of the continental United States.

General and Administrative

	Year Ended		Increase	Percentage Increase
	December 31, 2005	December 31, 2004		
	(In thousands, except percentages)			
General and administrative	<u>\$4,855</u>	<u>\$3,604</u>	<u>\$1,251</u>	35%
General and administrative as a percentage of revenues	<u>81%</u>	<u>191%</u>		

The increase in general and administrative expenses was primarily due to an increase in salary and benefits as a result of the addition of four employees to headcount as well as the adoption of a management bonus plan in 2005. We expect that general and administrative expenses will continue to increase in the near term as we add support structure for our growing business and as a result of costs related to operating a public company.

Interest Income and Interest Expense

Interest income is derived primarily from U.S. government securities, certificates of deposit and money market accounts. For the year ended December 31, 2005, interest income increased to \$0.6 million from \$0.1 million in 2004 primarily due to increased cash and investment balances after our initial public offering and slightly higher interest rates in 2005.

Interest expense relates to a debt agreement signed in December 2004. Interest expense increased from \$15,000 to \$763,000, or approximately \$748,000 in 2005 compared to 2004 due to this indebtedness being outstanding for a full calendar year.

Comparison of Years Ended December 31, 2004 and 2003

Revenues

Our revenues for 2004 and 2003 were as follows:

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
Revenues	<u>\$1,885</u>	<u>\$286</u>	<u>\$1,599</u>	559%

The increase in revenues was attributable to an increase in the sales and rentals of the System One and sales of the related disposable cartridges and treatment fluids in the critical care market in 2004, with 71% of revenues derived from this market. The remaining 29% of revenues resulted from growth in sales of the System One in the chronic market, primarily related to our IDE study that was initiated in late 2003 and continued in 2004 as well as our commercialization efforts in the chronic market that we commenced in September 2004.

Cost of Revenues and Gross Profit

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
Cost of revenues	<u>\$ 3,439</u>	<u>\$ 940</u>	<u>\$2,499</u>	266%
Gross profit	<u>\$(1,554)</u>	<u>\$ (654)</u>	<u>\$ 900</u>	138%
Gross profit percentage	<u>(82.4)%</u>	<u>(228.9)%</u>		

The increase in cost of revenues was directly attributable to the increase in sales volume and to the increased size of our service department which supported the increase in units sold. In both 2003 and 2004, cost of revenues exceeded our revenues as the scale of our operations did not afford opportunities for unit cost reductions that we expect will be associated with efficiency gains and improved purchasing terms resulting from higher unit volume production.

Research and Development

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
Research and development	<u>\$5,970</u>	<u>\$4,526</u>	<u>\$1,444</u>	32%
Research and development as a percentage of revenues	<u>317%</u>	<u>1583%</u>		

The increase in research and development expenses was attributable to third-party consulting and other expenses associated with the two concurrent clinical trials conducted in 2004: (a) an IDE trial related to home use of our system, and (b) a clinical trial to investigate the effectiveness of ultrafiltration as a means of addressing fluid overload in patients suffering from congestive heart failure. Total clinical expenses amounted to approximately \$1.6 million, or 25% of the total research and development expense in 2004. In addition, salary and benefits increased as a result of an increase in research and development headcount from seven employees to 34 employees by year end 2004. A small portion of the increase in research and development

expenses was attributable to the design and development of a new dialyzer to reduce manufacturing costs for higher volume production.

Selling and Marketing

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
Selling and marketing	<u>\$3,334</u>	<u>\$2,181</u>	<u>\$1,153</u>	53%
Selling and marketing as a percentage of revenues	<u>177%</u>	<u>763%</u>		

The increase in selling and marketing expenses was primarily attributable to an increase in salary and benefits as a result of increased headcount in the selling and marketing organization from 11 employees at December 31, 2003 to 24 employees at December 31, 2004 to facilitate the commercial launch of the System One in the chronic market. Expenses per sales representative increased due to an increase in travel to customers and potential customers.

Distribution

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
Distribution	<u>\$495</u>	<u>\$33</u>	<u>\$462</u>	1400%
Distribution as a percentage of revenues	<u>26%</u>	<u>11%</u>		

The increase in distribution expenses was attributable to the increase in units shipped and the sale of associated disposables in the critical care and chronic markets.

General and Administrative

	Year Ended		Increase	Percentage Increase
	December 31, 2004	December 31, 2003		
	(In thousands, except percentages)			
General and administrative	<u>\$3,604</u>	<u>\$2,868</u>	<u>\$736</u>	26%
General and administrative as a percentage of revenues	<u>191%</u>	<u>1003%</u>		

The increase in general and administrative expenses was attributable to an increase of approximately \$496,000 in salary and benefits resulting from an increase in general and administrative headcount by four employees to 11 employees at December 31, 2004, as well as an increase of approximately \$270,000 in accounting and legal fees.

Interest Income and Interest Expense

Interest income decreased by 11% to \$130,347 in 2004 from \$146,047 in 2003 due to a decrease in cash and investment balance in 2004 as compared to 2003. Interest expense decreased by 84% to \$14,542 in 2004 from \$91,985 in 2003 as a result of interest expense associated with warrants issued in 2003 in connection with obtaining a revolving line of credit.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of December 31, 2005, our accumulated deficit was \$(84.0) million and we had cash and cash equivalents of approximately \$61.2 million. 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 \$56.5 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. In December 2004, we obtained \$5.0 million of debt financing, which is repayable monthly with interest over three years through December 2007. In connection with this debt financing, we granted the lender a security interest in our assets.

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

	Years Ended December 31,		
	2005	2004	2003
Net cash used in operating activities	\$(27,348)	\$(15,172)	\$(10,836)
Net cash used in investing activities	(1,204)	(306)	(78)
Net cash provided by financing activities	71,782	24,704	15,769
Effect of exchange rate changes on cash	(141)	28	(2)
Net cash flow	<u>\$ 43,089</u>	<u>\$ 9,254</u>	<u>\$ 4,853</u>

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 amortization of deferred stock-based compensation. Significant uses of cash from operations include 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 for the placement of rental units with our customers represented \$4.4 million and \$1.1 million, respectively, during the years ended December 31, 2005 and December 31, 2004.

Net Cash Used in Investing Activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, primarily for research and development, information technology, manufacturing operations and capital improvements to our facilities. Excluded from these figures are our investments in and maturity of short-term investments, which are included as marketable securities in the consolidated balance sheets.

Net Cash Provided by Financing Activities. Net cash provided by financing activities primarily reflect net proceeds from our initial public offering of approximately \$56.5 million in November 2005, net proceeds from the sale of \$16.0 million of convertible preferred stock in July 2005 and \$0.7 million from the exercise of stock options and warrants, partially offset by the repayment of \$1.4 million of debt. During 2004, proceeds from debt raised totaled \$5.0 million, offset by \$0.3 million of debt repayment. During 2004 and 2003, net proceeds from the issuance of convertible preferred stock totaled \$20.0 million and \$15.9 million, respectively.

We expect to continue to incur net losses for the foreseeable future. We expect that our current cash position is sufficient to support operations at least through 2006. In the longer term, we expect to fund the working capital needs of our operations with revenue generated from product placements and sales but these resources may prove insufficient. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to sell additional equity or debt securities. Any sale of additional equity or debt securities may 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 could harm the growth of our business.

The following table summarizes our contractual commitments as of December 31, 2005 and the effect those commitments are expected to have on liquidity and cash flow in future periods:

	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
	(In thousands)				
Notes payable(1)	\$ 4,078	\$ 1,654	\$2,424	\$ —	\$ —
Operating leases	3,533	511	1,037	1,093	892
Purchase obligations(2)	16,904	16,704	100	100	—
Total	<u>\$24,515</u>	<u>\$18,869</u>	<u>\$3,561</u>	<u>\$1,193</u>	<u>\$892</u>

(1) Notes payable includes a balloon payment of \$650,000 due in December 2007.

(2) Purchase obligations include purchase commitments for System One components, primarily for equipment and fluids pursuant to contractual agreements with several of our suppliers.

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. 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 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. 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 chronic market, revenues are realized using the short or long-term rental arrangements.

In the critical care market, we recognize revenues from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms. For the chronic market we recognize revenues derived from short or long-term rental arrangements on a straight-line basis. These rental arrangements, which combine the use of a system 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.

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 disposables at a price that includes a premium above the otherwise average selling price of the disposables to recover the purchase 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.

When we enter into a multiple element arrangement, we allocate the total fee to all elements of the arrangement based on their respective fair values. Fair value is determined by the price charged when each element is sold separately.

We provide for estimated product returns at the time of revenue recognition. Payments received for products or services prior to shipment or prior to completion of the related services are recorded as deferred revenue.

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 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.

Field Equipment

We amortize field equipment using the straight-line method over an estimated useful life of five years. We review the estimated useful life of five years periodically for reasonableness. Factors considered in determining the reasonableness of the useful life include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns, actual equipment disposal rates, and the impact of planned design improvements. We believe the five year useful life to be reasonable as of December 31, 2005.

Accounting for Stock-Based Awards

We account for stock-based employee compensation in accordance with Accounting Principles Board, or APB, Opinion No. 25, "Accounting for Stock Issued to Employees", and related interpretations. Accordingly, compensation expense is recorded for stock options awarded to employees and directors to the extent that the option exercise price is less than the fair market value of our common stock on the date of grant, where the number of shares and exercise price are fixed. The difference between the fair value of our common stock and the exercise price of the stock option, if any, is recorded as deferred compensation and is 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 issuance of stock options. 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.

We follow the disclosure requirements of Statement of Financial Accounting Standard, or SFAS, No. 123, "Accounting for Stock-Based Compensation" for stock-based awards to employees. All stock-based awards to non-employees are 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.

We will adopt Statement of Financial Accounting Standards No. 123R (SFAS 123R) "*Share-Based Payment*" effective 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 will 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 that are subsequently modified, repurchased or cancelled after January 1, 2006 shall be subject to the provisions of SFAS 123R.

We will 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, this aggregate value will be recognized as compensation expense in our consolidated statement of operations ratably over the remaining vesting period and this non-cash stock-based compensation expense is expected to be \$1.6 million, \$1.0 million, \$0.9 million, \$0.8 million and \$0.1 million for the years 2006, 2007, 2008, 2009 and 2010, respectively. The \$4.4 million of stock-based compensation expense excludes any stock-based awards granted subsequent to December 31, 2005. Management continues to evaluate the use of stock-based equity awards and may consider other forms of equity-based compensation arrangements (such as restricted stock units), or reduce the volume of stock option award grants in the future.

Prospectively, we will use the Black-Scholes option-pricing model to estimate the fair value of equity-based compensation awards on the dates of grant. In accordance with Staff Accounting Bulletin 107, or 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 National Market (NASDAQ), we expect to use the following assumptions in the Black-Scholes option-pricing model to estimate the fair value of future equity-based compensation awards:

Expected Term — the expected term will be determined using the simplified method 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 will be based upon an analysis of the trading of similar companies in the medical device and technology industries, consistent with the methodology used in 2005. We may change our volatility assumption in the future once we have a sufficient amount of historical information regarding the volatility of our share price. For 2006, we will use a volatility rate assumption of 85%.

We will also estimate expected forfeitures of stock options upon adoption of SFAS 123R. In developing a forfeiture rate estimate, we considered our historical experience, our growing employee base and the limited liquidity of our common stock. Actual forfeiture activity may differ from our estimated forfeiture rate.

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, 2005, we had federal and state net operating loss carryforwards of approximately \$79.1 million and \$71.6 million, respectively, available to reduce future taxable income, if any. The federal net operating loss carryforwards will expire between 2019 and 2025, while the state net operating loss carryforwards will expire between 2006 and 2010. We also had combined federal and state research and development credit carryforwards of \$3.3 million at December 31, 2005, 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.

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, 2005 and 2004 to reflect these uncertainties.

Related-Party Transactions

Medisystems Corporation is our primary supplier of tubing and certain other components used in the System One disposable cartridge and completed cartridges. The chief executive officer and sole stockholder of Medisystems is a member of our board of directors and owns approximately 9.3% of our outstanding common stock as of December 31, 2005. We purchased approximately \$896,000, \$232,000 and \$41,000 of goods from Medisystems during the years ended December 31, 2005, 2004 and 2003, respectively. We anticipate significantly increasing the amount of materials that we purchase from Medisystems over the next few years. We do not have a long-term supply agreement with Medisystems, and we purchase products from Medisystems through purchase orders. We are currently negotiating a long-term supply agreement with Medisystems covering components, subassemblies and completed cartridges, although we cannot be certain that we will enter into an agreement with Medisystems. We believe that our purchases from Medisystems have been on terms no less favorable to us than could be obtained from unaffiliated third parties or through internal operations.

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

Refer to "Accounting for Stock-Based Awards" in the "Summary of Critical Accounting Policies and Estimates" section above for a summary of the expected impact of adopting SFAS 123R to our consolidated financial statements.

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

Interest Rate Exposure

Our investment portfolio consists primarily of high-grade commercial paper, high grade corporate bonds 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 an average maturity of less than six months and a maximum maturity of 12 months. 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, 2005, we had outstanding debt of \$3.1 million with a fixed interest rate of 7.0%. Movements in market interest rates could impact the fair value of our debt. As of December 31, 2005, the carrying amount of our debt approximated fair value.

Foreign Currency Exposure

We operate a manufacturing and research facility in Rosdorf, Germany. We purchase materials for that facility and pay our employees at that facility in the Euro. 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. 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, we do not 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 \$260,000 for 2005, which would have been less than 0.9% 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.

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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, 2005 and 2004, 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, 2005. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
January 31, 2006

NXSTAGE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 61,223,377	\$ 5,639,499
Marketable securities	—	12,495,000
Accounts receivable, net	1,367,860	524,265
Inventory	5,956,336	4,410,253
Prepaid expenses and other current assets	523,160	39,585
Total current assets	69,070,733	23,108,602
Property and equipment, net	2,070,387	759,008
Field equipment, net	4,843,398	1,041,263
Other assets	446,508	546,061
Total assets	\$ 76,431,026	\$ 25,454,934
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 3,027,524	\$ 1,409,269
Accrued expenses	2,344,318	1,020,426
Deferred rent obligation	84,997	—
Deferred revenue	—	25,720
Current portion of long-term debt	1,513,480	1,448,165
Total current liabilities	6,970,319	3,903,580
Deferred rent obligation	473,268	—
Long-term debt	1,633,070	3,005,717
Total liabilities	9,076,657	6,909,297
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock, at redemption value:		
Series B: zero and 1,875,000 shares authorized as of December 31, 2005 and 2004; zero and 1,875,000 shares issued and outstanding at December 31, 2005 and 2004	—	5,006,250
Series C: zero and 1,155,169 shares authorized as of December 31, 2005 and 2004; zero and 1,151,632 shares issued and outstanding at December 31, 2005 and 2004	—	6,000,003
Series D: zero and 5,011,173 shares authorized as of December 31, 2005 and 2004; zero and 4,857,622 shares issued and outstanding at December 31, 2005 and 2004	—	29,000,008
Series E: zero and 2,690,846 shares authorized as of December 31, 2005 and 2004; zero and 2,669,908 shares issued and outstanding at December 31, 2005 and 2004	—	15,939,351
Series F: zero and 2,829,671 shares authorized as of December 31, 2005 and 2004; zero and 2,747,253 shares issued and outstanding at December 31, 2005 and 2004	—	20,000,002
Total redeemable convertible preferred stock	—	75,945,614
Stockholders' equity (deficit):		
Undesignated preferred stock: par value \$0.001, 5,000,000 and zero shares authorized as of December 31, 2005 and 2004; zero shares issued and outstanding as of December 31, 2005 and 2004	—	—
Common stock: par value \$0.001, 100,000,000 and 20,000,000 shares authorized as of December 31, 2005 and 2004; 21,176,554 and 2,566,681 shares issued and outstanding as of December 31, 2005 and 2004	21,177	2,567
Additional paid-in capital	151,675,548	2,391,223
Deferred compensation	(259,910)	(420,509)
Accumulated deficit	(84,010,669)	(59,496,069)
Accumulated other comprehensive income (loss)	(71,777)	122,811
Total stockholders' equity (deficit)	67,354,369	(57,399,977)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 76,431,026	\$ 25,454,934

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2005	2004	2003
Revenues	\$ 5,993,739	\$ 1,884,569	\$ 285,954
Cost of revenues	9,585,286	3,438,832	940,371
Gross profit (deficit)	<u>(3,591,547)</u>	<u>(1,554,263)</u>	<u>(654,417)</u>
Operating expenses:			
Research and development	6,304,463	5,970,442	4,526,491
Selling and marketing	7,549,830	3,334,028	2,180,747
Distribution	2,059,279	494,786	32,602
General and administrative	4,854,471	3,603,967	2,868,304
Total operating expenses	<u>20,768,043</u>	<u>13,403,223</u>	<u>9,608,144</u>
Loss from operations	<u>(24,359,590)</u>	<u>(14,957,486)</u>	<u>(10,262,561)</u>
Other income (expense):			
Interest income	643,417	130,347	146,047
Interest expense	<u>(763,437)</u>	<u>(14,542)</u>	<u>(91,985)</u>
	<u>(120,020)</u>	<u>115,805</u>	<u>54,062</u>
Net loss	<u>\$(24,479,610)</u>	<u>\$(14,841,681)</u>	<u>\$(10,208,499)</u>
Net loss per share, basic and diluted	<u>\$ (4.31)</u>	<u>\$ (5.81)</u>	<u>\$ (4.10)</u>
Weighted-average shares outstanding, basic and diluted ..	<u>5,680,566</u>	<u>2,555,605</u>	<u>2,489,688</u>

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	Notes Receivable From Stockholders	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Comprehensive Loss
	Shares	Carrying Value	Shares	Amount						
Balance at December 31, 2002	7,884,254	\$ 40,006,261	2,560,644	\$ 2,561	\$ 1,496,459	\$ (95,843)	\$(289,615)	\$(34,367,595)	\$ (17,389)	
Sale of Series E redeemable convertible preferred stock, net of issuance costs of \$46,814	—	—	—	—	—	—	—	(46,814)	—	
Exercise of stock options	2,669,908	15,939,351	4,582	5	13,096	—	—	—	—	
Stock options issued to non-employees	—	—	—	—	9,000	(9,000)	—	—	—	
Amortization of deferred compensation	—	—	—	—	—	38,904	—	—	—	
Change in cumulative translation adjustment	—	—	—	—	—	—	—	(10,208,499)	(3,709)	\$ (3,709)
Net loss	—	—	—	—	—	—	—	—	—	(10,208,499)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	\$(10,212,208)
Balance at December 31, 2003	10,544,162	\$ 55,945,612	2,565,226	\$ 2,566	\$ 1,518,555	\$ (65,939)	\$(289,615)	\$(44,622,908)	\$ (21,098)	
Sale of Series F redeemable convertible preferred stock, net of issuance costs of \$31,480	—	—	—	—	—	—	—	(31,480)	—	
Exercise of stock options	2,747,253	20,000,002	1,455	1	5,264	—	—	—	—	
Stock options issued to non-employees	—	—	—	—	159,124	(159,124)	—	—	—	
Deferred compensation	—	—	—	—	285,780	(285,780)	—	—	—	
Amortization of deferred compensation	—	—	—	—	—	90,334	—	—	—	
Warrants issued in connection with debt agreement	—	—	—	—	422,500	—	—	—	—	
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	24,000	\$ 24,000
Forgiveness of note receivable	—	—	—	—	—	—	289,615	—	—	119,909
Change in cumulative translation adjustment	—	—	—	—	—	—	—	—	—	(14,841,681)
Net loss	—	—	—	—	—	—	—	(14,841,681)	—	\$(14,697,772)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	\$ 24,000
Balance at December 31, 2004	13,301,415	\$ 75,945,614	2,566,681	\$ 2,567	\$ 2,391,223	\$ (420,509)	—	\$(59,496,069)	\$ 122,811	
Sale of Series F-1 redeemable convertible preferred stock, net of issuance costs of \$34,990	—	—	—	—	—	—	—	(34,990)	—	
Conversion of redeemable convertible preferred stock to common stock	2,197,801	15,999,993	—	—	—	—	—	—	—	
Issuance of common stock, net of issuance costs	(15,499,216)	(91,945,607)	12,124,840	12,125	91,933,482	—	—	—	—	
Series D warrant extension	—	—	6,325,000	6,325	56,023,477	—	—	—	—	
Exercise of stock options	—	—	—	—	478,094	—	—	—	—	
Exercise of warrants	—	—	128,729	129	533,777	—	—	—	—	
Stock options issued to non-employees	—	—	31,304	31	223,029	—	—	—	—	
Deferred compensation	—	—	—	—	34,400	(34,400)	—	—	—	
Amortization of deferred compensation	—	—	—	—	58,066	(58,066)	—	—	—	
Realized gain on marketable securities	—	—	—	—	—	253,065	—	—	—	
Change in cumulative translation adjustment	—	—	—	—	—	—	—	—	—	
Net loss	—	—	—	—	—	—	—	(24,479,610)	(24,000)	\$ (24,000)
Total comprehensive loss	—	—	—	—	—	—	—	—	—	(170,588)
Balance at December 31, 2005	—	\$ —	21,176,554	\$ 21,177	\$ 151,675,548	\$ (259,910)	—	\$(84,010,669)	\$ (71,777)	

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2005	2004	2003
Cash flows from operating activities:			
Net loss	\$(24,479,610)	\$(14,841,681)	\$(10,208,499)
Adjustments to reconcile net loss to net cash used in operating activities:			
Realized gain on sale of marketable securities	(24,000)	—	—
Depreciation and amortization	1,033,688	452,925	370,797
Amortization of debt discount	140,833	—	—
Forgiveness of related party loans	—	289,615	62,913
Stock-based compensation	253,065	90,334	38,904
Changes in operating assets and liabilities:			
Accounts receivable	(843,595)	(375,579)	(148,677)
Inventory	(5,929,697)	(2,346,311)	(1,044,889)
Prepaid expenses and other current assets	(483,598)	11,002	89,893
Accounts payable	1,613,878	1,215,678	35,163
Accrued expenses	1,370,911	331,600	(31,193)
Net cash used in operating activities	<u>(27,348,125)</u>	<u>(15,172,417)</u>	<u>(10,835,588)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(1,198,222)	(195,071)	(80,084)
Sale of marketable securities	12,495,000	—	—
Purchase of marketable securities	—	(12,471,000)	—
Increase in other assets	(5,869)	(135,013)	1,678
Net cash (used in) provided by investing activities	<u>11,290,909</u>	<u>(12,801,084)</u>	<u>(78,406)</u>
Cash flows from financing activities:			
Net proceeds from issuance of redeemable convertible preferred stock	15,965,003	19,968,522	15,892,537
Net proceeds from issuance of common stock	56,507,896	—	—
Proceeds from exercise of stock options	533,906	5,265	13,101
Proceeds from exercise of warrants	223,060	—	—
Net borrowings (repayments) on loans and lines of credit	(1,448,164)	4,730,311	(136,417)
Net cash provided by financing activities	<u>71,781,701</u>	<u>24,704,098</u>	<u>15,769,221</u>
Foreign exchange effect on cash and cash equivalents	(140,607)	28,284	(2,470)
Increase (decrease) in cash and cash equivalents	55,583,878	(3,241,119)	4,852,757
Cash and cash equivalents, beginning of year	5,639,499	8,880,618	4,027,861
Cash and cash equivalents, end of year	<u>\$ 61,223,377</u>	<u>\$ 5,639,499</u>	<u>\$ 8,880,618</u>
Supplemental Disclosure			
Cash paid for interest	<u>\$ 270,098</u>	<u>\$ 14,542</u>	<u>\$ 28,092</u>
Noncash Investing Activities			
Transfers from inventory to field equipment	<u>\$ 4,366,981</u>	<u>\$ 1,091,198</u>	<u>\$ 63,180</u>
Leasehold improvement allowance	<u>\$ 614,798</u>	<u>\$ —</u>	<u>\$ —</u>
Noncash Financing Activities			
Warrants issued in connection with financing activity	<u>\$ —</u>	<u>\$ 422,500</u>	<u>\$ —</u>
Deferred compensation and paid-in capital	<u>\$ 92,466</u>	<u>\$ 444,904</u>	<u>\$ 9,000</u>
Conversion of preferred stock to common stock	<u>\$ 91,945,607</u>	<u>\$ —</u>	<u>\$ —</u>
Extension of Series D warrants	<u>\$ 478,094</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations

NxStage Medical, Inc. (the Company) is a medical device company that develops, manufactures and markets products for the treatment of kidney failure and fluid overload. The Company's primary product, the NxStage System One (the System), 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 is cleared by the United States Food and Drug Administration (FDA) and sold commercially in the United States for the treatment of acute and chronic kidney failure patients as well as patients with congestive heart failure suffering from fluid overload. The System 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.

During 2004, the Company commenced significant commercial activities and was no longer considered to be in the development stage. The Company's growth has been funded through a combination of private equity, bank debt, lease financing, and since November 1, 2005, through proceeds from its initial public offering of common stock. As of December 31, 2005, the Company had approximately \$61.2 million of unrestricted cash and the Company believes that it has sufficient cash and financing commitments to meet its funding requirements at least through 2006. The Company has experienced and continues to experience negative operating margins and negative cash flows from operations and there can be no assurance as to the availability or terms upon which additional financing may be available in the future.

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. Certain amounts in previously issued consolidated financial statements have been reclassified to conform to the current presentation.

On September 15, 2005, the Company's board of directors declared a one-for-1.3676 reverse stock split of the outstanding shares of common stock and adjusted conversion ratios of Series B, Series C, Series D, Series E, Series F and Series F-1 redeemable convertible preferred stock to reflect the one-for-1.3676 reverse stock split of the common stock. All references in the consolidated financial statements to the number of shares outstanding, per share amounts, and stock option data of the Company's common stock have been retroactively adjusted to reflect the effect of the reverse stock split for all periods presented.

(b) Use of Estimates

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

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

during the year. Gains and losses realized from transactions, including intercompany balances not considered permanent investments, are denominated in foreign currencies and are included in the consolidated statements of operations and were not material for the periods presented.

(d) Cash, Cash Equivalents and Marketable Securities

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 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 Statement of Financial Accounting Standards (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 investments in marketable securities as available-for-sale for the year ended December 31, 2004; there were no marketable securities at December 31, 2005. Marketable securities are reported at their fair value, with any unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity (deficit) as other comprehensive income (loss).

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

Financial instruments consist principally of cash and cash equivalents, marketable securities, 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 from the sale of the System One and related products, which cannot be used with any other dialysis system. If the System One is not a successful product or is withdrawn from the market for any reason, the Company does not have other products in development.

The Company uses and is dependent upon four 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 allowance for doubtful accounts are recorded in general and administrative expenses in

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the accompanying consolidated statements of operations. Activity related to allowance for doubtful accounts consisted of the following:

	<u>Balance at Beginning of Year</u>	<u>Provision</u>	<u>Write-Offs</u>	<u>Balance at End of Year</u>
Year ended December 31, 2005	\$21,933	\$15,750	\$(25,417)	\$12,266
Year ended December 31, 2004	\$ 9,599	\$24,750	\$(12,416)	\$21,933
Year ended December 31, 2003	\$ 9,599	—	—	\$ 9,599

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

<u>Year Ended</u>	<u>Revenue</u>		<u>Accounts Receivable</u>	
	<u>Number of Customers</u>	<u>Percent of Total Revenue</u>	<u>Number of Customers</u>	<u>Percent of Total Accounts Receivable</u>
December 31, 2005	3	33%	2	25%
December 31, 2004	3	37%	3	35%
December 31, 2003	2	63%	1	44%

(f) Inventory

Inventory is stated at the lower of cost (weighted-average) 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 medical device industry is characterized by rapid development and technological advances that could result in obsolescence of inventory. Additionally, the Company's estimates of future product demand may prove to be inaccurate.

(g) 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.

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, 2005 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.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	<u>Estimated Useful Life</u>
Leasehold improvements	Lesser of 5 years or lease term
Computer and office equipment	3 years
Machinery, equipment and tooling	5 years
Furniture	7 years
Field equipment	5 years

(h) 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 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. 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 chronic care market, revenues are realized using short-term rental arrangements.

In the critical care market, 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. For the chronic market, the Company recognizes revenue derived from short-term rental arrangements ratably over the rental period. These rental arrangements combine the use of a system with a specified number of disposable products supplied to customers for a fixed amount per month. Revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to customer purchase orders with fixed payment terms. Customer contracts are generally cancelable on a 30-days notice and there are no purchase requirements from customers under the Company's chronic agreements.

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 purchase 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. The Company records the cost of the equipment in inventory and amortizes the cost of the equipment through charges to cost of revenues consistent with the customer's minimum purchase requirement.

When the Company enters into a multiple-element arrangement, it allocates the total fee to all elements of the arrangement based on their respective fair values. Fair value is determined by the price charged when each element is sold separately. The Company's most common multiple-element arrangements are products sold under a disposables-based program in the critical care market as described above. The Company accounts for the disposables-based program as a single economic transaction and has determined that it does not have a basis to separate the transaction into multiple elements to recognize revenue at the time of shipment of each element. Rather, the Company recognizes revenue related to all elements over the term of the arrangement as the disposables are delivered.

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

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(i) Stock-Based Compensation

The Company accounts for stock-based employee compensation in accordance with Accounting Principles Board Opinion No. 25 (APB No. 25), "Accounting for Stock Issued to Employees", and related interpretations. Accordingly, compensation expense is recorded for stock options awarded to employees and directors to the extent that the option exercise price is 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 are fixed. The difference between the fair value of the Company's common stock and the exercise price of the stock option, if any, is recorded as deferred compensation and is amortized to compensation expense over the vesting period of the underlying stock option. The Company follows only the disclosure requirements of SFAS No. 123, "Accounting for Stock-Based Compensation" for stock-based awards to employees. All stock-based awards to nonemployees are accounted for at their fair value in accordance with SFAS No. 123 and related interpretations.

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. The weighted-average assumptions used are as follows:

	Years Ended December 31,		
	2005	2004	2003
Expected life of the options	4.75 - 7 years	7 years	7 years
Risk-free interest rate	3.88% - 4.68%	4.65% - 5.20%	2.91% - 4.05%
Expected stock price volatility	0% - 85%	—	—
Expected dividend yield	—	—	—

The effect of expensing the fair value of employee stock options, consistent with SFAS No. 123, would have been as follows:

	2005	2004	2003
Net loss as reported	\$(24,479,610)	\$(14,841,681)	\$(10,208,499)
Plus: Stock-based employee compensation expense, included in net loss, as reported	71,445	11,908	—
Less: Stock-based employee compensation expense determined under fair value based method for all awards	<u>(807,159)</u>	<u>(301,430)</u>	<u>(241,219)</u>
Pro forma net loss	<u><u>\$(25,215,324)</u></u>	<u><u>\$(15,131,203)</u></u>	<u><u>\$(10,449,718)</u></u>
Net loss per share, basic and diluted — as reported ...	\$ (4.31)	\$ (5.81)	\$ (4.10)
Net loss per share, basic and diluted — pro forma	\$ (4.44)	\$ (5.92)	\$ (4.20)

The recognized stock-based compensation expense represents the intrinsic value of a stock option award made to a newly hired executive officer on October 25, 2004 with an exercise price that was lower than the grant date fair value. This amount is included in general and administrative expenses in the accompanying consolidated statements of operations.

(j) 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

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

(k) Distribution Expenses

Distribution expenses consist of the costs incurred in shipping products to customers and are charged to operations as incurred. Prior to 2004, the Company did not charge any distribution costs to its customers. Starting in 2004, shipping and handling costs charged to customers totaled \$42,801 and \$25,754 for the years ended December 31, 2005 and 2004, respectively, and have been included in revenues.

(l) Research and Development Costs

Research and development costs are charged to operations as incurred.

(m) 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.

(n) Net Loss per Share

The Company calculates net loss per share in accordance with SFAS No. 128, *"Earnings per Share"* (SFAS No. 128), and EITF 03-6, *"Participating Securities and the Two Class Method under FASB Statement No. 128, Earnings per Share"* (EITF 03-6). EITF 03-6 clarifies the use of the "two-class" method of calculating earnings per share as originally prescribed in SFAS No. 128. Effective for periods beginning after March 31, 2004, EITF 03-6 provides guidance on how to determine whether a security should be considered a "participating security" for purposes of computing earnings per share and how earnings should be allocated to a participating security when using the two-class method for computing earnings per share. The Company has determined that its redeemable preferred stock represents a participating security because it may participate in dividends with common stock and, therefore, has calculated net loss per share consistent with the provisions of EITF 03-6 for all periods presented.

Net loss per share is calculated based on the weighted average number of shares of common stock outstanding, excluding unvested shares of restricted common stock. 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:

	December 31		
	2005	2004	2003
Options to purchase common stock	2,683,286	1,690,561	1,290,817
Warrants to purchase common stock	172,321	203,625	130,165
Unvested shares of common stock subject to repurchase	—	402	16,625
Redeemable convertible preferred stock	<u>10,098,497</u>	<u>10,165,879</u>	<u>7,717,172</u>
Total	<u>12,954,104</u>	<u>12,060,467</u>	<u>9,154,779</u>

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

(o) Comprehensive Income (Loss)

SFAS No. 130, "Reporting Comprehensive Income" (SFAS 130), 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 that are excluded from results of operations. Specifically, foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities are included in accumulated other comprehensive income in the accompanying consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit).

The components of accumulated other comprehensive income (loss) are as follows:

	December 31,	
	2005	2004
Foreign currency translation adjustments	\$(71,777)	\$ 98,811
Unrealized gain on marketable securities	—	24,000
Total	\$(71,777)	\$122,811

(p) Segment Reporting

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. All revenues were generated in the U.S. and substantially all assets are located in the U.S.

The Company sells products into two markets, critical care and chronic care. The critical care market consists of hospitals or facilities that treat patients that have suddenly, and possibly temporarily, lost kidney function. The chronic market consists of dialysis centers and hospitals that provide treatment options for patients that have end stage renal disease (ESRD). Revenues recognized in these markets were as follows:

	Years Ended December 31,		
	2005	2004	2003
Critical care market	\$2,829,960	\$1,332,053	\$268,576
Chronic care market	3,163,779	552,516	17,378
Total revenues	\$5,993,739	\$1,884,569	\$285,954

(q) Recent Accounting Pronouncements (Unaudited)

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (Revised 2004), "Share-Based Payment", or SFAS 123R, which replaces SFAS No. 123, "Accounting for Stock-Based Compensation," or SFAS 123, and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires companies to measure compensation cost for share-based payments to employees, including stock options, at fair value and expense such compensation cost over the service period beginning with the first interim or annual period after December 15, 2005. The pro forma disclosures previously permitted under SFAS 123 will no longer be an alternative to financial statement recognition.

The Company will adopt SFAS 123R effective January 1, 2006. Under SFAS 123R, companies must determine the appropriate fair value model to be used for valuing share-based payments, the amortization

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

method for compensation cost and the transition method to be used at the date of adoption. The Company will use the Black-Scholes option-pricing model to estimate the fair value of stock-based compensation awards and has elected to recognize stock-based compensation using a straight-line method of amortization. The Company will use a combination of the prospective and the modified prospective transition methods upon adoption of SFAS 123R. Under the prospective method, the Company will not recognize the remaining compensation cost for any stock option awards which had previously been valued using the minimum value method (i.e., stock options granted prior to July 19, 2005). Under the modified prospective method, the Company will (a) recognize compensation expense for all share-based payments granted after January 1, 2006 and (b) recognize compensation expense for awards granted to employees between July 19, 2005 and January 1, 2006 that remain unvested as of January 1, 2006. The unvested portion of stock options valued using the Black-Scholes option-pricing model that were granted subsequent to July 19, 2005 totaled approximately \$4.4 million as of December 31, 2005, which will be amortized as compensation expense over the remaining vesting period (2006-2010). The \$4.4 million excludes compensation expense related to stock options granted subsequent to December 31, 2005.

3. Marketable Securities

At December 31, 2004, all of the Company's marketable securities were classified as available-for-sale. There were no marketable securities at December 31, 2005. Marketable securities are carried on the balance sheet at their fair market value.

The following table summarizes the Company's marketable securities at December 31, 2004:

	2004				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value	Weighted-Average Date to Maturity
Debt	\$ 7,500,000	\$ —	\$—	\$ 7,500,000	< 1 year
Fixed income	2,376,000	24,000		2,400,000	< 1 year
Certificates of deposit	2,595,000	—	—	2,595,000	< 1 year
Total	<u>\$12,471,000</u>	<u>\$24,000</u>	<u>\$—</u>	<u>\$12,495,000</u>	

During the year ended December 31, 2005, available-for-sale securities were sold for total proceeds of \$12,495,000. The gross realized gains on these sales totaled \$24,000 in 2005. For purposes of determining gross realized gains, the cost of securities sold is based on specific identification. As a result of the sale of these securities, there are no unrealized holding gains on available-for-sale securities at December 31, 2005 in accumulated other comprehensive income. Net unrealized holding gains on available-for-sale securities in the amount of \$24,000 were included in accumulated other comprehensive income at December 31, 2004.

4. Inventory

Inventories at December 31, 2005 and 2004 are as follows:

	2005	2004
Purchased components	\$2,026,986	\$2,926,114
Finished goods	3,929,350	1,484,139
	<u>\$5,956,336</u>	<u>\$4,410,253</u>

Inventory is shown net of a valuation allowance of approximately \$646,000 and \$722,000 at December 31, 2005 and 2004, respectively.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

5. Property and Equipment and Field Equipment

The cost and accumulated depreciation of property and equipment at December 31, 2005 and 2004 are as follows:

	<u>2005</u>	<u>2004</u>
Computer and office equipment	\$ 829,298	\$ 611,423
Machinery, equipment and tooling	1,613,359	1,014,055
Furniture	279,815	241,491
Leasehold improvements	930,213	276,403
Construction-in-process	<u>246,639</u>	<u>34,550</u>
	3,899,324	2,177,922
Less accumulated depreciation and amortization	<u>(1,828,937)</u>	<u>(1,418,914)</u>
Property and equipment, net	<u>\$ 2,070,387</u>	<u>\$ 759,008</u>

Depreciation expense for property and equipment was \$469,000, \$342,000 and \$369,000 in 2005, 2004 and 2003, respectively.

The cost and accumulated depreciation of field equipment at December 31, 2005 and 2004 are as follows:

	<u>2005</u>	<u>2004</u>
Field equipment	\$5,521,359	\$1,154,378
Less accumulated depreciation and amortization	<u>(677,961)</u>	<u>(113,115)</u>
Field equipment, net	<u>\$4,843,398</u>	<u>\$1,041,263</u>

Depreciation expense for field equipment was \$565,000, \$111,000 and \$2,000 in 2005, 2004 and 2003, respectively.

6. Accrued Expenses

Accrued expenses at December 31, 2005 and 2004 are as follows:

	<u>2005</u>	<u>2004</u>
Payroll and related benefits	\$ 769,364	\$ 200,271
Warranty costs	62,071	35,401
Accrued interest on debt	351,869	—
Accrued audit, legal and consulting fees	311,700	235,315
Clinical trial costs	25,894	217,000
Deferred straight-line rent	139,697	46,446
Costs relating to initial public offering	225,434	—
Research and development expenses	101,828	153,034
General and administrative expenses	171,824	19,980
Selling and marketing expenses	<u>184,637</u>	<u>112,979</u>
Total accrued expenses	<u>\$2,344,318</u>	<u>\$1,020,426</u>

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

7. Financing Arrangements

Debt

In December 2004, the Company entered into a debt agreement in the principal amount of \$5.0 million, which is payable monthly over a three-year term and is secured by all the assets of the Company. Interest accrues at a rate of 7.0% annually and monthly principal and interest payments are made in advance. In addition, a final interest payment of \$650,000 is due at the maturity date in December 2007, or if the loan is prepaid in advance. This additional interest payment is accrued on a monthly basis using the interest method over the 36-month life of the loan and is included in accrued expenses in the accompanying consolidated balance sheets.

In connection with the debt agreement, the Company issued the lender a warrant to purchase 82,416 shares of Series F redeemable convertible preferred stock (Series F Preferred Stock) at an exercise price of \$7.28 per share (Note 12). The Company estimated the value of the warrant at \$422,500 using the Black-Scholes option-pricing model with an estimated volatility factor of 85%. This amount was recorded as original issue debt discount and is being amortized as additional interest expense over the 36-month life of the loan.

Annual maturities of principal under the Company's debt obligations and reconciliation to amounts included in the consolidated balance sheet as of December 31, 2005 are as follows:

2006	\$ 1,654,313
2007	<u>1,773,904</u>
Total future principal payments	3,428,217
Less: unamortized original issue debt discount	<u>(281,667)</u>
	3,146,550
Less: current portion of long-term debt	<u>(1,513,480)</u>
Long-term debt	<u>\$ 1,633,070</u>

8. Commitments and Contingencies

The Company maintains its corporate headquarters and principal operating activities in a leased building located in Lawrence, Massachusetts. During 2005, the Company renewed the lease agreement through 2012. The new lease agreement includes a tenant improvement allowance paid by the landlord of \$614,798, which has been recorded as both a leasehold improvement and a deferred rent obligation.

The future minimum rental payments under the Company's operating leases are as follows:

	<u>Amount</u>
2006	\$ 510,596
2007	505,967
2008	531,437
2009	541,242
2010	552,005
Thereafter	<u>891,824</u>
Total	<u>\$3,533,071</u>

Rent expense for the years ended December 31, 2005, 2004 and 2003 amounted to \$461,000, \$510,000 and \$508,000, respectively. The deferred rent obligation is apportioned on a straight-line basis over the lease term and is recorded as a reduction to rent expense.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

9. Income Taxes

At December 31, 2005 and 2004, deferred income tax assets and liabilities resulted from differences in the recognition of income and expense items for tax and financial reporting purposes. The sources and tax effects of these temporary differences are presented below:

	<u>2005</u>	<u>2004</u>
Deferred income tax assets:		
Net operating loss carryforwards	\$ 30,600,000	\$ 21,460,000
Capitalized start-up costs	457,000	932,000
Research and development credits	3,329,000	2,699,000
Other	350,000	355,000
Gross deferred income tax assets	34,736,000	25,446,000
Valuation allowance	(34,736,000)	(25,446,000)
Net deferred income tax assets	\$ —	\$ —

As of December 31, 2005, the Company had federal and state net operating loss carryforwards of approximately \$79.1 million and \$71.6 million, respectively, available to offset future taxable income, if any. The federal net operating loss carryforwards will expire between 2019 and 2025, while the state net operating loss carryforwards will expire between 2006 and 2010. The Company also had combined federal and state research and development credit carryforwards of approximately \$3.3 million, at December 31, 2005, 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 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.

A reconciliation of the federal statutory rate to the Company's effective tax rate is as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Federal statutory benefit rate	34.0%	34.0%	34.0%
Research and development credits	1.7	2.5	2.8
Valuation allowance	(34.8)	(35.1)	(34.3)
Other, net	(0.9)	(1.4)	(2.5)
Effective tax benefit rate	—%	—%	—%

10. Stock Plans

The Company maintains the 1999 Stock Option and Grant Plan (the 1999 Plan) under which the issuance of 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. ISOs may be granted only to employees, while nonqualified stock options may be granted to officers, employees, consultants and advisors of the Company. The Board determined the option exercise price for incentive and nonqualified stock options, 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. All stock options issued under the 1999 Plan expire 10 years from the date of grant and the

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 51,013 shares remain outstanding at December 31, 2005. Effective upon the closing of the Company's initial public offering, no further grants will be made under the 1999 Plan.

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. The number of shares available for grant under the 2005 Plan will be increased annually beginning in 2007 by the lesser of (a) 600,000 shares, or (b) 3% of the then outstanding shares of the Company's common stock, or (c) a number determined by the board. Unless otherwise specified by the Board or Compensation Committee, 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. At December 31, 2005, 717,001 options for shares of common stock are available for future grant under the 2005 Plan.

During 2005, the Company granted a consultant options to purchase 5,849 shares of common stock at an exercise price of \$6.84 per share and during 2004, the Company granted a consultant options to purchase 14,624 shares of common stock at an exercise price of \$5.47 per share. The fair value of the 2005 and 2004 option grants was \$5.88 and \$4.69 per share, respectively, which has been recorded as deferred compensation and is being recognized as compensation expense ratably over the awards' vesting period. Further, these warrants will be marked to market over their vesting period based upon changes in fair value. During 2004 the unvested portion of a previous option grant to a consultant was determined to have increased in fair market value resulting in additional compensation expense of approximately \$76,000 which is being recognized ratably over the remaining vesting term of the option.

The fair value of options granted to consultants is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were used for grants made in 2005 and 2004: dividend yield of zero percent for each year; expected volatility of 85% for each year; risk free interest rates ranging from 4.65 to 4.68 percent; and expected life of 10 years for each year. Stock-based compensation expense related to stock options granted to consultants was \$181,620, \$78,426 and \$38,904 for 2005, 2004 and 2003, respectively, and is included in general and administrative expenses in the accompanying consolidated statements of operations.

With the exception of one stock option grant award, all stock option awards granted to employees during 2005, 2004 and 2003 were made at exercise prices equal to or greater than the then fair value of the Company's company stock. The Company granted 208,962 stock options to a newly hired executive officer on October 25, 2004 with an exercise price of \$4.10, which was lower than the fair value at the date of grant of \$5.47. The intrinsic value of \$1.37 per option has been recorded as deferred compensation and is being recognized as compensation expense over the four-year vesting period.

For stock option grants between July 1, 2004 and the 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."

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of the Company's stock plan activity is as follows:

	2005		2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Fixed Options						
Outstanding at beginning of year	1,690,556	\$3.97	1,290,814	\$3.63	1,084,480	\$3.53
Granted	1,217,970	\$9.02	487,879	\$4.90	232,519	\$4.10
Exercised	(128,729)	\$4.14	(1,455)	\$3.62	(4,582)	\$2.86
Forfeited	(96,511)	\$5.03	(86,682)	\$4.18	(21,603)	\$3.72
Outstanding at end of year	<u>2,683,286</u>	\$6.22	<u>1,690,556</u>	\$3.97	<u>1,290,814</u>	\$3.63
Options exercisable at end of year	<u>1,448,571</u>		<u>865,116</u>		<u>1,290,814</u>	
Weighted average fair value of options granted during the year	\$ <u>5.15</u>		\$ <u>2.07</u>		\$ <u>0.85</u>	

The following table summarizes information about stock options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.34 to \$0.55	107,293	3.3 years	\$ 0.37	107,293	\$ 0.37
\$1.37	2,924	4.4 years	\$ 1.37	2,924	\$ 1.37
\$2.74 to \$4.10	1,175,182	6.7 years	\$ 3.94	936,371	\$ 3.90
\$5.47 to \$6.84	413,528	8.7 years	\$ 6.34	294,983	\$ 6.52
\$8.21 to \$9.10	746,909	7.7 years	\$ 8.56	—	—
\$12.59	<u>237,450</u>	6.2 years	\$12.59	<u>107,000</u>	\$12.59
\$0.34 to \$12.59	<u>2,683,286</u>	7.1 years	\$ 6.22	<u>1,448,571</u>	\$ 4.81

2005 Employee Stock Purchase Plan

The Company's 2005 Employee Stock Purchase Plan (the 2005 Purchase Plan) authorizes the issuance of up to 50,000 shares of common stock to participating employees through a series of periodic offerings. Each six-month offering period begins on either January 1 or July 1. The first offering under the 2005 Purchase Plan will extend from January 3, 2006 through June 30, 2006. An employee becomes eligible to participate in the 2005 Purchase Plan once he or she has been employed for at least 6 months and is regularly employed for at least 20 hours per week for more than five 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 common stock on the NASDAQ National Market on the day the offering terminates, unless otherwise determined by the Board or Compensation Committee. The first offering under the 2005 Purchase Plan will be compensatory under the provisions of SFAS 123R and will result in the recording of compensation expense.

The Company has reserved 3,400,287 shares of common stock for issuance upon exercise of stock options, 50,000 shares for issuance under the 2005 Purchase Plan and 172,321 shares for issuance upon exercise of warrants.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

11. 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 \$363,000, \$214,000 and \$186,000 in 2005, 2004 and 2003, respectively.

12. Redeemable Convertible Preferred Stock and Stockholders' Equity

Common and Preferred Stock

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. The Company received approximately \$56.5 million in net proceeds from the offering. 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.

Concurrent with the initial public offering, the Company amended and restated its certificate of incorporation to authorize 100,000,000 shares of common stock, par value \$0.001 per share. On July 8, 2005, the Company amended its articles of incorporation to (a) increase the number of authorized shares of preferred stock to 15,759,660 shares and (b) designate 2,197,801 shares of Series F-1 Preferred Stock. On September 19, 2005, the Company amended its articles of incorporation to authorize 30,000,000 shares of common stock. On October 14, 2005, the Company authorized 5,000,000 shares of undesignated preferred stock.

Prior to the initial public offering, the Company had authorized several series of \$0.001 par value preferred stock, of which 1,875,000 shares were designated as Series B, 1,155,169 shares were designated as Series C, 5,011,173 shares were designated as Series D, 2,690,846 shares were designated as Series E, 2,829,671 shares were designated as Series F and 2,197,801 shares were designated as Series F-1.

During 1999, the Company sold 1,875,000 shares of Series B Preferred Stock at \$2.67 per share, resulting in net proceeds of \$4,968,250. Upon the closing of the Series B Preferred Stock financing, all shares of the Company's Series A Preferred Stock converted into an equal number of shares of the Company's common stock. On January 22, 2000, the Company sold 1,151,632 shares of Series C Preferred Stock at \$5.21 per share, resulting in net proceeds of \$5,957,891. On May 21, 2001, the Company sold 4,857,622 shares of Series D Preferred Stock at \$5.97 per share, resulting in net proceeds of \$24,218,379. On April 15, 2003, the Company sold 2,669,908 shares of Series E Preferred Stock at \$5.97 per share, resulting in net proceeds of \$15,892,537. On August 18, 2004, the Company sold 2,747,253 shares of Series F Preferred Stock at \$7.28 per share, resulting in net proceeds of \$19,968,522. On July 8, 2005 and July 15, 2005, the Company sold an aggregate of 2,197,801 shares of Series F-1 Preferred Stock at \$7.28 per share, resulting in net proceeds of approximately \$15,965,003.

The rights, preferences and privileges of the previously outstanding Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock are described below.

Dividends

No dividends were declared by the Board of Directors on the preferred stock while it was outstanding and dividends were not cumulative.

Voting Rights

The preferred stockholders were entitled to vote on all matters with the common stockholders as if they were one class of stock. Limited special voting rights applied to the Series D, E, F and F-1 Preferred Stock.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The preferred stockholders were entitled to the number of votes equal to the number of shares of common stock into which each share of the Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock was then convertible. For so long as at least 100,000 shares of Series B, Series C, Series D, Series E, Series F and/or Series F-1 Preferred Stock remained outstanding, the vote of at least two-thirds of the outstanding shares of preferred stock was required to effect or validate certain material corporate transactions and equity issuances defined in the Company's Certificate of Incorporation, as amended and restated.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, as defined, the holders of the Preferred Stock then outstanding would have been entitled to be paid an amount equal to the original issue price per share, plus any dividends declared but unpaid on such shares prior to any payment to common stockholders. Amounts remaining after the preference payments to the holders of Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock, if any, would have been shared on a proportional basis among all stockholders, including the preferred stockholders, whose portion would have been determined based on the number of shares of common stock into which the Preferred Stock was then convertible.

Upon the closing of a sale of substantially all the assets of the Company or an acquisition of the Company, in which the total consideration per share to be received by the holders of Series F Preferred Stock was less than 1.7 times the effective Series F Preferred Stock conversion price, the Series F Preferred Stock conversion price would have been reduced to the higher of (a) the total consideration per share to be received by the holders of the Series F Preferred Stock divided by 1.7, and (b) \$8.16. The potential reduction in the conversion price of the Series F Preferred Stock described above represented a contingent beneficial conversion feature which was resolved upon the closing of the Company's initial public offering on November 1, 2005. Based on the initial public offering price of \$10.00 per share, the beneficial conversion feature was deemed to have no value; consequently, no dividend was recognized relating to this feature.

Upon the closing of a sale of substantially all the assets of the Company or an acquisition of the Company, in which the total consideration per share to be received by the holders of Series F-1 Preferred Stock was less than 1.5 times the effective Series F-1 Preferred Stock conversion price, the Series F-1 Preferred Stock conversion price would have been reduced to the higher of (a) the total consideration per share to be received by the holders of the Series F-1 Preferred Stock divided by 1.5, and (b) \$8.16. The potential reduction in the conversion price of the Series F-1 Preferred Stock described above represented a contingent beneficial conversion feature which was resolved upon the closing of the Company's initial public offering on November 1, 2005. Based on the initial public offering price of \$10.00 per share, the beneficial conversion feature was deemed to have no value; consequently, no dividend was recognized relating to this feature.

Conversion

Each share of Preferred Stock was convertible, at any time and at the option of the holder, into .7312 fully paid and nonassessable share of common stock, adjusted for certain dilutive events, as defined. In addition, all shares of Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock would be automatically converted into shares of common stock upon the vote of holders of at least 70% of the outstanding shares of Preferred Stock voting together as a class, or immediately upon the closing of an underwritten public offering in which the aggregate net proceeds to the Company are not less than \$20.0 million.

In the event of an initial public offering in which the price per share was less than \$16.93, the number of shares of common stock into which the outstanding shares of Series F Preferred Stock would convert would increase based on the actual initial public offering price up to a maximum of an additional 439,925 shares. In addition, in the event of an initial public offering in which the price per share was less than \$14.93, the

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

number of shares of common stock into which the outstanding shares of Series F-1 Preferred Stock would convert would increase based on the actual initial offering price up to a maximum of an additional 351,940 shares. The potential reduction in the conversion price of the Series F and F-1 Preferred Stock described above represented a contingent beneficial feature which was resolved upon the closing of the Company's initial public offering on November 1, 2005. Based on the initial public offering price of \$10.00 per share, the beneficial conversion feature was deemed to have no value; consequently, no dividend was recognized relating to this feature. The Company closed its initial public offering on November 1, 2005 at a price of \$10.00 per share. As a result, an additional 439,925 shares of common stock were issued to the holders of Series F Preferred Stock and an additional 351,940 shares of common stock were issued to the holders of Series F-1 Preferred Stock on November 1, 2005.

Redemption Rights

The Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock were subject to redemption after May 1, 2007, upon written request of 70% of the holders of the outstanding shares of Preferred Stock voting together as a class. Upon such a request, the Company would have been required to redeem, subject to certain conditions, all of the Series B, Series C, Series D, Series E, Series F and Series F-1 Preferred Stock at their original issue price of \$2.67, \$5.21, \$5.97, \$5.97, \$7.28 and \$7.28 per share, respectively, plus any accrued but unpaid dividends.

Warrants

At December 31, 2005, warrants for a total of 172,321 shares of common stock were outstanding. These warrants have a weighted average exercise price of \$7.66 and expire at various dates from 2006 to 2011. During the year ended December 31, 2005, certain warrant holders exercised warrants to purchase 31,304 shares of the Company's common stock for an aggregate exercise price of \$223,060.

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 \$478,094 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.

Notes Receivable from Stockholders

During 1999 and 2000, the Company entered into note agreements with four officers of the Company totaling \$289,615. These full recourse notes were issued in connection with the exercise of stock options by the officers and accrued interest at a range of 5.2% to 5.5%. The notes contained a 25% recourse provision and were secured by 476,776 shares of the Company's common stock held by the officers upon exercise of the stock options. In 2004, these notes were cancelled by the Company and the amount of the notes was charged to compensation expense.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

13. Related-Party Transactions

The Company purchases tubing and certain other components used in the System One disposable cartridge, and more recently completed cartridges, from Medisystems Corporation, an entity owned by a member of the Company's board of directors. Purchases from Medisystems Corporation for 2005, 2004 and 2003 totaled approximately \$896,000, \$232,000 and \$41,000, respectively. Amounts owed to Medisystems Corporation totaled \$81,000 and \$32,000 at December 31, 2005 and 2004, respectively, and are included in accounts payable in the accompanying consolidated balance sheets.

14. Quarterly Financial Data (Unaudited)

	Year Ended December 31, 2005			
	March 31, 2005	June 30, 2005	September 30, 2005	December 31, 2005
Revenues	\$ 1,033,792	\$ 1,403,383	\$ 1,496,785	\$ 2,059,779
Gross profit (deficit)	(748,373)	(657,996)	(774,079)	(1,411,099)
Net loss	(4,909,131)	(5,606,652)	(6,589,913)	(7,373,914)
Net loss per common share, basic and diluted	\$ (1.91)	\$ (2.18)	\$ (2.57)	\$ (0.49)
	Year Ended December 31, 2004			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Revenues	\$ 262,262	\$ 453,819	\$ 441,940	\$ 726,548
Gross profit (deficit)	(240,345)	(390,964)	(463,605)	(459,349)
Net loss	(3,648,561)	(3,445,647)	(3,631,599)	(4,115,874)
Net loss per common share, basic and diluted	\$ (1.43)	\$ (1.35)	\$ (1.42)	\$ (1.60)

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, 2005. 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. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2005, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There have been no changes in the Company's internal control over financial reporting that occurred during the fourth quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. *Other Information*

Not applicable.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

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

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

The information required by this Item 10 will be contained in the section entitled "Management" of the Company's definitive proxy statement for its 2006 Annual Meeting of Stockholders to be filed with the SEC, and such information is incorporated in this Annual Report on Form 10-K by this reference.

Item 11. *Executive Compensation*

The information required by this Item 11 will be contained in the section entitled "Executive Compensation" of the Company's definitive proxy statement for its 2006 Annual Meeting of Stockholders to be filed with the SEC, and such information is incorporated in this Annual Report on Form 10-K by this reference.

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

The information required by this Item 12 will be contained in the section entitled "Beneficial Security Ownership" of the Company's definitive proxy statement for its 2006 Annual Meeting of Stockholders to be filed with the SEC, and such information is incorporated in this Annual Report on Form 10-K by this reference.

Item 13. Certain Relationships and Related Transactions

The information required by this Item 13 will be contained in the section entitled "Certain Transactions" of the Company's definitive proxy statement for its 2006 Annual Meeting of Stockholders to be filed with the SEC, and such information is incorporated in this Annual Report on Form 10-K by this reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be contained in the section entitled "Statement of Independent Auditors Fees and Services" of the Company's definitive proxy statement for its 2006 Annual Meeting of Stockholders to be filed with the SEC, and such information is incorporated in this Annual Report on Form 10-K by this reference.

PART IV

Item 15. Exhibits, Consolidated 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	54
Consolidated Balance Sheets	55
Consolidated Statements of Operations	56
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)	57
Consolidated Statements of Cash Flows	58
Notes to Consolidated Financial Statements	59

(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

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 1, 2006

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u> /s/ Jeffrey H. Burbank </u> Jeffrey H. Burbank	President, Chief Executive Officer and Director	March 1, 2006
<u> /s/ David N. Gill </u> David N. Gill	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	March 1, 2006
<u> /s/ Philippe O. Chambon </u> Philippe O. Chambon, M.D., Ph.D.	Chairman of the Board of Directors	March 1, 2006
<u> /s/ Jean-Francois Formela </u> Jean-Francois Formela, M.D.	Director	March 1, 2006
<u> /s/ Daniel A. Giannini </u> Daniel A. Giannini	Director	March 1, 2006
<u> /s/ Craig W. Moore </u> Craig W. Moore	Director	March 1, 2006
<u> /s/ Reid S. Perper </u> Reid S. Perper	Director	March 1, 2006
<u> /s/ Peter P. Phildius </u> Peter P. Phildius	Director	March 1, 2006
<u> /s/ David S. Utterberg </u> David S. Utterberg	Director	March 1, 2006

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	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	S-1/A	10.3	10/7/2005	333-126711
10.4	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
10.5	Secured 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
10.6	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
10.7	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
10.8	Warrant to Purchase Series E Preferred Stock dated September 26, 2002 issued to Comerica Bank	S-1	10.8	7/19/2005	333-126711
10.9	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
10.10	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
10.11	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
10.12#	Employment Agreement dated October 19, 2005 between the Registrant and Jeffrey H. Burbank	S-1/A	10.12	10/20/2005	333-126711
10.13#	Employment Agreement dated October 17, 2004 between the Registrant and Philip R. Licari	S-1/A	10.13	10/20/2005	333-126711
10.14#	Employment Agreement dated October 18, 2005 between the Registrant and Joseph E. Turk, Jr.	S-1/A	10.15	10/20/2005	333-126711
10.15#	Employment Agreement dated October 18, 2005 between the Registrant and Winifred L. Swan	S-1/A	10.16	10/20/2005	333-126711
10.16†	Supply Agreement dated as of October 26, 2004 between the Registrant and B. Braun Medizintechnologie GmbH	S-1/A	10.17	10/20/2005	333-126711

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.17†	Supply Agreement dated October 1, 2004 amount the Registrant, EIR Medical, Inc. and Membrana GmbH	S-1	10.18	7/19/2005	333-126711
10.18†	Production Agreement dated as of June 27, 2005 between the Registrant and KMC Systems, Inc.	S-1	10.19	7/19/2005	333-126711
10.19#	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
10.20#	2005 Stock Incentive Plan, together with Form of Incentive Stock Option Agreement and Form of Nonstatutory Stock Option Agreement	S-1/A	10.22	10/20/2005	333-126711
10.21#	Employment Agreement dated October 19, 2005 between the Registrant and David N. Gill	S-1/A	10.23	10/20/2005	333-126711
10.22#	Director Compensation Policy	8-K	10.1	12/14/2005	333-126711
*21	List of Subsidiaries				
*23	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.				
*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.

**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, 2005 (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)) 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) [not applicable]
 - 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 1, 2006

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

I, David N. Gill, certify that:

1. I have reviewed this Annual Report on Form 10-K of NxStage Medical, Inc. for the fiscal year ended December 31, 2005 (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)) 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) [not applicable]

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/ David N. Gill

David N. Gill
Chief Financial Officer and Senior Vice
President

Date: March 1, 2006

**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 period ended December 31, 2005 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 1, 2006

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.

**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 period ended December 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, David N. Gill, 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/ David N. Gill

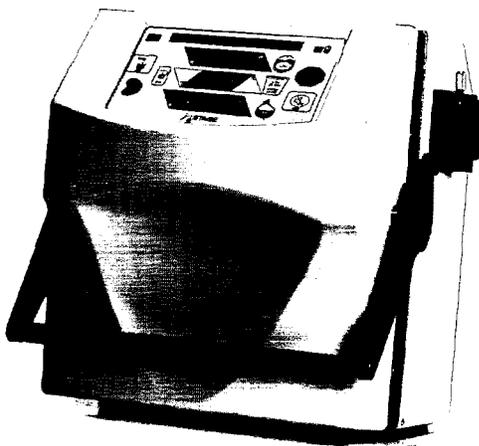
David N. Gill

Chief Financial Officer and Senior Vice President

Date: March 1, 2006

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

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bringing dialysis home.
changing lives.

NxStage is making a positive impact on peoples' lives by changing the way dialysis is delivered. We're leading the way to improved renal care with the world's most portable hemodialysis system. Our innovative yet simple approach provides dialysis clinics with exciting, new treatment alternatives. And it provides many more patients with the opportunity to manage their dialysis at home and improve their health and their daily lives. That's making a big difference.



Today, more than 350,000 Americans with End Stage Renal Disease (ESRD) undergo hemodialysis three times a week at more than 4,400 dialysis clinics across the U.S. This treatment model, in existence for decades, is labor intensive and increasingly costly. Worse yet, it provides patient care considered by many to be less than ideal, denying patients of an opportunity for a more healthy, normal life. There is significant room for improvement in the way dialysis treatment is provided. Indeed, a growing number of physicians recognize the clinical benefits of daily home dialysis: They report their patients are healthier, feel better and enjoy improved quality of life.

NxStage is leading the movement to make daily dialysis — at home or on the road — a practical option for many more ESRD patients. I am pleased to report that movement is well underway.

Achievements

Since its introduction in 2003, our breakthrough hemodialysis platform, the NxStage System One, has set a new standard for simplicity and accessibility, for both chronic and acute renal therapy. Our innovative approach to dialysis — simple, portable and flexible — has been validated by patients, physicians and nurses. This is demonstrated by our achievements in 2005:

- **We received FDA clearance for home use.** In June 2005, we received FDA clearance for home use of our system based on a clinical study comparing the safety and effectiveness of home and in-center hemodialysis with the NxStage System One.

- **We exceeded our expectations for new patients and dialysis centers,** achieving a total of 292 patients at 70 dialysis clinics, including seven dialysis centers with more than 10 NxStage patients each. This is a clear indication that we are emerging as the market leader in home hemodialysis — and that our clinic partners can build successful programs based on NxStage technology.

- **We increased annual revenue by 218% to \$6 million.** Notably, we increased revenue in the chronic home dialysis market by 473% to \$3.2 million. In the second half of 2005, our chronic care revenues surpassed our critical care revenues, a trend we expect to continue. Revenues also grew 112% in the critical care market, with 50 hospitals, including world-renowned institutions, now using the System One to treat their acute kidney failure patients.

- **We successfully completed our initial public offering in November 2005,** providing the resources necessary to advance our commercialization objectives.

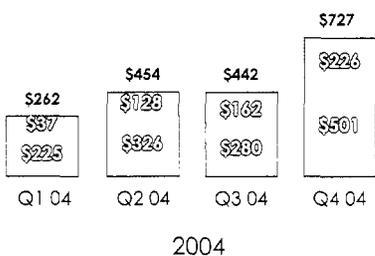
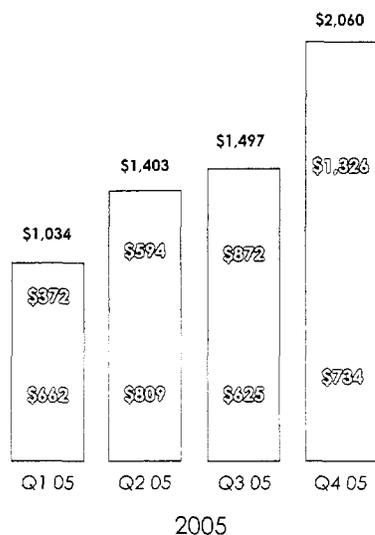
Goals for 2006

In 2006, we aim to surpass the very important 1,000-patient milestone. We plan to achieve this growth by expanding System One use at our existing 70 partner clinics, as well as adding more than 130 new clinics.

Today, the elements are in place to help us achieve our goals:

- **Strengthened marketing posture.** NxStage has a solid market presence, having expanded our field sales team to 20 salespeople and

Quarterly Growth in Revenues
(in thousands)



At NxStage, we're leading a movement to change the way dialysis is delivered.

22 clinical professionals. These are some of the most accomplished professionals in the marketplace, averaging more than 15 years of renal experience. In addition, we have launched a new corporate brand and invested in new marketing and training materials to support field sales and education.

□ **New frequent dialysis patient study.**

In February, 2006, we began enrolling patients in a new study called FREEDOM (Following Rehabilitation, Economics and Everyday Dialysis Outcome Measurements). This study is designed to quantify both the clinical benefits and the cost savings of daily therapy with the NxStage System One versus thrice-weekly, in-center dialysis.

□ **Positive reimbursement developments.** Important changes during 2005 and 2006 in Medicare reimbursement for dialysis have the potential to increase average treatment reimbursement rates by 15% - 20% for our patients. We continue to advocate further changes to better align reimbursement policies with today's dialysis realities. Our FREEDOM study is part of this effort.

□ **Enhanced patient support.** NxStage patients are passionate advocates for our approach and our products. Their word-of-mouth referrals to fellow patients are an important source of future growth. Accordingly, we have invested in customer service and support to help ensure our patients' success and satisfaction with NxStage daily dialysis.

□ **A proven model.** Home dialysis is not a new business model. Currently, more than 30,000 ESRD patients are treated at home using peritoneal dialysis. Leveraging this proven business model, NxStage makes home hemodialysis available to many of the patients for whom peritoneal dialysis is not an option. We are changing the way patients live, not the way business is conducted.

Pure opportunity

In conclusion, NxStage is positioned to leverage the exciting opportunities in today's renal care marketplace.

We have the innovative technology that changes dialysis as we know it, opening the door to daily home dialysis for many more patients. We are experiencing increasing market demand, as clinics and patients alike recognize the advantages of our innovative approach to dialysis. We have an experienced management team. And we have a team of employees driven by a shared commitment:

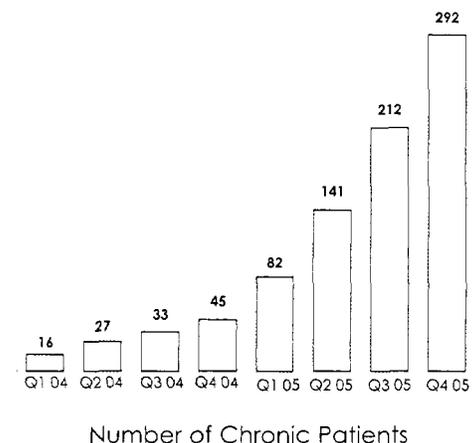
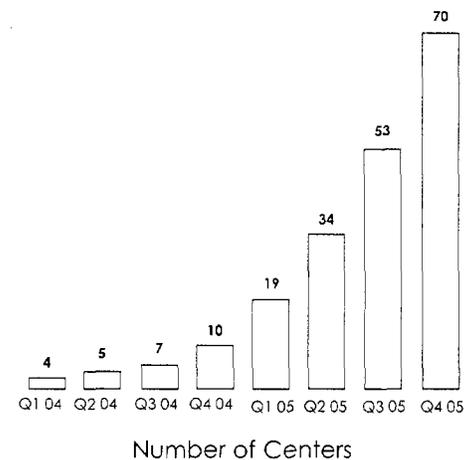
to lead a movement to dramatically improve renal care with innovative yet simple solutions that benefit patients, caregivers, and society.

The movement to transform renal care is in motion. And NxStage is leading the way.



Jeff Burbank, CEO

Chronic Patient and Center Adds





An Industry in Transition

For patients who depend on hemodialysis for survival, not much has changed in the past four decades. Despite incremental improvements in traditional dialysis technologies, mortality rates in the U.S. for patients with End Stage Renal Disease (ESRD) have not improved over the years. Each year, approximately 24% of ESRD patients die, often due to diabetes, hypertension and other serious conditions related to kidney dysfunction.

Meanwhile, dialysis service providers have undergone dramatic consolidation in an effort to increase efficiency and profitability. The resulting optimization around a short list of existing therapy options has limited opportunities for improving patient care.

But change is beginning to occur, driven by a number of important factors:

- **Growing patient population.** The number of ESRD patients is projected to double over the next 10-15 years. Yet the number of doctors and nurses available to care for them is not keeping pace.
- **Increasing costs.** Annual dialysis costs in the U.S. approach \$65,000 per patient, for a total cost of care exceeding \$20 billion in the U.S. alone.
- **Changing treatment protocols.** An increasing number of clinicians recognize *the health benefits of more frequent dialysis and the quality of life benefits of home therapy* have been long understood. Daily dialysis performed at home can lead to significant improvements in patients' health and quality of life. Yet these therapies have not achieved their potential due to the limitations of conventional dialysis clinic logistics and equipment.
- **Patient advocacy.** Many patients enduring the lifelong challenge of ESRD are yearning for — and advocating — treatment options that can help them gain control over their health, their treatment and their lives.

Dr. Stephen Korbet

Associate Director of Section of Nephrology,
Rush University Medical Center

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"NxStage leads the way in making practical the therapies we've wanted to offer, both in critical care and home settings. NxStage's simple technology, support, and track record of advancements enable more clinical flexibility. We've significantly expanded our scope of services with the system, and have made real positive impact on patients and families."



The NxStage Business Impact

By expanding the delivery of daily home dialysis, NxStage addresses these market realities in a profound way. While home dialysis accounts for just a small proportion of the hemodialysis market today, studies suggest that more than 25% of ESRD patients could take advantage of home therapies. NxStage estimates that by 2010, 60,000 to 70,000 U.S. patients could benefit from home hemodialysis — creating a potential \$1 billion home hemodialysis market in the U.S. alone.

Dialysis providers are responding to this emerging opportunity. Across the U.S., an increasing number of dialysis clinics are working to expand their home hemodialysis programs. By providing them with a new home treatment alternative, NxStage is helping partner clinics achieve their business objectives.

By making daily home therapy practical for many more patients, NxStage helps dialysis centers:

- Attract and retain patients by offering better, leading-edge therapy options.
- Treat more patients without expanding center footprint, buying more equipment or adding staff.
- Serve patients living farther away than is practical with an in-center program.
- Contribute to patient rehabilitation, improve patient lifestyles and, in many cases, enable patients to return to work and other life activities.
- Improve dialysis center economics through a more favorable mix of patients, including younger, healthier patients who wish to rejoin or stay in the workforce.

The NxStage Opportunity

- **Large, growing market:** ESRD patient population growing 6% each year
- **Two market segments:** Chronic (in-center and home) and Critical Care (hospital)
- **Recurring revenue model:** Ongoing disposable supply sales
- **Medicare reimbursement:** Explicitly covered, with recent changes favoring home dialysis
- **Breakthrough technology:** Smallest dialysis system FDA cleared for home use

The NxStage System One

Key to our vision of improving renal care is the NxStage System One, the first truly portable hemodialysis system for home use. The System One is designed to overcome many of the barriers that have prevented greater adoption of home dialysis...until now.

The System One offers important advantages for both acute and chronic renal care:

- For Chronic ESRD Patients, the System One offers the chance to enjoy the health benefits of daily hemodialysis, either at home or on the road. The compact size and simplicity of the System One make daily home hemodialysis a practical reality for many more patients.
- In Acute Care Settings, the System One gives clinicians the flexibility to deliver the more intensive renal therapies they believe will help their patients, while reducing the strain on overburdened critical care staff and resources.

The System One represents a major technology advance — and a major departure from traditional dialysis equipment.

NxStage Approach

- Simple and modular
- Compact and portable
- Designed for simplicity of training and use by patients and their caregivers
- Drop-in cartridge with automated setup
- Simple maintenance, wipe-down disinfection
- Flexible; physician can choose therapy modality, schedule and location

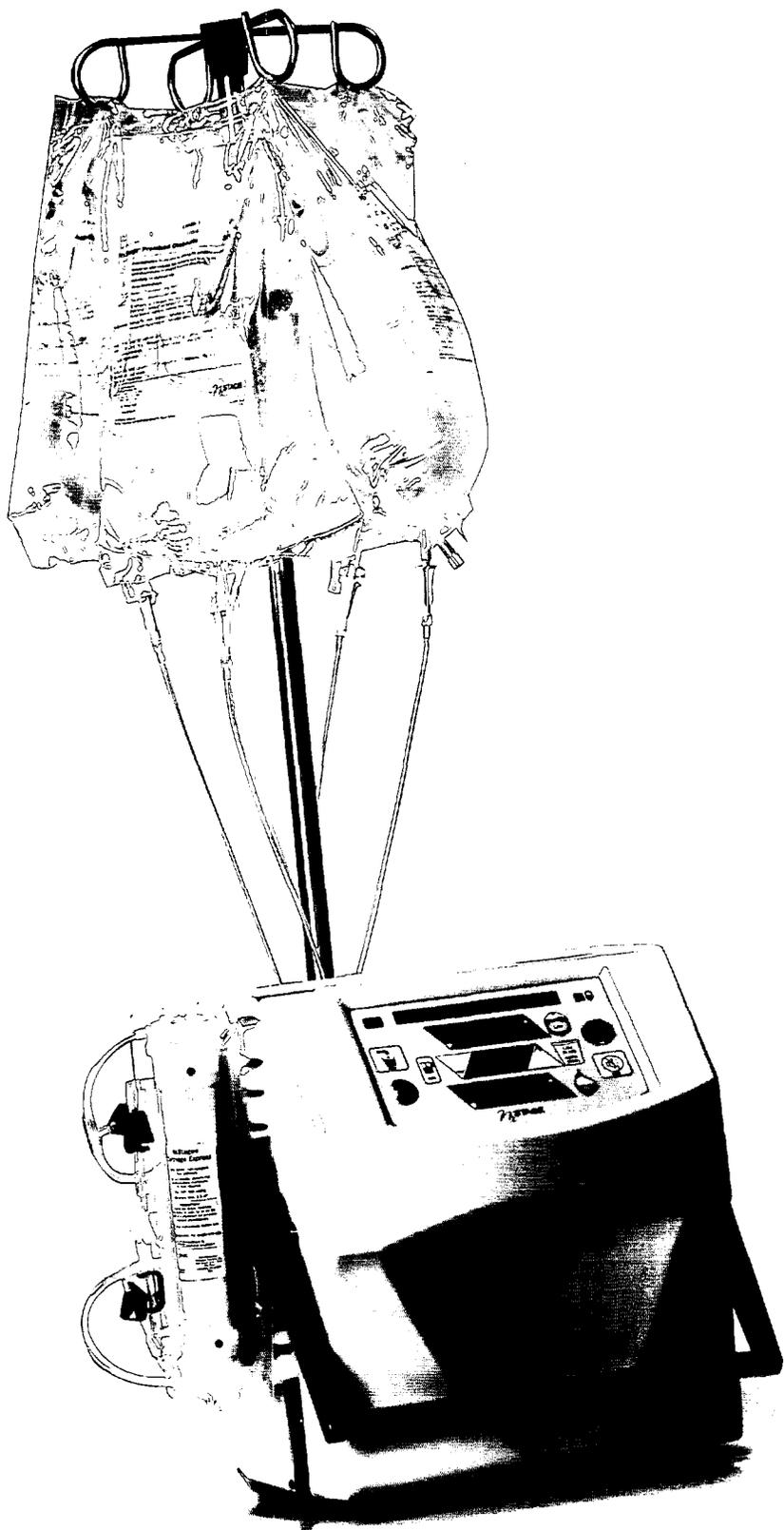


Jake Casey
2 year NxStage patient

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"Daily NxStage therapy gives me my life back. The up and down days of traditional dialysis are gone, and I feel great. I can go where I want. My life isn't scheduled around dialysis anymore – dialysis is scheduled around my life."

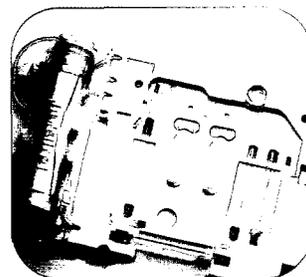
Technology Leadership

Our technology advancements are the product of a talented R&D team with more than 200 years of combined renal care experience and more than 100 patents. NxStage has built a patent portfolio of 20 issued patents and 66 worldwide patent applications (as of December 2005) related to our novel technologies for fluid management, disposable single use dialysis/filtration cartridges, innovative safety systems, and information and data systems.

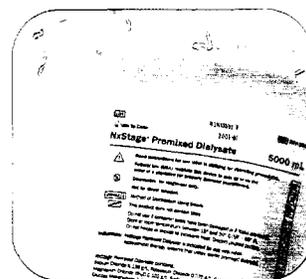


The NxStage System One was designed from the ground up to provide the simplicity and flexibility to make daily and home hemodialysis a practical reality, without compromising safety. These same simplicity advantages make the System One ideal for critical care hospital use, as well.

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Single-use, drop-in cartridge is key to the System One's simplicity. The integrated cartridge greatly simplifies set-up connections, and the pre-connected filter reduces the chance of blood or fluid leaks during treatment. The cartridge isolates the cyclor from fluid contact, simplifying maintenance and disinfection.



Sterile, prepackaged fluids simplify fluid preparation and dosing, while ensuring fluid quality. They also eliminate the need for special plumbing and complex water purification systems.

Transforming treatment. Creating opportunities.

As more physicians and patients discover the advantages of more frequent, more flexible dialysis therapy, the potential for improving lives is tremendous. Today, *daily home dialysis is poised to make a huge impact on the lives of many more patients. And NxStage is leading the way...*

...with innovative yet simple products that overcome the barriers that have prevented a better, more normal life in dialysis.

...with exclusive technology that makes renal care more flexible, simpler and, finally, truly portable.

...with a proven ability to expand its market presence — and the service offerings of its critical care and chronic care customers.

...with a solid strategy for achieving profitability and leading the way in a rapidly growing marketplace.

...with a shared passion for helping those in dialysis experience greater health, freedom and personal fulfillment.



Dr. John Moran
Senior Vice President,
Clinical Affairs
WellBound/Satellite Healthcare
.....

"NxStage finally makes home hemodialysis a real option for patients. The simple, clever design allows virtually anyone to consider it. The quality and flexibility of the therapy gives patients energy and freedom. Most patients honestly tell me this therapy gives them their lives back...and will often say they have not felt this well since before they developed kidney disease."



Corporate Information

Board of Directors

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

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

Jean-Francois Formela, MD
Senior Partner
Atlas Venture

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
Medisystems Corporation

Corporate Officers

Jeffrey H. Burbank
President and Chief Executive Officer

David N. Gill
Senior Vice President and
Chief Financial Officer

Philip R. Licari
Senior Vice President and
Chief Operating Officer

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

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

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 43010
Providence, RI 02940-3010
781-575-3100
www.computershare.com/equiserve

Independent Accountants

Ernst & Young, LLP
200 Clarendon Street
Boston, MA 02116

Annual Meeting

The Annual Meeting of Stockholders
will be held on Tuesday, May 30, 2006
at 10:00 a.m. at the offices of WilmerHale,
60 State Street, Boston, MA 02109

Market for NxStage Medical, Inc Stock

Nasdaq National 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 chronic and critical care dialysis markets in general and the home hemodialysis market in particular, the development and commercialization of our products, the adequacy of our funding and our ability to obtain additional funding, our ability to achieve profitable operations, 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 recent and 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. 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. 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.



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