NxStage Medical, Inc.
Form 10-Q
August 06, 2010

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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 June 30, 2010

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 o 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:

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

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 48,621,258 shares of the registrant s common stock outstanding as of the close of business on July 30, 2010.

NXSTAGE MEDICAL, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2010
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NXSTAGE MEDICAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2010	December 31, 2009
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,045	$ 21,720
Accounts receivable, net	14,769	14,238
Inventory	30,889	28,117
Prepaid expenses and other current assets	1,888	1,227
Total current assets	67,591	65,302
Property and equipment, net	8,633	10,336
Field equipment, net	17,340	21,726
Deferred cost of revenues	33,760	27,799
Intangible assets, net	26,810	28,208
Goodwill	42,698	42,698
Other assets	550	909
Total assets	$ 197,382	$ 196,978
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 18,868	$ 19,827
Accrued expenses	11,695	9,377
Current portion of long-term debt	53	61
Total current liabilities	30,616	29,265
Deferred revenues	47,234	38,490
Long-term debt	39,123	37,854
Other long-term liabilities	1,763	1,923
Total liabilities	118,736	107,532
Commitments and contingencies (Note 12)		
Stockholders equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of June 30, 2010 and December 31, 2009		
Common stock: par value $0.001, 100,000,000 shares authorized; 48,731,290 shares issued as of June 30, 2010 and 46,795,859 shares issued and outstanding as of December 31, 2009	48	47
Additional paid-in capital	374,320	365,548

Accumulated deficit	(293,969)	(276,714)
Accumulated other comprehensive (loss) income	(12)	565
Treasury stock, at cost: 174,757 shares as of June 30, 2010	(1,741)	
Total stockholders equity	78,646	89,446
Total liabilities and stockholders equity	$ 197,382	$ 196,978

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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenues	$ 44,008	$ 36,398	$ 84,416	$ 70,133
Cost of revenues	30,246	27,581	58,841	54,261
Gross profit	13,762	8,817	25,575	15,872
Operating expenses:				
Selling and marketing	8,565	7,411	16,582	14,642
Research and development	3,202	2,271	6,237	4,673
Distribution	3,632	3,525	7,043	7,209
General and administrative	5,643	4,749	10,581	9,704
Total operating expenses	21,042	17,956	40,443	36,228
Loss from operations	(7,280)	(9,139)	(14,868)	(20,356)
Other expense:				
Interest income		14		25
Interest expense	(1,148)	(3,337)	(2,256)	(4,372)
Other income (expense), net	330	(14)	213	79
	(818)	(3,337)	(2,043)	(4,268)
Net loss before income taxes	(8,098)	(12,476)	(16,911)	(24,624)
Provision for income taxes	158	39	344	119
Net loss	$ (8,256)	$ (12,515)	$ (17,255)	$ (24,743)
Net loss per share, basic and diluted	$ (0.17)	$ (0.27)	$ (0.37)	$ (0.53)
Weighted-average shares outstanding, basic and diluted	47,492	46,575	47,228	46,565

See accompanying notes to these condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2010	2009
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (17,255)	$ (24,743)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,077	10,229
Stock-based compensation	6,875	3,877
Other	1,128	1,197
Changes in operating assets and liabilities:		
Accounts receivable	(527)	2,494
Inventory	(13,327)	(2,179)
Prepaid expenses and other assets	(404)	700
Accounts payable	(399)	(2,788)
Accrued expenses and other liabilities	3,060	(144)
Deferred revenues	8,745	672
Net cash used in operating activities	(1,027)	(10,685)
Cash flows from investing activities:		
Purchases of property and equipment	(457)	(566)
Decrease in other assets		(582)
Net cash used in investing activities	(457)	(1,148)
Cash flows from financing activities:		
Proceeds from stock option and purchase plans	2,140	148
Purchase of treasury stock	(1,741)	
Proceeds from loans and lines of credit		39,895
Net repayments on loans and lines of credit	(28)	(30,506)
Net cash provided by financing activities	371	9,537
Foreign exchange effect on cash and cash equivalents	(562)	109
Decrease in cash and cash equivalents	(1,675)	(2,187)
Cash and cash equivalents, beginning of period	21,720	26,642
Cash and cash equivalents, end of period	$ 20,045	$ 24,455
Noncash Investing Activities		
Transfers from inventory to field equipment and deferred cost of revenues	$ 9,625	$ 3,225
Transfers from field equipment to deferred cost of revenues	$ 10,203	$ 1,712

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

NxStage Medical, Inc., or the Company, is a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. The Company s primary product, the NxStage System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis centers. The System One is cleared or approved for commercial sale in the United States, Europe and Canada for the treatment of acute and chronic kidney failure and fluid overload. The System One consists of an electromechanical medical device (cycler), a disposable blood tubing set and a dialyzer (filter) pre-mounted in a disposable, single-use cartridge. Dialysate used in conjunction with this system in the home is most frequently prepared using the Company s PureFlow SL hardware and premixed concentrate bags. The Company also sells needles and blood tubing to dialysis centers for the treatment of end-stage renal disease, or ESRD.

The Company has experienced negative operating margins and it expects to continue to incur net losses in the foreseeable future. Until the second quarter of 2010, the Company had experienced negative cash flows from operating activities. There can be no assurance that the Company will be able to continue to generate positive cash flows from operating activities. The Company believes, based on current projections and the current nature of the Company s business, that it has the required resources to fund its ongoing operating requirements. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, the availability of credit, and the potential investments in, or acquisitions of, complementary businesses, services or technologies.

Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2010 and for the three and six months ended June 30, 2010, and related notes, are unaudited but, in management s opinion, include all adjustments, consisting of normal recurring adjustments that the Company considers necessary for fair statement of the interim periods presented. The Company has prepared its unaudited, condensed consolidated financial statements following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under these rules, the Company has condensed or omitted certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP. The Company s accounting policies are described in the notes to the consolidated financial statements in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and updated, as necessary, in this Quarterly Report on Form 10-Q. Operating results for the three and six months ended June 30, 2010 are not necessarily indicative of results for the entire fiscal year or future periods. The December 31, 2009 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 the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

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

Concentration of Credit Risk

Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company makes substantial sales. One customer represented 17% of accounts receivable at June 30, 2010, and one customer represented 19% of accounts receivable at December 31, 2009.

Warranty Costs

The Company accrues estimated costs that it may incur under its 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 condensed consolidated statements of operations. Following is a rollforward of the Company s warranty accrual (in thousands):

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Balance at December 31, 2009	$ 205
Provision	219
Usage	(188)
Balance at June 30, 2010	$ 236

Recent Accounting Pronouncements

Effective January 1, 2010, the Company adopted an accounting standard update regarding accounting for transfers of financial assets. As codified under Accounting Standards Codification, or ASC, 860, this update prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor s continuing involvement in transferred financial assets. Specifically, among other aspects, the update amends Statement of Financial Accounting Standards No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. Because the update is effective for transfer of financial assets occurring on or after January 1, 2010 and the Company has not had any such transactions subsequent to January 1, 2010 to date, the adoption of this update did not have an impact on the Company s condensed consolidated financial statements.

Effective January 1, 2010, the Company adopted an accounting standard update regarding fair value measures. As codified under ASC 820, this update requires additional disclosures about fair value measurements including transfers in and out of Levels 1 and 2 and a higher level of disaggregation for the different types of financial instruments. For the reconciliation of Level 3 fair value measurements, information about purchases, sales, issuances and settlements should be presented separately. Because this update addresses disclosure requirements, the adoption of this update did not impact the Company s financial position, results of operations or cash flows.

3. Significant Revenue Contracts

National Service Provider Agreement and Stock Purchase Agreement with DaVita, Inc., or DaVita

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

In connection with the Original Agreement, the Company agreed to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The Original Agreement included other terms such as development efforts, training, market collaborations and volume discounts. The Original Agreement expired on December 31, 2009, but sales continued in accordance with the terms specified in the Original Agreement.

In July 2010, the Company entered into a First Amended and Restated National Service Provider Agreement, the Amended Agreement, with DaVita which supersedes the Original Agreement. Pursuant to the terms of the Amended Agreement, the Company will continue to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The Amended Agreement includes other terms such as rebates, training and volume discounts.

The sale of equipment and other items included in the Original and Amended Agreements were considered to be multiple-element sales arrangements pursuant to ASC 605, *Revenue Recognition*. The Company has determined that it cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under the Original and Amended Agreements are deferred and recognized as revenue on a straight-line basis over the expected term of the Company s obligation to supply disposables and service, which is seven years, and direct costs relating to the delivered equipment are deferred and amortized over the same period as the related revenues.

In connection with the Amended Agreement the Company issued to DaVita a warrant that may vest and become exercisable to purchase up to 5.5 million shares of the Company s common stock based upon the achievement of certain DaVita and NxStage System One home patient growth targets achieved at June 30, 2011, 2012 and 2013. The warrants have an exercise price of $14.22 per share are non-transferable and must be exercised in cash. The warrants will be recorded at fair value, using the Black-Scholes options pricing model, and recognized as a reduction of revenues over the same period as the related product revenues.

4. Inventory

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

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	June 30, 2010	December 31, 2009
Purchased components	$ 17,598	$ 14,214
Work in process	2,003	1,640
Finished goods	11,288	12,263
	$ 30,889	$ 28,117

5. Property and Equipment and Field Equipment

Accumulated depreciation on property and equipment was $10.0 million and $10.5 million at June 30, 2010 and December 31, 2009, respectively. Accumulated depreciation on field equipment was $27.1 million and $26.7 million at June 30, 2010 and December 31, 2009, respectively.

6. Intangible Assets

Accumulated amortization on intangible assets was $7.7 million and $6.3 million at June 30, 2010 and December 31, 2009, respectively.

7. Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net loss	$ (8,256)	$ (12,515)	$ (17,255)	$ (24,743)
Foreign currency translation adjustment	(569)	107	(577)	47
Comprehensive loss	$ (8,825)	$ (12,408)	$ (17,832)	$ (24,696)

8. Net Loss per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Options to purchase common stock	2,895	126	2,554	69
Restricted stock	723		697	
Warrants to purchase common stock	941		827	
Total	4,559	126	4,078	69

9. Debt

On March 10, 2010, the Company entered into a Loan and Security Agreement, the Credit Facility, with Silicon Valley Bank, or SVB, with a maturity date of April 1, 2012. The Credit Facility provides a credit commitment of up to $15.0 million, subject to certain limitations and calculations of borrowing amount. The Credit Facility is secured by all or substantially all of the Company s assets. Borrowings under the Credit Facility bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Credit Facility, the Company has agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the Credit Facility. The Credit Facility contains events of default customary for transactions of

this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. At June 30, 2010, there were no outstanding borrowings and the Company had approximately all of the $15.0 million credit commitment available for borrowing under the Credit Facility.

In connection with the Credit Facility, the Company amended its term loan and security agreement with Asahi Kasei Kuraray Medical Co., Ltd., or Asahi, a medical supply company headquartered in Japan, to provide for certain amendments, including granting to Asahi junior liens on certain of the Company s assets for so long as the Credit Facility remains outstanding. Upon termination of all obligations under the Credit Facility, Asahi s security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory.

10. Segment Disclosures

After an evaluation of the business activities regularly reviewed by the Company s chief operating decision-maker for which separate discrete financial information is available, management determined that the Company has two reporting segments, System One and In-Center.

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The accounting policies of the reportable segments are the same as those described in Note 2 to the consolidated financial statements included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009. The profitability measure employed by the Company and its chief operating decision maker for making decisions about allocating resources to segments and assessing segment performance is segment (loss) profit, which consists of sales, less cost of sales, selling and marketing and distribution expenses.

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

Within the System One segment, the Company derives revenue from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. Within the System One segment, the Company sells a similar technology platform of the System One with different features to the home and critical care markets. Some of the Company s largest customers in the home market provide outsourced renal dialysis services to some of the Company s customers in the critical care market. Sales of product to both markets are made 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, the Company sells blood tubing sets and needles for hemodialysis and needles for apheresis primarily for the treatment of ESRD patients at dialysis centers. Nearly all In-Center products are sold through national distributors.

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

	System One	In-Center	Unallocated	Total
Three Months Ended June 30, 2010				
Revenues from external customers	$ 27,467	$ 16,541	$	$ 44,008
Segment (loss) profit	(810)	2,375	(8,845)	(7,280)
Segment assets	82,554	14,204	100,624	197,382
Three Months Ended June 30, 2009				
Revenues from external customers	$ 20,446	$ 15,952	$	$ 36,398
Segment (loss) profit	(5,000)	2,881	(7,020)	(9,139)
Segment assets	70,775	17,397	110,793	198,965
Six Months Ended June 30, 2010				
Revenues from external customers	$ 52,569	$ 31,847	$	$ 84,416
Segment (loss) profit	(2,089)	4,039	(16,818)	(14,868)
Segment assets	82,554	14,204	100,624	197,382
Six Months Ended June 30, 2009				
Revenues from external customers	$ 39,268	$ 30,865	$	$ 70,133
Segment (loss) profit	(10,615)	4,637	(14,378)	(20,356)
Segment assets	70,775	17,397	110,793	198,965

Substantially all of the Company s revenues are derived from the rental and sale of the System One and related products, and from the sale of needles and blood tubing sets to customers located in the United States.

The following table summarizes the customers who individually comprise greater than 10% of total revenues for the periods shown below:

	Six Months Ended

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Customer A	22%	22%	22%	21%
Customer B	17%	35%	17%	36%
Customer C	13%		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. Almost all of Customer C s sales are to Customer A.

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

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	June 30, 2010	December 31, 2009
Total segment assets	$ 96,758	$ 91,880
Corporate assets:		
Cash and cash equivalents	20,045	21,720
Property and equipment, net	8,633	10,336
Intangible assets, net	26,810	28,208
Goodwill	42,698	42,698
Prepaid expenses and other assets	2,438	2,136
Total assets	$ 197,382	$ 196,978

11. Income Taxes

The Company s provision for income taxes of $158,000 and $39,000 for the three months ended June 30, 2010 and 2009, respectively, and $344,000 and $119,000 for the six months ended June 30, 2010 and 2009, respectively, relates to the profitable operations of certain foreign entities.

12. Commitments and Contingencies

Significant commitments and contingencies at June 30, 2010 are consistent with those discussed in Note 12 to the consolidated financial statements in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

13. Stock-Based Compensation

The captions in the Company s condensed consolidated statements of operations for the three and six months ended June 30, 2010 and 2009 include stock-based compensation as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Cost of revenues	$ 555	$ 370	$ 1,015	$ 664
Selling and marketing	1,470	787	2,481	1,451
Research and development	630	176	1,031	313
General and administrative	1,328	859	2,348	1,449
	$ 3,983	$ 2,192	$ 6,875	$ 3,877

Stock Options

The Company granted options to purchase 204,000 and 129,000 shares of common stock during the three months ended June 30, 2010 and 2009, respectively, and options to purchase 1,300,300 and 1,657,430 shares of common stock during the six months ended June 30, 2010 and 2009, respectively. The weighted-average fair value of options granted during the six months ended June 30, 2010 and 2009 was $5.52 and $1.21 per option, respectively.

Restricted Stock Awards

In March 2010, the Company s Compensation Committee of the Board of Directors, or the Compensation Committee, approved the Company s 2010 Performance Share Plan in which it committed to grant up to 811,800 shares of restricted stock to certain employees and executive officers based on the achievement of certain Company financial performance metrics for the year ending December 31, 2010. The restricted stock, if awarded, vests over a requisite service period of three years. Further, in March 2010, the Compensation Committee approved the Company s 2010 Corporate Bonus Plan. Payout under the 2010 Corporate Bonus Plan will be based on individual performance and the achievement of certain Company financial performance metrics for the year ending December 31, 2010 and

will be paid in cash, or in shares of the Company s common stock, at the discretion of the Compensation Committee. The estimated payout under the 2010 Corporate Bonus Plan is being recognized as compensation expense during 2010 and has been classified as a liability on the Company s condensed consolidated balance sheet.

14. Stockholders Equity

On March 3, 2010, the Company received 174,757 shares that were surrendered by employees in payment for the minimum required withholding taxes due on issuance of shares of the Company s common stock under the Company s 2009 Corporate Bonus Plan and vesting of the first tranche of the restricted stock awards under the Company s 2009 Performance Share Plan. These shares have been classified as treasury stock in the condensed consolidated balance sheets. The settlement of the Company s 2009 Corporate Bonus Plan obligation of $1.6 million during the first quarter of 2010 in shares of its common stock represents a noncash financing activity.

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15. Fair Value Measurements

At June 30, 2010, the Company had $11.8 million in money market funds, included in cash and cash equivalents, measured at fair value on a recurring basis utilizing quoted prices (unadjusted) in active markets of identical assets, also referred to as level 1 inputs.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, 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 the Company s long-term debt approximates fair value at June 30, 2010. The fair value of the Company s long-term debt was estimated using inputs derived principally from market observable data, also referred to as level 2 inputs, including current rates offered to the Company for debt of the same or similar remaining maturities.

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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 six months ended June 30, 2010, 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, 2009, 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 major customers, including DaVita, Inc.; the adequacy of our funding, our need for and our ability to obtain additional funding; whether and when we might achieve improvements to our gross margins and operating expenses; expectations with respect to our operating expenses and achieving our business plan; expectations with respect to achieving profitable operations; expectations with respect to achieving improvements in product reliability; the timing and success of the submission, acceptance and approval of regulatory filings, the scope of patent protection with respect to our products, expectations with respect to the clinical findings of our FREEDOM study, the impact of future changes to reimbursement for chronic dialysis treatments and the impact of current economic conditions on our business. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words expect , anticipate , intend , plan , believe , seek , estimate , potential , 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 Managements 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.

Overview

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

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 equipment and the sale of disposable products in the home and critical care markets. We define the home

market as the market devoted to the treatment of ESRD patients in the home and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. We offer a similar technology platform of the System One for the home and critical care markets with different features. In the In-Center segment, we derive our revenues from the sale of needles and blood tubing sets used predominantly in hemodialysis performed in-center as well as apheresis, which we refer to as the in-center market. Our blood tubing set products include the ReadySet High Performance Blood Tubing set and our next generation Streamline Airless Blood Tubing set. Streamline is designed to provide improved patient outcomes and lower costs to dialysis centers. Our needle product line includes AV fistula needle sets incorporating safety features including PointGuard Anti-Stick Needle Protectors and MasterGuard technology and ButtonHole needle sets.

In our System One segment, we market the System One in the home and critical care markets through a direct sales force in the United States primarily to dialysis centers, for ESRD hemodialysis patients, and hospitals. In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products internationally. However, to date, substantially all System One segment revenues have been derived from sales within the United States. In our In-Center segment, we market our blood tubing set and needle products primarily through distributors, although we also have a small dedicated sales force for that business. Nearly all In-Center sales are made to customers within the United States, with very limited amounts sold internationally through distributors.

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The manufacture of our products is accomplished through a complementary combination of outsourcing and internal production. We have manufacturing facilities in Mexico, Germany and Italy. We outsource the manufacture of premixed dialysate, needles, some blood tubing sets, and some components.

We received clearance from the Food and Drug Administration, or FDA, in July 2003 to market the System One for treatment of renal failure and fluid overload using hemodialysis as well as hemofiltration and ultrafiltration. In the first quarter of 2003, we initiated sales of the System One in the critical care market to hospitals and medical centers in the United States. In late 2003, we initiated sales of the System One for the treatment of patients with ESRD. In June 2005, the FDA cleared the System One for hemodialysis in the home. We presently have CE marking as well as Canadian regulatory authority to sell our System One as well as certain other products in Canada and Europe. We are currently pursuing a nocturnal indication for the System One under an IDE study started in the first quarter of 2008. We completed the IDE study in February 2010 and are currently seeking pre-market clearance from the FDA through the 510(k) clearance process.

Our customers, who include dialysis centers and hospitals, receive reimbursement for the dialysis treatments provided with our products typically from Medicare, and to a lesser degree from private insurers. Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. Reimbursement claims for dialysis therapy using the System One or our blood tubing sets and needles are typically submitted by the dialysis center or hospital to Medicare and other third-party payors using established billing codes for dialysis treatment or, in the critical care setting, based on the patient s primary diagnosis. Medicare presently limits reimbursement for chronic hemodialysis to three treatments per week, absent a finding of medical justification. Because most of our System One home dialysis patients are treated more than three times a week, expanding Medicare reimbursement over time to more predictably cover more frequent therapy may be critical to the market penetration of the System One in the home market and to our revenue growth in the future.

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. One of these initiatives was the Medicare Improvements for Patients and Providers Act, or MIPPA Act, which was signed into law in 2008. As a result of this legislation, the Centers for Medicare and Medicaid Services, or CMS, announced that, on January 1, 2011, it will implement a new bundled payment for dialysis treatment. Final rules were issued on July, 23, 2010 after publication of proposed rules and a formal comment period. One of the stated goals of this new prospective payment system is to encourage home hemodialysis and certain elements (e.g., bundling of certain drugs into the payment, a uniform treatment payment whether dialysis is administered in the center or at home and a separate payment adjustor for home dialysis training) are intended to support this objective. However, it is not possible at this time to determine what impact this new bundled payment will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

Further, 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 Health Care Act (H.R. 3590) and the Health Care and Education Reconciliation Act (H.R. 4872). Among other initiatives, these bills impose a 2.3% excise tax on domestic sales of medical devices following December 31, 2012. Outside of the excise tax, which will impact our results of operations following December 31, 2012, we cannot predict the effect such legislation will have on us.

Since inception, we have incurred losses every quarter, and at June 30, 2010, we had an accumulated deficit of approximately $294.0 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, and positive cash flows from operating activities, beginning in the second quarter of 2010, we cannot provide assurance that our cash flows from operating activities will remain positive, or improve, or that our gross margins will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable. Our ability to become profitable depends principally upon implementing design and process improvements to lower the costs of manufacturing our products, obtaining better purchasing terms and prices, growing revenue, increasing reliability of our products, improving the management of our field equipment assets, achieving

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

We have experienced negative operating margins and expect to continue to incur net losses in the foreseeable future. Until the second quarter of 2010, we had experienced negative cash flows from operating activities. There can be no assurance that we will be able to continue to generate positive cash flows from operating activities. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, the availability of credit, and the potential investments in, or acquisitions of, complementary businesses, services or technologies.

Statement of Operations Components

Revenues

In the System One segment we derive our revenues from the sale and rental of equipment and the sale of disposable products in the home and critical care markets. In the home market, customers rent or purchase the System One equipment, including the cycler

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and PureFlow SL hardware, and then purchase the related disposable products based on a specific patient prescription. In the critical care market, we sell or rent the System One and related disposables to hospital customers. In the In-Center segment, the majority of revenues are derived from supply and distribution contracts with distributors.

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

Our contracts with dialysis centers in the home market for ESRD home dialysis patients generally include terms providing for the sale of disposable products to accommodate up to the number of prescribed treatments per month per patient and the purchase or monthly rental of System One cyclers and, in some instances, our PureFlow SL hardware. These contracts typically have a term of one to three years, and may be renewed on a month-to-month basis thereafter, subject to a 30-day termination notice. Under these contracts, if home hemodialysis is prescribed, supplies are shipped directly to patient homes and paid for by the treating dialysis center. We also include vacation delivery terms, providing for the shipment of products to a designated vacation destination for a specified number of vacation days. We derive an insignificant amount of revenues from the sale of ancillary products, such as extra lengths of tubing. Over time, as more home patients are treated with the System One and more systems are placed in patient homes, we expect to derive a growing recurring revenue stream from the sale of related disposables.

In the critical care market we recognize revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms. Our contracts with hospitals in the critical care market generally include terms providing for the sale of our System One hardware and disposables, although we also provide a hardware rental option. These contracts typically have a term of one year. We derive a small amount of revenue from the sale of one and two year service contracts following the expiration of our standard one-year warranty period for System One hardware. To further support service in this market, we have a bio-medical training program, whereby we train bio-medical engineers on how to service and repair certain aspects of the System One in the critical care setting. Bio-medical training is not offered for the home market within our System One segment. Bio-medical training is typically provided under a two-year contract following the expiration of our standard one-year warranty period for System One hardware. Similar to our home market, as more System One equipment is placed within hospitals, we expect to derive a growing recurring revenue stream from the sale of disposable cartridges and fluids as well as, to a much lesser degree, from the sale of service and bio-medical training contracts.

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. These contracts contain minimum volume commitments with negotiated pricing triggers at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain cure rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events. In addition to contractually determined volume discounts, we offer rebates based on sales to specific end customers and discount incentives for early payment. Our revenues are presented net of these rebates, incentives, discounts and returns, collectively rebates and other discounts. As of June 30, 2010, we had $1.6 million reserved against trade accounts receivable for future rebates and other discounts. We recorded $1.2 million and $2.4 million during the three months ended June 30, 2010 and 2009, respectively, and $3.0 million and $4.9 million during the six months ended June 30, 2010 and 2009, respectively, as a reduction of revenues in connection with rebates and other discounts. Our In-Center segment revenues are subject to fluctuation as a result of changes in sales volumes and variations in inventory management policies of our distributors and end users. We regularly monitor the amount of inventory held by distributors to ensure it is not excessive when compared to end user demand.

Our customers in the System One segment are highly consolidated. Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States and collectively provide treatment to approximately 60% of United States dialysis patients. DaVita is our most significant customer for the System One segment. Sales to DaVita represented approximately 35% of our System One segment revenues for both the three and six months ended June 30, 2010 and approximately 38% of our System One segment revenues for both the three and six months ended

June 30, 2009. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. A small, but growing, percentage of our sales in the System One segment are to Fresenius, with nearly all of those sales in the home market.

In July 2010, we entered into a First Amended and Restated National Service Provider Agreement, or the Amended Agreement, with DaVita expiring on June 30, 2013. The Amended Agreement supersedes the National Service Provider Agreement dated as of February 7, 2007, as amended, or the Original Agreement. Pursuant to the terms of the Amended Agreement, we will continue to supply the System One and PureFlow SL and related supplies for home hemodialysis therapy to DaVita. Under the Amended Agreement, DaVita commits to continue to purchase, rather than rent, nearly all of its future System One equipment needs. The term of the Amended Agreement is for approximately three years through June 30, 2013, but may be automatically extended on a monthly basis unless terminated by either party pursuant to the Amended Agreement.

The Amended Agreement includes a modest increase to DaVita s pricing from the levels under the Original Agreement, and continues DaVita s right to receive most favored nations pricing for the System One and related supplies for home hemodialysis therapy, subject to certain requirements, including DaVita achieving certain System One home patient growth targets. In addition, under the Amended Agreement, 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

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and 2013, which require DaVita to continue to grow its home patient census every six months during the term of the Amended Agreement. Under this tiered rebate structure, DaVita would be required to grow its net patients on the NxStage System One at a compounded annual growth rate of approximately 20 percent, from its current level, to receive the lowest level of warrants during each of the three years. Achieving the highest level of warrants will require a significant increase above that. The warrant-based rebate structure preserves NxStage s 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 and are non-transferable and must be exercised in cash.

In connection with the issuance of the warrants, we entered into a Registration Rights Agreement with DaVita pursuant to which we 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 issued to DaVita under the warrant. We are required to use our best efforts to cause the registration statement to be declared effective as promptly as possible after the filing but in any event not later than (i) July 30, 2011 or (ii) the date on which any warrants become exercisable and vested, whichever is later.

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 45% of our In-Center segment revenues during both the three and six months ended June 30, 2010 and approximately 80% of our In-Center segment revenues during both the three and six months ended June 30, 2010. Our second largest distributor is Gambro Renal Products, Inc., or Gambro. Revenues from Gambro represented approximately 35% of our In-Center segment revenues during both the three and six months ended June 30, 2010. During the later part of 2009, in connection with our Gambro agreement, we transitioned our sales of blood tubing sets to DaVita from Henry Schein to Gambro, significantly reducing our sales to Henry Schein.

Sales of products through distributors to DaVita accounted for nearly half of In-Center segment revenues for the three and six months ended June 30, 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. However, in June 2009, we entered into a five year distribution agreement in the United States with Gambro, which contractually obligates Gambro to exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines to DaVita.

Our distribution agreement with Henry Schein, a significant distributor for the In-Center segment, will expire in April 2012. Our agreements with two other distributors for the In-Center segment are scheduled to expire in July 2011 and February 2012, respectively. Our blood tubing set distribution agreement with Gambro expires in July 2014.

Cost of Revenues

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

Operating Expenses

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

Research and Development. Research and development expenses consist primarily of salary, benefits and stock-based compensation for research and development personnel, supplies, materials and expenses associated with product design and development, clinical studies, regulatory submissions, reporting and compliance and expenses

incurred for outside consultants or firms who furnish services related to these activities.

Distribution. Distribution expenses include the freight costs of delivering our products to our customers or our customers patients, depending on the market and the specific agreements with our customers, salary, benefits and stock-based compensation for distribution personnel and the cost of any equipment lost or damaged in the distribution process. We use common carriers and freight companies to deliver our products and do not operate our own delivery service. Also included in this category are the expenses of shipping products under warranty from customers back to our service center for repair and the related expense of shipping a replacement product to our customers or their patients.

General and Administrative. General and administrative expenses consist primarily of salary, benefits and stock-based compensation for our executive management, legal and finance and accounting staff, fees of outside legal counsel, fees for our annual audit and tax services, and general expenses to operate the business, including insurance and other corporate-related expenses.

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Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	**2009**	**2010**	**2009**
Revenues	100%	100%	100%	100%
Cost of revenues	69%	76%	70%	77%
Gross profit	31%	24%	30%	23%
Operating expenses:				
Selling and marketing	20%	20%	20%	21%
Research and development	7%	6%	7%	7%
Distribution	8%	10%	8%	10%
General and administrative	13%	13%	13%	14%
Total operating expenses	48%	49%	48%	52%
Loss from operations	(17%)	(25%)	(18%)	(29%)
Other expense:				
Interest income				
Interest expense	(3%)	(9%)	(2%)	(6%)
Other income (expense), net	1%			
	(2%)	(9%)	(2%)	(6%)
Provision for income taxes				
Net loss	(19%)	(34%)	(20%)	(35%)

Comparison of the Three and Six Months Ended June 30, 2010 and 2009

Revenues

Our revenues for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended		Six Months Ended	
	June 30, 2010	**June 30, 2009**	**June 30, 2010**	**June 30, 2009**
System One segment				

Home	$ 20,815	47%	$ 15,205	42%	$ 39,858	47%	$ 29,559	42%
Critical Care	6,652	15%	5,241	14%	12,711	15%	9,709	14%
Total System One segment	27,467	62%	20,446	56%	52,569	62%	39,268	56%
In-Center segment	16,541	38%	15,952	44%	31,847	38%	30,865	44%
Total	$ 44,008	100%	$ 36,398	100%	$ 84,416	100%	$ 70,133	100%

The increase in revenues for both periods was primarily attributable to increased sales and rentals of the System One and related disposables in both the home and critical care markets, primarily as a result of the growing number of patients using the System One as we continue to penetrate the market place.

In the home market, revenues increased $5.6 million, or 37%, and $10.3 million, or 35%, for the three and six months ended June 30, 2010, respectively, versus the prior year comparable periods, primarily as a result of an increase in the number of patients prescribed to use and centers offering the System One. Critical care market revenues increased $1.4 million, or 27%, and $3.0 million, or 31%, for the three and six months ended June 30, 2010, respectively, versus the prior year comparable periods, primarily due to increased sales of the System One resulting from our efforts to continue to penetrate the market and increased sales of disposables from our growing number of installed units. Future demand for our products in both the home and critical care markets is expected to remain strong due to the life-sustaining, non-elective nature of dialysis therapy. Revenues in the home and critical care markets are expected to continue to increase as we further penetrate the market place and as we expand internationally. However, in the critical care market, we expect, at least in the short-term, to see a continuation of a conservative capital spending environment.

In-Center segment revenues increased $0.6 million, or 4%, and $1.0 million, or 3%, for the three and six months ended June 30, 2010, respectively, versus the prior year comparable periods, due to increased sales of our needle products resulting from strong end

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user demand and changes in distributor inventory levels. We expect future demand will be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users.

Gross Profit

Our gross profit and gross profit as a percentage of revenues for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended				Six Months Ended			
	June 30, 2010	% Revenues	June 30, 2009	% Revenues	June 30, 2010	% Revenues	June 30, 2009	% Revenues
System One segment	$ 9,756	36%	$ 4,654	23%	$ 18,395	35%	$ 8,710	22%
In-Center segment	4,006	24%	4,163	26%	7,180	23%	7,162	23%
Gross Profit	$ 13,762	31%	$ 8,817	24%	$ 25,575	30%	$ 15,872	23%

The increase in gross profit for both periods was a result of increased revenues and improvement in gross profit as a percentage of revenues. The improvement in gross profit as a percentage of revenues was attributable to the System One segment, specifically, decreased service costs resulting from improved equipment reliability and lower overall costs of manufacturing as we continue to realize the benefits of leveraging our manufacturing infrastructure, certain cost saving initiatives and improvements in product design.

Gross profit for the In-Center segment remained relatively consistent for the six months ended June 30, 2010, versus the prior year comparable period. Gross profit for the three months ended June 30, 2010 decreased slightly in absolute dollars and as a percentage of revenues, versus the prior year comparable period, due to costs incurred related to manufacturing process improvements.

We expect gross profit as a percentage of revenues will continue to improve over time 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 cost than our current products. Second, we anticipate that increased sales volume and realization of economies of scale will lead to better purchasing terms and prices and efficiencies in manufacturing and supply chain overhead costs. Finally, we expect to continue to improve product reliability, which would reduce service costs. However, there is no certainty that our expectations will be achieved with respect to these cost reduction plans.

Selling and Marketing

Our selling and marketing expenses for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended			Six Months Ended		
	June 30, 2010	June 30, 2009	% Change	June 30, 2010	June 30, 2009	% Change
System One segment	$ 7,410	$ 6,495	14%	$ 14,319	$ 12,817	12%
In-Center segment	1,155	916	26%	2,263	1,825	24%
Total Selling and marketing	$ 8,565	$ 7,411	16%	$ 16,582	$ 14,642	13%

Selling and marketing increased in absolute dollars for both the three and six months ended June 30, 2010, versus the prior year period, but decreased as a percentage of revenues from 21% for the six months ended June 30, 2009 to 20% for the six months ended June 30, 2010. The increase in selling and marketing expense was primarily the result

of increased personnel and personnel-related costs, primarily non-cash stock-based compensation expenses, and increased spending due to expanded marketing programs. We anticipate that selling and marketing expenses will continue to increase as we broaden our marketing initiatives to increase public awareness of the System One in the home market and to support growth in international markets.

Research and Development

Our research and development expenses for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended			Six Months Ended		
	June 30, 2010	**June 30, 2009**	**% Change**	**June 30, 2010**	**June 30, 2009**	**% Change**
Research and development	$ 3,202	$ 2,271	41%	$ 6,237	$ 4,673	33%

Research and development increased in absolute dollars but remained relatively consistent as a percentage of revenues at 7% for both the three and six months ended June 30, 2010, as compared to 6% and 7% for the three and six months ended June 30, 2009, respectively. The increase in research and development expenses was primarily due to increased personnel and personnel-related costs, including non-cash stock-based compensation expense, due to increased headcount and an increase in other project related spending. This increase was partially offset by a decrease in clinical trials expenses primarily related to our nocturnal IDE as we

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completed the IDE study in February 2010 and are currently seeking pre-market clearance from the FDA through the 510(k) clearance process. We expect research and development expenses will increase in absolute dollars but remain relatively constant as a percentage of revenues in the foreseeable future as we seek to further enhance our System One and related products, and their reliability, and with activity associated with our FREEDOM study.

Distribution

Our distribution expenses for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended			Six Months Ended		
	June 30, 2010	June 30, 2009	% Change	June 30, 2010	June 30, 2009	% Change
System One segment	$ 3,156	$ 3,159	(0%)	$ 6,165	$ 6,508	(5%)
In-Center segment	476	366	30%	878	701	25%
Total Distribution	$ 3,632	$ 3,525	3%	$ 7,043	$ 7,209	(2%)

Distribution expenses decreased as a percentage of revenues to 8% for the three and six months ended June 30, 2010 versus 10% for the prior year comparable periods. Distribution expenses for the System One segment decreased as a percentage of revenues to 11% and 12% for the three and six months ended June 30, 2010, respectively versus 15% and 17% for the prior year comparable periods, due primarily to efficiencies gained from economies of scale resulting from increased business volume, improved product reliability of our System One and PureFlow SL hardware and better pricing obtained from carriers. Distribution expenses as a percentage of revenue for the In-Center segment increased slightly as a percentage of revenues to 3% for the three and six months ended June 30, 2010 versus 2% for the prior year comparable periods, due primarily to increased delivery costs for certain products shipped 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. We cannot predict the estimated impact, if any, of fuel costs on future distribution costs.

General and Administrative

Our general and administrative expenses for the three and six months ended June 30, 2010 and 2009 were as follows (in thousands, except percentages):

	Three Months Ended			Six Months Ended		
	June 30, 2010	June 30, 2009	% Change	June 30, 2010	June 30, 2009	% Change
General and administrative	$ 5,643	$ 4,749	19%	$ 10,581	$ 9,704	9%

General and administrative expenses increased in absolute dollars but remained relatively consistent as a percentage of revenues at 13% for both the three and six months ended June 30, 2010 and 13% and 14% for the three and six months ended June 30, 2009, respectively. The increase in general and administrative expenses for both periods was primarily related to non-cash stock-based compensation expenses. These increases were offset by lower spending on corporate support functions, including consulting and legal expenses, due to our continued initiative to control 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 Income and Expense

Interest income is derived primarily from investments in money market funds. The decrease in interest income is due to lower interest rates on investments.

Interest expense decreased $2.2 million, or 66%, for the three months ended June 30, 2010 and decreased $2.1 million, or 48%, for the six months ended June 30, 2010, versus the prior year comparable periods due primarily to prepayment and other transaction fees of $2.0 million incurred during the three months ended June 30, 2009 to pay off the entire debt obligation owed under our credit and security agreement with General Electric Capital Corporation, or GE.

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 $158,000 and $344,000 for the three and six months ended June 30, 2010, respectively, and $39,000 and $119,000 for the three and six months ended June 30, 2009, respectively, relates to the profitable operations of certain of our foreign entities.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of June 30, 2010, our accumulated deficit was $294.0 million and we had cash and cash equivalents of $20.0 million and working capital of $37.0 million.

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Our primary ongoing cash requirements will be to fund operating activities, product development and debt service. Our primary sources of liquidity are cash on hand and ongoing revenues. A number of our home market customers, including DaVita, have purchased System One equipment, with certain customers committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. The decision by our customers to purchase, rather than rent, our System One equipment allows us to recover the cost of our products upon initial sale rather than over an extended period of time which has resulted in a significant decrease in our cash usage. However, there can be no assurance that we will be able to continue to expand the percentage of our equipment placements that are purchased rather than rented. A significant factor affecting the management of our ongoing cash requirements is our ability to continue to improve the management of our field equipment assets and execute upon cost reduction initiatives to lower product cost.

We have the flexibility under our term loan with Asahi Kasei Kuraray Medical Co., Ltd., or Asahi, a medical supply company headquartered in Japan, to seek additional debt at market interest rates to fund our growth objectives and in March 2010 we chose to do so. On March 10, 2010, we entered into a Loan and Security Agreement, the Credit Facility, with Silicon Valley Bank, or SVB, with a maturity date of April 1, 2012. The Credit Facility provides a credit commitment of up to $15.0 million, subject to certain limitations and calculations of borrowing amount. The Credit Facility is secured by all or substantially all of our assets. Borrowings under the Credit Facility bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Credit Facility, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the Credit Facility. The Credit Facility contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. At June 30, 2010, we were in compliance with the covenants, there were no outstanding borrowings and we had approximately all of the $15.0 million credit commitment available for borrowing under the Credit Facility.

In connection with the Credit Facility, 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 Credit Facility remains outstanding. Upon termination of all obligations under the Credit Facility, Asahi s security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory.

At June 30, 2010, we had $41.8 million in principal and deferred interest outstanding under our term loan and security agreement with Asahi, or Term Loan. The Term Loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The Term Loan is secured by substantially all of our assets. In the event the Term Loan reaches maturity, Asahi may require that all of the principal and interest on the Term Loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions.

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

We 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 $1.5 million as other long-term liabilities at June 30, 2010 for costs associated with these plans. The expense recorded in connection with these plans was not significant for the three and six months ended June 30, 2010 or 2009.

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

	Six Months Ended June 30,	
	2010	**2009**

Net cash used in operating activities	$ (1,027)	$ (10,685)
Net cash used in investing activities	(457)	(1,148)
Net cash provided by financing activities	371	9,537
Effect of exchange rate changes on cash	(562)	109
Net cash flow	$ (1,675)	$ (2,187)

Net Cash Used in Operating Activities. For each of the periods above, net cash used in operating activities was attributable primarily to net losses after adjustment for non-cash charges, such as depreciation, amortization and stock-based compensation expense. Net cash used in operating activities decreased by $9.7 million during the six months ended June 30, 2010, versus the prior year comparable period. The decrease in net cash used in operating activities was primarily due to a decrease in our net loss after adjustments for non-cash charges as we continue to reduce product costs and improve the management of our field equipment assets, and increases in deferred revenues. Deferred revenues increased $8.7 million and $0.7 million during the six months ended June 30,

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2010 and 2009, respectively. The increase in deferred revenues in both periods was a result of the increase in the number of customers who chose to purchase, rather than rent, the System One equipment, offset by the amortization of this equipment totaling $2.7 million and $1.5 million during the three months ended June 30, 2010 and 2009, respectively, and $5.0 million and $2.8 million during the six months ended June 30, 2010 and 2009, respectively, of deferred revenues into revenues. Currently, over half of our sales to customers in the home market include the purchase, rather than the rental, of System One equipment. The decreases in net cash used in operating activities were partially offset by increases in inventory to support the growing number of customers using our System One equipment and accounts receivable as we continue to expand our business. Non-cash transfers from inventory to field equipment and deferred costs of revenues for the placement of units with our customers increased $6.4 million during the six months ended June 30, 2010, versus the prior year comparable period to support the growing number of patients using the System One. Non-cash transfers from field equipment to deferred costs of revenues increased $8.5 million during the six months ended June 30, 2010, versus the prior year comparable period, primarily due to an increase in the number of customers who have purchased rather than rented our System One 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 to our facilities, research and development and information technology.

Net Provided by Financing Activities. Net cash provided by financing activities during the six months ended June 30, 2010 included $2.1 million of proceeds from stock option and stock purchase plans offset by cash used to repurchase 174,757 shares of our common stock that were surrendered by employees in payment for the minimum required withholding taxes due on issuance of shares of our common stock under our 2009 Bonus Plan and vesting of restricted stock awards under our 2009 Performance Share Plan. Net cash provided by financing activities during the six months ended June 30, 2009 included $40.0 million of borrowings under our Asahi Term Loan offset by $0.1 million in fees paid in connection with the Asahi debt issuance, $30.0 million in repayments of borrowing under our credit and security agreement with GE and $0.5 million amendment fee paid in connection with the March 16, 2009 amendment to our credit and security agreement with GE.

We have experienced negative operating margins and expect to continue to incur net losses in the foreseeable future. Until the second quarter of 2010, we had experienced negative cash flows from operating activities. There can be no assurance that we will be able to continue to generate positive cash flows from operating activities. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, the availability of credit, and the potential investments in, or acquisitions of, complementary businesses, services or technologies.

Significant commitments and contingencies at June 30, 2010 are consistent with those discussed in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

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.

A summary of those accounting policies and estimates that we believe are most critical to fully understanding and evaluating our financial results is described in Item 7 in our Annual Report on Form 10-K for the fiscal year ended

December 31, 2009. There have been no changes to our critical accounting policies and estimates since December 31, 2009. This summary should be read in conjunction with our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q.

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, 2009 and in Note 2 to the condensed consolidated financial statements included in this quarterly report on Form 10-Q.

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, 2009. There have been no material changes to the market risks described in our Annual Report on Form 10-K for December 31, 2009.

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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 June 30, 2010. 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 June 30, 2010, 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 June 30, 2010 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 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 2010 and in the foreseeable future, we will continue to derive a significant percentage of our revenues from the System One, and that we will derive the remainder of our revenues from the sale of a few key disposable products acquired in the Medisystems Acquisition, including blood tubing sets and needles. To the extent that any of our primary products are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted, and we do not have other significant products in development that could readily replace these revenues.

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

We believe our largest future product market opportunity is the home hemodialysis market. However this market is presently very small and adoption of the home hemodialysis treatment options has been limited. The most widely adopted form of dialysis therapy used in a setting other than a dialysis clinic is peritoneal dialysis. Based on the most recently available data from the United States Renal Data System, or USRDS, the number of patients receiving peritoneal dialysis was approximately 26,000 in 2006, representing approximately 8% of all patients receiving dialysis treatment for ESRD in the United States. Very few ESRD patients receive hemodialysis treatment outside of the clinic setting. Because the adoption of home hemodialysis has been limited to date, the number of patients who desire to, and are capable of, administering their own hemodialysis treatment with a system such as the System One is unknown and there is limited data upon which to make estimates. In addition, many dialysis clinics do not presently have the infrastructure in place to support home hemodialysis and most do not have the infrastructure in place to support a significant home hemodialysis patient population. Our long-term growth will depend on the number of patients who adopt home-based hemodialysis and how quickly they adopt it, which in turn is driven by the number of physicians willing to prescribe home hemodialysis and the number of dialysis clinics able or willing to establish and support home hemodialysis therapies.

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered five or more times a week, the market adoption of our System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider supply costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for Medicare patients by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. Presently, we understand that a number of our customers are unable to obtain such additional reimbursement, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times per week. Both of these facts will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to grow our revenue in the future.

New regulations particularly impacting home hemodialysis technologies can also negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. In 2008, CMS released new Conditions for Coverage applicable to our customers. These Conditions for Coverage impose water testing requirements on our patients using our PureFlow SL product. These water testing requirements increase the burden of our therapy for our patients and may impair market adoption, especially for our PureFlow SL product. To the

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extent additional regulations are introduced unique to the home environment, market adoption could be even further impaired.

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

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

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our products. As a result of legislation passed by the United States Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the United States for ESRD. With approximately 75% of United States ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can rent or sell our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification provided by the patient s physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for the additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis, based on documentation provided by our customers. If daily therapy is prescribed, a clinic s decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic s patients. Medicare is switching from intermediaries to Medicare authorized contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. We understand that some of our customers may not be able to obtain additional reimbursement for more frequent therapy in all cases, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times a week. Both of these factors will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to more predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to our revenue growth in the future. Additionally, any adverse changes in the rate paid by Medicare for ESRD treatments in general would likely negatively affect demand for our products in the home market and the prices we charge for them.

CMS issued, on July 23, 2010, the final rule for implementation of a new bundled payment for dialysis treatment effective January 1, 2011. Under this new ESRD prospective payment system, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services and home dialysis, and will include certain drugs (including ESAs, iron, and Vitamin D). It will replace the current system which pays facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that are not included in the composite rate. The new bundled payment systems 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. Although a stated goal of the new bundled payment system is to encourage home dialysis, and the inclusion of drugs into the bundled 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 bundle 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 require significant capital to build our business, and financing may not be available to us on reasonable terms, if at all.

We have experienced negative operating margins and we expect to continue to incur net losses in the foreseeable future. Until the second quarter of 2010, we had experienced negative cash flows from operating activities. There can be no assurance that we will be able to continue to generate positive cash flows from operating activities. In addition,

our System One home market relies heavily upon a rental sales model whereby less than half of our sales to customers in the home market include the rental rather than the purchase of System One equipment. This sales model requires significant amounts of working capital to manufacture System One equipment for rental to dialysis clinics. A number of our home market customers, including DaVita, have purchased System One equipment, with certain

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customers committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. There can, however, be no assurance that we will be able to continue to expand the percentage of our equipment placements that are purchased rather than rented.

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

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

We have limited operating experience, a history of net losses and an accumulated deficit of $294.0 million at June 30, 2010. We cannot guarantee if, when and the extent to which we will become profitable, or that we will be able to maintain profitability if it is achieved.

Since inception, we have incurred losses every quarter, and at June 30, 2010, we had an accumulated deficit of approximately $294.0 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, and positive cash flows from operating activities, beginning in the second quarter of 2010, we cannot provide assurance that our cash flows from operating activities will remain positive, or improve, or that our gross margins will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable. Our ability to become profitable depends principally upon implementing design and process improvements to lower the costs of manufacturing our products, obtaining better purchasing terms and prices, growing revenue, increasing reliability of our products, improving the management of our field equipment base, achieving efficiencies in manufacturing and supply chain overhead costs, achieving efficiencies in the distribution of our products and achieving a sufficient scale of operations.

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

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Collectively, these entities provide treatment to approximately 60% of United States dialysis patients. Additionally, DaVita has certain dialysis supply purchase obligations to Gambro under a long-term preferred supplier agreement. Each of Fresenius and DaVita may choose to offer their dialysis patients only the dialysis equipment manufactured by them or their affiliates, to offer the equipment they contractually agreed to offer or to otherwise limit access to the equipment manufactured by competitors. 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 small, but growing, percentage of our home market sales to Fresenius. However, we have no assurance that our sales to DaVita or Fresenius will continue to grow. With less than 40% of United States dialysis patients cared for by independent dialysis clinics, our market adoption, at least within the United States, will be more constrained without the presence of one or both of DaVita and Fresenius as customers for our System One and In-Center products.

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

DaVita is our most significant customer. Sales through distributors to DaVita of products accounted for nearly half of In-Center segment revenues for the three and six months ended June 30, 2010, and direct sales to DaVita accounted

for approximately 35% of our System One segment revenues for both the three and six months

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ended June 30, 2010. 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. Further, given the significance of DaVita as a customer, any change in DaVita s ordering or clinical practices could have a significant impact on our revenues, especially in the near term.

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

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

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

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

On March 10, 2010, we entered into an Agreement with SVB for a $15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi s security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy.

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

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

Our System One in the critical care market competes against Gambro AB, Fresenius Medical Care AG, Baxter Healthcare, B. Braun and others. Our System One in the home market is currently the only system specifically

indicated for use in the home market in the United States. Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter Healthcare, JMS and others. Our competitors each market one or more FDA-cleared medical devices for the treatment of acute or

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

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our products, including our System One. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices. Baxter has announced a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it hopes to commence clinical studies of DEKA s new home hemodialysis system in 2010 and launch in international markets in 2011. We are unable to predict when, if ever, this product, or products from other companies, may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it would likely adversely affect our sales and growth. Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of ESRD and/or in the treatment of acute kidney failure or fluid overload. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

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

Our future success will depend in part on our timely development and introduction of new and improved products that address changing market requirements. To the extent that we fail to introduce new and innovative products or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological or other reasons, to successfully develop and introduce new or improved products could reduce our growth rate or otherwise damage our business. We cannot assure you that our developments will keep pace with the marketplace or that our new or improved products will adequately meet the requirements of the marketplace.

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

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

- the failure by us to demonstrate to operators of dialysis clinics, hospitals, nephrologists, dialysis nurses, patients and others that our products are equivalent or superior to existing therapy options;

competition from products sold by companies with longer operating histories and greater financial resources, more recognizable brand names and better established distribution networks and relationships with hospitals or dialysis clinics;

the failure by us to continue to improve product reliability and the ease of use of our products;

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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 and such conditions may increase other risks that affect our business.

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

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 Health Care Act (H.R. 3590) and the Health Care and Education Reconciliation Act (H.R. 4872). Among other initiatives, these bills impose a 2.3% excise tax on domestic sales of medical devices following December 31, 2012. Outside of the excise tax, which will impact our results of operations following December 31, 2012, we cannot predict the effect such legislation will

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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, sales and marketing and on-going development capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various partners, suppliers, manufacturers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our information technology infrastructure, operational, financial and management controls and reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

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

We have not yet achieved our long term reliability objectives for certain of our products, and as a result we continue to incur increased service and distribution costs. This, in turn, negatively impacts our gross margins and increases our working capital requirements. Additionally, product reliability issues associated with any of our product lines could lead to decreases in customer satisfaction and our ability to grow or maintain our revenues and could negatively impact our reputation. We continue to work to improve product reliability for all products, and have achieved some improvements to date. If we are unable to continue to improve product reliability, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

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

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

While kidney transplantation is the treatment of choice for most ESRD patients, it is not currently a viable treatment for most- patients due to the limited number of donor kidneys, the high incidence of kidney transplant rejection and the higher surgical risk associated with older ESRD patients. According to USRDS data, in 2007, approximately 17,500 patients received kidney transplants in the United States. The development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants or any other advances in kidney transplantation could limit the market for our products. The development of viable medical or other solutions for renal replacement may also limit the market for our products.

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

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a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance.

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

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

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

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

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

We currently rely upon Kawasumi, a third-party manufacturer, to manufacture a significant percentage of our blood tubing set products using our supplied components and all of our needles.

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

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

We sell the majority of our In-Center products through several distributors, which collectively accounted for substantially all of In-Center revenues for the three and six months ended June 30, 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 blood tubing set business through Streamline or products that we introduce in the future, we will continue to be susceptible to further pressures to reduce product pricing and more vulnerable to the loss of our blood tubing set business to competitors in the dialysis industry.

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

The activities of our business involve the import of finished goods into the United States from foreign countries, subject to customs inspections and duties, and the export of components and certain other products from other countries into Germany, Mexico and Thailand. 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. 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 President and Chief Executive Officer.

Risks Related to the Regulatory Environment

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

Our products are medical devices subject to extensive regulation in the United States, and in foreign markets we may wish to enter. To market a medical device in the United States, approval or clearance by the FDA is required, either through the pre-market approval process or the 510(k) clearance process. We have obtained the FDA clearances necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications for our products. Presently, we are pursuing a nocturnal indication for the System One under an IDE study started in the first quarter of 2008. We recently completed the IDE study and have submitted the associated 510(k). We cannot provide assurance that this or other clearances or approvals will be forthcoming, or, if forthcoming, what the timing and expense of obtaining such clearances or approvals might be. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our

products. Although the 510k regulation has not changed, it is under review and based on comments made by FDA in public forums, changes are likely.

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

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

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

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

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

Our products are subject to market withdrawals or product recalls after receiving FDA clearance or approval, and market withdrawals and product recalls could cause the price of our stock to decline and expose us to product

liability or other claims or could otherwise harm our reputation and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. These could lead to a government mandated or voluntary recall by us. The FDA has the authority to require the recall of our products in the event a product presents a reasonable probability that it would cause serious adverse health consequences or death. Similar regulatory agencies in other countries have

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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 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.

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

Historically, we have not sold or marketed the System One outside the United States and Canada. In 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 and the Middle East, and 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 and Europe. However, in order to market directly our products in other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States, which could negatively affect our overall market penetration. Additionally, any loss of foreign regulatory approvals, for any reason, could negatively affect our business.

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

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we learn patient names and addresses when we ship our System One supplies to home hemodialysis patients. We may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customer s staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and

Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. At this time, we are not a HIPAA covered entity. However, we have entered into business associate agreements with covered entities that contain commitments to protect the

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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 several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. Some state statutes, such as the one in Massachusetts, impose an outright ban on gifts to physicians. These laws are often referred to as gift ban or aggregate spend laws and carry substantial fines if they are violated. Similar legislation, known as the Physician Payments Sunshine Act, has been introduced in Congress each year for the past several years but has not yet been enacted. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs; we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If one of our sales representatives were to offer an inappropriate inducement to purchase our products to a customer, we could be subject to a claim under the Medicare/Medicaid anti-kickback laws or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable Medicare/Medicaid anti-kickback laws or similar state laws.

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

business and results of operations.

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

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

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

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

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

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

Risks Related to Operations

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

We depend on a number of single-source suppliers for some of the raw materials and components we use in our products. We also obtain sterilization services from a single supplier. Membrana GmbH is our sole supplier of the fiber used in our filters for System One products. Kawasumi is our only supplier of needles. We also obtain certain other products and components from other single source suppliers or a limited group of suppliers. Our dependence on single source suppliers of components, subassemblies and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries, and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation, or customers switching to competitive products. Any interruption in supply could be particularly damaging to our customers using the System One to treat chronic ESRD and who need access to the System One and related disposables.

Finding alternative sources for these components and subassemblies would be difficult in many cases and may entail a significant amount of time and disruption. In the case of Membrana, for fiber, we are contractually prevented from obtaining an alternative source of supply for our System One products. In the case of other suppliers, we would

need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our System One or other products and, potentially, further FDA clearance or approval of any modification, thereby causing further costs and delays.

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our proprietary technology and prevent others from duplicating our products. However, these means may afford only

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limited protection and may not:

prevent our competitors from duplicating our products;

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

permit us to gain or maintain a competitive advantage.

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

We hold multiple U.S. and foreign patents and license multiple patients under our license agreement with DSU Medical Corporation. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. We cannot provide assurance that any pending or future patent applications we hold will result in an issued patent or that if patents are issued to us, that such patents will provide meaningful protection against competitors or against competitive technologies. The issuance of a patent is not conclusive as to its validity or enforceability. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. Competitors may also be able to design around our patents. Our patents and patent applications cover particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, it would likely have an adverse effect on our sales.

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

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

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

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

cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenues;

pay substantial damages for past use of the asserted intellectual property;

obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all and which could reduce profitability; and

redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do

so.

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

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements

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

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

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

Risks Related to our Common Stock

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

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

- timing of market launch and/or market acceptance of our products;
- timing of achieving profitability from operations;
- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;
- developments or disputes with key vendors or customers;
- disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across the border, or the failure of third party suppliers to produce needed products or components;
- reports by officials or health or medical authorities, the general media or the FDA regarding the potential benefits of the System One or of similar dialysis products distributed by other companies or of daily or home dialysis;
- announcements by the FDA of non-clearance or non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;
- product recalls;
- defaults under our material contracts, including without limitation our credit agreement;

regulatory developments in the United States and foreign countries;

changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments;

litigation involving our company or our general industry or both;

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

developments or disputes concerning our patents or other proprietary rights;

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

significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

departures of key personnel; and

investors general perception of our company, our products, the economy and general market conditions.

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

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

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

a prohibition on actions by our stockholders by written consent;

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

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

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

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

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

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. We have 48,556,553 shares of common stock outstanding as of June 30, 2010. 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 485,566 shares, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

At June 30, 2010, subject to certain conditions, holders of an aggregate of approximately 24,280,888 shares of our common stock have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission, or SEC. If we register their shares of common stock following the expiration of the lock-up

agreements, they can more easily sell those shares in the public market.

As of June 30, 2010, 10,270,704 shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan and outstanding stock options. As of June 30, 2010, 8,490,150 shares were subject to outstanding options, of which 4,451,068 were exercisable and can be freely sold in the public market upon

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issuance, subject to the restrictions imposed on our affiliates under Rule 144.

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

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

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 are required to use our best efforts to cause the registration statement to be declared effective as promptly as possible after the filing but in any event not later than (i) July 30, 2011 or (ii) the date on which any shares become exercisable and vested under the warrant, whichever is later.

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 7,133,329 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, directors and current and principal stockholders own a large percentage of our voting common stock and could limit new stockholders influence on corporate decisions or could delay or prevent a change in corporate control.

Our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially hold, in the aggregate, approximately 57% of our outstanding common stock. David S. Utterberg, one of our directors, holds approximately 16% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in control of our company;

entrenching our management and/or Board;

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impeding a merger, consolidation, takeover or other business combination involving our company; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

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

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

potential disruption of our ongoing business and distraction of management;

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

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

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

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

impairment of relationships with partners and customers;

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

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

potential loss of key employees of the acquired company; and

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

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

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Item 6. ***Exhibits****

Exhibit Number	
10.1	First Amended and Restated National Service Provider Agreement dated as of July 22, 2010 between the Registrant and DaVita Inc.
10.2	Warrant to Purchase Shares of Common Stock dated July 22, 2010 issued to DaVita Inc.
10.3	Registration Rights Agreement dated as of July 22, 2010 between the Registrant and DaVita Inc.
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.

* Filed herewith.

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

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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)

August 6, 2010