NxStage Medical, Inc.
Form 10-Q
November 03, 2011

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, DC 20549**
**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2011**

**OR**

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

**For the transition period from _____ to _____**

**Commission file number: 000-51567**

**NxStage Medical, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **04-3454702** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(I.R.S. Employer Identification No.)* |
| **439 S. Union St., 5th Floor, Lawrence, MA** | **01843** |
| *(Address of Principal Executive Offices)* | *(Zip Code)* |

**(978) 687-4700**

(*Registrant s Telephone Number, Including Area Code)*

*(Former Name, Former Address, and Former Fiscal year, If Changed Since Last Report)*

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

There were 55,201,471 shares of the registrant s common stock outstanding as of the close of business on October 28, 2011.

**NXSTAGE MEDICAL, INC.**
**QUARTERLY REPORT ON FORM 10-Q**
**FOR THE QUARTER ENDED SEPTEMBER 30, 2011**
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## PART I FINANCIAL INFORMATION

**Item 1.** ***Financial Statements (unaudited)***

### NXSTAGE MEDICAL, INC.
### CONDENSED CONSOLIDATED BALANCE SHEETS
### (Unaudited)

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| | (In thousands, except share data) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 101,247 | $ 104,339 |
| Accounts receivable, net | 17,497 | 14,107 |
| Inventory | 35,563 | 34,950 |
| Prepaid expenses and other current assets | 3,104 | 2,084 |
| Total current assets | 157,411 | 155,480 |
| Property and equipment, net | 14,276 | 8,290 |
| Field equipment, net | 12,718 | 13,660 |
| Deferred cost of revenues | 41,355 | 40,081 |
| Intangible assets, net | 23,314 | 25,412 |
| Goodwill | 42,698 | 42,698 |
| Other assets | 1,497 | 473 |
| Total assets | $ 293,269 | $ 286,094 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 19,195 | $ 16,811 |
| Accrued expenses | 16,265 | 19,537 |
| Current portion of long-term debt | | 43 |
| Total current liabilities | 35,460 | 36,391 |
| Deferred revenues | 56,682 | 55,366 |
| Long-term debt | 42,521 | 40,454 |
| Other long-term liabilities | 6,994 | 1,754 |
| Total liabilities | 141,657 | 133,965 |
| Commitments and contingencies (Note 10) | | |
| Stockholders equity: | | |
| Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of September 30, 2011 and December 31, 2010 | | |
| Common stock: par value $0.001, 100,000,000 shares authorized; 55,617,552 and 54,043,317 shares issued as of September 30, 2011 and December 31, 2010, respectively | 55 | 53 |
| Additional paid-in capital | 485,191 | 465,642 |
| Accumulated deficit | (325,264) | (308,426) |

| | | |
|---|---|---|
| Accumulated other comprehensive income | 146 | 85 |
| Treasury stock, at cost: 480,923 and 325,104 shares as of September 30, 2011 and December 31, 2010, respectively | (8,516) | (5,225) |
| Total stockholders equity | 151,612 | 152,129 |
| Total liabilities and stockholders equity | $ 293,269 | $ 286,094 |

See accompanying notes to these condensed consolidated financial statements.

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**NXSTAGE MEDICAL, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| | (In thousands, except per share data) | | | |
| Revenues | $ 55,903 | $ 45,033 | $ 160,235 | $ 129,449 |
| Cost of revenues | 36,363 | 30,073 | 103,797 | 88,914 |
| Gross profit | 19,540 | 14,960 | 56,438 | 40,535 |
| Operating expenses: | | | | |
| Selling and marketing | 9,446 | 8,452 | 28,025 | 25,034 |
| Research and development | 3,388 | 3,132 | 10,694 | 9,369 |
| Distribution | 4,709 | 3,788 | 13,298 | 10,831 |
| General and administrative | 5,708 | 6,023 | 16,750 | 16,604 |
| Total operating expenses | 23,251 | 21,395 | 68,767 | 61,838 |
| Loss from operations | (3,711) | (6,435) | (12,329) | (21,303) |
| Other expense: | | | | |
| Interest expense | (1,186) | (1,176) | (3,513) | (3,432) |
| Other (expense), net | (146) | (341) | (342) | (128) |
| | (1,332) | (1,517) | (3,855) | (3,560) |
| Net loss before income taxes | (5,043) | (7,952) | (16,184) | (24,863) |
| Provision for income taxes | 235 | 212 | 654 | 556 |
| Net loss | $ (5,278) | $ (8,164) | $ (16,838) | $ (25,419) |
| Net loss per share, basic and diluted | $ (0.10) | $ (0.17) | $ (0.31) | $ (0.54) |
| Weighted-average shares outstanding, basic and diluted | 54,428 | 48,049 | 53,953 | 47,501 |

See accompanying notes to these condensed consolidated financial statements.

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**NXSTAGE MEDICAL, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2011 | 2010 |
| | (In thousands) | |
| Cash flows from operating activities: | | |
| Net loss | $ (16,838) | $ (25,419) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 17,415 | 16,879 |
| Stock-based compensation | 10,166 | 10,985 |
| Other | 2,387 | 1,750 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (3,414) | (303) |
| Inventory | (15,196) | (20,504) |
| Prepaid expenses and other assets | (2,067) | (327) |
| Accounts payable | 2,296 | (3,376) |
| Accrued expenses and other liabilities | 195 | 3,980 |
| Deferred revenues | 1,316 | 14,087 |
| Net cash used in operating activities | (3,740) | (2,248) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (3,330) | (981) |
| Net cash used in investing activities | (3,330) | (981) |
| Cash flows from financing activities: | | |
| Proceeds from stock option and purchase plans | 6,471 | 5,552 |
| Purchase of treasury stock | (2,533) | (1,741) |
| Repayments on loans and lines of credit | (46) | (42) |
| Net cash provided by financing activities | 3,892 | 3,769 |
| Foreign exchange effect on cash and cash equivalents | 86 | (286) |
| (Decrease) increase in cash and cash equivalents | (3,092) | 254 |
| Cash and cash equivalents, beginning of period | 104,339 | 21,720 |
| Cash and cash equivalents, end of period | $ 101,247 | $ 21,974 |
| **Noncash Investing Activities** | | |
| Transfers from inventory to field equipment | $ 13,432 | $ 15,612 |
| Transfers from field equipment to deferred cost of revenues | $ 9,663 | $ 15,999 |

See accompanying notes to these condensed consolidated financial statements.

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**NXSTAGE MEDICAL, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(Unaudited)**

## 1. Nature of Operations

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

Over the past several years we have improved our cash flows from operating activities and continue to work towards our long-term goal of sustained positive cash flows from operating activities. However, we expect cash flows from operating activities in the near term to fluctuate between negative and positive on a quarterly basis, primarily due to changes in working capital. There can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Our ability to and the rate at which we continue to improve cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross profits, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment.

### Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2011 and for the three and nine months then ended, and related notes, are unaudited but, in the opinion of our management, include all adjustments, consisting of normal recurring adjustments that are necessary for fair statement of the interim periods presented. Our unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under these rules, we have condensed or omitted certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP. Our accounting policies are described in the notes to the consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and updated, as necessary, in this Quarterly Report on Form 10-Q. Operating results for the three and nine months ended September 30, 2011 are not necessarily indicative of results for the entire fiscal year or future periods. The December 31, 2010 condensed consolidated balance sheet contained herein was derived from audited financial statements, but does not include all disclosures required by GAAP. For further information, refer to the consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

## 2. Summary of Significant Accounting Policies

### *Principles of Consolidation and Basis of Presentation*

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

consolidation.

***Use of Estimates***

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

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***Revenue Recognition***

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

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

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

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

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

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

The adoption of the amended guidance did not change the accounting for arrangements entered into prior to January 1, 2011. Therefore, these arrangements with multiple elements were divided into separate units of accounting if there was objective and reliable evidence of fair value of the undelivered items and if other criteria were met, including whether the delivered element had stand-alone value to the customer. If either criteria were not met, the arrangement was accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment were deferred and are recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery. The adoption of the amended guidance did not have a material impact on our revenues for the three and nine months ended September 30, 2011.

*System One Segment*

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

For customers that purchase the System One and PureFlow SL hardware, in the home U.S. market, due to the depot service model whereby equipment requiring service is picked up and a replacement device is shipped to the site of care, we recognize fees received from equipment sale as revenue on a straight-line basis over the expected term of our

remaining service obligation and direct costs relating to the delivered equipment are deferred and amortized over the same expected period as the related revenue. Disposable products revenue is recognized on a monthly basis upon delivery.

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

Our sales arrangements with our international distributors are structured as direct product sales and have no significant post delivery obligations with the exception of standard warranty obligations. However, under the previous guidance, for arrangements entered into prior to January 1, 2011 we determined that we could not account for the sale of equipment as a separate unit of accounting and, therefore, the fees received upon the completion of delivery of equipment were deferred and

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recognized as revenue on a straight-line basis over the expected term of our remaining service obligation and direct costs relating to the delivered equipment were amortized over the same expected period as the related revenue. Under the amended guidance, for arrangements entered into or materially modified on or after January 1, 2011, we will recognize revenues and related direct costs upon delivery in accordance with contract terms. Disposable product revenue is recognized on a monthly basis upon delivery under both the previous and amended guidance.

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

*In-Center Segment*

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

***Concentration of Credit Risk***

Concentration of credit risk with respect to accounts receivable is primarily limited to certain customers to whom we make substantial sales. One customer represented 22% and 23% of accounts receivable at September 30, 2011 and December 31, 2010, respectively.

***Warranty Costs***

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

| | |
|---|---|
| Balance at December 31, 2010 | $ 268 |
| Provision | 505 |
| Usage | (420) |
| Balance at September 30, 2011 | $ 353 |

***Recent Accounting Pronouncements***

In September 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-08, *Intangibles Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. This update allows an entity the option to make a qualitative evaluation about the likelihood of goodwill impairment to determine whether it should calculate the fair value of a reporting unit. Under these amendments, an entity would not be required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The amendments include a number of events and circumstances for an entity to consider in conducting the qualitative assessment. The amendments in this ASU are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill impairment tests performed as of a date before September 15, 2011, if an entity s financial statements for the most recent annual or interim period have not yet been issued. We do not expect that adoption of this update will have a material impact on our financial position or results of operations.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220)*. This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. This update does not change the items that must

be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor does it affect how earnings per share is calculated or presented. This update is required to be applied retrospectively and is effective for us for fiscal years and interim periods within those years beginning January 1, 2012. As this update only requires enhanced disclosure, the adoption of this update will not impact our financial position or results of operations.

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In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. This update clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This update is effective on a prospective basis for our annual and interim reporting periods beginning on January 1, 2012. We do not expect that adoption of this standard will have a material impact on our financial position or results of operations.

**3. Inventory**

Inventory includes material, labor and overhead, and is stated at lower of cost (first-in, first-out) or market. The components of inventory are as follows (in thousands):

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| Purchased components | $ 14,091 | $ 14,928 |
| Work in process | 9,906 | 6,372 |
| Finished goods | 11,566 | 13,650 |
| | $ 35,563 | $ 34,950 |

**4. Property and Equipment and Field Equipment**

Accumulated depreciation on property and equipment was $14.4 million and $11.8 million at September 30, 2011 and December 31, 2010, respectively. Accumulated depreciation on field equipment was $32.8 million and $29.1 million at September 30, 2011 and December 31, 2010, respectively.

At September 30, 2011, we had $5.2 million recorded in property and equipment and other long-term liabilities related to construction of a new manufacturing facility in Germany pursuant to the terms of our Dialyzer Production Agreement entered into in May 2009 with Asahi Kasei Kuraray Medical, or Asahi. We are overseeing construction of this new facility and will operate the new facility under a manufacturing agreement upon its completion. Asahi will fund construction costs up to an original fixed amount; however, we will be responsible for any additional costs. If the agreement is terminated during the construction period due to our breach, insolvency or bankruptcy, Asahi has the option to require us to pay for all amounts expended for construction of the new facility. If such event occurs we would take title to the land and any construction in process. Subsequent to the completion of construction, if the agreement is terminated due to our breach, insolvency or bankruptcy, or by us pursuant to certain terms of the agreement, Asahi has the option to require us to purchase the new facility from them by paying one hundred percent of the then net book value of the new facility, as calculated in accordance with GAAP. Given these options and our involvement in the construction, we are considered the owner of the new facility for accounting purposes and will therefore record its cost as construction-in-process and a corresponding liability has been recorded for the construction cost funded by Asahi. The $5.2 million recorded at September 30, 2011 reflects the construction costs incurred to date in connection with this project.

**5. Intangible Assets**

Accumulated amortization on intangible assets was $11.2 million and $9.1 million at September 30, 2011 and December 31, 2010, respectively.

**6. Comprehensive Loss**

The following table presents the components of comprehensive loss (in thousands):

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| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Net loss | $ (5,278) | $ (8,164) | $ (16,838) | $ (25,419) |
| Foreign currency translation (loss) gain | (249) | 256 | 61 | (321) |
| Comprehensive loss | $ (5,527) | $ (7,908) | $ (16,777) | $ (25,740) |

**7. Net Loss per Share**

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Options to purchase common stock | 2,752 | 3,268 | 3,187 | 2,817 |
| Restricted stock | 843 | 748 | 747 | 716 |
| Warrants to purchase common stock | 1,085 | 1,076 | 1,135 | 933 |
| Total | 4,680 | 5,092 | 5,069 | 4,466 |

**8. Segment Disclosures**

After an evaluation of the business activities regularly reviewed by our chief operating decision maker for which separate discrete financial information is available, we determined that we have two reporting segments, System One and In-Center. The accounting policies of the reportable segments are the same as those described in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. The profitability measure employed by us and our chief operating decision maker for making decisions about allocating resources to segments and assessing segment performance is segment profit (loss), which consists of revenues less cost of revenues, selling and marketing and distribution expenses.

Our management measures are designed to assess performance of these operating segments, excluding certain items. As a result, certain corporate expenses are excluded from the segment operating performance measures, including research and development expenses and general and administrative expenses, as they are managed centrally.

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

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

distributors.

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

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| | System One | In-Center | Unallocated | Total |
|---|---|---|---|---|
| Three Months Ended September 30, 2011 | | | | |
| Revenues from external customers | $ 36,388 | $19,515 | $ | $ 55,903 |
| Segment profit (loss) | 3,566 | 1,819 | (9,096) | (3,711) |
| Segment assets | 88,547 | 18,586 | 186,136 | 293,269 |
| Three Months Ended September 30, 2010 | | | | |
| Revenues from external customers | $ 29,163 | $15,870 | $ | $ 45,033 |
| Segment profit (loss) | 464 | 2,256 | (9,155) | (6,435) |
| Segment assets | 84,053 | 15,316 | 101,773 | 201,142 |
| Nine Months Ended September 30, 2011 | | | | |
| Revenues from external customers | $105,475 | $54,760 | $ | $160,235 |
| Segment profit (loss) | 9,253 | 5,862 | (27,444) | (12,329) |
| Segment assets | 88,547 | 18,586 | 186,136 | 293,269 |
| Nine Months Ended September 30, 2010 | | | | |
| Revenues from external customers | $ 81,732 | $47,717 | $ | $129,449 |
| Segment (loss) profit | (1,626) | 6,296 | (25,973) | (21,303) |
| Segment assets | 84,053 | 15,316 | 101,773 | 201,142 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Customer A | 20% | 22% | 21% | 22% |
| Customer B | 13% | 16% | 13% | 17% |
| Customer C | 14% | 12% | 14% | 13% |

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

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

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| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| Total segment assets | $ 107,133 | $ 102,798 |
| Corporate assets: | | |
| Cash and cash equivalents | 101,247 | 104,339 |
| Property and equipment, net | 14,276 | 8,290 |
| Intangible assets, net | 23,314 | 25,412 |
| Goodwill | 42,698 | 42,698 |
| Prepaid expenses and other assets | 4,601 | 2,557 |
| Total assets | $ 293,269 | $ 286,094 |

**9. Income Taxes**

The provision for income taxes of $0.2 million for the three months ended September 30, 2011 and 2010, respectively, and $0.7 million and $0.6 million for the nine months ended September 30, 2011 and 2010, respectively, relates to the profitable operations of certain foreign entities.

**10. Commitments and Contingencies**

In June 2011, we entered into a new lease agreement with 350 Riverwalk LLC. The lease is for a new corporate headquarters to be located in Lawrence, MA. The term of the lease will begin on or before June 1, 2012 and continue for an initial term of eleven years with an early termination provision after seven years, subject to certain terms and conditions. We have two, five year options to extend this lease on substantially the same terms and at rent equal to ninety-five percent of the then fair market value. In addition, we are responsible for the real estate taxes and operating expenses related to this facility. The landlord is providing us a $4.3 million tenant improvement allowance pursuant to the agreement. The future minimum annual rental payments under this agreement are estimated to be $0.8 million, $1.2 million, $1.4 million and $1.6 million, during 2012, 2013, 2014 and 2015, respectively, and $14.6 million thereafter.

Other significant commitments and contingencies at September 30, 2011 are consistent with those discussed in Note 11 to the consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

**11. Stock-Based Compensation**

***Stock-based Compensation Expense***

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| Cost of revenues | $ 498 | $ 629 | $ 1,532 | $ 1,644 |
| Selling and marketing | 1,432 | 1,460 | 4,062 | 3,940 |
| Research and development | 258 | 587 | 924 | 1,618 |
| General and administrative | 1,277 | 1,434 | 3,648 | 3,783 |
| | $ 3,465 | $ 4,110 | $ 10,166 | $ 10,985 |

***Stock Options and Restricted Stock Units***

The Company granted options to purchase 12,544 and 55,000 shares of common stock during the three months ended September 30, 2011 and 2010, respectively, and options to purchase 485,939 and 1,355,300 shares of common

stock during the

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nine months ended September 30, 2011 and 2010, respectively. The weighted-average fair value of options granted during the nine months ended September 30, 2011 and 2010 was $11.23 and $5.55 per option, respectively.

The Company awarded 20,270 and 122,509 restricted stock units during the three and nine months ended September 30, 2011. The restricted stock units vest based on continued employment over a period of two or four years. The weighted-average fair value of restricted stock units granted during the nine months ended September 30, 2011 was $18.78 per unit.

***Performance Based Plans***

In May 2011, the Company s Compensation Committee of the Board of Directors, or the Compensation Committee, approved the Company s 2011 Performance Share Plan in which it committed to grant up to 285,670 restricted stock units to certain employees and executive officers based on the achievement of certain Company financial performance metrics for the year ending December 31, 2011. The restricted stock units, if awarded, vest over a requisite service period of three years. The estimated expense under the 2011 Performance Share Plan is being recognized as stock-based compensation expense over the requisite service period. Further, in March 2011, the Compensation Committee approved the Company s 2011 Corporate Bonus Plan. Payout under the 2011 Corporate Bonus Plan will be based on individual performance and the achievement of certain Company financial performance metrics for the year ending December 31, 2011 and will be paid in shares of the Company s common stock, or in cash, at the discretion of the Compensation Committee. The estimated payout under the 2011 Corporate Bonus Plan is being recognized as compensation expense during 2011, with nearly all of this compensation expense classified as stock-based compensation expense, and has been classified as a liability on the Company s condensed consolidated balance sheet.

**12. Stockholders Equity**

We received 115,418 and 174,757 shares during the quarter ended March 31, 2011 and 2010, respectively, that were surrendered by employees in payment for the minimum required withholding taxes associated with awards under our Corporate Bonus and Performance Share Plans. We received 40,401 shares that were surrendered in payment for the exercise of stock options through the nine months ended September 30, 2011. The settlement of $2.8 million and $1.6 million during the first quarter of 2011 and 2010, respectively, of the Company s 2010 Corporate Bonus Plan obligation in shares of our common stock represents a noncash financing activity.

**13. Fair Value Measurements**

At September 30, 2011, we had $84.8 million in money market funds, included in cash and cash equivalents, measured at fair value on a recurring basis utilizing quoted prices (unadjusted) in active markets for identical assets, also referred to as level 1 inputs.

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

The carrying amount of our long-term debt approximates fair value at September 30, 2011. The fair value of our long-term debt was estimated using inputs derived principally from market observable data, including current rates offered to us for debt of the same or similar remaining maturities. Within the hierarchy of fair value measurements, these are level 2 inputs.

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**Item 2.** ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

**Special Note Regarding Forward Looking Statements**

The following discussion should be read with our unaudited condensed consolidated financial statements and notes included in Part I, Item 1 of this Quarterly Report for the three and nine months ended September 30, 2011, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2010, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC.

This Quarterly Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to: the market adoption of our products in the United States and internationally; the growth of the home, critical care and in-center dialysis markets in general and the home hemodialysis market in particular; the development and commercialization of our products; changes in the historical purchasing patterns and preferences of our key customers, including DaVita Inc. and Fresenius Medical Care; the adequacy of our funding; our ability to achieve and sustain positive cash flows; whether and when we might achieve improvements to our gross profit as a percentage of revenues and operating expenses; expectations with respect to our operating expenses and achieving our business plan; expectations with respect to achieving profitable operations; expectations with respect to achieving improvements in product reliability; the timing and success of the submission, acceptance and approval of regulatory filings and the impact of any changes in the regulatory environment with respect to our products or business; the scope of patent protection with respect to our products; expectations with respect to the clinical findings of our FREEDOM study and other ongoing clinical studies evaluating home and/or daily hemodialysis; expectations as to the continued availability of raw materials, components, and finished goods from key single source suppliers; expectations with respect to our ability to supply on a timely and uninterrupted basis all products ordered by our customers; and the impact of new and future changes to reimbursement for chronic dialysis treatments. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words expect , anticipate , intend , plan , believe , seek estimate , potential , continue , predict , may , and similar expressions are intended to 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.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II. We undertake no obligation to revise or update publicly any forward-looking statement for any reason. Readers should carefully review the factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report and in Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as in other documents filed by us with the SEC, as they may be amended from time to time, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

**Introduction**

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

primarily to dialysis clinics for the treatment of end-stage renal disease, or ESRD. These products are cleared or approved for commercial sale in the United States, Europe, Canada and other select markets. We believe our largest future product market opportunity is for our System One used in the home hemodialysis market for the treatment of ESRD.

We report the results of our operations in two segments: System One and In-Center. We distribute our products in three markets: home, critical care and in-center. In the System One segment we derive our revenues from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. In the In-Center segment, we derive our revenues from the

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sale of blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers and needles for apheresis, which is referred to as the in-center market.

**Segment and Market Highlights**

Our customers in the System One segment are highly consolidated. Fresenius Medical Care, or Fresenius, and DaVita Inc., or DaVita, own and operate the two largest chains of dialysis clinics in the United States and collectively provide treatment to approximately two-thirds of United States dialysis patients. DaVita is our most significant customer for the System One segment. Sales to DaVita represented approximately 31% and 33% of our System One segment revenues for the three and nine months ended September 30, 2011 and 2010, respectively. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. A growing percentage of our sales are to Fresenius, which is our second largest customer in the System One segment, with nearly all of those sales in the home market. Increased sales to DaVita and Fresenius have driven a large portion of our historical revenue growth and will be important to future growth. If the purchasing patterns of either of these customers adversely change, our business could be negatively affected.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Revenues from Henry Schein, Inc., or Henry Schein, a significant distributor, represented approximately 40% and 45% of our In-Center segment revenues during the three and nine months ended September 30, 2011 and 2010, respectively. Our other largest distributor is Gambro Renal Products, Inc., or Gambro. Revenues from Gambro represented approximately 40% and 35% of our In-Center segment revenues during the three and nine months ended September 30, 2011 and 2010, respectively.

DaVita is also a significant customer in the in-center market. Sales of our products through distributors to DaVita accounted for approximately half of In-Center segment revenues for both the three and nine months ended September 30, 2011 and 2010. DaVita has contractual purchase commitments under two agreements: one with us for needles and one with Gambro for blood tubing sets. DaVita s purchase obligations with respect to needles will expire under an agreement with us in January 2013. Gambro s long term product supply agreement with DaVita, entered into in connection with the sale of Gambro s United States dialysis clinic business to DaVita, obligates DaVita to purchase a significant majority of its blood tubing set requirements from Gambro. Our distribution agreement with Gambro, which expires in June 2014, contractually obligates Gambro to exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines, to DaVita.

We offer certain customers rebates based on sales to specific end users and discounts for early payment. Our revenues are presented net of these rebates and discounts. As of September 30, 2011, we had $1.8 million and $0.5 million reserved against trade accounts receivable for future rebates and discounts for customers in our In-Center and System One segments, respectively. We recorded $1.8 million and $1.0 million during the three months ended September 30, 2011 and 2010, respectively, and $4.8 million and $3.9 million during the nine months ended September 30, 2011 and 2010, respectively, as a reduction of In-Center segment revenues in connection with rebates and discounts. For the System One segment, we recorded $0.8 million and $0.2 million during the three months ended September 30, 2011 and 2010, respectively, and $1.5 million and $0.5 million during the nine months ended September 30, 2011 and 2010, respectively, in connection with rebates and discounts.

As an alternative to a cash-based rebate, we issued to DaVita a warrant that may vest and become exercisable to purchase up to 5.5 million shares of our common stock based upon the achievement of certain System One home patient growth targets at June 30, 2011, 2012 and 2013. This warrant-based rebate structure preserves our cash, and provides for the issuance of shares upon the exercise of any warrants earned only if patient access to home hemodialysis with the System One is materially expanded. The warrants have an exercise price of $14.22 per share, expire during 2013, are non-transferable and must be exercised in cash. The accounting for these warrants is similar to the accounting for cash-based rebates. Specifically, the warrants are measured at fair value through their date of vesting and recognized as a reduction of revenues, based on the number of warrants expected to vest over the same expected period as the related expected product revenues, which is 7 to 10 years. Estimates of the number of warrants expected to vest and the fair value of the warrants will be revised each reporting period through the date of vesting. For the period ended June 30, 2011, DaVita achieved System One home patient growth targets that entitled DaVita to become vested in warrants to purchase 250,000 shares of our common stock. The reduction of revenues recorded in

connection with these warrants was not significant during the three or nine months ended September 30, 2011.

**Financial Performance**

During the three and nine months ended September 30, 2011, we grew our revenues by 24% to $55.9 million and $160.2 million, respectively, with growth occurring in each market: home, critical care and in-center. Home revenues drove the growth, increasing $4.9 million, or 22%, and $18.1 million, or 29%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable period, due primarily to an increase in the number of patients prescribed to use and centers offering the System One, including the continued adoption of System One internationally. We expect to see continued growth in our revenues, primarily driven by the System One segment as we further penetrate the markets, and expand internationally.

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We continue to see improvements in our financial performance below the revenue line. We have not yet achieved profitable operating margins, but we have made improvements to gross profit as a percentage of revenues. Gross profit as a percentage of revenues increased to 35% for the three and nine months ended September 30, 2011, respectively, from 33% and 31% for the prior year comparable periods. The improvement in gross profit as a percentage of revenues for both periods was mainly attributable to lower product and service costs, partially offset by unfavorable foreign exchange rates versus the U.S. dollar and costs incurred by our In-Center segment related to the transition of manufacturing of certain blood tubing sets from a contract manufacturer to our own manufacturing facility beginning in the second quarter of 2011. While we expect to continue to improve gross profit as a percentage of revenues as a result of various initiatives including the consolidation of our manufacturing network, these improvements will continue to be offset in the short-term by unfavorable foreign exchange rates versus the U.S. dollar and costs to transition certain blood tubing sets from a contract manufacturer to our own manufacturing facility.

Over the long-term, we expect to see continued improvements to our cash flows from operating activities, driven in meaningful part through continued improvement in our gross profit. However, in the near term, we expect cash flows from operating activities on a quarterly basis to fluctuate between negative and positive, primarily due to changes in working capital.

We are encouraged by the improvements to our operating margins and are continuing to work hard toward our long-term goal of achieving profitable operating margins. However, there can be no assurance that we will be able to continue to improve our operating margins or achieve positive operating margins. Our ability to become profitable and its timing and sustainability, depends principally upon continued improvements in gross profit, growing revenues, and leverage of our operating infrastructure. including the effects of any investment in selling and marketing or research and development activities.

**Comparison of the Three and Nine Months Ended September 30, 2011 and 2010**

*Revenues*

Our revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| System One segment | | | | | | | | |
| Home | $ 27,218 | 49% | $ 22,346 | 50% | $ 80,276 | 50% | $ 62,204 | 48% |
| Critical Care | 9,170 | 16% | 6,817 | 15% | 25,199 | 16% | 19,528 | 15% |
| Total System One segment | 36,388 | 65% | 29,163 | 65% | 105,475 | 66% | 81,732 | 63% |
| In-Center segment | 19,515 | 35% | 15,870 | 35% | 54,760 | 34% | 47,717 | 37% |
| Total | $ 55,903 | 100% | $ 45,033 | 100% | $ 160,235 | 100% | $ 129,449 | 100% |

The increase in revenues over the comparable prior year periods was mainly attributable to increased sales and rentals of the System One and related disposables in both the home and critical care markets, primarily as a result of the growing number of patients using the System One as we continue to penetrate these markets, including the continued adoption of the System One internationally.

In the home market, revenues increased $4.9 million, or 22%, and $18.1 million, or 29%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, primarily due to an increase in the number of patients prescribed to use and centers offering the System One and, to a lesser extent, the impact of adopting a new accounting standard which effected revenue recognition for sales to our international distributors. In the U.S. we have increased the average number of patients at existing centers and the number of total centers offering the System One through new and existing relationships with service providers, including DaVita and

Fresenius. Critical care market revenues increased $2.4 million, or 35%, and $5.7 million, or 29%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, due to increased sales of disposables from our growing number of System One equipment placed within hospitals and increased sales of our System One equipment. Future demand for our products and revenue growth in both the home and critical care markets is expected to remain strong as we further penetrate these markets, expand internationally, and leverage the annuity nature of our business. As our international business grows our System One revenue may be susceptible to fluctuations in international equipment sales and changes in inventory levels at our international distributors. Our two largest customers in the home market, DaVita and Fresenius, will be important to that growth, specifically in the U.S. market. If the purchasing patterns of either of these customers adversely change, our business could be negatively affected.

In-Center segment revenues increased $3.6 million, or 23%, and $7.0 million, or 15%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, due to higher sales volumes of our blood tubing

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sets, primarily Streamline, driven by increased end user demand and changes in distributor inventory levels. While quarterly revenues continue to be susceptible to fluctuations in inventory levels at our distributors, end user demand of both our blood tubing sets and our needle products continues to grow. We expect future revenues will continue to be susceptible to fluctuation, especially in the near term, due to the transition of our major distributors and customers to our next generation Streamline blood tubing set and, longer-term, as a result of increased competition and variations in inventory management policies with both our distributors and end users.

*Gross Profit*

Our gross profit and gross profit as a percentage of revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| System One segment | $ 15,412 | 42% | $ 10,978 | 38% | $ 44,351 | 42% | $ 29,373 | 36% |
| In-Center segment | 4,128 | 21% | 3,982 | 25% | 12,087 | 22% | 11,162 | 23% |
| Gross profit | $ 19,540 | 35% | $ 14,960 | 33% | $ 56,438 | 35% | $ 40,535 | 31% |

Gross profit increased $4.6 million, or 31%, and $15.9 million, or 39%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, driven by the System One segment. Gross profit for the System One segment increased $4.4 million, or 40%, and $15.0 million, or 51%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, due to increased revenues and improvement in gross profit as a percentage of revenues. The improvement in gross profit as a percentage of revenues for both periods was attributable to several factors, including lower product manufacturing and service costs driven by continued leveraging of our manufacturing infrastructure, certain cost saving initiatives and improvements in product design and reliability, and lower depreciation expense on our field equipment assets resulting from the change in the useful life of certain of these assets from five to seven years during the fourth quarter of 2010. These favorable changes were partially offset by unfavorable impact of changes in foreign exchange rates versus the U.S. dollar.

Gross profit for the In-Center segment for the three and nine months ended September 30, 2011 increased slightly in absolute dollars and decreased as a percentage of revenues versus the prior year comparable period. Gross profit changes in the three and nine month periods were driven by increased revenues offset by the unfavorable impact of changes in foreign currency rates versus the U.S. dollar, costs incurred relating to the transition of certain blood tubing sets from a contract manufacturer to our own manufacturing facility, increased freight costs and increased resin costs as a result of higher oil prices.

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

may see an increase in the cost of certain raw materials, due to increases in the cost of commodities, particularly resin. Fourth, we expect future demand for our products to continue to grow; however, higher relative sales of lower margin products and certain pricing strategies would have a negative impact on gross profit as a percentage of revenues. Finally, rationalization and consolidation of our manufacturing operations, in an effort to drive long-term gross margin improvement, will require us to incur additional costs in the short-term.

*Selling and Marketing*

Our selling and marketing expenses and selling and marketing as a percent of revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

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| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| System One segment | $ 8,085 | 22% | $ 7,185 | 25% | $ 24,088 | 23% | $ 21,505 | 26% |
| In-Center segment | 1,361 | 7% | 1,267 | 8% | 3,937 | 7% | 3,529 | 7% |
| Total Selling and marketing | $ 9,446 | 17% | $ 8,452 | 19% | $ 28,025 | 17% | $ 25,034 | 19% |

Selling and marketing expenses increased $1.0 million, or 12%, and $3.0 million, or 12%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, but decreased as a percentage of revenues. The increases in both periods were primarily due to increased personnel and personnel-related costs, and increased spending due to expanded marketing programs within both segments. Selling and marketing expenses for the System One segment decreased as a percentage of revenues for both the three and nine months ended September 30, 2011, versus the prior year comparable periods, due to our initiative to continue to leverage our infrastructure. Selling and marketing expenses for the In-Center segment decreased slightly as a percentage of revenues for the three months ended September 30, 2011, and remained consistent as a percentage of revenues for the nine months ended September 30, 2011, versus the prior year comparable periods, as we continue to broaden our marketing programs. We anticipate that selling and marketing expenses will continue to increase in absolute dollars but continue to decline as a percentage of revenues as we broaden our marketing initiatives to increase public awareness of the System One in the home market and to support growth in international markets.

*Research and Development*

Our research and development expenses and research and development as a percent of revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| Research and development | $ 3,388 | 6% | $ 3,132 | 7% | $ 10,694 | 7% | $ 9,369 | 7% |

Research and development expenses increased $0.3 million, or 8%, and $1.3 million, or 14%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, decreased slightly as a percentage of revenues for the three months ended September 30, 2011, and remained consistent as a percentage of revenues for the nine months ended September 30, 2011. The increase in research and development expenses for the three months ended September 30, 2011, was primarily due to increased project related spending. The increase in research and development expenses for the nine months ended September 30, 2011, was primarily due to increased personnel and personnel-related costs and increased project related spending. For the near term, we expect research and development expenses will increase as we seek to further develop and enhance our System One and related products.

*Distribution*

Our distribution expenses and distribution as a percent of revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| System One segment | $ 3,761 | 10% | $ 3,329 | 11% | $ 11,010 | 10% | $ 9,494 | 12% |
| In-Center segment | 948 | 5% | 459 | 3% | 2,288 | 4% | 1,337 | 3% |
| Total Distribution | $ 4,709 | 8% | $ 3,788 | 8% | $ 13,298 | 8% | $ 10,831 | 8% |

Distribution expenses increased $0.9 million, or 24%, and $2.5 million, or 23%, for the three and nine months ended September 30, 2011, respectively, versus the prior year comparable periods, due primarily to increased business volumes. Distribution expenses remained consistent as a percentage of revenues for the three and nine months ended September 30, 2011. Distribution expenses for the System One segment decreased slightly as a percentage of revenues for both the three and nine months ended September 30, 2011 versus the prior year comparable periods, due to efficiencies gained from economies of scale resulting from increased business volume, improved product reliability of our System One and PureFlow SL hardware and efficiencies in our distribution network. Distribution expenses for the In-Center segment increased as a percentage of revenues

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for both the three and nine months ended September 30, 2011 versus the prior year comparable periods, due primarily to overall increased fuel prices and increased costs associated with shipping certain of our products from our international manufacturing locations to our customers. We expect that distribution expenses will increase at a lower rate than revenues due to expected efficiencies gained from increased business volume and improved reliability of System One equipment. However, these favorable impacts may be offset by overall increases in fuel costs.

*General and Administrative*

Our general and administrative expenses and general and administrative expenses as a percent of revenues for the three and nine months ended September 30, 2011 and 2010 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2011 | | 2010 | | 2011 | | 2010 | |
| General and administrative | $ 5,708 | 10% | $ 6,023 | 13% | $ 16,750 | 10% | $ 16,604 | 13% |

General and administrative expenses decreased $0.3 million, or 5%, and decreased as a percentage of revenue to 10% versus 13% for the three months ended September 30, 2011 versus the prior year comparable period as a result of lower non-cash stock based compensation expenses. For the nine months ended September 30, 2011, general and administrative expenses increased $0.1 million, or 1%, and decreased as a percentage of revenue to 10% from 13% for the prior year comparable period as a result of increased personnel and personnel-related costs and other infrastructure related costs. We expect that general and administrative expenses will decrease as a percentage of revenues over time as we continue to leverage our existing infrastructure.

*Other Expense*

Interest expense increased 1% and 2% for the three and nine months ended September 30, 2011, versus the prior year comparable periods, due primarily to fees and amortization of debt issuance costs associated with our loan and security agreement with Silicon Valley Bank, or SVB, which was entered into in March 2010. We have no debt outstanding under this facility.

The change in other expense during both periods is derived primarily by foreign currency gains and losses.

*Provision for Income Taxes*

The provision for income taxes of $0.2 million for the three months ended September 30, 2011 and 2010, and $0.7 million and $0.6 million for the nine months ended September 30, 2011 and 2010, respectively, relates to the profitable operations of certain foreign entities.

**Liquidity and Capital Resources**

We have operated at a loss since our inception in 1998. As of September 30, 2011, our accumulated deficit was $325.3 million and we had cash and cash equivalents of $101.2 million and working capital of $122.0 million.

Our primary ongoing cash requirements will be to fund operating activities, product development and debt service. Our primary sources of liquidity are cash on hand and ongoing revenues.

Over the past several years we have improved our cash flows from operating activities and continue to work towards our long-term goal of sustained positive cash flows from operating activities. However, we expect cash flows from operating activities in the near term to fluctuate between negative and positive on a quarterly basis, primarily due to changes in working capital. There can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Our ability to and the rate at which we continue to improve cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross profit, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment.

Historically, our business was fairly capital intensive due to the manner in which we placed our System One equipment in the home market. However, over the past several years there has been an increase in the number of customers who choose to purchase rather than rent their System One equipment, which has been important to our historical cash flow improvements. Shifting our customers to an equipment purchase versus rental model allows us to

recover the cost of our products upon initial sale rather than over an extended period of time, thereby reducing our working capital requirements. A majority of our home

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market customers, have committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. While currently approximately 75% of patients use purchased rather than rented System One equipment, there can be no assurance that we will be able to continue to expand or sustain the percentage of our equipment placements that are purchased rather than rented.

Another important factor that has affected our historical improvements in our cash flows is our effective management of our field equipment assets, including those rented by customers and our service pool equipment, which is equipment owned and maintained by us that is swapped for equipment owned or rented by our customers that needs repair or maintenance. Any excess equipment, unused equipment or material defects or write-offs of equipment would negatively impact our working capital requirements.

We have two material debt instruments: the term loan and security agreement with Asahi and the loan and security agreement with SVB.

In May 2009, we entered into a term loan and security agreement with Asahi. The $40.0 million term loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of our assets. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions.

The term loan and security agreement with Asahi includes certain affirmative covenants, including requirements to make timely filings and limitations on contingent debt obligations and sales of assets. At September 30, 2011, we were in compliance with these covenants. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness, subject to the rights of SVB s senior security interest. Any of these remedies would likely have a material adverse effect on our business.

We have the flexibility under our term loan with Asahi to seek up to $40.0 million in additional debt at market interest rates. In March 2010, we entered into a loan and security agreement with SVB for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The agreement was amended in March 2011 to reduce the interest rate on borrowings, fees on unused revolving line of credit and monthly reporting requirements. The agreement is secured by all or substantially all of our assets. In connection with the agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi s security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the agreement, as amended, bear interest at a floating rate per annum equal to 0.5% percentage points above the prime rate (initial prime rate of 4.00%). Pursuant to the agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the agreement with SVB. The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. At September 30, 2011, we were in compliance with the covenants, and there were no outstanding borrowings against the credit commitment. We have nearly all of the $15 million of the credit commitment available for borrowing.

We have begun construction of a new manufacturing facility in Germany pursuant to the terms of our Dialyzer Production Agreement entered into in May 2009 with Asahi. We are overseeing construction of this new facility and will operate the new facility under a manufacturing agreement upon its completion. Asahi will fund construction costs up to an original fixed amount; however, we will be responsible for any additional costs. If the agreement is terminated during the construction period due to our breach, insolvency or bankruptcy, Asahi has the option to require us to pay for all amounts expended for construction of the new facility. If such event occurs we would take title to the land and any construction in process. Subsequent to the completion of construction, if the agreement is terminated due to our breach, insolvency or bankruptcy or by us pursuant to certain terms of the agreement, Asahi has the option to require us to purchase the new facility from them by paying one hundred percent of the then net book value of the new

facility, as calculated in accordance with GAAP. Given these options and our involvement in the construction, we are considered the owner of the new facility for accounting purposes and will therefore record its cost as construction-in-process and a corresponding liability has been recorded for the construction cost funded by Asahi. The $5.2 million recorded at September 30, 2011 reflects the construction costs incurred to date in connection with this project.

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. The plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of $1.6 million as other long-term liabilities at

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September 30, 2011 for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2011 or 2010.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2011 | 2010 |
| Net cash used in operating activities | $ (3,740) | $ (2,248) |
| Net cash used in investing activities | (3,330) | (981) |
| Net cash provided in financing activities | 3,892 | 3,769 |
| Effect of exchange rate changes on cash | 86 | (286) |
| Net cash flow | $ (3,092) | $ 254 |

*Net Cash Used in Operating Activities.* Net cash used in operating activities increased by $1.5 million during the nine months ended September 30, 2011, versus the prior year comparable period. Net loss after adjustments for non-cash charges, such as depreciation, amortization and stock-based compensation expense, had a favorable impact on cash flows increasing to a positive $13.1 million during the nine months ended September 30, 2011 versus a positive $4.2 million for the prior year comparable period. This improvement in cash flows was offset by an increase in working capital requirements driven in part by lower sales of previously rented equipment and a $4.3 million one-time customer prepayment on first quarter 2011 orders received by us during the fourth quarter of 2010, partially offset by an increase in accounts payable related to increased inventory levels. We expect working capital to fluctuate from quarter to quarter due to various factors including inventory requirements and timing of payments from our customers and to our vendors. Deferred revenues decreased $12.8 million to $1.3 million during the nine months ended September 30, 2011 versus $14.1 million for the prior year comparable period, due to lower sales of previously rented equipment, the change in accounting for equipment sales to our international distributors and an increase in amortization of deferred revenues into revenues. During the nine months ended September 30, 2011 and 2010, we recognized $11.7 million and $8.1 million, respectively, of deferred revenues into revenues.

Non-cash transfers from inventory to field equipment for the placement of units with our customers decreased $2.2 million during the nine months ended September 30, 2011 versus the prior year comparable period. This activity fluctuates due to the timing of home market patient additions and the equipment levels required in our service pool. Non-cash transfers from field equipment to deferred costs of revenues decreased $6.3 million during the nine months ended September 30, 2011 versus the prior year comparable period due, in part, to lower purchases of previously rented equipment.

*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 manufacturing operations and capital improvements for our facilities and research and development and information technology. The increase of $2.3 million in purchases of property and equipment was driven by capital improvements to and expansion of certain of our manufacturing facilities to accommodate the increased demand for our Streamline blood tubing sets and the transition of manufacturing of certain of our blood tubing sets from our contract manufacturer to our own manufacturing facility.

*Net Cash Provided in Financing Activities.* During the nine months ended September 30, 2011 and 2010 we received $6.5 million and $5.6 million, respectively, of proceeds from stock option and stock purchase plans due to an increase in the number of stock options exercised. This cash inflow was offset by $2.5 million and $1.7 million during the nine months ended September 30, 2011 and 2010, respectively, of cash used to repurchase shares of our common stock that were surrendered by employees in payment for the minimum required withholding taxes associated with awards under our annual Bonus and Performance Share Plans.

**Contractual Obligations**

The following table summarizes our contractual commitments as of September 30, 2011 and the effect those commitments are expected to have on liquidity and cash flows in the future periods (in thousands):

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| | Total | Less Than One Year | 1-3 Years | 3-5 Years | More Than 5 Years |
|---|---|---|---|---|---|
| Debt obligations | $ 50,774 | $ 1,627 | $ 49,147 | $ | $ |
| Operating leases | 20,564 | 1,278 | 2,695 | 3,286 | 13,305 |
| Purchase obligations | 51,355 | 34,277 | 13,514 | 3,168 | 396 |
| Total | $ 122,693 | $ 37,182 | $ 65,356 | $ 6,454 | $ 13,701 |

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

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

**Summary of Critical Accounting Policies and Estimates**

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

The accounting policies and estimates that we believe are most critical to fully understanding and evaluating our financial results are described in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There were no new accounting pronouncements adopted during the nine months ended September 30, 2011 that had a material impact on our financial statements.

***Revenue Recognition***

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

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

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

We enter into multiple-element arrangements that may include a combination of equipment, related disposables and services. Effective January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*, as required, using the prospective method as permitted under the guidance. Accordingly, this guidance is being applied to all revenue arrangements entered into or materially modified on or after January 1, 2011. The impact of adopting this amended guidance on our results of operations has been limited to products sold internationally through distributors in the System One segment, which revenue has not been significant in the current or historical periods. ASU No. 2009-13 amended the previous guidance for multiple-element

arrangements. Pursuant to the amended guidance in ASU 2009-13 our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer, and the consideration received is allocated among the separate units based on their respective selling price, and the applicable revenue recognition criteria are applied to each of the separate units.

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

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

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

*System One Segment*

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

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

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

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

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

*In-Center Segment*

Our In-Center segment sales are structured as direct product sales primarily through distributors, and we have no significant post delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms. Some of our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers.

Each agreement may be canceled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

**Recent Accounting Pronouncements**

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and updated as necessary in Note 2 to the condensed consolidated financial statements included in this quarterly report on Form 10-Q.

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**Item 3.** ***Quantitative and Qualitative Disclosures About Market Risk***

We are subject to market risks in the normal course of our business, including changes in interest rates and exchange rates. For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There have been no material changes to the market risks described in our Annual Report on Form 10-K for December 31, 2010.

**Item 4.** ***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 September 30, 2011. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2011, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective to achieve their stated purpose.

No change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II OTHER INFORMATION

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

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

**Risks Related to our Business**

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

Since our inception, we have devoted a substantial amount of our efforts to the development of the System One and the related products used with the System One. We commenced marketing the System One and the related disposable products to the critical care market in February 2003. We commenced marketing the System One for chronic hemodialysis treatment in September 2004. Prior to the acquisition of the Medisystems Corporation and certain affiliated entities, or the Medisystems Acquisition, on October 1, 2007, nearly 100% of our revenues were derived from the rental or sale of our System One and the sale of related disposables. Although the Medisystems Acquisition broadened our product offerings, we expect that in 2011 and in the foreseeable future, we will continue to derive a significant percentage of our revenues from the System One, and that we will derive the remainder of our revenues from the sale of a few key disposable products acquired in the Medisystems Acquisition, including blood tubing sets and needles. To the extent that any of our primary products are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted and we do not have other significant products in development that could readily replace these revenues.

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

We believe our largest future product market opportunity is the home hemodialysis market. However, this market is presently very small and adoption of the home hemodialysis treatment options has been limited. The most widely adopted form of dialysis therapy used in a setting other than a dialysis clinic is peritoneal dialysis. Based on the most recently available data from the United States Renal Data System, or USRDS, less than 10% of all United States patients receiving dialysis treatment for ESRD receive either peritoneal dialysis or home hemodialysis. Because the adoption of home hemodialysis has been limited to date, the number of patients and their partners who desire to, and are capable of, administering hemodialysis treatment with a system such as the System One is unknown and there is limited data upon which to make estimates. In addition, many dialysis clinics do not presently have the infrastructure in place to support home hemodialysis and most do not have the infrastructure in place to support a significant home hemodialysis patient population. Our long-term growth will depend on the number of patients who adopt home-based hemodialysis and how quickly they adopt it, which in turn is driven by the number of physicians willing to prescribe home hemodialysis and the number of dialysis clinics able or willing to establish and support home hemodialysis therapies.

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered five or more times a week, the market adoption of our System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider supply costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for U.S. Medicare patients, by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. Based on analysis of historical Medicare payment files and customer reports, those delivering and billing for more frequent dialysis receive reimbursement, on average, for more than three treatments per week. However, providing medical justification for treatments beyond three times per week increases administrative burden, and some customers may not receive additional reimbursement in all cases. Although access to home daily hemodialysis continues to grow, we believe that current Medicare reimbursement leads to adoption rates lower than rates commensurate with the percentage of patients experts believe can perform and medically benefit from this therapy. More certain Medicare reimbursement with less administrative burden would allow adoption of more frequent home hemodialysis at rates more consistent with those believed to be appropriate by the expert medical community.

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

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

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

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our products. As a result of legislation passed by the United States Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the United States for ESRD. With approximately 75% of United States ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can sell or rent our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient s physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for the additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis, based on documentation provided by our customers. If daily therapy is prescribed, a clinic s decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic s patients. Medicare is switching from intermediaries to Medicare administrative contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. Based on analysis of historical Medicare payment files and customers, those delivering and billing for more frequent dialysis receive reimbursement, on average, for more than three treatments per week. However, providing medical justification for treatments beyond three times per week increases administrative burden, and some customers may not receive additional reimbursement in all cases. Although access to home daily hemodialysis continues to grow, we believe that current Medicare reimbursement leads to adoption rates lower than rates commensurate with the percentage of patients experts believe can perform and medically benefit from this therapy. More certain Medicare reimbursement with less administrative burden would allow adoption of more frequent home hemodialysis at rates more consistent with those believed to be appropriate by the expert medical community.

CMS published, on August 12, 2010, the final rule for implementation of the new prospective payment system for dialysis treatment effective January 1, 2011. Under this new ESRD prospective payment system, CMS makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all renal dialysis services and home dialysis and includes certain drugs (including erythropoiesis stimulating agents, or ESAs, iron, and Vitamin D). It has replaced the former system which paid facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that were not included in the composite rate. The prospective payment system still limits the number of hemodialysis treatments paid by Medicare to three times a week, unless there is medical justification provided by the patient s physician for additional treatments. In addition, in 2014 CMS is expected to expand the prospective payment system s single bundled payment to include oral medications. Although a stated goal of the prospective payment system is to encourage home dialysis, and the inclusion of drugs into the prospective rate and the retention of a home patient training payment adjustment with a modest update from current levels are intended to support this goal, it is not possible at this time to determine what impact the new payment system or healthcare legislation will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

***We have limited operating experience, a history of net losses and an accumulated deficit of $325.3 million at September 30, 2011. We cannot guarantee if, when and the extent to which we will become profitable, or that we will be able to maintain profitability if it is achieved.***

Since inception, we have incurred negative operating margins and losses every quarter. At September 30, 2011, we had an accumulated deficit of approximately $325.3 million. We expect our operating expenses to continue to increase

as we grow our business. While we have achieved positive gross profit for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross profit as a percentage of revenues will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable.

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

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States and collectively provide treatment to approximately two-thirds of United States dialysis patients; and this percentage may continue to grow with further market consolidation. DaVita, for example, recently announced its plans to acquire DSI Renal, Inc. More recently, Fresenius announced its plans to acquire Liberty Dialysis Holdings, Inc., the holding company for Liberty Dialysis and Renal Advantage. With less than 40% of United States dialysis patients cared for by independent dialysis clinics, our market

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adoption, at least within the United States, would be more constrained without the presence of both DaVita and Fresenius as customers for our System One and In-Center products.

Additionally, Fresenius is not only a dialysis service provider, it is also the leading manufacturer of dialysis equipment worldwide. On February 18, 2011 we learned that Fresenius obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy in February 2011. DaVita does not manufacture dialysis equipment, but has certain dialysis supply purchase obligations to Gambro, a dialysis equipment manufacturer, under a long-term preferred supplier agreement. Fresenius may choose to offer its dialysis patients only the dialysis equipment Fresenius manufactures, including its recently cleared home hemodialysis system. DaVita may choose to offer their dialysis patients the equipment it contractually agreed to offer in its agreement with Gambro. Fresenius and DaVita may also choose to otherwise limit access to the equipment manufactured by competitors. DaVita is our most significant customer, and we expect it to continue to be, at least for the foreseeable future. Our earlier agreement with DaVita contained certain limited exclusivity rights which restricted our ability to sell the System One in certain markets and to Fresenius. These restrictions do not exist under our July 2010 Amended and Restated National Service Provider Agreement with DaVita and we have a growing percentage of our home market sales to Fresenius, which is our second largest customer in the System One segment. Our Amended and Restated National Service Provider Agreement with DaVita expires on December 31, 2013, which term will be automatically extended on a month to month basis. Our agreements with DaVita and other large home market customers are intended to support the continued expansion of patient access to home hemodialysis with the System One, but like all our agreements with home market customers, our agreements with DaVita and other large customers are not requirements contracts and they contain no minimum purchase volumes. We have no assurance that our sales to DaVita, Fresenius or other large customers will continue to grow, and we cannot predict what impact Fresenius recently cleared home hemodialysis system will have on our sales to Fresenius in the home market or our overall performance in the home market going forward. Given the significance of DaVita and Fresenius as customers in the home market, any adverse change in either customer s ordering or clinical practices, as might be the case in periodic contract negotiations, would have a significant adverse impact on our home market revenues, especially in the near term.

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

DaVita is our most significant customer. Sales through distributors to DaVita of products accounted for approximately half of In-Center segment revenues for the three and six months ended September 30, 2011, and direct sales to DaVita accounted for approximately 31% of our System One segment revenues during the same period. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. Although we expect that DaVita will continue to be a significant customer in the home market, we cannot be certain that DaVita will continue to purchase and/or rent the System One or add additional System One patients in the future. Our contract for needles with DaVita, expiring in December 2013, includes certain minimum order requirements; however, these can be reduced significantly under certain circumstances. Our contract for blood tubing sets with DaVita expired in September 2009. However, in June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines, to DaVita. The partial or complete loss of DaVita as a customer for any of these product lines would adversely affect our business, at least in the near term.

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

In May 2009, we entered into a $40.0 million term loan, with Asahi. The four year term loan, maturing in May 2013, bears interest at 8% annually, payable on the first day of November and May beginning on November 1, 2009, with 50% of the interest deferred to maturity. The term loan is secured by substantially all of our assets.

The term loan and security agreement includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains

customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness, subject to the rights of Silicon Valley Bank s senior security interests. Any of these remedies would likely have a material adverse effect on our business.

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

On March 10, 2010, we entered into an agreement with SVB for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The agreement is secured by all or substantially all of our assets. In connection with this agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi

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junior liens on certain of our assets for so long as the agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi s security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the agreement, as amended, bear interest at a floating rate per annum equal to 0.5% percentage points above the prime rate (initial prime rate of 4.00%). Pursuant to the agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our agreement with SVB. The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy.

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

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

Our System One in the critical care market competes against Gambro AB, Fresenius Medical Care AG, B. Braun and others. Our System One in the home market is currently the only portable system specifically indicated for use in the home market in the United States. However, on February 18, 2011 we learned that Fresenius, our second largest customer in the System One segment, with nearly all of those sales in the home market, obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy in February 2011. Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter International, JMS CO., LTD and others. Our competitors each market one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offers products that have been in use for a longer time than our System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy and, Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our products, including our System One. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices. In addition to the recent clearance of the Fresenius 2008K At Home for use in home chronic therapy, Baxter International has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it commenced an IDE clinical study seeking to support the clearance of DEKA s new home hemodialysis in the US. Baxter International has publicly indicated that it had temporarily suspended its U.S. IDE study shortly after the study commenced, and that it expects to recommence the study later this year. Baxter International has indicated that it hopes to obtain regulatory approval for DEKA s system in Europe in 2012, and to submit for regulatory approval for a nocturnal indication in the U.S. in 2013. Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of these products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it could adversely affect our sales and growth. We also are unable to predict what impact the recent clearance of a Fresenius home hemodialysis systems will have on our sales to Fresenius or our overall home market performance. Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of ESRD and/or in

the treatment of acute kidney failure or fluid overload. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

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

Our future success will depend in part on our timely development and introduction of new and improved products that address changing market requirements. To the extent that we fail to introduce new and innovative products or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological, regulatory or other reasons, to successfully develop and introduce new or improved products could

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reduce our growth rate or otherwise damage our business. We cannot assure you that our developments will keep pace with the marketplace or that our new or improved products will adequately meet the requirements of the marketplace.

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

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

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

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

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

***Our business and results of operations may be negatively impacted by general economic and financial market conditions, including fluctuations in foreign exchange rates, and such conditions may increase other risks that affect our business.***

Global macro economic conditions and the world s financial markets continue to experience some degree of turmoil, resulting in reductions in available credit, foreign currency fluctuations and volatility in the valuations of securities generally. In general, we believe demand for our products in the home and in-center market will not be substantially affected by the changing market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, there is no assurance that future

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economic changes or global uncertainties would not negatively impact our business, especially the manner and pace in which we sell equipment in the System One segment or delay equipment placements. Hospitals or clinics facing pressure to reduce capital spending may choose to rent equipment rather than purchase it outright, or to enter into other less-capital intensive purchase structures with us, which may, in turn, have a negative impact on our cash flows. Our ability to sell products internationally is particularly vulnerable to adverse impacts from global macro economic conditions. Government funded hospitals in various international markets may seek to defer capital purchases or tenders. Distributors with reduced access to capital may be less willing to purchase our equipment outright, impairing our ability to sell our products. Further, unfavorable changes in foreign exchange rates versus the U.S. dollar would increase our product costs which would negatively impact our gross profit and gross profit as a percentage of revenues.

***The non-cash discounts we have offered to DaVita may lead to reductions in our future net revenues that will fluctuate because the amount of the discount is based upon the number of warrants earned and our stock price.***

Under our July 22, 2010 agreement with DaVita, we offered DaVita the opportunity to earn pricing discounts based upon the achievement of System One home patient growth targets at June 30, 2011, 2012 and 2013. In order to preserve cash, the discount takes the form of warrants to purchase up to 5.5 million shares of our common stock that become exercisable based on the achievement of certain System One home patient growth targets (reflecting home patients who have remained on contiguous home hemodialysis therapy for at least three full months with the System One) at June 30, 2011, 2012 and 2013, and which further require DaVita to continue to grow its home patient census every six months during the term of the agreement. The discount associated with these warrants will be measured at fair value through the date of vesting using a Black-Scholes option pricing model, and is being recognized as a reduction of revenues over the same period as the related product revenues (between seven to ten years) based on the number of warrants expected to vest. The warrants are non-transferable, must be exercised in cash and have an exercise price of $14.22 per share, which is equal to the trailing fifteen day volume weighted average price of a share of NxStage Common Stock on the NASDAQ Global Market as of the close of business on July 21, 2010, the day prior to entering into our agreement.

For the period ended June 30, 2011, DaVita achieved System One home patient growth targets that entitled DaVita to become vested in warrants to purchase 250,000 shares of our common stock. The reduction of revenues recorded in connection with these warrants was not significant during the three or nine months ended September 30, 2011. However, there can be no assurance that the value of the discount, and, therefore, the amount of reduction of revenues recorded, will not be higher in the future based upon the level of warrants DaVita actually earns under the agreement, as well as the price of our stock on the date the warrants vest. Should our stock price increase above its current price, the amount of the discount would be increased.

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

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

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

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

As our business continues to grow, we will need to expand our manufacturing, product distribution, sales and marketing and on-going development capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various partners, suppliers, manufacturers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our information technology infrastructure, operational, financial and management controls, reporting systems and procedures and management resources. Our rationalization and consolidation of our manufacturing activities will place additional burdens on the existing infrastructure at our plants, particularly at our manufacturing facility in Tijuana Mexico. If we are unable to continue to grow and improve our information technology infrastructure, operational, financial and management controls, reporting systems and procedures and management resources, our ability to run our business efficiently and effectively could be impaired.

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

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

We also need to establish strong product reliability for all new products we offer. With new products, we are more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature. We also choose from time to time to transition the manufacturing and supply of products and components to different suppliers or locations . As we make these changes, we are also more exposed to risks relating to product quality and reliability until the manufacturing processes mature. In May 2011, we agreed not to renew our supply and distribution agreement with Kawasumi and we are currently working to consolidate all of our bloodline supply in our manufacturing facility in Tijuana Mexico in order to achieve long term margin improvements and other efficiencies. Recently, we also agreed not to renew our agreements with the Entrada Group, through which we have access to our Fresnillo Mexico facility. As a result of this decision, we will now be consolidating our equipment manufacturing and service activities, which have been conducted in Fresnillo, into our manufacturing facility in Tijuana Mexico. These transitions could expose us to product quality and reliability issues. Like all transitions of this nature, these transitions will also lead us to incur additional costs in the short term, which will negatively impact our gross profits in the short term.

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

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

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

While kidney transplantation is the treatment of choice for most ESRD patients, it is not currently a viable treatment for most patients due to the limited number of donor kidneys, the high incidence of kidney transplant rejection and the higher surgical risk associated with older ESRD patients. According to USRDS data, in 2008, approximately 17,400 patients received kidney transplants in the United States. The development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants or any other advances in kidney transplantation could limit the market for our products. The development of viable medical or other solutions for renal replacement or prolonging kidney life may also limit the market for our products.

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

If any of our employees or products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. Claims of this nature may also adversely affect our reputation, which could damage our position in the market. While we maintain insurance, including professional liability, product and excess liability, claims may be brought against us that could result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. In addition, due to the recent tightening of global credit and the disruption in the

financial markets, there may be a disruption in our insurance coverage or delay or disruption in the payment of claims by our insurance providers. Our insurance policies also have various exclusions and we may be subject to a product or professional liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance.

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Any product liability or professional liability claim brought against us, with or without merit, could result in the increase of our product liability or professional liability insurance rates, respectively, or the inability to secure additional insurance coverage in the future. A product liability claim, whether meritorious or not, could be time consuming, distracting and expensive to defend and could result in a diversion of management and financial resources away from our primary business, in which case our business may suffer.

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

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

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

We operate manufacturing facilities in Germany, Italy and Mexico. We also purchase components, products and supplies from foreign vendors. We are subject to a number of risks and challenges that specifically relate to these international operations, and we may not be successful if we are unable to meet and overcome these challenges. Significant among these risks are risks relating to foreign currency, in particular the Euro, Peso and Thai Baht. We do not currently hedge our foreign currency transactions. To the extent we fail to control our exchange rate risk, our gross profit as a percentage of revenues and profitability could suffer and our ability to maintain mutually beneficial and profitable relationships with foreign vendors could be impaired. In addition to these risks, through our international operations, we are exposed to costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods, difficulty managing operations in multiple locations, local regulations that may restrict or impair our ability to conduct our operations, and health issues, such as pandemic disease risk, which could disrupt our manufacturing and logistical and import activities. In certain locations, such as Mexico, we are also exposed to risks associated with local instability, including threats of increased violence, which could lead to disruptions in supply at our manufacturing facilities or key vendors.

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

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

Finding alternative sources for these raw materials, components, finished goods and sterilization services would be difficult and in many cases entail a significant amount of time and disruption. In the case of Membrana, for fiber, we are contractually prevented from obtaining an alternative source of fiber for our System One products. Our relationship with Asahi could afford us back-up supply in the event of an inability to supply by Membrana, however, switching to Asahi fiber at this time would likely entail significant delays and difficulties. We do not have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the United States. Additionally, the performance of Asahi fiber in our System One has not yet been validated. We purchase all of our needles, and, until recently, a significant amount of our bloodlines, from Kawasumi. Kawasumi s contractual obligation to manufacture

bloodlines expires in February 2012, and recent flooding at the site of Kawasumi s bloodline manufacturing facility in Thailand will prevent Kawasumi from supplying any further bloodlines to us prior to the expiration of that agreement. Although we have recently been successfully transitioning bloodline supply from Kawasumi to our Tijuana Mexico manufacturing facility, and we believe that we can manufacture at this facility any products ordered from Kawasumi that it is now not able to supply, there is no guarantee that we will not experience any interruption in our ability to supply Streamline or ReadySet bloodlines, or that the transition of this supply will not increase our product costs or impair our product quality or reliability, at least in the near term. Kawasumi s contractual obligation to supply needles to us expires in February 2014, with opportunities to extend the term beyond that date. Kawasumi s contractual obligation to supply needles to us is, at times, less than our forecasted demand. In the event Kawasumi supplies no more than the amount of their

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required maximum monthly supply, or in the event of any inability of Kawasumi to supply, we may not have enough needle supply to meet the demands of our customers. Presently, the flooding experienced by Kawasumi at its bloodline manufacturing facility in Thailand has not impacted its needle manufacturing operations. However, there can be no assurance that its operations will not be impacted by the floods or by any other event which could lead to an interruption in supply. We maintain a limited extra supply of needles to mitigate against the risk of any intermittent shortfalls in needle supply, but do not have sufficient quantities to address any significant interruption in Kawasumi s ability to supply our forecasted demand for needles. Any significant interruption in our key single source suppliers ability to supply products to us would impair our business, at least in the near term.

We manufacture filters only at our facility in Germany. We manufacture our System One cartridges and related disposables and Medisystems bloodlines only at our facility in Tijuana Mexico. With the planned termination of our relationship with Entrada, we will soon only manufacture and service our equipment at the same Tijuana Mexico facility. We perform most of our molding activities at our facility in Italy. The loss of any of these facilities due to fire, flood, natural disaster, war, strike, or other cause beyond our control could cause significant production delays, an inability to meet customer demand, and a substantial loss in revenues. As we consolidate bloodline and equipment manufacturing and equipment service to our facility in Tijuana, Mexico, the risks associated with the loss of that facility for any reason are significantly increased.

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

We sell the majority of our In-Center segment products through several distributors, which collectively accounted for substantially all of In-Center revenues during the three and six months ended September 30, 2011 and 2010, with Henry Schein and Gambro being our most significant distributors. Our distribution agreement with Henry Schein expires in April 2012. Our distribution agreement with Gambro expires in June 2014. The loss of Gambro or Henry Schein as our distributors for any reason could materially adversely affect our business, at least in the near term.

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

Our blood tubing set business has historically been a commodities business. Prior to the Medisystems Acquisition, Medisystems competed favorably and gained share through the development of a high quality, low-cost, standardized blood tubing set, which could be used on several different dialysis machines. Our products continue to compete favorably in the dialysis blood tubing set business, but are increasingly subject to pricing pressures, especially given recent market consolidation in the United States dialysis services industry, with Fresenius and DaVita collectively controlling approximately two-thirds of the United States dialysis services business. Unless we can successfully demonstrate to customers the differentiating features of our current In-Center segment products or products that we introduce in the future, we may be susceptible to further pressures to reduce our product pricing and more vulnerable to the loss of our blood tubing set business to competitors in the dialysis industry.

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

We import into the United States disposable medical supplies from Germany, Thailand and Mexico. We also import into the United States disposable medical components from Germany and Italy and export components and assemblies into Mexico, Thailand and Italy. We also import into Mexico components and assemblies from Germany, Italy and Thailand. To a lesser, but increasing degree, our business also involves the export of finished goods from the United States to foreign countries. The import and export of these items are subject to extensive laws and regulations with which we will need to comply. To the extent we fail to comply with these laws or regulations, or fail to interpret our obligations accurately, we may be subject to significant fines, liabilities and a disruption to our ability to deliver product, which could cause our combined businesses and operating results to suffer. To the extent there are modifications to the Generalised System of Preferences or cancellation of the Nairobi Protocol Classification such that

our products would be subject to duties, our profitability would also be negatively impacted.

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

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

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**Risks Related to the Regulatory Environment**

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

Our products are medical devices subject to extensive regulation in the United States and in foreign markets we may wish to enter. To market medical devices 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 clearance necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications of our products. Regulatory pathways for such clearances may be difficult to define and could change. For example, we completed an approval IDE study intended to support a home nocturnal indication for the System One. Enrollment started in the first quarter of 2008 and we submitted the associated 510(k) to the FDA in 2010. We met our primary safety and efficacy endpoints for the study. Nevertheless, the FDA notified us that their standards for what will be required for a home nocturnal clearance may have changed from what was required in our approved IDE. The FDA did not clear our 510(k) application for home nocturnal use, and we continue to evaluate next steps in determining a pathway to clearance for our System One for nocturnal use. Although we do not see the delay in timing for our home nocturnal clearance as material to our opportunities, we cannot be certain when this clearance will be obtained. We also cannot provide assurance that this or other clearances or approvals might be obtained. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Although the 510(k) regulation has not been formally changed, the FDA has announced that it is intending to implement modifications to the 510(k) process. New draft guidance issued by FDA suggests that modifications to the FDA s process will soon be made. Any changes in regulatory policies could have an adverse affect on our ability to gain regulatory clearance, sell, and promote our products and our business as a whole.

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

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

***Even if we obtain the necessary 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. We face similar requirements outside of the U.S. where our products are distributed. If we manufacture or supply products with manufacturing errors, design defects and/or labeling inadequacies, or if

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we fail to comply with any applicable regulatory requirements, we could be subject to an enforcement action by the FDA or other regulatory agency, 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.

Any of these events could impair our business, at least in the near term, and certain of these events would materially harm our business.

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

Medical devices can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. These could lead to a government mandated or voluntary recall by us. The FDA has the authority to require the recall of our products in the event a product presents a reasonable probability that it would cause serious adverse health consequences or death. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers.

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

Our finished goods manufacturing processes, and those of some of our contract manufacturers, are required to comply with the FDA s Quality System Regulations, or QSRs, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its QSRs through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. We were inspected by the FDA in the second quarter of 2010, and received no inspectional observations. While all of our previous inspections have resulted in no significant observations, we cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities, or that future inspections would have the same result.

If one of our manufacturing facilities or those of any of our contract manufacturers fails to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action, including issuing a public warning letter, shutting down our manufacturing operations, embargoing the import of components from outside of the United States, recalling our products, refusing to approve new marketing applications, instituting legal

proceedings to detain or seize products or imposing civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer.

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

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

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

In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products outside of the United States. We are currently selling the System One in Europe, the Middle East and other select markets. We are assessing other international markets for the System One as well. Our In-Center products are presently sold in the United States as well as in several other countries, through distributors. We presently have CE marking as well as Canadian regulatory authority to sell our System One as well as certain other products in Canada, Europe and selected other geographies. However, in order to market directly our products in other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional 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 other markets outside the United States, which could negatively affect our overall market penetration. Additionally, any loss of foreign regulatory approvals, for any reason, could negatively affect our business.

***Failure to meet applicable technical product standards and directives would prevent us from marketing our products globally.***

We must comply with numerous and varying technical standards and directives in order to market our products globally. Standard setting bodies such as UL, AAMI, and IEC routinely review and modify their standards. One such technical standard, IEC 60601-1, was recently updated, with mandatory adoption dates in Europe of June 2012, and the U.S. in July 2013. We continue to have ongoing and active development programs to ensure that we meet all requisite standards, but failure to meet the dates required for compliance with the new IEC 60601-1 standards , or any new standards or directives introduced in the future, could negatively affect our business.

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

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we learn patient names and addresses when we ship our System One supplies to home hemodialysis patients. We may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customer s staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. At this time, we are not a HIPAA covered entity. However, we have entered into agreements with covered entities that contain commitments to protect the privacy and security of patients health information and, in some instances, require that we indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability and/or our reputation and business could be harmed. In addition, the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted in February 2009, expands the HIPAA privacy and security rules, including imposing many of the requirements of those rules directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement provisions and associated penalties. Many of these requirements went into effect on February 17, 2010. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability.

Many other federal and state laws apply to the use and disclosure of health information, as well as certain financial 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 or cover different subject matter. 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 similar state laws, prohibit payments that are intended to induce health care professionals or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. A number of states have enacted laws that require pharmaceutical and medical device companies to

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monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. In addition, some state statutes, most notably laws in Massachusetts, Minnesota, and Vermont, impose outright bans on certain gifts to physicians. Some of these laws referred to as aggregate spend laws or gift laws, carry substantial fines if they are violated. Recently, the federal Physician Payments Sunshine Act was enacted by Congress in 2010 as part of the comprehensive health care reform legislation and it will require us to begin publicly disclosing certain payments and other transfers of value to physicians and teaching hospitals beginning in 2013. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with all applicable requirements, these laws are broadly written and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If we were to offer or pay inappropriate inducements to purchase our products, we could be subject to a claim under the Medicare/Medicaid anti-kickback laws or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws.

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

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

Historically, our marketing efforts had been confined nearly exclusively to the United States. In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products internationally. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business. Further, reimbursement provided to our products in other jurisdictions could change, positively or negatively. In the event reimbursements were to be negatively changed, such as, for example, in the United Kingdom, our ability to sell our products could be impaired.

***Failure to comply with the United States Foreign Corrupt Practices Act or similar laws could subject us to penalties and other adverse consequences.***

We are subject to the United States Foreign Corrupt Practices Act which generally prohibits United States companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at

foreign controlled subsidiaries. Through our international activities, we are also subject to the UK Anti Bribery Act and other similar anti bribery laws. While we have policies and procedures in place designed to prevent noncompliance, we can make no assurance that our employees or other agents will not engage in prohibited conduct under these laws for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

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

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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**

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

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

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

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

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

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

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

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

**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:

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prevent our competitors from duplicating our products;

prevent our competitors from gaining access to our proprietary information and technology; or

permit us to gain or maintain a competitive advantage.

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

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

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

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

**Risks Related to our Common Stock**

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

The market price of our common stock could be subject to significant fluctuations. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing of market launch and/or market acceptance of our products;
- timing of achieving profitability from operations;
- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;
- developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers;
- disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across the border, or the failure of third party suppliers to produce needed products or components;
- reports by officials or health or medical authorities, the general media or the FDA regarding the potential benefits of the System One or of similar dialysis products distributed by other companies or of daily or home dialysis;
- announcements by the FDA of non-clearance or non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;
- product recalls;
- defaults under our material contracts, including without limitation our credit agreement;
- regulatory developments in the United States and foreign countries;
- changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments, or the willingness of Medicare contractors to pay for more than three treatments a week where medically justified;
- litigation involving our company or our general industry or both;
- announcements of technical innovations or new products by us or our competitors;
- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture and supply our products to commercial standards;

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

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stock. In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

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

a prohibition on actions by our stockholders by written consent;

the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;

advance notice requirements for nominations of directors or stockholder proposals; and

the requirement that board vacancies be filled by a majority of our directors then in office.

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

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

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell a large number of shares of common stock, the market price of our common stock could decline significantly. We have 55,136,629 shares of common stock outstanding as of September 30, 2011. Except where sales are made pursuant to an effective registration statement, shares held by our affiliates may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which approximates 551,366 shares, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale. With the higher trading volumes we have recently observed in our stock, the number of shares that can be sold by our affiliates pursuant to Rule 144 is significantly above the 1% of shares outstanding limitation of Rule 144 as of the time of the filing of this report.

At September 30, 2011, subject to certain conditions, holders of an aggregate of approximately 9 million shares of our common stock have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission, or SEC. If we register their shares of common stock, they can more easily sell those shares in the public market.

As of September 30, 2011, 10,248,937 shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan, outstanding stock options and unvested restricted stock units. As of September 30, 2011, 1,209,587 shares were subject to unvested restricted stock units and 5,550,615 shares were subject to outstanding options, of which 3,839,531 shares were exercisable and can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144.

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

In 2008, we sold an aggregate of 9,555,556 shares of our common stock and warrants to purchase an additional 1,911,111 shares of our common stock in a private placement. We were required to register the common stock and the common stock issuable upon exercise of the warrants with the Securities and Exchange Commission, which we did on August 8, 2008. If

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the holders of the shares or the accompanying warrant shares are unable to sell such shares or warrant shares under the registration statement for more than 30 days in any 365 day period after the effectiveness of the registration statement, we may be obligated to pay damages equal to up to 1% of the share purchase price per month that the registration statement is not effective and the investors are unable to sell their shares.

On July 22, 2010, we issued to DaVita a warrant which, subject to the achievement of certain System One growth targets, may be exercisable for up to a cumulative total of 5,500,000 shares of our common stock. In connection with issuance of this warrant we entered into a registration rights agreement with DaVita, pursuant to which (subject to certain conditions) we have agreed to file, on or prior to April 1, 2011, a registration statement on Form S-3 with respect to the resale by DaVita of any shares of our common stock issued to DaVita under the warrant. We registered the shares of common stock issuable upon the exercise of the warrant on February 16, 2011 on our automatic shelf registration statement on Form S-3 (No. 333-170654) filed on November 17, 2010.

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

***Our outstanding warrants, and the provisions of our Term Loan with Asahi, may result in substantial dilution to our stockholders.***

Warrants held by DaVita and certain investors in our 2008 private placement could result in the issuance of up to 6.9 million additional shares of common stock. In addition, in the event our Term Loan with Asahi reaches maturity, Asahi may require that all of the principal and interest on the Term Loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date. The issuance and sale of any of these shares could result in substantial dilution to our stockholders in the form of immediate and substantial dilution in net tangible book value per share.

***Our executive officers and directors 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 and executive officers, together with their affiliates and related persons, beneficially hold, in the aggregate, approximately 18% of our outstanding common stock. David S. Utterberg holds approximately 9% of our outstanding common stock. Although these numbers are lower than they have been historically, due to certain recent selling by larger affiliated stockholders, these stockholders, if acting together, may nevertheless still have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

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

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

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

difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;

potential disruption of our ongoing business and distraction of management;

potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;

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difficulty in incorporating acquired technology and rights into our products and technology;

unanticipated expenses and delays in completing acquired development projects and technology integration;

management of geographically remote units both in the United States and internationally;

impairment of relationships with partners and customers;

customers delaying purchases of our products pending resolution of product integration between our existing and our newly acquired products;

entering markets or types of businesses in which we have limited experience;

potential loss of key employees of the acquired company; and

inaccurate assumptions of the acquired company s product quality and/or product reliability.

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

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**Item 6.** ***Exhibits***

| **Exhibit Number** | |
|---|---|
| *31.1 | Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) or 15d-14(a), 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(a) or 15d-14(a), 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. |
| *101.INS | XBRL Instance Document |
| *101.SCH | XBRL Taxonomy Extension Schema |
| *101.CAL | XBRL Taxonomy Extension Calculation Linkbase |
| *101.LAB | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase |

* Filed herewith.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NXSTAGE MEDICAL, INC.

By: /s/ Robert S. Brown
Robert S. Brown
*Chief Financial Officer*
*(Duly authorized officer and principal financial and accounting officer)*

November 3, 2011