NxStage Medical, Inc.
Form 10-Q
August 07, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 000-51567

NxStage Medical, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(978) 687-4700

(Registrant s Telephone Number, Including Area Code)

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. þ Yes ¨ No

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). þ Yes ¨ No

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 þ	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company ¨

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

There were 61,826,278 shares of the registrant s common stock outstanding as of the close of business on July 31, 2014.

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NXSTAGE MEDICAL, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2014

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Note Regarding Trademarks

NxStage®, Streamline®, ButtonHole® and MasterGuard® are registered trademarks of NxStage Medical, Inc. PureFlow™ and System One™ are trademarks of NxStage Medical, Inc.

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PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

NXSTAGE MEDICAL, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2014	December 31, 2013
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,079	$ 84,134
Accounts receivable, net	31,086	20,158
Inventory	43,350	37,801
Prepaid expenses and other current assets	4,537	4,027
Total current assets	141,052	146,120
Property and equipment, net	60,629	52,478
Field equipment, net	17,808	13,041
Deferred cost of revenues	33,097	34,730
Intangible assets, net	15,802	17,194
Goodwill	41,817	41,817
Other assets	2,573	1,582
Total assets	$ 312,778	$ 306,962
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 22,525	$ 14,610
Accrued expenses	21,195	21,025
Current portion of long-term debt	103	102
Other current liabilities	1,870	1,870
Total current liabilities	45,693	37,607
Deferred revenues	51,831	53,277
Long-term debt	1,004	1,044
Other long-term liabilities	24,030	20,273
Total liabilities	122,558	112,201
Commitments and contingencies (Note 10)		
Stockholders equity:		

Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of June 30, 2014 and December 31, 2013		
Common stock: par value $0.001, 100,000,000 shares authorized; 62,185,421 and 61,666,048 shares issued as of June 30, 2014 and December 31, 2013, respectively	62	61
Additional paid-in capital	575,123	567,468
Accumulated deficit	(375,930)	(363,542)
Accumulated other comprehensive income (OCI)	567	212
Treasury stock, at cost: 579,121 and 575,895 shares as of June 30, 2014 and December 31, 2013, respectively	(10,010)	(9,963)
Total NxStage Medical, Inc. stockholders equity	189,812	194,236
Noncontrolling interest	408	525
Total stockholders equity	190,220	194,761
Total liabilities and stockholders equity	$ 312,778	$ 306,962

See accompanying notes to these condensed consolidated financial statements.

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NXSTAGE MEDICAL, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands, except per share data)			
Revenues	$ 74,083	$ 65,462	$ 146,304	$ 127,106
Cost of revenues	46,553	40,375	89,840	78,019
Gross profit	27,530	25,087	56,464	49,087
Operating expenses:				
Selling and marketing	13,589	11,716	26,807	22,412
Research and development	5,708	4,366	10,842	9,474
Distribution	6,485	5,037	13,035	9,945
General and administrative	8,399	8,239	17,220	16,063
Total operating expenses	34,181	29,358	67,904	57,894
Loss from operations	(6,651)	(4,271)	(11,440)	(8,807)
Other expense:				
Interest expense	(195)	(150)	(393)	(300)
Other (expense) income, net	(17)	(10)	6	(186)
	(212)	(160)	(387)	(486)
Net loss before income taxes	(6,863)	(4,431)	(11,827)	(9,293)
Provision for (benefit from) income taxes	332	(1,026)	678	(894)
Net loss	(7,195)	(3,405)	(12,505)	(8,399)
Less: Net loss attributable to noncontrolling interests	(82)		(117)	
Net loss attributable to stockholders of NxStage Medical, Inc.	$ (7,113)	$ (3,405)	$ (12,388)	$ (8,399)
Net loss per share, basic and diluted	$ (0.12)	$ (0.06)	$ (0.20)	$ (0.14)
Weighted-average shares outstanding, basic and diluted	61,469	60,036	61,484	59,706
Other comprehensive income (loss)	173	(704)	355	(559)
Total comprehensive loss	(7,022)	(4,109)	(12,150)	(8,958)

Less: Comprehensive loss attributable to noncontrolling interests	(82)		(117)	
Total comprehensive loss attributable to stockholders of NxStage Medical, Inc.	$ (6,940)	$ (4,109)	$ (12,033)	$ (8,958)

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,	
	2014	2013
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (12,505)	$ (8,399)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,343	12,259
Stock-based compensation	5,740	5,435
Other	450	1,226
Changes in operating assets and liabilities:		
Accounts receivable	(10,927)	(1,853)
Inventory	(17,523)	(12,067)
Prepaid expenses and other assets	(550)	(2,584)
Accounts payable	7,948	1,955
Accrued expenses and other liabilities	1,206	(1,270)
Deferred revenues	(1,395)	(4,439)
Net cash used in operating activities	(14,213)	(9,737)
Cash flows from investing activities:		
Purchases of property and equipment	(8,682)	(5,368)
Net cash used in investing activities	(8,682)	(5,368)
Cash flows from financing activities:		
Proceeds from exercise of stock options and warrants and employee stock purchase plan	2,610	2,257
(Repayments on) proceeds from loans and lines of credit	(50)	1,136
Repayments on capital leases	(762)	(295)
Debt issuance costs	(801)	
Net cash provided by financing activities	997	3,098
Foreign exchange effect on cash and cash equivalents	(157)	(135)
Decrease in cash and cash equivalents	(22,055)	(12,142)
Cash and cash equivalents, beginning of period	84,134	106,439
Cash and cash equivalents, end of period	$ 62,079	$ 94,297

See accompanying notes to these condensed consolidated financial statements.

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NXSTAGE MEDICAL, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Nature of Operations

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis centers. Given its design, the System One is particularly well-suited for home hemodialysis and a range of dialysis therapies including more frequent 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 U.S., Canada and certain other markets, and is CE marked in the EU, for the treatment of acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the U.S. Food and Drug Administration (FDA) for home hemodialysis as well as therapeutic plasma exchange in a clinical environment. The System One is also CE marked in the EU for nocturnal home hemodialysis. We also sell needles and blood tubing sets primarily to dialysis centers for the treatment of end-stage renal disease (ESRD). These products are cleared or approved for commercial sale in the U.S., Canada and certain other markets and are CE marked in the EU. We believe our largest market opportunity is for the System One used in the home dialysis market for the treatment of ESRD. We are operating a small number of NxStage Kidney Care dialysis centers, and plan to open additional centers, focused on supporting home therapy and providing flexible in-center options with NxStage technology as part of our market development activities to increase home therapy access. We continue to make significant investments in marketing, research and development, and these dialysis centers, all of which are intended to help us to further penetrate and expand the market for our products.

For convenience, in this Quarterly Report on Form 10-Q, NxStage, we, us, and the Company refer to NxStage Medical, Inc. and our consolidated subsidiaries, taken as a whole.

Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2014 and for the three and six months then ended, and related notes, are unaudited but, in the opinion of our management, include all adjustments, consisting of normal recurring adjustments, that are necessary for fair statement of the interim periods presented. Our unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under these rules, we have condensed or omitted certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles (GAAP). Our accounting policies are described in the notes to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2013 (2013 Form 10-K) and updated, as necessary, in this Quarterly Report on Form 10-Q. Operating results for any interim period are not necessarily indicative of results for the entire year or future periods. The accompanying condensed consolidated financial statements and related notes should be read in conjunction with the consolidated financial statements and notes thereto included in our 2013 Form 10-K. The December 31, 2013 condensed consolidated balance sheet contained herein was derived from audited financial statements, but does not include all disclosures that would be required for audited financial statements under GAAP. For further information, refer to the consolidated financial statements and notes thereto included in our 2013

Form 10-K.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of NxStage Medical, Inc. and our wholly-owned and majority-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. Certain immaterial reclassifications have been made to prior periods financial statements to conform to the 2014 presentation.

Use of Estimates

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

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Revenue Recognition

Services Segment

Revenues in our Services segment are derived from dialysis care services provided to patients at our recently opened NxStage Kidney Care dialysis centers.

Revenues are recognized based on a customary fee schedule, net of estimated contractual allowances to reflect the estimated amounts to be received from the payor. Revenues are recognized in the period in which services are provided when we have the ability to reasonably estimate amounts ultimately collectible from the payor. In instances where we do not have the ability to reasonably estimate amounts ultimately collectible, as is often the case with non-contracted commercial health plans and amounts due from patients (including co-pay and deductible amounts), revenue is recognized in the period in which cash is received.

Concentration of Credit Risk

Concentration of credit risk with respect to accounts receivable is primarily limited to certain customers to whom we make substantial sales. Two customers represented 16% and 12% of accounts receivable at June 30, 2014. One customer represented 19% of accounts receivable at December 31, 2013.

Warranty Costs

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

Balance at December 31, 2013	$ 297
Provision	231
Usage	(217)
Balance at June 30, 2014	$ 311

Recent Accounting Pronouncements

Effective January 1, 2014, we adopted Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists, which impacts the presentation of unrecognized tax benefits on the statement of financial position. As a result, unrecognized tax benefits are presented as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward. To the extent the tax benefit is not available at the reporting date under the governing tax law or if we do not intend to use the deferred tax asset for such purpose, the unrecognized tax benefit is presented as a liability and not combined with deferred tax assets. The adoption of this standard did not impact our condensed consolidated financial statements, as our practice was consistent with this standard prior to its effective date.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which provides guidance for revenue recognition. The standard s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company is currently assessing the potential impact of ASU No. 2014-09 on its financial statements.

3. Inventory

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

	June 30, 2014	December 31, 2013
Purchased components	$ 19,269	$ 15,946
Work in process	11,884	10,762
Finished goods	12,197	11,093
Total	$ 43,350	$ 37,801

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4. Property and Equipment and Field Equipment

Accumulated depreciation on property and equipment was $25.0 million and $21.8 million at June 30, 2014 and December 31, 2013, respectively. Accumulated depreciation on field equipment was $38.2 million and $36.7 million at June 30, 2014 and December 31, 2013, respectively.

5. Intangible Assets

Accumulated amortization of intangible assets was $18.9 million and $17.5 million at June 30, 2014 and December 31, 2013, respectively.

6. Net Loss per Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Options to purchase common stock	898	1,073	917	1,030
Unvested restricted stock	195	133	216	126
Warrants to purchase common stock		93		93
Total	1,093	1,299	1,133	1,249

7. Accrued expenses and Other long-term liabilities

The components of accrued expenses are as follows (in thousands):

	June 30, 2014	December 31, 2013
Payroll, compensation and related benefits	$ 10,316	$ 9,041
Distribution expenses	2,544	2,762
General and administrative expenses	1,739	2,207
Accrued taxes	1,083	860
Audit, legal, and consulting fees	1,505	2,725
Other	4,008	3,430

Total	$ 21,195	$ 21,025

The components of other long-term liabilities are as follows (in thousands):

	June 30, 2014	December 31, 2013
Capital lease obligations	$ 16,469	$ 14,133
Lease incentive obligations	4,589	3,589
Benefit plan obligations	1,881	1,770
Other	1,091	781
Total	$ 24,030	$ 20,273

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8. Debt

We had a loan and security agreement with Silicon Valley Bank, or SVB, that provided for a $15.0 million revolving line of credit. This agreement, as amended, matured as of March 31, 2014.

On June 10, 2014, we entered into a new revolving line of credit with General Electric Capital Corporation, or GECC, and SVB that allows for borrowings up to $35 million. Availability of credit is subject to a borrowing base that is calculated with reference to certain of our accounts receivable, inventory and equipment. The new revolving line of credit is secured by substantially all of our assets and expires in June 2019. Borrowings bear interest at an annual rate equal to (1) a LIBOR rate plus 2.5% or (2) a base rate plus 1.5%, where the base rate is the highest of (a) the Prime Rate, (b) the Federal Funds Rate plus 0.5% and (c) a LIBOR rate plus 1%, at our election. The new revolving credit facility requires us to comply with certain covenants while borrowings are outstanding and contains events of default customary for a transaction of this type.

As of June 30, 2014, there were no outstanding borrowings under the new revolving line of credit, we were in compliance with all applicable covenants and we had approximately $30 million of credit commitment available for borrowing.

9. Segment Disclosures

With our continued investment in our NxStage Kidney Care dialysis centers, effective with the first quarter of 2014, it was determined that the operations of NxStage Kidney Care should be presented separately. Prior to 2014 its operations were included within the Other category. We now have three reportable business segments: System One, In-Center, and Services. The operating results of NxStage Kidney Care are included in our Services segment. We distribute our products in three markets: home, critical care and in-center. Prior period information has been updated to conform with the current presentation.

Our System One segment includes revenues from the sale and rental of the System One and PureFlow SL dialysate preparation 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. Some of our largest customers in the home market provide outsourced renal dialysis services to some of our customers in the critical care market. Sales of products 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. The results of our international business are included in the System One segment.

Our In-Center segment includes revenues from the sale of blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers and needles for apheresis. Nearly all In-Center products are sold through national distributors.

Our Services segment includes revenues from dialysis services provided to patients at our NxStage Kidney Care dialysis centers.

The remainder of our operations and financial information, included within the Other category, relates to the manufacturing of dialyzers for sale to Asahi Kasei Kuraray Medical Co., Ltd. (Asahi) and research and development and general and administrative expenses that are excluded from the segment operating performance measures.

The accounting policies of our reportable segments are described in Note 2 to the consolidated financial statements included in our 2013 Form 10-K and updated, as necessary, in Note 2 to the condensed consolidated financial statements included in this Quarterly Report. Our chief operating decision maker allocates resources to our business segments and assesses segment performance based on segment profit (loss), which consists of revenues less cost of revenues, selling and marketing and distribution expenses.

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The following summarizes the operating performance of our reportable segments (in thousands):

	System One	In-Center	Other	Services	Intersegment Revenue Elimination	Total
Three Months Ended June 30, 2014						
Revenues from external customers	$ 50,709	$ 21,003	$ 1,943	$ 428	$	$ 74,083
Intersegment revenues	201				(201)	
Revenues	50,910	21,003	1,943	428	(201)	74,083
Segment profit (loss)	7,766	3,157	(14,328)	(3,246)		(6,651)
Depreciation and amortization	4,925	427	1,210	190		6,752
Three Months Ended June 30, 2013						
Revenues from external customers	$ 43,497	$ 21,238	$ 727	$	$	$ 65,462
Intersegment revenues						
Revenues	43,497	21,238	727			65,462
Segment profit (loss)	5,613	4,298	(13,088)	(1,094)		(4,271)
Depreciation and amortization	4,506	337	1,336			6,179
Six Months Ended June 30, 2014						
Revenues from external customers	$ 101,844	$ 39,919	$ 3,997	$ 544	$	$ 146,304
Intersegment revenues	253				(253)	
Revenues	102,097	39,919	3,997	544	(253)	146,304
Segment profit (loss)	16,991	6,111	(28,341)	(6,201)		(11,440)
Depreciation and amortization	9,902	703	2,394	344		13,343
Six Months Ended June 30, 2013						
Revenues from external customers	$ 85,666	$ 39,938	$ 1,502	$	$	127,106
Intersegment revenues						
Revenues	85,666	39,938	$ 1,502			127,106
Segment profit (loss)	12,126	7,736	(26,691)	(1,978)		(8,807)
Depreciation and amortization	8,929	682	2,648			12,259

The following table presents assets allocated to our reportable segments along with a reconciliation of the total segment assets to total assets (in thousands):

	June 30, 2014	December 31, 2013
System One	$ 127,019	$ 110,124
In-Center	30,112	26,414
Services	10,144	4,273
Total segment assets	167,275	140,811
Corporate assets:		

Cash and cash equivalents	62,079	84,134
Accounts receivable, net	1,249	397
Property and equipment, net	17,446	17,000
Intangible assets, net	15,802	17,194
Goodwill	41,817	41,817
Prepaid and other assets	7,110	5,609
Total assets	$ 312,778	$ 306,962

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

The following table summarizes the customers who individually comprise greater than ten percent of total revenues and their respective portion of total revenues:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
DaVita	21%	21%	22%	22%
Fresenius	15%	13%	15%	13%
Gambro	10%	11%	10%	12%
Schein	8%	11%	8%	10%

Sales to DaVita HealthCare Partners Inc. (DaVita) and Fresenius Medical Care (Fresenius) are in the System One segment. Sales to Gambro and Schein are in the In-Center segment. All of Gambro s sales of our products are to DaVita. A portion of Schein s sales of our products are to DaVita.

10. Commitments and Contingencies

Contingencies

A civil complaint was filed against us on February 28, 2012 in the U.S. District Court for the District of Massachusetts by Gambro Renal Products, Inc., or Gambro (Case No. 1:12cv10370-PBS). The complaint alleged that we violated Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Massachusetts General Laws Chapter 93A by making false and misleading statements about our and Gambro s allegedly competing products in the critical care market in commercial and promotional activities. The complaint also alleged that we wrongfully interfered with contractual and advantageous relationships of Gambro in its critical care business. Gambro sought compensatory and treble damages, disgorgement of profits and injunctive relief.

Effective January 2, 2014, we and Gambro agreed to a settlement of this litigation without any admission of wrongdoing or liability by either party and dismissal of all related claims with prejudice. The settlement required us to pay a one-time cash payment to Gambro which was primarily offset by reimbursement from our insurance company. At the same time, we entered into a patent cross-license agreement with Baxter International, Inc. (Baxter) that provides for the cross-license of three patents and the Third Amendment to Extracorporeal Disposables Distribution Agreement that amends the length and other terms of a distribution agreement between us and Gambro. The settlement as a whole can be viewed as a multi-element arrangement as defined by FASB Accounting Standards Codification (ASC) 605-25 *Multiple Element Arrangements*, which required us to identify and estimate a fair value for each element to properly account for the settlement. We recorded the settlement, reimbursement and consideration of the multi-element arrangement guidance within general and administrative expense on the consolidated statements of comprehensive loss.

Other significant commitments and contingencies at June 30, 2014 are consistent with those discussed in Note 10 to the consolidated financial statements in our 2013 Form 10-K.

11. Income Taxes

We recognized a provision for income taxes during 2014 and 2013 related to the profitable operations of certain foreign subsidiaries. However, the 2013 provision was offset by the recognition of a $1.2 million gain during the second quarter of 2013 resulting from the favorable conclusion of a foreign income tax audit and the recognition of a gain during the first quarter of 2013 related to a foreign legislative change.

As of June 30, 2014, we had a liability for unrecognized tax benefits included in the balance sheet of approximately $0.5 million, including accrued interest and penalties of $0.1 million. There have been no significant changes to these amounts during the three months ended June 30, 2014.

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12. Stock-Based Compensation

Stock-based Compensation Expense

Our stock-based compensation expense is allocated among the following components of our condensed consolidated statements of comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of revenues	$ 221	$ 234	$ 419	$ 555
Selling and marketing	1,071	1,062	1,926	1,761
Research and development	372	438	697	885
General and administrative	1,435	1,055	2,698	2,234
Total	$ 3,099	$ 2,789	$ 5,740	$ 5,435

Stock Options and Restricted Stock Units

The Company granted options to purchase 187,152 and 158,545 shares of common stock during the three months ended June 30, 2014 and 2013, respectively, and options to purchase 956,741 and 991,282 shares of common stock during the six months ended June 30, 2014 and 2013, respectively. The weighted-average fair value of options granted during the six months ended June 30, 2014 and 2013 was $5.86 and $6.18 per option, respectively.

The Company awarded 58,220 and 30,990 restricted stock units during the three months ended June 30, 2014 and 2013, respectively, and 226,447 and 227,765 restricted stock units during the six months ended June 30, 2014 and 2013, respectively, which vest based on continued employment over a period of four years. The weighted-average fair value of these restricted stock units awarded during the six months ended June 30, 2014 and 2013 was $14.37 and $11.44 per unit, respectively.

Performance Based Plans

In March 2014, the Compensation Committee of our Board of Directors approved the grant of up to 369,136 restricted stock units pursuant to performance based awards subject to the achievement of certain Company financial performance metrics for the year ending December 31, 2014. The restricted stock units, if earned, vest over a requisite service period of three years and have a fair value of $14.66 per unit. The estimated expense will be recognized as stock-based compensation expense over the requisite service period based on the number of shares expected to vest.

Further, in March 2014, the Compensation Committee made awards subject to individual performance and the achievement of certain Company financial performance metrics for the year ending December 31, 2014. Awards are payable in shares of the Company s common stock or in cash, at the discretion of the Compensation Committee. The estimated payout of these awards is being recognized as compensation expense during 2014, with a portion of this compensation expense classified as stock-based compensation expense, and has been recorded on the Company s condensed consolidated balance sheet within accrued expenses.

13. Stockholders Equity

We received 3,226 and 34,311 shares of common stock that were surrendered in payment for the exercise of stock options through the six months ended June 30, 2014 and 2013, respectively.

14. Noncontrolling Interest

In 2013, NxStage Kidney Care entered into a joint venture agreement with an unaffiliated not-for-profit dialysis provider operating independent dialysis centers. The other venturer contributed $0.5 million as an initial investment into the joint venture, which is reflected in the condensed consolidated balance sheet as noncontrolling interest. Noncontrolling interest represents the minority shareholder s proportionate share of our majority owned subsidiary.

The following table sets forth the changes in non-controlling interest for the three and six months ended June 30, 2014 and 2013 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Balance at beginning of period	$ 490	$	$ 525	$
Net loss attributable to non-controlling interest in consolidated subsidiary	(82)		(117)	
Balance at end of period	$ 408	$	$ 408	$

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15. Derivative Instruments and Hedging

We operate a manufacturing and service facility in Mexico where we purchase materials and pay our employees in Pesos, and as such, we are potentially exposed to adverse as well as beneficial movements in foreign currency exchange rates. To minimize the impact of foreign currency exchange rate fluctuations on these Peso denominated expenses, we have entered into foreign exchange forward contracts. These contracts have a duration of up to twelve months and are designated as cash flow hedges. The counterparties to these foreign exchange forward contracts are creditworthy financial institutions; therefore, we do not consider the risk of counterparty nonperformance to be material. As of June 30, 2014 and December 31, 2013, the notional amount of our outstanding contracts that are designated as cash flow hedges was $11.1 million and $10.4 million, respectively. The fair value of these contracts is recorded on the balance sheet within prepaid expenses and other current assets or accrued expenses depending on the gain (loss) position. These amounts were not material at June 30, 2014 or December 31, 2013.

Gains or losses related to hedge ineffectiveness are recognized within other income (expense) and were not material during the three and six months ended June 30, 2014 or 2013. Given the short-term nature of our contracts, any gains or losses recorded within accumulated other comprehensive income (loss) will be recognized in earnings within the next twelve months. Gains and losses are presented in the statement of cash flows within other adjustments to reconcile net loss to net cash used in operating activities.

The following table presents the effect of these contracts designated as cash flow hedges on our condensed consolidated financial statements (in thousands):

	Gain (Loss) Recognized in OCI (Effective Portion)	Gain (Loss) Reclassified from OCI into Income (Effective Portion)	Classification within the Condensed Consolidated Statement of Comprehensive Loss
Three Months Ended June 30, 2014			
Foreign exchange forward contracts	$ 146	$ 13	Cost of revenues
Six Months Ended June 30, 2014			
Foreign exchange forward contracts	$ 179	$ (88)	Cost of revenues
Three Months Ended June 30, 2013			
Foreign exchange forward contracts	$ (410)	$ 288	Cost of revenues
Six Months Ended June 30, 2013			
Foreign exchange forward contracts	$ 155	$ 640	Cost of revenues

16. Accumulated Other Comprehensive (Loss) Income

The following additional information is provided with respect to the accumulated other comprehensive (loss) income as presented on the condensed consolidated balance sheets (in thousands):

	Unrealized gain (loss) on derivative instruments	Other (2)	Total

Balance, net of tax, at beginning of year	$ (123)	$ 335	$ 212
Other comprehensive income before reclassifications	179	88	267
Loss reclassified to earnings (1)	88		88
Total other comprehensive income	267	88	355
Balance, net of tax, at end of period	$ 144	$ 423	$ 567

(1) Reclassifications of gains (losses) on derivative instruments are included in cost of revenues on the condensed consolidated statement of comprehensive loss. See Note 15 for further information.
(2) Other includes cumulative translation adjustments and pension benefits.

17. Fair Value Measurements

We have certain financial assets and liabilities measured at fair value on a recurring and non-recurring basis recorded in our condensed consolidated balance sheets. The fair value measurements used are based on quoted prices, when available, or through the use of alternative approaches. The inputs used to determine fair value have been classified as Level 1, 2 or 3. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves for similar instruments and model-derived valuations whose inputs are observable. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

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We measure the fair value of our foreign exchange forward contracts classified as derivative instruments using an income approach, based on prevailing market forward rates less the contract rate multiplied by the notional amount. The product of this calculation is then adjusted for counterparty risk.

Our contingent consideration liability related to deferred payments made in January and April 2014 in connection with our acquisition of substantially all of the System One assets of Kimal PLC, a distributor of our products in the United Kingdom, on April 2, 2013. The liability recorded at December 31, 2013 was measured using probability weighted discounted cash flow method and includes certain significant unobservable inputs, namely, a discount rate of 11.5% and patient growth rates.

We did not have any transfers between Level 1 and Level 2 during the six months ended June 30, 2014.

The following tables present assets and liabilities measured at fair value on a recurring basis and their level within the value hierarchy (in thousands):

June 30, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Money market funds (1)	$ 49,779	$	$	$ 49,779
Foreign exchange forward contracts (2)		178		178
Liabilities				
Foreign exchange forward contracts (2)	$	$ 18	$	$ 18
Contingent consideration liability (3)				

December 31, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Money market funds (1)	$ 69,779	$	$	$ 69,779
Foreign exchange forward contracts (2)		34		34
Liabilities				
Foreign exchange forward contracts (2)	$	$ 192	$	$ 192
Contingent consideration liability (3)			540	540

(1) Money market funds are included within cash and cash equivalents.
(2) Foreign exchange forward contracts are included within prepaid expenses and other current assets or accrued expenses depending on the gain (loss) position.
(3) Net present value of expected payments under contingent consideration liability are reported in accrued expenses.

The following table presents the rollforward of the contingent consideration liability classified as Level 3 within the value hierarchy (in thousands):

Balance at beginning of year	$ 540
Less: Payments Made	(540)
Balance at end of period	$

The carrying amount of our long-term debt approximates fair value at June 30, 2014 and December 31, 2013. The fair value of our long-term debt was estimated using inputs derived principally from market observable data, including current rates offered to us for debt of the same or similar remaining maturities. Within the hierarchy of fair value measurements, these are Level 2 inputs.

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18. Supplemental Cash Flow Information

The following additional information is provided with respect to the condensed consolidated statements of cash flows (in thousands):

	Six Months Ended June 30,	
	2014	2013
Noncash Investing and Financing Activities:		
Transfers from inventory to field equipment	$ 11,309	$ 5,140
Transfers from field equipment to deferred cost of revenues	4,961	3,217
Payment of corporate bonus in common stock		1,034
Market value of shares received in payment for exercise of stock options	47	412
Construction-in-process financed by construction liability	2,848	2,604
Property and equipment acquired under capital lease	76	745
Acquisition of business		3,861
Deferred revenues and deferred costs related to acquiree recorded as a reduction of consideration paid		335

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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, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the year ended December 31, 2013, included in our 2013 Form 10-K.

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: our market opportunity and the market adoption of our products in the U.S. and internationally; the growth of the home, critical care and in-center dialysis markets; access to home and more frequent hemodialysis; plans for expanding internationally; the development and commercialization of new products and improvements to existing products; the results and timing of clinical studies and plans for regulatory submissions; sales to our key customers, including DaVita HealthCare Partners Inc., or DaVita, and Fresenius Medical Care, or Fresenius; the adequacy of our funding; expectations with respect to future demand for our products and revenue growth; the timing, scope and success of our initiatives to improve our gross profit as a percentage of revenues, and other operational and financial improvements; improvements in certain segment cash flows; our manufacturing operations and supply chain; our plans to open and operate NxStage Kidney Care dialysis centers and the financial, commercial and operational impact of this initiative; planned investments in marketing and research and development; expectations with respect to our expenses and working capital levels and requirements; changes in deferred revenue; the financial impact of expanding our international business; availability of, and changes in, reimbursement for home and more frequent hemodialysis; achieving our business plan; the impact of global economic conditions; the impact of product recalls; expectations with respect to achieving positive operating margins, positive cash flows and profitable operations; volatility of our stock price; product cost reduction plans; the financial impact of manufacturing dialyzers for sale to Asahi Kasei Kuraray Medical Co.; expectations with respect to achieving improvements in product reliability; our ability to withstand supply chain disruptions; and anticipated requirements for premixed dialysate. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words expect , anticipate , intend , plan , believe , seek , estimate , potential , continue , predict , may , will and similar expressions are inten 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.

Readers should carefully review the Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations set forth in this Quarterly Report, as these sections describe important factors that could cause actual results to differ materially from those indicated by our forward-looking statements. We undertake no obligation to revise or update publicly any forward-looking statement.

Introduction

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis centers. Given its design, the System One is particularly well-suited for

home hemodialysis and a range of dialysis therapies including more frequent 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 U.S., Canada and certain other markets, and is CE marked in the EU, for the treatment of acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the U.S. Food and Drug Administration (FDA) for home hemodialysis as well as therapeutic plasma exchange in a clinical environment. The System One is also CE marked in the EU for nocturnal home hemodialysis. We also sell needles and blood tubing sets primarily to dialysis centers for the treatment of end-stage renal disease (ESRD). These products are cleared or approved for commercial sale in the U.S., Canada and certain other markets and are CE marked in the EU. We believe our largest market opportunity is for the System One used in the home dialysis market for the treatment of ESRD. We are operating a small number of NxStage Kidney Care dialysis centers, and plan to open additional centers, focused on supporting home therapy and providing flexible in-center options with NxStage technology as part of our market development activities to increase home therapy access. We continue to make significant investments in marketing, research and development, and these dialysis centers, all of which are intended to help us to further penetrate and expand the market for our products.

We have three reportable business segments: System One, In-Center and Services. We distribute our products in three markets: home, critical care and in-center.

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Our System One segment includes revenues from the sale and rental of the System One and PureFlow SL dialysate preparation 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. Some of our largest customers in the home market provide outsourced renal dialysis services to some of our customers in the critical care market. Sales of product to both markets are made primarily through dedicated sales forces and distributed directly to the customer, or the patient, with certain products sold through distributors internationally. The results of our international business are included in the System One segment.

Our In-Center segment includes revenues from the sale of blood tubing sets and needles for hemodialysis primarily for the treatment of ESRD patients at dialysis centers and needles for apheresis. Nearly all In-Center products are sold through national distributors.

Our Services segment includes revenues from dialysis services provided to patients at our recently opened NxStage Kidney Care dialysis centers.

The remainder of our operations and financial information, included within the Other category, relates to the manufacturing of dialyzers for sale to Asahi and research and development and general and administrative expenses that are excluded from the segment operating performance measures.

Segment and Market Highlights

Our customers in the System One segment are highly concentrated. DaVita and Fresenius own and operate the two largest chains of dialysis centers in the U.S. and collectively provide treatment to approximately two-thirds of U.S. dialysis patients. DaVita and Fresenius are our two largest and most significant customers in the System One segment.

Our agreement with DaVita, which covers use of our products for home hemodialysis in the U.S., extends through December 31, 2015, and thereafter, automatically extends on a monthly basis unless terminated by us or DaVita. Direct sales to DaVita represented 31% of our System One segment revenues for the three month periods ended June 30, 2014 and 2013. For the six month periods ended June 30, 2014 and 2013, direct sales to DaVita represented 32% of our System One segment revenues. Further, DaVita is our largest customer in the home market, with over 40% of our home hemodialysis patients.

Our agreement with Fresenius, which covers use of our products for home hemodialysis therapy in the U.S. extends through 2016, with monthly renewals thereafter unless terminated by either party. Direct sales to Fresenius represented 21% and 20% of our System One segment revenues for both the three and six months ended June 30, 2014 and 2013, respectively.

Increased sales to DaVita and Fresenius have driven a large portion of our historical revenue growth and will be important to future growth. If the purchasing patterns of either of these customers adversely change, including in response to our initiative to establish NxStage Kidney Care dialysis centers, our business could be negatively affected.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Our two largest distributors are Gambro AB, or Gambro, and Henry Schein, Inc., or Henry Schein. Revenues from Gambro represented 34% of our In-Center segment revenues for both the three months ended June 30, 2014 and 2013 and 37% and 39% for the six months ended June 30, 2014 and 2013, respectively. Revenues from Henry Schein represented 29% and 35% of our In-Center segment revenues for the three months ended June 30, 2014 and 2013 and 29% and 33% for the six months ended June 30, 2014 and 2013, respectively.

DaVita is also a significant customer in the In-Center segment. Sales of our products through distributors to DaVita accounted for approximately half of In-Center segment revenues for both the three and six months ended June 30, 2014 and 2013. DaVita has purchase commitments for our products pursuant to two agreements: one with us for needles and one with Gambro for blood tubing sets. DaVita s needle purchase agreement with us extends through December 31, 2014. DaVita s requirement to purchase needles modestly ramps down during 2014 and DaVita has no contractual obligations at this time to purchase needles from us thereafter. Currently, DaVita s product supply agreement with Gambro requires DaVita to purchase a significant majority of its blood tubing set requirements from Gambro, and our distribution agreement with Gambro requires Gambro to exclusively supply our blood tubing sets to DaVita. Our distribution agreement with Gambro extends through December 31, 2015, with annual renewals thereafter unless terminated by either party. Our distribution agreement with Henry Schein renews annually unless terminated by either party.

We offer certain customers rebates based on sales to specific end users and discounts for early payment. Our revenues are presented net of these rebates and discounts. As of June 30, 2014, we had $1.7 million and $3.6 million reserved against trade accounts receivable for future estimated rebates and discounts for customers in our System One and In-Center segments, respectively. We recorded $2.0 million and $1.4 million during the three months ended June 30, 2014 and 2013, respectively, and $4.5 million and $3.5 million during the six months ended June 30, 2014 and 2013, respectively, as a reduction of System One segment revenues in connection with rebates and discounts. For the In-Center segment, we recorded $2.5 million and $1.9 million during the three months ended June 30, 2014 and 2013, respectively, and $4.5 million and $3.0 million during the six months ended June 30, 2014 and 2013, as a reduction of revenues in connection with rebates and discounts.

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Financial Performance

For several years, we have focused on operating and financial improvements. During the six months ended June 30, 2014, these efforts resulted in revenues increasing by 15% to $146.3 million versus the prior year comparable period with our home and critical care markets each experiencing growth. While driving continued improvements within our System One and In-Center segments will remain an area of focus in 2014 and beyond, at the same time, we expect to make significant investments in our Services segment as we continue to open NxStage Kidney Care dialysis centers. We expect that these investments will have a negative impact on our total operating performance in the near term and likely outweigh performance improvements we expect in our System One and In-Center segments.

Comparison of the Three and Six Months Ended June 30, 2014 and 2013

Revenues

Our revenues for the three and six months ended June 30, 2014 and 2013 were as follows (in thousands, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
System One segment								
Home	$ 38,488	52%	$ 32,671	50%	$ 74,983	51%	$ 64,130	51%
Critical Care	12,422	17%	10,826	17%	27,114	19%	21,536	17%
Total System One segment	50,910	69%	43,497	67%	102,097	70%	85,666	68%
In-Center segment	21,003	28%	21,238	32%	39,919	27%	39,938	31%
Other	1,943	2%	727	1%	3,997	3%	1,502	1%
Products subtotal	73,856	99%	65,462	100%	146,013	100%	127,106	100%
Services segment	428	1%		%	544	%		%
Elimination of intersegment revenues	(201)	%		%	(253)	%		%
Total	$ 74,083	100%	$ 65,462	100%	$ 146,304	100%	$ 127,106	100%

In the home market, revenues increased $5.8 million, or 18%, and $10.9 million, or 17%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable period. The change is driven primarily by the increase in the number of patients prescribed to use the System One both in the U.S. and internationally. We expect future demand for our products and revenue growth in the home market to be strong as we further penetrate this market, both in the U.S. and internationally, and leverage the annuity nature of our business. Note, this revenue growth may be slightly offset on an ongoing basis, as it has been in the past, by lower deferred revenue recognized on previously sold System One equipment in the U.S. home market as a result of equipment reaching the end of its related revenue amortization period. Additionally, as our international business grows, our System One revenue will be susceptible to fluctuations in equipment sales and changes in inventory levels at our international distributors.

Critical care market revenues increased $1.6 million, or 15%, and $5.6 million, or 26%, during the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods. We expect future demand for our

products and revenue growth to be strong as we seek to further penetrate this market, expand internationally, and leverage the annuity nature of our business.

In-Center segment revenues decreased $0.2 million, or 1%, for the three months ended June 30, 2014 and remained relatively consistent for the six months ended June 30, 2014, versus the prior year comparable periods. Future revenues may continue to fluctuate as a result of increased competition and variations in inventory management policies with both our distributors and end users.

Other revenues for the three and six months ended June 30, 2014 and 2013 relates to dialyzers sold to Asahi which has increased as we ramp-up production capacity at the new manufacturing plant in Germany which commenced operations in late 2012. Sales to Asahi may fluctuate due to timing of sales and inventory management policies at Asahi.

Revenues from our Services segment for the three and six months ended June 30, 2014 relates to dialysis services provided to patients at our recently opened NxStage Kidney Care dialysis centers.

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Gross Profit (Loss)

Our gross profit (loss) (in thousands, except as percentages of revenues) for the three and six months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
System One segment	$ 23,956	47%	$ 19,367	45%	$ 49,266	48%	$ 38,710	45%
In-Center segment	5,190	25%	6,244	29%	10,119	25%	11,572	29%
Subtotal	29,146	41%	25,611	40%	59,385	42%	50,282	40%
Other	(221)	n/a	(483)	n/a	(279)	n/a	(1,154)	n/a
Products subtotal	28,925	39%	25,128	38%	59,106	40%	49,128	39%
Services segment	(1,395)	n/a	(41)	n/a	(2,642)	n/a	(41)	n/a
Gross profit	$ 27,530	37%	$ 25,087	38%	$ 56,464	39%	$ 49,087	39%

Gross profit increased $2.4 million, or 10%, and $7.4 million, or 15%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods.

Gross profit for the System One segment increased $4.6 million, or 24%, and $10.6 million, or 27%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods, due to increased revenues and increased gross profit as a percentage of revenues. The increase in gross profit as a percentage of revenues was driven by favorable product mix and contractual price improvements, partially offset by unfavorable foreign currency exchange rates versus the U.S. Dollar.

Gross profit for the In-Center segment decreased $1.1 million, or 17%, and $1.5 million, or 13%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods, due to decreased gross profit as a percentage of revenues driven by contractual pricing, unfavorable product mix and unfavorable foreign currency exchange rates versus the U.S. Dollar.

We expect to continue to see improvements in gross profit as a percentage of revenue in our System One segment as we lower costs through process improvements and product design changes, increase volume, and rationalize our manufacturing operations. These improvements will be offset, at least in the near-term, by costs associated with our continued investment in our Services segment and may be offset by other factors including unfavorable fluctuations in foreign currency exchange rates, increased freight costs and higher relative sales of lower margin products.

The Other category relates to costs associated with the manufacturing of dialyzers for sale to Asahi, which should provide us with long term cost efficiencies through increased dialyzer production volumes. These cost efficiencies may be offset in the short-term as we incur additional costs to expand capacity in this facility.

The loss incurred by our Services segment was driven by costs associated with starting up our NxStage Kidney Care dialysis centers. We expect the Services segment gross margin will continue to be negatively impacted by costs associated with starting up new dialysis centers.

Selling and Marketing

Our selling and marketing expenses (in thousands, except as percentages of revenues) for the three and six months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
System One segment	$ 10,311	20%	$ 9,368	22%	$ 20,368	20%	$ 17,870	21%
In-Center segment	1,427	7%	1,295	6%	2,880	7%	2,605	7%
Services segment	1,851	n/a	1,053	n/a	3,559	n/a	1,937	n/a
Total Selling and marketing	$ 13,589	18%	$ 11,716	18%	$ 26,807	18%	$ 22,412	18%

Selling and marketing expenses increased $1.9 million, or 16%, and $4.4 million, or 20%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods.

Selling and marketing expenses for the System One and In-Center segments increased due to increased personnel and personnel-related costs, marketing activities and clinical training.

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Selling and marketing expenses for our Services segment increased $0.8 million and $1.6 million for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods. These expenses contain personnel and other costs associated with our market development activities to establish, develop and operate NxStage Kidney Care dialysis centers including administrative support functions directly related to the startup and support of this initiative.

We anticipate that selling and marketing expenses will continue to increase as revenues continue to grow and as we broaden our marketing and market development initiatives, including with respect to NxStage Kidney Care, increase public awareness of the System One in the home market and support growth in international markets.

Research and Development

Our research and development expenses (in thousands, except as percentages of revenues) for the three and six months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
Research and development	$ 5,708	8%	$ 4,366	7%	$ 10,842	7%	$ 9,474	7%

Research and development expenses increased $1.3 million, or 31%, and $1.4 million, or 14%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods. The increase in research and development costs is due to increased personnel and personnel-related costs and increased project related spending. Further, research and development costs for the three and six months ended June 30, 2013 were reduced by $0.6 million due to the recognition of a tax incentive received from the Massachusetts Life Sciences Center.

For the near term, we expect research and development expenses will increase as we seek to further develop and enhance the System One, invest in our peritoneal dialysis product development program and expand our product portfolio.

Distribution

Our distribution expenses (in thousands, except as percentages of revenues) for the three and six months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
System One segment	$ 5,879	12%	$ 4,386	10%	$ 11,907	12%	$ 8,714	10%
In-Center segment	606	3%	651	3%	1,128	3%	1,231	3%
Total Distribution	$ 6,485	9%	$ 5,037	8%	$ 13,035	9%	$ 9,945	8%

Distribution expenses increased $1.4 million, or 29%, and $3.1 million, or 31% for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods. Increased costs in the System One segment were due to increased volumes and higher expedited delivery services costs due to short term supply issues. We

expect that distribution expenses as a percentage of revenue will normalize over the near term and then will increase at a rate consistent with revenues due to expected distribution network efficiencies and improved reliability of System One equipment; however, these favorable impacts may be offset by overall increases in fuel costs and carrier pricing.

General and Administrative

Our general and administrative expenses (in thousands, except as percentages of revenues) for the three and six months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
General and administrative	$ 8,399	11%	$ 8,239	13%	$ 17,220	12%	$ 16,063	13%

General and administrative expenses increased $0.2 million, or 2%, and $1.2 million, or 7%, for the three and six months ended June 30, 2014, respectively, versus the prior year comparable periods. The increase in general and administrative expenses was due to increased personnel and personnel related costs and other related infrastructure costs and higher medical device excise tax expense driven by an increase in the amount of our products sold on which the tax is assessed, all offset by lower professional service fees.

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Other Expense

Interest expense includes interest costs and other fees related to our debt obligations, including our capital lease obligations.

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

Provision for (benefit from) income taxes

We recognized a provision for income taxes of $0.3 million and $0.7 million during the three and six months ended June 30, 2014, respectively, related to the profitable operations of certain foreign subsidiaries.

We recognized a provision for income taxes during 2014 and 2013 related to the profitable operations of certain foreign subsidiaries. However, the 2013 provision was offset by the recognition of a $1.2 million gain during the second quarter of 2013 resulting from the favorable conclusion of a foreign income tax audit and the recognition of a gain during the first quarter of 2013 related to a foreign legislative change.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. At June 30, 2014, our accumulated deficit was $375.9 million and we had cash and cash equivalents of $62.1 million, with nearly all of that cash located in the U.S., and working capital of $95.4 million.

We expect to make continued improvements in cash flows associated with our System One and In-Center segments, driven primarily by revenue growth, operating leverage, and improving profitability. Over the long term we expect to generate positive cash flow from these segments. In addition, we have invested and expect to continue to invest cash in our Services segment to establish NxStage Kidney Care dialysis centers. In the near term, these investments will offset the improvements we expect to achieve in our System One and In-Center segments. 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 for our System One, In-Center and Services segments, which include selling and marketing activities to increase public awareness of the System One, our research and development activities to develop new products and enhance our existing products, and our planned investments in NxStage Kidney Care. If we decide to expand any of these initiatives, we may choose to access the credit or capital markets to provide additional liquidity. However, we can provide no guarantees that we will be successful in securing such additional financing.

We had a $15.0 million revolving line of credit with Silicon Valley Bank, or SVB, that expired in March 2014. On June 10, 2014, we entered into a new revolving line of credit with General Electric Capital Corporation, or GECC, and SVB that allows for borrowing up to $35.0 million. Availability of credit is subject to a borrowing base that is calculated with reference to certain of our accounts receivable, inventory and equipment. The new revolving line of credit imposes certain financial covenants, contains certain customary events of default and is secured by substantially all of our assets. As of June 30, 2014, there were no outstanding borrowings under the new revolving line of credit, we were in compliance with all applicable covenants and we had approximately $30 million of credit commitment available for borrowing.

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 $1.9 million at June 30, 2014 for costs associated with these plans. The expense recorded in connection with these plans was not significant during

2014 or 2013.

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

	Six Months Ended June 30,	
	2014	**2013**
Net cash used in operating activities	$ (14,213)	$ (9,737)
Net cash used in investing activities	(8,682)	(5,368)
Net cash provided by financing activities	997	3,098
Foreign exchange effect on cash and cash equivalents	(157)	(135)
Net cash flow	$ (22,055)	$ (12,142)

Net cash used in operating activities. Net cash used in operating activities increased by $4.5 million during the six months ended June 30, 2014, versus the prior year comparable period driven by increased net loss after adjustments for noncash expenses coupled with unfavorable changes in working capital requirements driven in large part by increases in accounts receivable due to timing of payments from our customers and higher inventory requirements to support ongoing operations and our new product offerings. Our accounts receivable balance has returned to more normalized levels. However, we expect working capital to fluctuate from quarter to quarter due to various factors including inventory requirements and timing of payments from our customers and to our vendors.

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Cash flows from deferred revenues increased $3.0 million during the six months ended June 30, 2014 versus the prior year comparable period, as a result of timing of equipment purchases. This reflects a decrease in amortization of deferred revenues into revenues of $0.2 million, from $9.3 million during the six months ended June 30, 2013 to $9.1 million during the six months ended June 30, 2014 as a result of equipment reaching the end of its relative revenue amortization period coupled with increased sales of System One equipment.

Non-cash transfers from inventory to field equipment for the placement of units with our customers increased $6.2 million during the six months ended June 30, 2014 versus the prior year comparable period. Non-cash transfers from field equipment to deferred costs of revenues increased $1.7 million during the six months ended June 30, 2014 versus the prior year comparable period. These activities fluctuate due to increased equipment levels required for our service pool, efficiencies in our customers utilization of purchased equipment, the timing of home patient additions, and new product introductions.

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 our manufacturing facilities as a result of our efforts to rationalize and expand our manufacturing operations, along with the build-out of NxStage Kidney Care dialysis centers and purchases of equipment for research and development and information technology. The increase of $3.3 million in purchases of property and equipment was driven primarily by spending related to the build-out of our NxStage Kidney Care dialysis centers.

Net cash provided by financing activities. During the six months ended June 30, 2014 and 2013, we received $2.6 million and $2.3 million, respectively, of proceeds from stock option and stock purchase plans. Proceeds from stock option and purchase plans are subject to fluctuation based on the number of options exercised and, to a lesser extent, the weighted-average exercise price. Cash provided by financing activities during both the six months ended June 30, 2014 and 2013 were reduced by cash used to pay our capital lease obligations of $0.8 million and $0.3 million, respectively. Further our cash provided by financing activities during the six months ended June 30, 2014 was reduced by $0.8 million due to costs associated with obtaining our new revolving credit facility. Finally, cash provided by financing activity during the six months ended June 30, 2013 included $1.1 million of proceeds from the issuance of debt in connection with financing the acquisition of a manufacturing facility in Italy.

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 GAAP. The preparation of these consolidated financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ substantially from our estimates.

The significant accounting policies used in preparation of our condensed consolidated financial statements for the three and six months ended June 30, 2014 are described in Note 2 to the consolidated financial statements included in our 2013 Form 10-K and updated as necessary in Note 2 to the condensed consolidated financial statements included in this Quarterly Report. The critical accounting policies and the significant judgments and estimates used in the preparation of our condensed consolidated financial statements for the three and six months ended June 30, 2014 are consistent with those described in Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, in our 2013 Form 10-K.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements included in our 2013 Form 10-K and updated as necessary in Note 2 to the condensed consolidated financial statements included in this Quarterly Report.

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. A discussion of market risk affecting us is included in Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our 2013 Form 10-K. There have been no material changes to our market risks or to our management of such risks during the six months ended June 30, 2014.

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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, 2014. 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 Securities and Exchange Commission 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, 2014, 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 three months ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

Please refer to Note 10, *Commitments and Contingencies* to our condensed consolidated financial statements included within this report, which is incorporated into this item by reference.

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 factors that could materially and adversely affect our business, financial condition, results of operations and common stock price and cause our actual results to differ materially from those projected in any forward-looking statements.

Risks Related to our Business

We expect to derive most of our future revenues from the System One and related products.

We expect to derive most of our future revenues from the sale or rental of the System One and the related products used with the System One, with the remainder of our revenues largely coming from the sale of a few key disposable products, 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 and business prospects will be adversely impacted.

The home hemodialysis market may be smaller than we expect and may be slow to develop.

We believe our largest product market opportunity is the home dialysis market. However, this market is presently very small and adoption of home hemodialysis therapies has been limited. Currently, less than 10% of U.S. chronic dialysis patients receive some form of dialysis treatment at home, with most of such patients receiving peritoneal dialysis rather than home hemodialysis. Most dialysis centers presently do not have the infrastructure to support a significant home hemodialysis patient population. Our growth depends on a significant shift in patients and the medical community s understanding and view of home hemodialysis, and will require a substantial increase in the number of patients who adopt home hemodialysis, physicians who are willing to prescribe home hemodialysis, and dialysis centers that are able and willing to establish and support home hemodialysis. We recently opened a small number of dialysis centers focused on supporting home therapy with NxStage technology as part of our market development activities to increase home therapy access, but these efforts ultimately may not be successful in expanding the market for our products.

Because nearly all our home hemodialysis patients are also receiving dialysis more frequently than the traditional thrice weekly treatment, market adoption of the System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider costs associated with providing more frequent dialysis, market acceptance will be impacted, especially for U.S. Medicare patients, by whether dialysis centers obtain adequate reimbursement for additional dialysis treatments provided in excess of three times a week, which is discussed in the immediately following risk factor. New regulations particularly impacting home hemodialysis technologies may impede further market expansion of the System One for home hemodialysis. We saw the impact of such regulations in 2008, when the Centers for Medicare and Medicaid Services released new Conditions for Coverage that imposed water testing requirements on patients

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using our PureFlow SL product. These water testing requirements increased the burden of our therapy for patients and may have impaired market adoption, especially for our PureFlow SL product. To the extent additional regulations are introduced that are unique to the home environment, market adoption of the System One could be further impaired.

We are in a developing market and we will need to continue to devote significant resources to developing the home market without any assurances that our efforts will be successful.

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

Medicare provides broad and well-established reimbursement in the U.S. for treating end-stage renal disease patients with hemodialysis three times a week. Most patients using the System One in the home, however, treat themselves, with the help of a care partner, up to six times per week. Reimbursement for more frequent hemodialysis requires medical justification provided by the dialysis facility based on information from the patient s physician. One reimbursement study showed that in 2009 the average number of Medicare payments per month for home hemodialysis was approximately 1.5 times that of in-center hemodialysis. The total number of paid treatments varied across Medicare Administrative Contractors, but there was a positive correlation between number of paid treatments per month and home hemodialysis utilization in a given jurisdiction. This variance arises from differing policies of Medicare Administrative Contractors, as well as from varying center billing practices. Currently, only four of the Medicare Administrative Contractor jurisdictions have formal local coverage determinations; the majority do not have a formal policy and thus review claims on a case by case basis. Some customers may not receive or pursue additional reimbursement in all cases, and providing the required medical justification for treatments beyond three times per week increases administrative burden. Although access to home and more frequent hemodialysis continues to grow, we believe that current Medicare reimbursement policies lead to adoption rates lower than rates commensurate with the percentage of patients experts believe can competently perform and medically benefit from this therapy. We believe that more predictable Medicare reimbursement for more frequent dialysis with less administrative burden, including further improving Medicare reimbursement for home hemodialysis training, would allow adoption of more frequent home hemodialysis at rates more consistent with what are deemed to be appropriate by the medical community. These beneficial changes, however, may never materialize. Conversely, any reduction in reimbursement rates or adverse changes in the reimbursement criteria for home or more frequent hemodialysis could materially reduce our revenues, earnings and cash flows.

In 2011, the Centers for Medicare and Medicaid Services implemented a new prospective payment system for dialysis treatment. Under the new prospective payment system, the Centers for Medicare and Medicaid Services makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all renal dialysis services, inclusive of home dialysis and most drugs frequently administered to dialysis patients. The bundled payment is calculated by adjusting a base payment rate per treatment session to account for geographic variations in labor costs and patient and facility characteristics. This payment system replaced the former system which paid facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, and other services that were not included in the composite rate. With a vast majority of U.S. patients with end-stage renal disease covered by Medicare, the Medicare reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can sell or rent our products. A stated goal of the new prospective payment system was to encourage home dialysis. To date, it has not had a positive impact on the adoption of home or more frequent hemodialysis or the price for which we can sell our products. However, the prospective payment system has had a significant positive impact on the adoption of peritoneal dialysis as evidenced by the significantly increased training rates for peritoneal dialysis. We believe this increased focus on peritoneal dialysis growth and peritoneal dialysis training has been to the detriment of home hemodialysis training rates, as home

training resources, including home training nurses in particular, have been more devoted to peritoneal dialysis training, leaving less time for home hemodialysis training.

As part of the American Taxpayer Relief Act of 2012, Congress instructed the Centers for Medicare and Medicaid Services to recalculate the base payment rate under the prospective payment system for services furnished in 2014 and thereafter to account for changes in utilization of renal dialysis drugs since the prospective payment system was implemented. In response, the Centers for Medicare and Medicaid Services enacted a 12% reduction to the base payment rate to be implemented over a three- to four-year transition period, with overall payments for 2014 remaining unchanged. However, the Protecting Access to Medicare Act of 2014 replaced this phased-in reduction with reductions to the annual inflation adjustment to the base rate (known as the market basket adjustment) in 2015 2018. As a result, there is no reduction to the market basket adjustment in 2015, and the reduction is 1.25 percentage points in 2016 and 2017, and 1 percentage point in 2018. The effect of this change on the adoption of home and more frequent hemodialysis is not yet known.

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We have a history of net losses and a significant accumulated deficit, and we may be unable to become profitable or to maintain profitability if and when we achieve it.

Since inception, we have incurred negative operating margins and losses every quarter. At June 30, 2014, we had an accumulated deficit of approximately $376 million. We expect our operating expenses to continue to increase as we grow and expand our business. While we have achieved positive gross profit for our products since the fourth quarter of 2007, we cannot provide assurance that our gross profit as a percentage of revenues will improve or, if it does improve, the rate at which it will improve. Achieving gross profit improvements will depend upon our ability to introduce additional process improvements and product design changes, further rationalize our manufacturing operations and supply chain, realize additional economies of scale, and continue to improve product reliability. We may not be successful at these and other cost reduction initiatives, and cannot provide assurance about achieving profitability, or the timing, extent or sustainability of such profitability.

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

DaVita and Fresenius own and operate the two largest chains of dialysis centers in the U.S. Collectively, these entities provide treatment to approximately two-thirds of U.S. dialysis patients, and this percentage may continue to grow with further market consolidation. For example, DaVita acquired DSI Renal, Inc. in September 2011 and Fresenius acquired Liberty Dialysis Holdings, Inc., the holding company for Liberty Dialysis and Renal Advantage, in February 2012. With less than one-third of U.S. dialysis patients cared for by independent dialysis centers, our market adoption, at least within the U.S., would be more constrained without the presence of both DaVita and Fresenius as customers.

Additionally, Fresenius is not only a dialysis service provider, it is also the leading manufacturer of dialysis equipment worldwide. In February 2011, Fresenius obtained clearance for its 2008K@home hemodialysis system for use in home therapy. DaVita does not manufacture dialysis equipment, but has certain dialysis supply purchase obligations to Gambro, a dialysis equipment manufacturer and subsidiary of Baxter, under a product supply agreement. Fresenius may choose to offer its dialysis patients only the dialysis equipment Fresenius manufactures, including its 2008K@home system. We cannot predict what impact Fresenius 2008K@home system will have on our sales to Fresenius in the home market or our overall performance in the home market going forward.

Our agreements with DaVita, Fresenius and other large home market customers are intended to support the continued expansion of patient access to home hemodialysis with the System One, but like all our agreements with home market customers, these agreements are not requirements contracts and they contain no minimum purchase volumes. Our home market agreement with DaVita expires at the end of 2015 and our home market agreement with Fresenius expires at the end of 2016, and there can be no assurance that we will renew or extend these agreements on similar terms, if at all, before their expiration. We have no assurance that our sales to DaVita, Fresenius or other large customers will continue to grow. Given the significance of DaVita and Fresenius as customers in the home market, any adverse change in either customer s ordering or clinical practices, as might be the case in periodic contract negotiations or in response to the establishment of our NxStage Kidney Care dialysis centers, would have a significant adverse impact on our home market revenues, especially in the near term.

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

DaVita is our most significant customer. Over 40% of home patients using the System One are DaVita patients. Direct sales to DaVita represented 31% of our System One segment revenues during the first half of 2014. In addition, sales of products through distributors to DaVita accounted for approximately half of In-Center segment revenues for the

same period. 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 or rent the System One or add additional System One patients in the future. Our home market agreement with DaVita expires at the end of 2015 and our needle purchase agreement with DaVita extends through the end of 2014. DaVita s requirement to purchase needles modestly ramps down during 2014 and DaVita has no contractual obligations at this time to purchase needles from us thereafter. In addition, we have a distribution agreement in the U.S. with Gambro that extends through the end of 2015, pursuant to which Gambro will exclusively supply our blood tubing sets to DaVita. The partial or complete loss of DaVita as a customer for any of our product lines would adversely affect our business, at least in the near term.

We face additional risks from the acquisition or development of new lines of business, including in connection with establishing our NxStage Kidney Care dialysis centers.

In the course of evaluating growth opportunities, we may acquire or develop a new line of business or products. For example, we recently began establishing NxStage Kidney Care dialysis centers, which are dialysis centers focused on the provision of home therapy and flexible in-center options. There are substantial risks and uncertainties associated with any change in business lines or strategy, particularly in instances where our customers may perceive the new activity or business line to be in direct competition with their business, which could, in turn, lead them to stop or reduce their purchases of products from us. In addition to the external risks such new businesses or strategies may represent, we may face internal risks relating to developing knowledge of and experience in the new business and recruiting professionals, as well as business execution risks.

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New strategies and businesses may also require significant investment and involvement of our senior management, which will take away from the time they ordinarily spend on the remainder of our business.

If we make any strategic businesses acquisitions, we may encounter substantial integration risks that may prevent us from realizing the anticipated benefits of our acquisitions. These risks include:

- difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including with respect to differing and complex accounting and financial reporting systems;
- disruption of our ongoing business and distraction of management;
- 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;
- difficulty in managing 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;
- loss of key employees of the acquired company; and
- inaccurate assumptions of the acquired company s product quality or product reliability.

Failure to manage the risks associated with the development and implementation of new businesses or strategies could materially and adversely affect our business, results of operations and financial condition.

Our NxStage Kidney Care dialysis centers introduce significant new risks to our business.

In addition to implicating some of the same business and regulatory risks as are applicable to our medical products business (including in particular risks related to Medicare reimbursement rates), establishing our NxStage Kidney Care dialysis centers requires that we comply with complex regulatory requirements applicable to this new business. As health care providers and participants in federal health care programs, our NxStage Kidney Care dialysis centers are subject to extensive government regulations, including:

- Medicare and Medicaid payment rules, including coverage rules that limit the clinical circumstances under which payment will be made for more frequent dialysis treatments;
- anti-kickback and related laws prohibiting payments and other remuneration intended to influence the referral of health care business or selection of a provider;
- antitrust laws;
- prohibitions on submitting false claims for government reimbursement;
- laws regulating the use and disclosure of patient health information; and
- laws regulating the storage and administration of pharmaceuticals.

Violations of such laws and regulations may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional damages and interest, if we are found to have submitted improper claims for reimbursement to the government. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect 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.

Fresenius, our second largest customer in the System One segment, with nearly all of those sales in the home market, markets a system for use in home chronic therapy. Fresenius has also indicated that it is seeking clearance for its sorbent technology within the critical care setting, and has suggested that it would seek clearance for its Portable Artificial Kidney to

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market in the United States for in-center use. Baxter has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC for the development of a new home hemodialysis system. Baxter has commented that it obtained CE marking for this system in the European Union in December 2013, for which it plans a limited launch in Europe in 2014, followed by a broader launch in Europe in 2015. Baxter has also indicated that it expects to complete additional clinical studies and to file for regulatory approval for a home hemodialysis nocturnal indication in the U.S. in late 2015. Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of these products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but the introduction of additional viable products to the home market could adversely affect our sales and growth. We are also unable to predict what impact the Fresenius home hemodialysis systems will have on our sales to Fresenius or our overall home market performance.

The System One in the critical care market competes against Gambro, a subsidiary of Baxter, Fresenius, B. Braun Medical, Inc. and others. Our product lines in the in-center market compete directly against products produced by Fresenius, Gambro, Nipro Medical Corporation, B. Braun, Baxter, JMS Co. Ltd. and others. Our competitors in each of these markets sell one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offers products that have been in use for longer than the System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and personnel 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, including Fresenius which owns and operates a chain of dialysis centers. 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. Further consolidation within the highly competitive dialysis industry, demonstrated most recently by Baxter s acquisition of Gambro, may exacerbate these risks.

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 centers 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 the 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.

Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of end-stage renal disease or in the treatment of acute kidney failure or fluid overload. If we are unable to effectively respond to and compete against competitors, alternative treatments and pharmacological and technological advances, it will be difficult for us to expand the market for, 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, including without limitation the next generation System One, or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological, regulatory, operational or other reasons, to successfully develop and introduce new or improved products could reduce our growth rate or otherwise damage our business. Our developments may not keep pace with the marketplace and our new or

improved products may not 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 the System One.

In the home market, we have to convince five distinct constituencies involved in the choice of dialysis therapy, namely operators of dialysis centers, nephrologists, dialysis nurses, patients and payors (private payors and Medicare), that the System One provides an effective alternative to other existing dialysis equipment. In the in-center market, we have to convince most of the same constituencies 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.

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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 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 centers;
- the failure by us to continue to improve product reliability and the ease of use of our products;
- limitations on the existing infrastructure in place to support home hemodialysis, including without limitation, home hemodialysis training nurses, and the willingness, costs associated with, and ability of dialysis centers 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, such as the 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 center, may be smaller than we estimate; and
- the availability of satisfactory reimbursement from healthcare payors.

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 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. We will need to convince hospitals and healthcare providers that using the System One is as effective as using conventional or intensive care hemodialysis systems for treating acute kidney failure or fluid overload and that it provides advantages over conventional or intensive care 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.

Global macro-economic conditions and the world s financial markets remain susceptible to significant stresses, resulting in reductions in available credit, foreign currency fluctuations and volatility in the valuations of securities generally. In general, we believe demand for our products in the home and in-center markets will not be substantially affected by the changing market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, hospitals or centers 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. Uncertainty in the general economic environment and governmental spending on public health programs may also lead to a reduction in hospital days (particularly those due to elective procedures) and delays in capital purchases, both of which can negatively impact our critical care business. Our ability to sell products internationally is particularly vulnerable to adverse impacts from global macro economic conditions. Government funded hospitals in various international markets may seek to defer capital purchases or tenders. Distributors with reduced access to capital may be less willing to purchase our equipment outright, impairing our ability to sell our products. Furthermore, unfavorable changes in foreign exchange rates versus the U.S. dollar would increase our product costs which would negatively impact our gross profit and gross profit as a percentage of revenues.

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, and in foreign countries, for comprehensive reforms affecting the availability of and reimbursement for healthcare services in the United States and other countries. These initiatives have ranged from fundamental changes to federal and state healthcare reimbursement programs, such as providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs.

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In 2010, comprehensive health care reform legislation was passed that, among other things, imposes a 2.3% excise tax on domestic sales of certain medical devices. Our profitability has been negatively impacted due to the medical device excise tax assessed on nearly all of our products sold in the United States since the beginning of 2013. Subsequent legislation required an adjustment to the Medicare payment rates to account for changes in the utilization of drugs and biologicals, which resulted in a 12% reduction to the base payment rate that will be implemented over a three- to four-year transition period, with overall payments for 2014 remaining unchanged. Later legislation pushed these payment reductions to later years, starting with 2016. These changes could affect the adoption of home and more frequent hemodialysis in the future, particularly if NxStage customers are distracted in efforts to address any revenue shortfalls, or choose to redirect home training resources toward other center activities. Additional healthcare reforms in the United States may have a material adverse effect on our financial condition and results of operations.

The governments of foreign countries are actively pursuing similar actions intended to reduce costs related to provision of healthcare. The results of these actions may also 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. Also, if demand for our products continues to grow we may not be able to increase our manufacturing capacity fast enough to meet customer demand.

If we are unable to maintain strong product reliability for our products, we may be unable to grow our business and achieve profitability.

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

We also need to establish strong product reliability for all new products we offer. With new products, we are more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature. We also choose from time to time to transition the manufacturing and supply of products and components to different suppliers or locations. As we make these changes, we are more exposed to risks relating to product quality and reliability until the manufacturing processes mature. Like all transitions of this nature, they could also lead us to incur additional costs in the near-term, which would negatively impact our gross profits in the near-term.

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

Because our home market relies upon an equipment service swap model and, for some of our customers, an equipment rental model, our ability to manage System One equipment is important to minimizing our working capital requirements. Both approaches require that we maintain a significant level of field equipment of the System One and PureFlow SL hardware. While a majority of our home market customers have committed to purchase, rather than rent, the significant majority of their future System One equipment requirements, there can be no assurance that we will be able to continue to expand or sustain this level of equipment placements that are purchased rather than rented. Any excess rental or service swap equipment would increase our ongoing cash requirements to fund working capital. 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 incur increased costs, realize increased cash requirements and have material write-offs of equipment. This would negatively impact our working capital requirements and future profitability.

We may be subject to litigation claims from time to time.

From time to time, we are threatened with individual actions involving our business, including without limitation products liability, employment, intellectual property, commercial and tort claims. The manufacture and marketing of medical devices, in particular, has an attendant risk of product liability claims. 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. Any claims made against us could adversely affect our reputation, which could damage our position in the market. Claims can also 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.

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While we maintain insurance at levels deemed adequate by management, future claims could exceed our insurance coverage.

We maintain insurance for property and general liability, directors and officers liability, product liability, malpractice related to NxStage Kidney Care dialysis centers, workers compensation, and other coverage in amounts and on terms deemed to be adequate by management based on our expectations for future claims. Future claims, however, may be brought against us that result in court judgments or settlements that exceed the limits of our insurance coverage. In addition, our insurance policies have various exclusions, and we may be subject to a claim for which we have no coverage. As a result, we may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by any insurance, which may have a material adverse effect on our financial condition and results of operations.

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

We operate manufacturing facilities in Germany, Italy and Mexico. We also purchase components, products and supplies from foreign vendors. We are subject to a number of risks and challenges that specifically relate to these international operations, and we may not be successful if we are unable to meet and overcome these challenges. Significant risks relate to foreign currency, in particular the Euro, Peso, Yen and Thai Baht. To mitigate our foreign currency exposure we engage in hedging transactions on Peso denominated expenses. To the extent we fail to control our exchange rate risk, our gross profit as a percentage of revenues and profitability could suffer and our ability to maintain mutually beneficial and profitable relationships with foreign vendors could be impaired. In addition to these risks, through our international operations we are exposed to costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods, difficulty managing operations in multiple locations, local regulations that may restrict or impair our ability to conduct our operations and increase compliance costs, health issues, such as pandemic disease risk, and natural disasters, such as flooding, hurricanes and earthquakes, which could disrupt our manufacturing and logistical and import activities. Risks associated with our international operations may increase where we sell our products and services directly rather than through distributors, such as in the United Kingdom. Furthermore, in certain locations, such as Mexico, we are also exposed to risks associated with local instability, including threats of violence, which could lead to disruptions in supply at our manufacturing facilities or key vendors.

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

The majority of our products for the in-center market are sold through several distributors, which collectively account for substantially all of our in-center revenues. Relying on third-party distributors exposes us to many risks, including competitive pressure, compliance risks, credit risk and concentration. Distributors may sell products that compete with our products, and we may be unsuccessful in motivating our distributors to focus their efforts on selling our products. Any failure on the part of our distributors to comply with applicable laws in the sale and marketing of our products or to fulfill any responsibilities they may have to protect the intellectual property rights underlying our products could have an adverse effect on our revenues and involve us in legal proceedings. Distributors may face financial difficulties, including bankruptcy, which could harm our collection of accounts receivable and financial results. In addition, Gambro (a subsidiary of Baxter) and Henry Schein are our most significant distributors for the in-center market, and the loss of Gambro or Henry Schein as our distributors for any reason could materially adversely affect our business, at least in the near term.

Unless we can demonstrate sufficient product differentiation in our In-Center segment products, we will continue to be susceptible to further pressures to reduce product pricing and more vulnerable to the loss of our blood tubing

set or needle business to competitors in the dialysis industry.

Our blood tubing set and needle businesses have historically been commodities businesses. Our products continue to compete favorably in the dialysis blood tubing set and needle business, but are increasingly subject to pricing pressures, especially given recent market consolidation in the U.S. dialysis services industry, with Fresenius and DaVita collectively controlling approximately two-thirds of the U.S. dialysis services business. Unless we can successfully demonstrate to customers the differentiating features of our Streamline blood tubing set, MasterGuard needle, ButtonHole needle or products that we introduce in the future, we may continue to be susceptible to pressures to reduce our product pricing and more vulnerable to the loss of our blood tubing set and needle business to competitors in the dialysis industry.

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 our business.

Our success depends 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 our Chief Executive Officer.

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If kidney transplantation becomes a viable treatment option for more patients with end-stage renal disease, 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 patients with end-stage renal disease, 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 patients. 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 and services. The development of viable medical, pharmaceutical, or other solutions for renal replacement or prolonging kidney life may also limit the market for our products and services.

Risks Related to the Regulatory Environment

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. 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 clearance necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications of our products. Regulatory pathways for such clearances may be difficult to define and could change. For example, in 2010 we completed an approved Investigational Device Exemption clinical study intended to support a home nocturnal indication for the System One and submitted the associated 510(k) to the FDA. Although we met our primary safety and efficacy endpoints for the study, the FDA notified us that their standards for what will be required for a home nocturnal clearance changed from what was required in our approved Investigational Device Exemption. As a result, the FDA did not clear our 510(k) application for home nocturnal use. In July 2012, the FDA approved a continuation of our Investigational Device Exemption study designed to support a nocturnal indication for the System One. We have completed the re-started trial and have resubmitted an application for a home nocturnal clearance. We cannot be certain when this or other clearances will be obtained. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products.

The FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our future products. Although the 510(k) regulation has not been formally changed, the FDA has announced that it is intending to implement modifications to the 510(k) process. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and the ability to sell and promote our products.

Our products are also subject to extensive regulation in foreign markets in which we are currently present or which we may wish to enter. The regulatory approval process outside the United States exposes us to many of the same risks associated with obtaining FDA clearance. Accordingly, we may be unable to obtain foreign regulatory approvals on a timely basis, if at all, which would limit our market expansion goals, and any existing foreign regulatory approvals may be curtailed, suspended or withdrawn, which would adversely affect our business. In addition, the regulatory approval procedure in foreign markets varies from country to country and requires that we comply with numerous

regulatory requirements that differ from the FDA clearance process and are not superseded by obtaining clearance or approval from the FDA or another country s regulatory authority. In certain foreign markets, some of our products are classified as drugs rather than medical devices, which requires us to demonstrate compliance with separate regulations applicable to drug manufacturers and distributors. These complex regulations may impose additional approval, manufacturing, surveillance and reporting requirements. Compliance with these additional requirements may increase our costs of doing business in new foreign markets and delay our entry into such markets.

New regulations affecting our business are periodically adopted in the United States and in other countries. These regulations may require us to change our existing product technologies, operating procedures or marketing practices in order to continue selling our products. This may expose us to increased costs, as well as risks that we may be unable to satisfy the new regulatory requirements. For example, extensive revisions to current EU medical device legislation, which is currently being discussed by the Council of the European Union, will impose significant additional obligations. If we are unable to comply with the new obligations imposed by the regulation, we may need to suspend, curtail or otherwise modify our selling and marketing efforts in the European Union. Any additional regulatory developments in the European Union or elsewhere may adversely affect our ability to market our existing products or introduce new products in a timely manner, which would have a negative impact on our business.

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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.

In the United States, 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, require 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 and require such a submission. If the FDA requires us to submit a 510(k) for any modification to a previously cleared device, 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, and may be subject to fines or other sanctions for failing to obtain such clearance in advance. In the future, we intend to introduce new products and enhancements and improvements to existing products, which may not be cleared by the FDA in a timely manner, if at all. In addition, the FDA may characterize any new products or significantly modified marketed products in a class that requires submission of a more costly and lengthy pre-market approval application before commercial distribution would be permissible. Compared to 510(k) submissions, pre-market approval applications require substantially more data and their review by the FDA typically takes significantly longer. Also, products subject to pre-market approval applications 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 the growth of our revenues.

Outside the United States, modifications to approved devices expose us to many of the same risks associated with modifications to 510(k) cleared devices. For example, in the European Union any substantial changes to a CE marked device may require a new conformity assessment and a new CE Certificate of Conformity from our notified body before the proposed change is implemented. There is limited guidance, however, on whether a change to a device should be considered substantial. Therefore, there is a risk that the competent authorities in the European Union or our notified body disagree with our assessment of the changes introduced to our products, and may come to a different conclusion than the FDA concerning such changes. Delays in conduct of any regulatory assessments in the European Union or elsewhere will cause delays in our ability to sell our products in those markets and will have a negative effect on our revenue growth.

Even if we obtain the necessary regulatory 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.

Numerous regulatory requirements apply to our products following clearance or approval in the United States, European Union, and other markets, including regulations governing:

registration of medical devices;

pricing and reimbursement of medical devices;

establishment of post-marketing surveillance;

field safety corrective actions, including product recalls and withdrawals;

filing reports of device corrections and removals;

marketing and promotion of medical devices; and

interactions with physicians.

In addition, we are subject to the Medical Device Reporting 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 death or serious injury. Similar obligations are imposed in foreign countries.

Our failure to comply with these or other applicable regulatory requirements may result in enforcement measures being taken by regulatory authorities, which may include:

untitled letters, warning letters, fines, injunctions and civil penalties;

detention of medical devices believed to be adulterated or misbranded;

customer notification, or orders for repair, replacement or refund;

voluntary or mandatory recall, withdrawal or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

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refusal to review or delay in issuing pre-market notification or pre-market approval submissions;

rescission of a regulatory clearance or approval that has already been granted;

refusal to issue export documentation or approval for our products;

suspension, withdrawal or variations of CE Certificates of Conformity or delay in obtaining new CE Certificates of Conformity; and

criminal prosecution.

Such enforcement measures would require unanticipated expenditures to address or defend such actions and would have an adverse effect on the marketing of our products and, consequently, on our business and financial position.

Any market withdrawals or recalls of our products could expose us to product liability claims and harm our reputation and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. From time to time we have chosen to voluntarily recall certain products that we believed were mislabeled or otherwise defective. Although we do not believe that any of our recent recalls have had any long-term negative effect on our business, future recalls may materially divert management attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers.

If we or our contract manufacturers fail to comply with the FDA s Quality System Regulations and other quality system requirements, 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, must comply with the FDA s Quality System Regulations which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. Foreign regulatory authorities impose similar obligations. The FDA enforces these regulations through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been subject to such inspections on multiple occasions and we anticipate additional inspections in the future. While 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 quality system inspection, the FDA, the notified body, or the competent authorities in the European Economic Area could take enforcement action, including:

issuing a public warning letter;

shutting down part or all of our manufacturing operations;

suspending or withdrawing our existing CE Certificates of Conformity;

embargoing the import of certain components;

ordering the recall or detention of our products;

refusing to approve new marketing applications or to issue new CE Certificates of Conformity;

instituting legal proceedings to detain, seize or enjoin the manufacture or distribution of our products; and

imposing administrative, civil or criminal penalties or other sanctions.

Any of these actions could harm our business, reputation and operating results.

We have obligations to protect the privacy and security of patient health information. Failure or perceived failure to comply with applicable federal and state requirements could subject us to criminal or civil penalties, and contractual liability.

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 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 customers staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. We also receive and maintain confidential patient health information in

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connection with the operation of our NxStage Kidney Care dialysis centers. U.S. federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended under the Health Information Technology for Economic and Clinical Health Act, or HIPAA, governs the use and disclosure of confidential patient health information known as protected health information. HIPAA and the rules promulgated thereunder require certain entities to comply with established standards, including standards regarding the privacy and security of protected health information known as the HIPAA Privacy and Security Rules, and to provide notification following a data breach involving protected health information. We are subject to HIPAA with regard to certain aspects of our business. In addition, many other state and federal laws regulate the use and disclosure of health information, including state medical privacy laws, breach notification laws and federal and state consumer protection laws. In many cases, these laws are not necessarily preempted by HIPAA, particularly if they afford greater protection to the individual than does HIPAA.

Complying with these federal and state privacy and security requirements impose compliance related costs, subjects us to potential regulatory audits, and may restrict our business operations. These various laws may be subject to varying interpretations by courts and government agencies creating potentially complex compliance issues for our business. If we were to violate any of our legal obligations to safeguard any confidential patient health information or protected health information against improper use and disclosure, we could lose customers and be exposed to liability, including potential civil and criminal penalties under HIPAA and contractual liabilities, and our reputation and business could be harmed. Concerns or allegations about our practices with regard to the privacy or security of personal health information or other privacy-related matters, even if unfounded, could damage our reputation and harm our business.

We are also subject to laws and regulations in foreign countries covering data privacy and other protection of health and employee information that may be more onerous than corresponding U.S. laws. These regulations may require that we obtain individual consent before we collect or process any personal data, restrict our use or transfer of personal data, impose technical and organizational measures to ensure the security of personal data, and require that we notify regulatory agencies, individuals or the public about any data security breaches. As we expand our international operations, we may be required to expend significant time and resources to put in place additional mechanisms to ensure compliance with multiple data privacy laws. Failure to comply with these laws may result in significant fines and other administrative penalties and harm our business.

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

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

Medical devices in the European Union may be promoted only for the intended purpose for which the devices have been CE marked. Failure to comply with this requirement could lead to the imposition of penalties by the competent authorities of the EU Member States. The penalties could include warnings, orders to discontinue the promotion of the medical device, seizure of the promotional materials and fines. Our promotional materials must also comply with various laws and codes of conduct developed by medical device industry bodies in the European Union governing promotional claims, comparative advertising, advertising of medical devices reimbursed by the national health insurance systems and advertising to the general public. If our promotional materials do not comply with these laws and industry codes we could be subject to penalties that could include significant fines. Our reputation could also be damaged and the adoption of our products could be impaired.

We are subject to federal and state laws prohibiting kickbacks and false and fraudulent claims which, if violated, could subject us to substantial penalties.

The federal healthcare program Anti-Kickback Statute, and similar state laws, prohibit payments and other forms of remuneration that are intended to induce health care professionals or others either to refer patients or to purchase, lease, order or arrange for or recommend the purchase, lease or order of healthcare products or services. Other laws prohibit remuneration intended to induce patients to select a particular provider of services, including for dialysis. A number of states have enacted

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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, most notably laws in Massachusetts and Vermont, impose outright bans on certain manufacturer gifts to physicians. Some of these laws, referred to as aggregate spend or gift laws, carry substantial fines if they are violated. In addition, under the federal Physician Payments Sunshine Act we must collect and report certain data on payments and other transfers of value to physicians and teaching hospitals, which are expected to become publicly available for the first time in September 2014. It is widely anticipated that public reporting under the Sunshine Act will result in increased scrutiny of the financial relationships between industry, physicians and teaching hospitals.

These anti-kickback, public reporting and aggregate spend 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, including patients, of medical devices and services. 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. For our NxStage Kidney Care dialysis centers, they also affect our arrangements with any joint venture partners in a position to refer patients, our medical directors and our patient billing and collection practices. Although we seek to structure such arrangements in compliance with all applicable requirements, these laws are broadly written and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If we were to offer or pay inappropriate inducements to purchase, order or use our products or services, or to refer patients to our NxStage Kidney Care dialysis centers, we could be subject to a claim under the federal healthcare program Anti-Kickback Statute, the federal patient inducement prohibition or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws.

Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Medical device manufacturers can be held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all prescribing decisions, including the decision as to whether to order dialysis services more frequently than three times per week. In addition, our NxStage Kidney Care dialysis centers are directly subject to these laws with respect to the reimbursement claims they file with government payors. Potential false or fraudulent claim risk can arise from promoting and billing for services the government deems excessive or not medically necessary, as well as from other billing improprieties and from failure to timely return any identified overpayments. We are making every effort, including adhering strictly to guidelines in any local coverage determinations issued by Medicare Administrative Contractors with jurisdiction over claims from any of our NxStage Kidney Care dialysis centers, to ensure that billing by our NxStage Kidney Care dialysis centers is proper and that physicians who order NxStage Kidney Care dialysis services fully document medical need for patients for whom more frequent than thrice weekly therapy is ordered. 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, physicians and patients concerning the benefits and potential coverage of more frequent therapy. Likewise, our financial relationships with customers, physicians, patients or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial, and given the possibility of exclusion from participation in government health care programs, potentially crippling to the line of business involved. 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.

Increasingly, foreign countries are adopting laws similar in application and consequence to the anti-kickback, false claims and Sunshine Act laws in the United States. In the European Union, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medical devices is prohibited. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. One such example is the UK Bribery Act. Increasingly, national laws or industry codes are imposing obligations of public disclosure of payments made to physicians in certain EU Member States. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician s employer or competent professional organization or the competent authorities of the individual EU Member States. If we fail to comply with these laws we may face civil or criminal penalties. The negative consequences of any failure to comply with these laws may also harm our ability to operate in foreign countries and have a negative effect on our reputation that discourages third parties from doing business with us.

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

We have begun to market the System One and certain of our other products internationally. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. 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. Furthermore, reimbursement provided for our products in other jurisdictions could change, positively or negatively. In the event reimbursements were to be negatively changed, such as in the United Kingdom where we sell our products directly, our ability to sell our products could be impaired.

If we violate import and export 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 our manufacturing facilities and vendors located outside the United States. We have manufacturing facilities in Mexico, Germany and Italy and export various components and assemblies related to those operations. To a lesser but increasing degree, we also export finished goods from the United States to foreign countries. The import and export of these items are subject to extensive and complex laws and regulations. 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, import holds and a disruption in our ability to deliver product, which could harm our business and operating results to suffer. To the extent there are modifications to the Generalized System of Preferences or cancellation of the Nairobi Protocol tariff classifications that apply to our products such that our products would be subject to duties, our profitability would also be negatively impacted.

Failure to comply with the U.S. Foreign Corrupt Practices Act, UK Anti-Bribery Act or similar anti-bribery laws in other countries could subject us to penalties and other adverse consequences.

We are subject to the U.S. Foreign Corrupt Practices Act which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign controlled subsidiaries. Through our international activities, we are also subject to the UK Anti-Bribery Act and other similar anti-bribery laws in other countries. While we have policies and procedures in place designed to promote compliance with such laws, our employees or other agents may nonetheless engage in prohibited conduct under these laws for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

If we violate environmental and occupational safety laws regulating the use of hazardous materials, 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, as well as the laws of foreign countries, governing the use, handling and disposal of 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.

Our business may be affected by U.S. government contracting risks.

We have agreements with Veterans Health Administration facilities and are one of the key subcontractors on a government contract to develop a portable medical device to treat sepsis. As a result, we must comply with and are affected by laws and regulations relating to the award, administration and performance of U.S. government contracts which, among other things, impose additional costs on our business. If we violate any of these laws or regulations, we may be liable for fines, penalties and any additional costs the government incurs in procuring replacement services, and we may be excluded from future U.S. government contracting.

Risks Related to Operations

We obtain some of our raw materials and production services from a single source or a limited group of suppliers, the loss of which may cause production delays and prevent us from delivering our products on a timely basis.

We depend upon a number of single-source suppliers for certain of our raw materials, components and finished goods, including the fiber used in our System One filters, our needles, premixed dialysate and sterile bags, as well as sterilization services. Some of our most critical single-source supply relationships are with Membrana, Kawasumi and Laboratorios PiSA.

Membrana is our sole supplier of the fiber used in our filters for System One products, and contractually we cannot obtain an alternative source of fiber for our System One products. While our relationship with Asahi could afford us back-up supply in the event of supply disruptions at Membrana, we do not have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the United States and the performance of Asahi fiber in the System One has not yet been validated.

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Kawasumi is our only supplier of needles that we sell to our customers. Kawasumi s contractual obligation to supply needles to us expires in February 2017. Our supply chain maintains a limited extra supply of needles to mitigate against the risk of intermittent shortfalls in needle supply, at least in the near term. However, any significant interruption in Kawasumi s ability to supply products to us would impair our business, at least in the short term.

Laboratorios PiSA is our only supplier of premixed dialysate. Our supply agreement with Laboratorios PiSA extends through December 2019. We have committed to purchase from Laboratorios PiSA a minimum quantity of premixed dialysate over the term of the agreement, which we believe is less than our anticipated requirements. While we can purchase premixed dialysate from other qualified suppliers, any significant disruption in Laboratorios PiSA s ability to supply premixed dialysate to us would impair our business, at least in the near term.

Our dependence upon these and other single-source suppliers of raw materials, components, finished goods and sterilization services 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 end-stage renal disease and who need access to the System One and related disposables to continue their therapy.

Finding alternative sources for these raw materials, components, finished goods and sterilization services would be difficult and in many cases entail a significant amount of time, disruption and cost. Although we believe our supply chain has sufficient inventory of raw materials, components and finished goods to withstand a temporary disruption in supply from any single source supplier, any permanent or long-term disruption in supply from any single source supplier could lead to supply delays or interruptions which would damage our business and impair our reputation, at least in the near term.

Natural disasters, labor disputes and other adverse developments at our manufacturing facilities may cause production delays and prevent us from delivering our products on a timely basis.

We rely on our manufacturing facilities in Mexico, Italy and Germany for the production of our equipment and disposables. The loss of any of these facilities due to fire, natural disaster, war, power failure or other cause beyond our control could cause significant production delays, prevent us from meeting customer demand for our products, increase our product costs, impair our product quality or reliability, and result in substantially decreased revenues.

While we have labor agreements with our production employees in Mexico and Italy, we may experience strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes, anti-union behavior, or other labor disputes at our manufacturing facilities. Some of our key single-source suppliers also have labor agreements in place, but nonetheless may be subject to similar risks related to labor disputes. Any such activity likely would cause production delays and prevent us from delivering our production commitments to customers, 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 our suppliers. Many of our 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, we may be unable to meet customer demand which could harm our competitive position and reputation. In addition, if we fail to effectively

manage our relationships with our suppliers, we may be required to change suppliers, which may be time consuming and lead to disruptions in our product supply. Although we believe our supply chain has sufficient inventory of raw materials, components and finished goods to withstand a temporary disruption in supply from any single-source supplier, any permanent or long-term disruption in supply from any single-source supplier could lead to supply delays or interruptions which would damage our business and impair our reputation, at least in the near term.

Increasing prices for resin, a key material in the manufacture of our products, could impair our ability to achieve profitability.

Resin is a key material in the manufacture of our products, including the System One cartridge. We currently source resin from a small number of suppliers. Rising prices over the last several years for crude oil, natural gas and other petrochemical intermediates from which resin is produced have resulted in significant price increases for this material, and resin prices may continue to increase. Our contracts with customers restrict our ability to immediately pass on these price increases, and future pricing to customers may be insufficient to accommodate increasing resin costs. In addition, our overall cost reduction plans may not sufficiently offset the impact of increased resin costs, which could result in declining margins and operating results.

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Increasing fuel prices could impair our ability to achieve profitability.

We currently incur significant inbound and outbound distribution costs, which 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.

Risks Related to Intellectual Property

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

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our proprietary technology and prevent others from duplicating our products. However, these means may afford only limited protection and may not:

prevent our competitors from duplicating our products;

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

permit us to gain or maintain a competitive advantage.

These risks may increase in foreign countries whose laws do not protect intellectual property rights effectively or to the same extent as U.S. laws.

Any of our patents, including those we may license, may be challenged, invalidated, rendered unenforceable or circumvented. We may not prevail if our patents are challenged by competitors or other third parties. The U.S. federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents, find them unenforceable, or narrow their scope. Furthermore, competitors may be able to design around our patents, or obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, our products may become less competitive and sales of our products may decline.

We have filed numerous patent applications seeking protection of products and other inventions originating from our research and development. Our patent applications may not result in an issued patent, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies.

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

The medical device industry 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 for more than 30 years and our competitors hold a significant number of patents relating to kidney replacement devices, therapies, products and supplies. Competitors and other third parties may allege that our products or methods infringe their patents or other intellectual property rights, and the possibility of such infringement claims may increase as our business expands into new markets.

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 divert management and key personnel from other tasks important to the success of the business. In addition, intellectual property litigation or claims could require us to:

- 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.

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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 rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and trade secrets and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover or reverse engineer trade secrets and proprietary information, and in such cases we may be unable to 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 have worked at other medical device companies focused on the development of dialysis products, including our competitors. 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 and harm to our reputation and be a distraction to management.

Risks Related to our Common Stock

The market price of our common stock may fluctuate significantly.

There may be periods of volatility in the market price of our common stock that delay or prevent you from selling your common stock at or above the price you paid for it. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing of market launch and market acceptance of our products;
- timing of achieving profitability from operations;
- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;

developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers and distributors;

disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across international borders, 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, similar dialysis products distributed by other companies, or more frequent or home dialysis;

the FDA or foreign regulatory agencies and notified bodies declining to clear or approve our product candidates or to issue CE Certificates of Conformity, or delays in the FDA or other foreign regulatory agency and notified body review processes;

product recalls and withdrawals;

defaults under our material contracts, including without limitation our credit agreement;

regulatory developments in the United States and foreign countries;

changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments, or the willingness of Medicare contractors to pay for more than three treatments a week where medically justified;

litigation involving our company or our general industry;

announcements of technical innovations or new products by our competitors;

developments or disputes concerning our patents or other proprietary rights;

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

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

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departures of key personnel;

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

the other risks and uncertainties described in these *Risk Factors*.

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.

Provisions in our governing documents and under Delaware law may discourage potential acquisition proposals and changes in management that stockholders may favor.

Provisions in our charter and bylaws and under the corporation law of Delaware, where we are incorporated, may delay or prevent a takeover attempt that could be viewed as beneficial to stockholders who wish to receive a premium for their shares from a potential bidder. These provisions may also discourage stockholders from attempting to replace or remove members of our board of directors, which in turn may delay or prevent changes in our current management team that stockholders may favor. These provisions include:

a prohibition on stockholder actions 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;

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

the prohibition on 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.

If we obtain additional financing for acquisitions and other growth initiatives, it may reduce the market value of our common shares.

As part of our growth strategy, we may acquire other businesses and technologies and pursue additional business opportunities. To finance such activity, we may issue equity securities, which may dilute our existing stockholders,

and incur debt, which may place restrictions on our business operations. Such financing activity may reduce the market value of our common shares and other securities, in particular if the initiatives being funded are not viewed favorably by our stockholders and are ultimately unsuccessful.

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Item 6. ***Exhibits***

Exhibit Number	Description
10.1*	Credit Agreement dated as of June 9, 2014 among the Registrant and certain of its subsidiaries, General Electric Capital Corporation and Silicon Valley Bank.
10.2#	2014 Omnibus Incentive Plan. Filed as Appendix B to the Registrant s Definitive Proxy Statement on Schedule 14A filed on April 24, 2014 (Commission File No. 0-51567) and incorporated herein by reference.
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith.
** Furnished herewith.
# Management contract or compensatory plan or arrangement.

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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/ Matthew W. Towse
Matthew W. Towse
Chief Financial Officer

(Duly authorized officer and principal financial officer)

August 7, 2014