UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2018

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 Incorporation or Organization)	*(I.R.S. Employer 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. ☑ 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).

☑ Yes ☐ No

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

Large accelerated filer ☑ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☑ No

There were 66,496,907 shares of the registrant's common stock outstanding as of the close of business on May 4, 2018.

NXSTAGE MEDICAL, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2018
TABLE OF CONTENTS

Note Regarding Nomenclature

For convenience, in this Quarterly Report “NxStage,” “we,” “us,” and “the Company” refer to NxStage Medical, Inc. and our consolidated subsidiaries, taken as a whole.

Note Regarding Trademarks

NxStage® is a registered trademark of NxStage Medical, Inc. PureFlow™ and System One™ are trademarks of NxStage Medical, Inc.

PART I - FINANCIAL INFORMATION

Item 1. ***Financial Statements***

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

	March 31, 2018	December 31, 2017
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,619	$ 64,928
Accounts receivable, net	38,689	31,625
Inventory	52,118	49,212
Prepaid expenses and other current assets	9,795	7,609
Total current assets	163,221	153,374
Property and equipment, net	59,458	60,262
Field equipment, net	23,446	24,264
Deferred cost of revenues	31,568	31,410
Intangible assets, net	7,154	7,660
Goodwill	42,748	42,748
Other assets	6,360	5,911
Total assets	$ 333,955	$ 325,629
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,443	$ 14,785
Accrued expenses	26,193	27,985
Current portion of long-term debt	105	101
Other current liabilities	4,716	4,559
Total current liabilities	46,457	47,430
Deferred revenues	47,205	46,874
Long-term debt	522	520
Other long-term liabilities	18,286	17,824
Total liabilities	112,470	112,648
Commitments and contingencies (Note 10)		
Noncontrolling interests subject to put provisions	(171)	(165)
Stockholders' equity:		
Undesignated preferred stock: par value $0.001 per share, 5,000,000 shares authorized; no shares issued and outstanding as of March 31, 2018 and December 31, 2017	—	—
Common stock: par value $0.001 per share, 100,000,000 shares authorized; 67,561,597 and 67,341,819 shares issued as of March 31, 2018 and December 31, 2017, respectively	67	67
Additional paid-in capital	660,769	657,640
Accumulated deficit	(416,982)	(421,593)
Accumulated other comprehensive loss	(2,514)	(3,673)
Treasury stock, at cost: 1,074,909 and 1,046,870 shares as of March 31, 2018 and December 31, 2017, respectively	(19,957)	(19,283)
Total NxStage Medical, Inc. stockholders' equity	221,383	213,158
Noncontrolling interests not subject to put provisions	273	(12)
Total stockholders' equity	221,656	213,146
Total liabilities and stockholders' equity	$ 333,955	$ 325,629

See accompanying notes to these condensed consolidated financial statements.

NXSTAGE MEDICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
	(In thousands, except per share data)	
Revenues	$ 107,298	$ 96,829
Cost of revenues	61,133	55,639
Gross profit	46,165	41,190
Operating expenses:		
Selling and marketing	18,055	16,770
Research and development	9,438	9,508
Distribution	9,342	7,643
General and administrative	10,460	8,950
Total operating expenses	47,295	42,871
Loss from operations	(1,130)	(1,681)
Other expense:		
Interest expense, net	(109)	(203)
Other expense, net	(295)	(270)
	(404)	(473)
Net loss before income taxes	(1,534)	(2,154)
Provision for (benefit from) income taxes	264	(613)
Net loss	(1,798)	(1,541)
Less: Net loss attributable to noncontrolling interests	(339)	(352)
Net loss attributable to NxStage Medical, Inc.	$ (1,459)	$ (1,189)
Net loss per share, basic and diluted	$ (0.02)	$ (0.02)
Weighted-average shares outstanding, basic and diluted	66,355	65,275
Other comprehensive income:		
Unrealized income on derivative instruments, net of income taxes	461	2,184
Other income	698	721
Total other comprehensive income	1,159	2,905
Total comprehensive (loss) income	(639)	1,364
Less: Comprehensive loss attributable to noncontrolling interests	(339)	(352)
Total comprehensive (loss) income attributable to NxStage Medical, Inc.	$ (300)	$ 1,716

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2018	2017
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (1,798)	$ (1,541)
Adjustments to reconcile net loss to net cash flow from operating activities:		
Depreciation and amortization	8,304	8,467
Stock-based compensation	2,697	2,574
Other	418	(623)
Changes in operating assets and liabilities:		
Accounts receivable	(2,458)	(6,911)
Inventory	(7,302)	(7,848)
Prepaid expenses and other assets	(16)	(7)
Accounts payable	481	4,200
Accrued expenses and other liabilities	(1,417)	(4,579)
Deferred revenues	222	(1,026)
Net cash used in operating activities	(869)	(7,294)
Cash flows from investing activities:		
Purchases of property and equipment	(1,092)	(1,605)
Net cash used in investing activities	(1,092)	(1,605)
Cash flows from financing activities:		
Issuance of shares under stock incentive plans, net of payroll taxes paid	(268)	4,742
Repayments on loans and lines of credit	(14)	(75)
Repayments on capital leases	(399)	(338)
Net cash (used in) provided by financing activities	(681)	4,329
Foreign exchange effect on cash and cash equivalents	333	393
Decrease in cash and cash equivalents	(2,309)	(4,177)
Cash and cash equivalents, beginning of period	64,928	59,632
Cash and cash equivalents, end of period	$ 62,619	$ 55,455

See accompanying notes to these condensed consolidated financial statements.

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

1. Nature of Operations, Proposed Merger, Basis of Presentation and Principles of Consolidation

Nature of Operations

We are a medical technology company that develops, manufactures, markets and provides innovative products and services for patients suffering from chronic or acute kidney failure. Our primary product, the System One, was designed to satisfy an unmet clinical need for a system capable of delivering the therapeutic flexibility and clinical benefits of 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 and home-like settings, including skilled nursing facilities, 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 that are more practical to deliver in the home setting, including more frequent hemodialysis and nocturnal hemodialysis. Clinical literature suggests such therapies provide patients better clinical outcomes and improved quality of life. In addition to the System One, we provide patients with our PureFlow SL accessory which prepares on-site premixed dialysate fluid in the patient's home using ordinary tap water and dialysate concentrate.

We also operate a small number of NxStage Kidney Care dialysis centers, independently and in some instances as joint ventures, that treat end-stage renal disease (ESRD) patients directly. These centers provide us with the opportunity to innovate and foster new care delivery models to advance the standard of renal care across other markets. At these centers, we offer a range of treatment options, including home hemodialysis, peritoneal dialysis and flexible in-center hemodialysis.

We are headquartered in Lawrence, Massachusetts, with manufacturing facilities in Mexico, Germany and Italy. Through our international network of affiliates and distribution partners, patients in over 21 countries have been treated with our products.

Proposed Merger

On August 7, 2017, we entered into the Merger Agreement with Fresenius Medical Care Holdings, Inc. (Fresenius), pursuant to which we will merge with a wholly-owned subsidiary of Fresenius, subject to certain conditions. At the closing of the Merger, all outstanding shares of our common stock (except those held by us, Fresenius or its wholly-owned subsidiaries or any stockholders properly exercising their appraisal rights under the General Corporation Law of the State of Delaware) would be converted into the right to receive $30.00 per share in cash, subject to any applicable tax withholdings.

The closing of the Merger is conditioned, among other things, on receipt of regulatory approval from the U.S. Federal Trade Commission (FTC) and the expiration of applicable waiting periods, or extensions thereof, under the Hart-Scott-Rodino Act of 1976, as amended (HSR Act). Pursuant to the HSR Act, we and Fresenius each submitted pre-merger notification filings to the FTC and Department of Justice, Antitrust Division. On October 18, 2017, we and Fresenius each received a Request for Additional Information and Documentary Material (also known as a Second Request) from the FTC. The effect of the Second Request is to extend the waiting period imposed by the HSR Act until 30 days after Fresenius and we have substantially complied with the Second Request, unless that period is terminated sooner by the FTC. By agreement with the FTC, the parties may voluntarily extend the time for closing beyond the expiration of the HSR Act waiting period. The parties continue to work to obtain FTC approval of the proposed transaction. On October 27, 2017, the stockholders of NxStage Medical, Inc. voted to approve the Merger Agreement. In addition, the Merger has cleared antitrust review in Germany and the UK. See “Risk Factors” in Part I Item 1A of our 2017 Annual Report for additional information.

The Merger Agreement may be terminated by us or Fresenius if the Merger is not closed by August 7, 2018 (the End Date), although Fresenius may extend the End Date for up to 180 days under certain circumstances in order to obtain required antitrust clearances. The Merger Agreement generally requires each party to use its reasonable best efforts to obtain all consents and clearances required under any antitrust law, except that Fresenius is not required (i) to litigate against a governmental entity or (ii) to divest or to take any other actions with respect to any assets or business of Fresenius, its subsidiaries or the Company, other than, if necessary to obtain antitrust clearances, with respect to certain Company assets.

Fresenius is required to pay us a termination fee of $100 million (the Reverse Termination Fee) if the Merger Agreement is terminated by us or Fresenius (i) if the End Date and any applicable extension has passed or (ii) if a court or other governmental entity issues a final, nonappealable order or takes any other actions that permanently prohibits the Merger or makes closing the Merger illegal (in each case because approval under applicable antitrust laws remains the only unsatisfied closing condition).

We would be required to pay Fresenius a termination fee of $60 million (the Termination Fee) if all of the following conditions were applicable: (i) the Merger Agreement is terminated because the End Date has passed or we have breached a

representation or warranty, (ii) an alternative acquisition proposal has been publicly made and not publicly withdrawn at least ten days prior to the termination, and (iii) within 12 months following such termination, we enter into an alternative acquisition agreement or an alternative acquisition is consummated. Nonetheless, we will not be required to pay the Termination Fee if the Merger Agreement is terminated due to failure to obtain required antitrust approvals by the End Date and Fresenius is required to pay the Reverse Termination Fee.

The Merger Agreement includes customary representations, warranties and covenants. Pursuant to the Merger Agreement, we agreed to use commercially reasonable efforts to operate our business in all material respects in the ordinary course until closing.

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2018 and December 31, 2017 and for the three months ended March 31, 2018 and 2017, 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, 2017 (2017 Annual Report) and updated, as necessary, in this Quarterly Report on Form 10-Q (Quarterly Report). Operating results for any interim period are not necessarily indicative of results for the entire year or future periods. The December 31, 2017 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 footnotes thereto included in our 2017 Annual Report.

We adopted Accounting Standards Update (ASU) No. 2014-9: “Revenue from Contracts with Customers” (ASC 606) with a date of initial application of January 1, 2018. We applied ASC 606 using the cumulative effect method, i.e., by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under ASC 605. The details of the significant changes and quantitative impact of the changes are outlined in Note 2.

The preparation of our condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Such financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair presentation of the results of the periods presented. All such adjustments are of a normal recurring nature.

Principles of Consolidation

Our condensed consolidated financial statements include the accounts of NxStage Medical, Inc. and our wholly-owned subsidiaries and other entities in which we maintain a majority voting interests or for which we maintain effective control, including variable interest entities ("VIEs") for which we are deemed the primary beneficiary. All significant intercompany balances and transactions have been eliminated. Noncontrolling interests represent the proportionate equity interests in the consolidated entities that are not wholly owned by us. Noncontrolling interests of acquired entities are recognized at their initial fair value.

2. Summary of Significant Accounting Policies

Revenue Recognition

We recognize revenue from product sales and services when earned through fulfillment of our performance obligations. The amount of revenue recognized is based on the total consideration that we ultimately expect to collect relative to the good or service provided.

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

Any tax assessed by a governmental authority that is incurred as a result of a revenue transaction (e.g. sales tax) is excluded from revenues and reported on a net basis. In general, we do not have any significant extended payment terms as payment is received at or shortly after the point of sale. The expected costs associated with our standard product warranties continue to be recognized as expense when the products are sold. When shipping and handling activities are performed after the

transfer of control to the customer (e.g., when control transfers prior to delivery), they are considered as fulfillment activities, and accordingly, the costs are accrued for when the related revenue is recognized.

System One Segment

We derive revenue in the home market primarily from sales of the System One hardware and sales of disposable products.

We enter into arrangements with customers that may include multiple elements including equipment lease transactions pursuant to the depot service model described below or equipment sales with no post-delivery obligations other than standard warranty obligations, disposable product sales and services. The transaction price is allocated to the elements including allocation to the lease and non-lease elements of the arrangement, where applicable, based on their relative standalone selling price and recognized pursuant to the applicable guidance.

System One hardware sales to dialysis clinic customers in the home market are made under the depot service model whereby equipment requiring service is picked up and a replacement device is shipped to the site of care. Accordingly, we recognize upfront fees received from equipment transactions as revenue on a straight-line basis over the term of our remaining service obligation, which generally range between 5 and 7 years, and direct costs relating to the delivered equipment are classified in deferred cost of revenues and amortized over the same expected period as the related revenue. Disposable products sales are recognized in accordance with the contract terms.

We also offer a month-to-month System One hardware rental arrangements. Under these arrangements, revenue is recognized on a monthly basis in accordance with agreed upon arrangements with the customers.

Our sales arrangements with our international distributors are structured as direct product sales and have no significant post-delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms.

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

Some of our contracts with customers in the System One segment contain contractually determined volume discounts offered to similar classes of customers. In addition, in many agreements we offer rebates and discounts for early payment which result in the ultimate payment being variable. The variable consideration paid by the customer is estimated and recognized when we satisfy our performance obligation (generally upon delivery) to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized to date will not occur. We are able to reliably estimate the amount of rebates and discounts and record them as a reduction to revenue and accounts receivable at the time of sale.

In-Center Segment

Our In-Center segment sales are structured as direct product sales primarily through distributors, and we have no significant post-delivery obligations with the exception of standard warranty obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms.

Some of our distribution contracts for the In-Center segment contain rebates and discounts for early payment which results in the ultimate payment being variable. The variable fee paid by the distributor is estimated and recognized when we satisfy our performance obligation (generally upon delivery to the distributor) to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized to date will not occur. We are able to reliably estimate the amount of rebates/discounts and record them as a reduction to revenue and trade accounts receivable at the time of sale.

Services Segment

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

Revenues are recognized in the period in which services are provided. For revenues associated with Medicare, Medicaid or commercial insurers with which we have formal agreements, revenue is recognized based on contractual rates or rates established by statute or regulation in the case of Medicare and Medicaid. For certain classes of payors, for example non-contracted commercial health insurance payors and amounts due from patients (including co-pay and deductible amounts), revenue is recognized based on our estimate of the consideration that will be ultimately received from the payor which results

in the ultimate payment being variable. The variable fee is estimated using historical collections experience with similar classes of payors and recognized when we satisfy our performance obligation (when services are provided) to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized to date will not occur. Overall, these estimates reflect the Company's best estimates of the amount of consideration to which it is entitled from these customers. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect revenues and earnings in the period such variances become known. Such changes, if material, will be disclosed in the period such variances become known.

Other

Other revenues relate to the manufacturing of dialyzers for sale to Asahi Kasei Kuraray Medical Co. (Asahi). Sales to Asahi are structured as direct product sales and we have no significant post-delivery obligations. Revenue from direct product sales is recognized upon delivery in accordance with contract terms.

Costs to Obtain or Fulfill a Contract

We capitalize commission fees as costs of obtaining a contract, when they are incremental and if they are expected to be recovered, and amortize them consistently with the pattern of transfer of the good to which the asset relates. If the expected amortization period is one year or less, the commission fee is expensed when incurred.

Direct costs related to the delivered equipment within the System One home market are capitalized as deferred cost of revenues and amortized over the same expected period as the related revenue.

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. No customer represented more than 10% of accounts receivable at March 31, 2018 or December 31, 2017.

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, 2017	$	293
Provision		72
Usage		(114)
Balance at March 31, 2018	$	251

Intangibles and Other Long-Lived Assets

Intangible assets are carried at cost less accumulated amortization. For assets with determinable useful lives, amortization is recognized using the straight-line method over the estimated economic lives of the respective intangible assets. Long-lived assets, including intangible assets, are evaluated for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. Recoverability of long-lived assets is assessed at the lowest level for which discrete cash flows are available and is measured by comparing the asset group's carrying value to its expected non-discounted future cash flows. If the sum of the expected non-discounted future cash flows is less than the carrying amount of the long-lived assets, an impairment loss is recognized for excess of the carrying amount of the asset group over its fair value.

In 2018, events and circumstances have indicated that certain long-lived tangible assets in the Services segment may not be recoverable. Therefore, a recoverability test was performed at the center level by comparing the carrying value of each center to its estimated future undiscounted cash flows, within the initial lease term (which is the equivalent to the depreciable life of the centers' most significant asset, its leasehold improvements). As of March 31, 2018, our expected non-discounted future cash flows for the majority of our centers indicated such carrying amounts were expected to be recovered. No impairment charge was recognized during the first quarter of 2018.

Our expected non-discounted future cash flows used in our impairment testing are based upon cash flow projections and, if appropriate, include assumed proceeds upon sale of the asset group at the end of the cash flow period. We believe our procedures for developing cash flow projections, including the estimated sales proceeds, are reasonable and consistent with current market conditions for each of the dates when impairment testing has been performed.

Developing cash flow projections requires significant estimates and judgment. Among other things, slower than expected patient ramp or lower than expected reimbursement rates would negatively impact our cash flow projections in the near term. Fair value of the asset group was estimated using a discounted cash flow approach. Estimating fair value requires significant judgment in the selection of the valuation technique and assumptions used in developing cash flow projections, growth rates and discount rates. Our assumptions are based on our best estimates, using appropriate and customary market participant assumptions. Any adverse changes in certain valuation assumptions could result in the need to record additional impairment to write down all or a portion the centers' remaining asset carrying value.

We had $12.8 million of long-lived assets at our Services segment at March 31, 2018. It is reasonably possible that our cash flow projections may change in the near term resulting in the need to record an impairment charge for at least some portion of these assets.

Goodwill

We test goodwill for impairment during the fourth quarter, or more frequently when events or changes in circumstances indicate that the goodwill might be impaired. This test includes first a qualitative assessment and then, if necessary, a quantitative assessment to determine if the fair value of a reporting unit is less than its carrying amount. Our System One, In-center and Services reporting units contain goodwill of $41.1 million, $0.5 million and $1.1 million, respectively. Factors considered in the qualitative assessment include, but are not limited to, both macroeconomic conditions and entity-specific conditions. For the quantitative assessment the reporting unit's fair value is estimated using a discounted cash flow or other fair value measurement.

During 2017 and 2016 we utilized the qualitative assessment to assess the fair value of our System One and In-center reporting units and concluded that it was more likely than not that the fair value of our reporting units was greater than their carrying value. During 2016, for our Services reporting unit, we utilized the quantitative assessment noting that the fair value of the reporting unit exceeds its carrying value, indicating that goodwill was not impaired. We estimated the fair value of our Services reporting unit using a discounted cash flow approach. Estimating the fair value of our Services reporting unit requires significant judgment in the selection of the valuation technique and assumptions used in cash flow projections, growth rates and discount rates. Our assumptions are based on our best estimates, using appropriate and customary market participant assumptions.

There have been no events or changes in circumstances since the date of our last goodwill impairment tests that would indicate it is more likely than not that the fair value of our reporting units is less than their carry value. Developing cash flow projections involves significant judgment with respect to patient additions and reimbursement rates, operating income, capital expenditures and changes in working capital. Reductions in our cash flow projections due to slower than expected patient ramp or lower than expected reimbursement rates, among other things, or adverse changes in certain valuation assumptions or changes in the reporting units net assets could result in a goodwill impairment charge of up to $1.1 million in our Services reporting unit in the future.

Recent Accounting Pronouncements

Recently Implemented Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-9: "Revenue from Contracts with Customers" (ASC 606). The standard provides that revenue should be recognized when an entity 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. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenues and cash flow arising from contracts with customers. The FASB has issued several amendments and updates to the new revenue standard, including how an entity should identify performance obligations. As amended, the new guidance was effective for us beginning January 1, 2018. We adopted ASC 606 using the modified retrospective method approach as of January 1, 2018. This approach was applied to all contracts not completed as of January 1, 2018.

We recognized the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods. See above in Note 2 for discussion of our updated Revenue Recognition policy.

We do not expect the adoption of the new revenue standard to have a material impact to our net income on an ongoing basis. The adoption of ASC 606 impacted the timing of revenue recognition for our Services segment and resulted in enhanced footnote disclosures related to customer contracts as included in Note 3 to these condensed consolidated financial statements. It also modified the accounting for commissions fees as it requires such incremental and recoverable costs to be capitalized and amortized over the estimated life of the asset. Previously, these costs were expensed as incurred.

The cumulative effect of the changes made to our condensed consolidated balance sheet for the adoption of ASC 606 was as follows (in thousands):

	As Reported December 31, 2017	Adjustment due to ASC 606	January 1, 2018
ASSETS			
Accounts receivable, net	$ 31,625	$ 4,553	$ 36,178
Prepaid expenses and other current assets	7,609	1,895	9,504
Deferred cost of revenues	31,410	(139)	31,271
Other assets	5,911	379	6,290
LIABILITIES AND STOCKHOLDERS' EQUITY			
Noncontrolling interests subject to put provisions	(165)	51	(114)
Accumulated deficit	(421,593)	6,070	(415,523)
Noncontrolling interests not subject to put provisions	(12)	567	555

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on our condensed consolidated statement of comprehensive loss for the three months ended March 31, 2018 was as follows (in thousands):

	Three Months Ended March 31, 2018		
	As Reported	Balance without adoption of ASC 606	Effect of Change
Revenue	$ 107,298	$ 108,434	$ (1,136)
Cost of revenues	61,133	61,194	(61)
Selling and marketing	18,055	18,155	(100)

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on our condensed consolidated balance sheet at March 31, 2018 was as follows (in thousands):

	March 31, 2018		
ASSETS	As Reported	Balance without adoption of ASC 606	Effect of Change
Accounts receivable, net	$ 38,689	$ 35,288	$ 3,401
Prepaid expenses and other current assets	9,795	7,801	1,994
Deferred cost of revenues	31,568	31,645	(77)
Other assets	6,360	5,981	379
LIABILITIES AND STOCKHOLDERS' EQUITY			
Noncontrolling interests subject to put provisions	$ (171)	$ (171)	$ —
Accumulated deficit	(416,982)	(422,699)	5,717
Noncontrolling interests not subject to put provisions	273	295	(22)
Accumulated other comprehensive loss	(2,514)	(2,516)	2

The impacts noted above are primarily attributable to the change in the timing of revenue recognition for our Services segment as the standard requires revenues to be estimated and recognized upon transfer of the promised goods and services and accounting for capitalization of certain commissions.

In January 2016, the FASB issued ASU No. 2016-01: "Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" which impacts the recognition, measurement, presentation and disclosure of financial assets and financial liabilities. Among other things, the standard generally requires all equity investments (except those accounted for under the equity method and those that result in consolidation of the investee) be measured at fair value through earnings. For those equity instruments that do not have readily determinable fair values, the standard permits the application of a measurement alternative using the cost of the investment, less any impairments, plus or minus changes resulting from observable price changes for an identical or similar investment of the same issuer with such changes recognized in net income. The new guidance was effective for us beginning January 1, 2018. We have made this measurement alternative policy election for our equity investments without readily determinable fair values. The adoption of this standard did not have an impact on our financial position or results of operation.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02: "Accounting for Leases" which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than twelve months. For lessees, leases will continue to be classified as either operating or financing in the income statement. This ASU is required to be applied with a modified retrospective approach and requires application of the new standard at the beginning of the earliest comparative period presented. The new guidance is effective for us beginning January 1, 2019 and early adoption is permitted. We intend to adopt this standard as of January 1, 2019. We are currently evaluating the potential impact this standard will have on our financial statements.

In August 2017, the FASB issued ASU 2017-12: "Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities" which amends the hedge accounting recognition and presentation requirements. The update is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting and increase transparency as to the scope and results of hedge programs. The update is effective for us beginning January 1, 2019, with early adoption permitted. We are currently evaluating the potential impact this update will have on our financial statements.

3. Revenues

The following table disaggregates our revenues by market (in thousands):

	Three Months Ended March 31, 2018
System One segment	
Home	$ 58,679
Critical Care	24,208
Total System One segment	82,887
In-Center segment	17,357
Other	2,820
Products subtotal	103,064
Services segment	5,419
Elimination of intersegment revenues	(1,185)
Total	$ 107,298

For the three months ended March 31, 2018, revenue recognized from performance obligations related to prior periods, including changes to variable consideration estimates, was not material.

Capitalized commission fees are amortized consistently with the pattern of transfer of the good to which the asset relates which is approximately 21 months. Capitalized commission fees were $2.1 million and $2.0 million as of March 31, 2018 and January 1, 2018, respectively, and are included in prepaid expenses and other current assets and other assets on our condensed consolidated balance sheet. During the three months ended March 31, 2018, we recorded $0.6 million of amortization expense related to capitalized commissions, which is included in sales and marketing expense, and there was no impairment loss in relation to the costs capitalized.

Long-term deferred revenues primary relate to sales of System One hardware to dialysis clinic customers in the home market made under the depot service model which is deemed to be a lease element of the respective home transactions and, to a lesser extent, deferred revenue related to our Dialyzer Production Agreement with Asahi which is recognized in revenues on a straight-line basis over the expected term of the agreement. Other revenue expected to be recognized in future years related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less and contracts where revenue is recognized as invoiced, is immaterial.

4. Inventory

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

	March 31, 2018	December 31, 2017
Purchased components	$ 15,162	$ 14,947
Work in process	14,849	13,433
Finished goods	22,107	20,832
Total	$ 52,118	$ 49,212

5. Property and Equipment, Field Equipment and Deferred Cost of Revenues

Accumulated depreciation on property and equipment was $60.5 million and $56.8 million at March 31, 2018 and December 31, 2017, respectively. Accumulated depreciation on field equipment was $52.9 million and $51.6 million at March 31, 2018 and December 31, 2017, respectively. Accumulated amortization on deferred costs of revenues was $109.5 million and $106.3 million at March 31, 2018 and December 31, 2017, respectively.

6. Intangible Assets

Accumulated amortization of intangible assets was $27.5 million and $27.0 million at March 31, 2018 and December 31, 2017, respectively.

7. Net Loss per Share

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

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

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	952	1,331
Unvested restricted stock	233	310
Total	1,185	1,641

8. Accrued Expenses, Other Current Liabilities and Other Long-Term Liabilities

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

	March 31, 2018	December 31, 2017
Payroll, compensation and related benefits	$ 12,172	$ 13,195
Distribution expenses	4,199	4,914
Other	9,822	9,876
Total	$ 26,193	$ 27,985

The components of other current liabilities are as follows (in thousands):

	March 31, 2018	December 31, 2017
Capital lease obligations	$ 2,178	$ 2,131
Deferred revenue, current portion	1,571	1,473
Other	967	955
Total	$ 4,716	$ 4,559

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

	March 31, 2018	December 31, 2017
Capital lease obligations	$ 11,702	$ 11,589
Lease incentive obligations	2,779	2,652
Benefit plan obligations	2,161	2,060
Other	1,644	1,523
Total	$ 18,286	$ 17,824

9. Segment Disclosures

We 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 refer to our System One segment, In-Center segment, and Other category as our products business.

Our System One segment includes revenues from sales and rentals of the System One and PureFlow SL dialysate preparation equipment and the sale of disposable products to customers in the home market, including through our NxStage Kidney Care dialysis centers, and critical care market. The home market is devoted to the treatment of ESRD patients in the home or a home-like setting, including skilled nursing facilities, 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.

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.

The remainder of our products business, which is 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.

Our Services segment includes revenues from dialysis services provided to patients at our NxStage Kidney Care dialysis centers. Sales of the System One and related products to our NxStage Kidney Care dialysis centers are included in System One segment revenues, which are then eliminated upon consolidation.

The accounting policies of our reportable segments are described in Note 2 to the consolidated financial statements included in our 2017 Annual Report 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.

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

	System One	In-Center	Other	Services	Intersegment Elimination	Total
Three Months Ended March 31, 2018						
Revenues from external customers	$ 81,702	$ 17,357	$ 2,820	$ 5,419	$ —	$ 107,298
Intersegment revenues	1,185	—	—	—	(1,185)	—
Revenues	82,887	17,357	2,820	5,419	(1,185)	107,298
Segment profit (loss)	21,720	2,299	(19,625)	(5,559)	35	(1,130)
Depreciation and amortization	5,435	488	1,084	1,343	(46)	8,304
Three Months Ended March 31, 2017						
Revenues from external customers	$ 73,274	$ 15,606	$ 2,899	$ 5,050	$ —	$ 96,829
Intersegment revenues	1,387	—	—	—	(1,387)	—
Revenues	74,661	15,606	$ 2,899	5,050	(1,387)	96,829
Segment profit (loss)	19,848	2,359	(18,261)	(5,605)	(22)	(1,681)
Depreciation and amortization	5,634	525	1,072	1,268	(32)	8,467

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

The following table summarizes the number of customers who individually make up greater than ten percent of total revenues:

	Three Months Ended March 31,	
	2018	2017
DaVita	20%	20%
Fresenius	19%	19%

Sales to DaVita HealthCare Partners Inc. (DaVita) and Fresenius Medical Care (Fresenius) are in the System One segment.

10. Commitments and Contingencies

Significant commitments and contingencies at March 31, 2018 are consistent with those discussed in Note 10 to the consolidated financial statements in our 2017 Annual Report.

11. Income Taxes

We recognized a provision for income taxes during the three months ended March 31, 2018 and 2017 related to the profitable operations of certain foreign subsidiaries. However, the provision recognized during both periods includes the impact of an allocation of U.S. tax expense between continuing operations and total other comprehensive (loss) income of $0.1 million and $0.9 million for the three months ended March 31, 2018 and 2017, respectively. This allocation has no impact on total comprehensive loss or total stockholders' equity for 2018. However, it did result in a net tax benefit from income taxes in continuing operations of $0.6 million during the three months ended March 31, 2017.

In accordance with Subject to Staff Accounting Bulletin 118, we recognized provisional tax impacts related to the Tax Cuts and Jobs Act of 2017 (Tax Reform) for the year ended December 31, 2017. Specifically, we remeasured our tax assets at December 31, 2017 based on the new Federal income tax rate of 21%. No additional adjustments were recorded in the current quarter. We are still in the process of completing our evaluation of the impact of the Tax Reform on our financial statements. We will continue to make and refine our calculations as additional analysis is completed and gain a more thorough understanding of the Tax Reform.

As of March 31, 2018, we had a liability for unrecognized tax benefits included in the balance sheet of approximately $0.9 million, including a nominal accrual for interest and penalties of less than $0.1 million. There have been no significant changes to these amounts during the three months ended March 31, 2018.

12. Stock-Based Compensation

Stock-based Compensation Expense

The following table presents stock-based compensation expense included in our condensed consolidated statements of comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2018	2017
Cost of revenues	$ 251	$ 304
Selling and marketing	827	856
Research and development	382	383
General and administrative	1,237	1,031
Total	$ 2,697	$ 2,574

Stock Options and Restricted Stock Units

The Company granted no new options during the three months ended March 31, 2018. The Company granted options to purchase 537,448 shares of common stock during the three months ended March 31, 2017 which vest based on continued employment over a period of one to four years. The weighted-average fair value of options granted during the three months ended March 31, 2017 was $10.02 per option.

The Company awarded no new restricted stock units during the three months ended March 31, 2018. The Company awarded 133,188 restricted stock units during the three months ended March 31, 2017, which vest based on continued employment over a period of three to four years. The weighted-average fair value of these restricted stock units awarded during the three months ended March 31, 2017 was $27.76 per unit.

13. Stockholders' Equity

We received 28,039 and 81,280 shares of common stock that were surrendered in payment for the exercise of stock options during the three months ended March 31, 2018 and 2017, respectively.

14. Noncontrolling Interest

As of March 31, 2018, we have 5 VIEs included in our consolidated financial statements all of which are NxStage Kidney Care dialysis centers. We are the managing member or we have a majority seat on the entity's board of managers, manage these entities through a management services agreement.

The analysis upon which these consolidation determinations rest are complex, involve uncertainties, and require significant judgment on various matters. At March 31, 2018 and December 31, 2017, total assets of our VIEs were $6.7 million and $5.6 million, and total liabilities and noncontrolling interests of our VIEs were $6.6 million and $5.8 million, respectively.

We have potential obligations to purchase the noncontrolling interests held by third parties in certain of our consolidated subsidiaries. These obligations are in the form of put provisions and are contingently exercisable at the third-party owners' discretion given specific facts and circumstances as outlined in each specific put provision. If these put provisions were exercised, we would be required to purchase all the third-party owners' noncontrolling interests at a fair value at the time of exercise pursuant to the terms of the agreement. At March 31, 2018 the Company's noncontrolling interests subject to put provisions were $(0.2) million and none of the rights were exercisable.

The following table sets forth the changes in noncontrolling interest not subject to put provisions for the three months ended March 31, 2018 and 2017 (in thousands):

	Three Months Ended March 31,	
	2018	2017
Balance at beginning of period	$ (12)	$ 625
Adjustment due to adoption of ASC 606	567	—
Net loss attributable to noncontrolling interest in consolidated subsidiary	(282)	(328)
Balance at end of period	$ 273	$ 297

15. Derivative Instruments and Hedging

We operate manufacturing and service facilities in Mexico, Germany, and Italy, and we purchase materials and pay our employees at those facilities in pesos and euros, and as such, we are potentially exposed to adverse as well as beneficial movements in currency exchange rates. We enter into foreign exchange forward contracts to minimize the impact of currency exchange rate fluctuations on these peso and euro denominated expenses. These contracts have durations 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 March 31, 2018 and December 31, 2017, the notional amount of our outstanding contracts that are designated as cash flow hedges was $25.8 million and $24.1 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. The fair value of these contracts was a net asset of $0.7 million at March 31, 2018 and a net asset of less than $0.1 million at December 31, 2017, respectively. The cash flows related to our currency exchange contracts are classified as operating cash flows, which is consistent with the cash flow treatment of the underlying items being hedged.

Gains or losses related to hedge ineffectiveness recognized in earnings were not material during the three months ended March 31, 2018 and 2017. 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.

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 March 31, 2018			
Foreign exchange forward contracts	$ 1,355	$ 554	Cost of revenues
Three Months Ended March 31, 2017			
Foreign exchange forward contracts	$ 2,532	$ (601)	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, as of December 31, 2017	$ (1,284)	$ (2,389)	$ (3,673)
Other comprehensive income before reclassifications, net of $340 tax during 2018	1,015	698	1,713
Gain reclassified to earnings (1)	(554)	—	(554)
Total other comprehensive income, net of tax	461	698	1,159
Balance, net of tax, as of March 31, 2018	$ (823)	$ (1,691)	$ (2,514)

(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, *Derivative Instruments and Hedging* for further information.

(2) Other includes cumulative translation adjustments and, to a lesser extent, 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.

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.

We did not have any transfers between Level 1 and Level 2 and Level 3 during the three months ended March 31, 2018.

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

March 31, 2018	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)	$ 35,120	$ —	$ —	$ 35,120
Foreign exchange forward contracts (2)	—	813	—	813
Liabilities				
Foreign exchange forward contracts (2)	$ —	$ 96	$ —	$ 96

December 31, 2017	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)	$ 35,020	$ —	$ —	$ 35,020
Foreign exchange forward contracts (2)	—	690	—	690
Liabilities				
Foreign exchange forward contracts (2)	$ —	$ 661	$ —	$ 661

(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.

The carrying amount of our long-term debt approximates fair value at March 31, 2018 and December 31, 2017. 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.

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

At March 31, 2018 and December 31, 2017, we had an equity instrument without readily determinable fair values of $2.5 million for which we have elected the measurement alternative. We have evaluated this investment for any impairment, as well as any observable price changes for an identical or similar equity instrument of the same issuer, and determined that no material adjustment in the carrying value was required for the three months ended March 31, 2018.

18. Supplemental Cash Flow Information

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

	Three Months Ended March 31,	
	2018	2017
Noncash Investing and Financing Activities:		
Transfers from inventory to field equipment	$ 4,187	$ 5,903
Transfers from field equipment to deferred cost of revenues	3,423	2,313
Market value of shares received in payment for exercise of stock options	674	2,295
PP&E financed by construction liability	58	109

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

Cautionary 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, 2017, included in our 2017 Annual Report.

This Quarterly Report and certain information incorporated by reference herein contain forward-looking statements concerning our business, operations and financial condition, including statements with respect to:

- the growth of our business and the drivers of such growth;
- the ability of enhancements to our product portfolio to help us expand existing markets and enter new ones;
- achieving greater operating leverage and improved financial results in the future;
- estimates of the number of end-stage renal disease (ESRD) patients that could be treated at home with the System One;
- patients' access to home and more frequent hemodialysis;
- sales to our key customers, including DaVita HealthCare Partners Inc. and Fresenius Medical Care;
- the adequacy of our funding;
- expectations with respect to future demand for our products and revenue growth, with components of such revenue growth including sales of disposable products;
- future financial results for our System One, In-Center and Services segments, Other revenues and total company;
- expectation of sustaining gross profit as a percentage of revenue in our System One segment above 50% and the underlying elements of such objective;
- future selling and marketing, research and development, distribution, and general and administrative expenses and the drivers for such expenses;
- our manufacturing operations and supply chain; the scope, timing and impact of our research and development efforts;
- expectations with respect to our working capital levels and requirements;
- availability of credit under our revolving credit facility;
- global economic conditions;
- impact of the adoption of new accounting standards and the Tax Cuts and Jobs Act of 2017 (Tax Reform);
- the availability of, and impact of changes in, reimbursement for home and more frequent hemodialysis, and the expected impact of draft local coverage determinations on reimbursement for more frequent hemodialysis in the United States;
- the anticipated timing and likelihood of completion of our proposed merger of us with a subsidiary of Fresenius (Merger);
- disruptions to our business operations due to the pendency of the proposed Merger;
- anticipated benefits of manufacturing dialyzers for sale to Asahi Kasei Kuraray Medical Co. (Asahi) and future sales to Asahi;
- our ability to withstand supply chain disruptions;
- the scope and adequacy of patent protection with respect to our products; and
- the financial, commercial and operational impact of any of the above.

All statements other than statements of historical facts included in this Quarterly Report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this Quarterly Report, the words "expect", "anticipate", "intend", "plan", "believe", "seek", "estimate", "potential", "continue", "predict", "may", "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements.

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 caution investors not to view forward-looking statements as guarantees of future outcomes. We undertake no obligation to revise or update publicly any forward-looking statement.

Introduction

We are a medical technology company that develops, manufactures, markets and provides innovative products and services for patients suffering from chronic or acute kidney failure. Since our initial public offering in 2005, we have built a strong business that we believe serves as a solid foundation for future growth. As a leader in home hemodialysis, we remain committed to not only growing this and our other existing markets, but also expanding to new markets, including skilled

nursing facilities, where we believe our current and future technology has the ability to deliver value for both patients and our customers.

We report our operating results through three segments: System One, In-Center and Services. We sell our products in and provide our services in three markets: home, critical care and in-center. Our other business activities excluded from segment operating performance measures are reported in an Other category. The operating results of our dialysis centers business, which we refer to as NxStage Kidney Care, are included in our Services segment. Sales of our System One and related products to our NxStage Kidney Care dialysis centers are included in System One segment home market revenues, which are then eliminated upon consolidation. For convenience, we use the term "products business" to refer collectively to our System One segment, In-Center segment, and Other category.

On August 7, 2017, we entered into a definitive Merger Agreement, pursuant to which we will merge with a wholly-owned subsidiary of Fresenius, subject to the conditions set forth therein. See "Risk Factors" in Part II Item 1A of this Quarterly Report and Note 1, "Nature of Operations, Proposed Merger, Basis of Presentation and Principles of Consolidation" to the unaudited condensed consolidated financial statements contained herein for additional information. We have incurred $1.4 million of incremental costs for the three months then ended March 31, 2018 for professional service fees and costs related to the performance based restricted stock unit awards being deemed earned pursuant to the terms of the Merger Agreement. The majority of these expenses have been recorded as general and administrative costs in our condensed consolidated statement of comprehensive loss.

Segment and Market Highlights

Our customers in the System One segment are highly consolidated. DaVita and Fresenius own and operate the two largest chains of dialysis clinics in the U.S. and are our two largest customers for products used in the home. Collectively, they provide treatment to more than two-thirds of U.S. dialysis patients and a similar portion of our home patients, and account for the majority of our System One segment revenues. Increased sales to DaVita and Fresenius have driven a large portion of our historical revenue growth and will be important to future growth. Our home market customer agreements with DaVita and Fresenius 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 contain no minimum purchase volumes. Our home agreement with DaVita extends through December 31, 2018, with monthly renewals thereafter unless terminated by either party with 30 days' prior notice. Our home agreement with Fresenius continues to renew on a monthly basis unless we and Fresenius choose to modify the terms with an amendment or new agreement.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Henry Schein, Inc., accounted for 22% and 23% of our In-Center segment revenues for the three months ended March 31, 2018 and 2017, respectively. B. Braun Medical, Inc. accounted for 26% and 21% of our In-Center segment revenues for the three months ended March 31, 2018 and 2017, respectively. Gambro AB (a subsidiary of Baxter International, Inc.) accounted for 21% and 21% of our In-Center segment revenues for the three months ended March 31, 2018 and 2017, respectively, with all of Gambro's sales of our products being to DaVita.

We offer certain distributors rebates based on sales to specific end users. Our revenues are presented net of these rebates. For our System One segment, as of March 31, 2018, we had $2.9 million reserved against trade accounts receivable for future distributor rebates and recorded $4.9 million and $4.0 million during the three months ended March 31, 2018 and 2017, respectively, as a reduction of revenues in connection with distributor rebates. For the In-Center segment, as of March 31, 2018, we had $2.3 million reserved against trade accounts receivable for future estimated distributor rebates and recorded $1.9 million and $1.4 million during the three months ended March 31, 2018 and 2017, respectively, as a reduction of revenues in connection with distributor rebates.

Our Services segment includes revenues from dialysis services provided to patients at our NxStage Kidney Care dialysis centers. As of March 31, 2018 we have 21 centers operating in 13 states. At these centers, we provide patients with a range of therapy options to address their clinical and lifestyle needs. For appropriate patients, such therapies may include home hemodialysis, flexible in-center hemodialysis and peritoneal dialysis.

We adopted ASC 606 with a date of initial application of January 1, 2018. As a result, we changed our accounting policy for revenue recognition as detailed in Note 2. We applied ASC 606 using the cumulative effect method, i.e., by recognizing the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under ASC 605. The details of the significant changes and quantitative impact of the changes are outlined in Note 2.

Financial Performance

The following table summarizes our consolidated results (in thousands, except percentages):

	Three Months Ended March 31,	
	2018	2017
Products Business (System One Segment, In-Center Segment & Other)		
Revenues	$ 103,064	$ 93,166
Gross profit	$ 49,729	$ 44,650
Gross margin percentage	48%	48%
Income from operations	$ 4,394	$ 3,946
Services Segment		
Revenues	$ 5,419	$ 5,050
Gross profit	$ (3,599)	$ (3,438)
Gross margin percentage	n/a	n/a
Loss from operations	$ (5,559)	$ (5,605)
Eliminations		
Elimination of intersegment revenues	$ (1,185)	$ (1,387)
Elimination of intersegment gross profit	$ 35	$ (22)
Total Company		
Revenues	$ 107,298	$ 96,829
Gross profit	$ 46,165	$ 41,190
Gross margin percentage	43%	43%
Loss from operations	$ (1,130)	$ (1,681)

For several years, we have focused on operating and financial improvements. During the three months ended March 31, 2018 these efforts resulted in revenues increasing by 11% to $107.3 million versus the prior year comparable periods with sales in the home and critical care markets principally driving the growth. Driving continued improvements will remain an area of focus in 2018 and beyond within our products business. At the same time, we expect operating losses in our Services segment to have a negative impact, along with costs related to the proposed merger, on our total operating performance in the near term.

Comparison of the Three Months Ended March 31, 2018 and 2017

Revenues

Our revenues for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
System One segment				
Home	$ 58,679	55 %	$ 54,561	56 %
Critical Care	24,208	22 %	20,100	21 %
Total System One segment	82,887	77 %	74,661	77 %
In-Center segment	17,357	16 %	15,606	16 %
Other	2,820	3 %	2,899	3 %
Products subtotal	103,064	96 %	93,166	96 %
Services segment	5,419	5 %	5,050	5 %
Elimination of intersegment revenues	(1,185)	(1)%	(1,387)	(1)%
Total	$ 107,298	100 %	$ 96,829	100 %

Home product revenues increased $4.1 million, or 8% for the three months ended March 31, 2018 versus the prior year comparable period, driven primarily by the increase in the number of patients prescribed to use the System One both in the U.S. and internationally coupled with contractual price improvements. 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. We further expect that our System One segment revenues will be susceptible to fluctuations in equipment sales, changes in purchasing patterns and subsequent inventory levels at our international distributors and changes in currency exchange rates.

Critical Care product revenues increased $4.1 million, or 20% during the three months ended March 31, 2018 versus the prior year comparable period driven by higher sales of System One consumables. We expect future demand for our products and revenue growth to be strong as we seek to further penetrate this market and leverage the annuity nature of our business. However, sales of our System One equipment in critical care may fluctuate due to timing of sales and the overall capital spending environment of our customers.

In-Center segment revenues increased $1.8 million, or 11% for the three months ended March 31, 2018, versus the prior year comparable period. The overall increase is attributable to increased sales of our blood tubing sets. We expect In-Center segment revenues will increase modestly but may fluctuate due to inventory management policies at both our distributors and end users.

Other revenues for the three months ended March 31, 2018 and 2017 relate to dialyzers sold to Asahi. The fluctuation in revenues was due to changes in volume. Sales to Asahi are expected to decline in 2018 due to lower volume.

Service segment revenues for the three months ended March 31, 2018 and 2017 relate to dialysis services provided to patients at our NxStage Kidney Care dialysis centers. We expect Service segment revenues to increase modestly, but may fluctuate in the near term based on payor mix. Effective January 1, 2018, we adopted the new revenue recognition guidance under ASC 606. This resulted in a change to the timing of revenue recognition for our Services segment as the standard requires revenues to be estimated and recognized upon transfer of the promised goods and services. Please refer to Note 2 to the accompanying financial statements for further discussion of the impact of our adoption of ASC 606.

Gross Profit (Loss)

Our gross profit (loss) for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
System One segment	$ 44,993	54%	$ 39,833	53%
In-Center segment	4,463	26%	4,620	30%
Subtotal	49,456	49%	44,453	49%
Other	273	n/a	197	n/a
Products subtotal	$ 49,729	48%	$ 44,650	48%
Services segment	(3,599)	n/a	(3,438)	n/a
Elimination of intersegment gross profit	35	n/a	(22)	n/a
Gross profit	$ 46,165	43%	$ 41,190	43%

Gross profit as a percentage of revenues for the System One segment improved versus the prior year comparable period primarily driven by contractual price improvements, currency exchange rates and product mix, offset in part by increased costs. We expect to sustain gross profit as a percentage of revenues in our System One segment above 50% as we continue to work to lower costs through process improvements, increase volume and improve our manufacturing operations in order to offset potential increases in material costs and labor rates.

Gross profit as a percentage of revenues for the In-Center segment decreased for the three months ended March 31, 2018, versus the prior year comparable period, driven primarily by changes in product mix and pricing offset by favorable currency exchange rates. We expect gross profit as a percentage of revenues will fluctuate as a result of competitive pricing pressures and changes in product mix.

The Other category relates to costs associated with the manufacturing of dialyzers for sale to Asahi, which have provided us with long term cost efficiencies through increased dialyzer production volumes.

The negative gross profit as a percentage of revenues incurred by our Services segment was driven by costs associated with continued support of our NxStage Kidney Care dialysis centers, many of which are not at scale. We expect the Services segment gross margin will continue to be negative in 2018.

In aggregate, we expect total company gross profit as a percentage of revenues will continue to be negatively impacted by projected losses from our Services segment in 2018.

Selling and Marketing

Our selling and marketing expenses and selling and marketing expenses as a percentage of revenues for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
System One segment	$ 14,457	17%	$ 12,713	17%
In-Center segment	1,638	9%	1,890	12%
Products subtotal	16,095	16%	14,603	16%
Services segment	1,960	36%	2,167	43%
Total Selling and marketing	$ 18,055	17%	$ 16,770	17%

Selling and marketing expenses increased $1.3 million, or 8% for the three months ended March 31, 2018 versus the prior year comparable period, but remained relatively consistent as a percentage of revenues.

Selling and marketing expenses for the System One segment increased due to increased personnel and personnel-related costs. Selling and marketing for the In-Center segment decreased due to decreased personnel and personnel-related costs.

Selling and marketing expenses for our Services segment decreased $0.2 million, or 10% for the three months ended March 31, 2018, versus the prior year comparable period. The decrease was driven by decreased personnel and personnel related costs. These expenses include the personnel and other costs associated with our market development activities to establish, develop and operate our NxStage Kidney Care dialysis centers, including administrative support functions directly related to the support of this initiative.

In aggregate, we anticipate that selling and marketing expenses will continue to increase but remain relatively consistent as a percentage of revenues in the near term.

Research and Development

Our research and development expenses for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
Research and development	$ 9,438	9%	$ 9,508	10%

Research and development expenses remained consistent for the three months ended March 31, 2018 versus the prior year comparable period.

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

Distribution

Our distribution expenses for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
System One segment	$ 8,816	11%	$ 7,272	10%
In-Center segment	526	3%	371	2%
Total Distribution	$ 9,342	9%	$ 7,643	8%

Distribution expenses increased $1.7 million, or 22% for the three months ended March 31, 2018 versus the prior year comparable period, driven primary by higher shipment volumes in the System One segment. Distribution expenses for the three months ended March 31, 2018 included costs associated with a consumable product quality issue and related expedited shipments. We expect that distribution expenses will remain consistent as a percentage of revenues at least in the near term.

General and Administrative

Our general and administrative expenses for the three months ended March 31, 2018 and 2017 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended March 31,			
	2018		2017	
General and administrative	$ 10,460	10%	$ 8,950	9%

General and administrative expenses increased by $1.5 million, or 17% for the three months ended March 31, 2018 versus the prior year comparable period. The increase was primarily due to professional service fees and other costs incurred in connection with the proposed merger. We recognized $1.1 million of expenses incurred in connection with the proposed merger during the three months ended March 31, 2018. We expect general and administrative expenses as a percentage of revenues will increase in 2018 compared to prior periods, driven by costs associated with the proposed merger.

Other Expense

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

Other expense, net includes foreign currency gains and losses.

Provision for Income Taxes

We recognized a provision for income taxes during the three months ended March 31, 2018 and 2017 related to the profitable operations of certain foreign subsidiaries. However, the provision recognized during both periods includes the impact of an allocation of U.S. tax expense between continuing operations and total other comprehensive (loss) income of $0.1 million and $0.9 million for the three months ended March 31, 2018 and 2017, respectively. This allocation has no impact on total comprehensive loss or total stockholders' equity for 2018. However, it did result in a net tax benefit from income taxes in continuing operations of $0.6 million during the three months ended March 31, 2017.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of March 31, 2018, our accumulated deficit was $417.0 million and we had cash and cash equivalents of $62.6 million, with substantially all of that cash located in the U.S., and working capital of $116.8 million.

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, 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 support of our existing NxStage Kidney Care dialysis centers, which have continued to experience operating losses, in aggregate.

Our ongoing cash requirements include funding normal working capital needs including inventory and field equipment assets as well as funding the losses from our NxStage Kidney Care dialysis centers. Field equipment assets include System One equipment rented to customers under our month-to-month rental program and our "service pool" of equipment, which is equipment owned and maintained by us that is swapped for equipment at our home market customers, including patient homes, that needs repair or maintenance. While a majority of System One equipment sold in the home market is paid for upfront by our customers versus on a monthly basis, any excess rental or service swap equipment would increase our working capital requirements.

We have a revolving credit facility with Capital One Financial Corporation and Silicon Valley Bank that allows for borrowing up to $35 million and expires in June 2019. Availability of credit is subject to a borrowing base that is calculated with reference to certain of our accounts receivable, inventory and equipment, and adjustments to such borrowing base are at the discretion of the lenders. The revolving credit facility requires that we comply with certain covenants while borrowings are outstanding, contains events of default customary for an agreement of this type and is secured by substantially all of our assets. As of March 31, 2018, there were no outstanding borrowings under the revolving credit facility, we were in compliance with all applicable covenants and, subject to the lenders' adjustments described above and any restrictions pursuant to the Merger Agreement, we had approximately $32 million of credit commitment available for borrowing.

We maintain post-employment 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 $2.2 million at March 31, 2018 for costs associated with these plans. The expense recorded in connection with these plans was not significant during the three months ended March 31, 2018 or 2017.

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

	Three Months Ended March 31,	
	2018	2017
Net cash used in operating activities	$ (869)	$ (7,294)
Net cash used in investing activities	(1,092)	(1,605)
Net cash (used in) provided by financing activities	(681)	4,329
Foreign exchange effect on cash and cash equivalents	333	393
Net cash flow	$ (2,309)	$ (4,177)

Net cash used in operating activities. Net cash flows from operating activities increased by $6.4 million during the three months ended March 31, 2018, versus the prior year comparable period. Improvements in net loss after adjustments for non-cash items such as depreciation, amortization and stock-based compensation during 2018 when compared to 2017 coupled with timing of accounts receivable collections were offset by other working capital changes, primarily driven by the timing of payments to our vendors. We expect working capital to fluctuate due to various factors including inventory requirements and the timing of certain payments from our customers and to our vendors.

Cash flow from deferred revenues improved by $1.2 million during the three months ended March 31, 2018, versus the prior year comparable period. Amortization of deferred revenues into revenues relating to sales of home equipment was $4.2 million and $4.7 million during the three months ended March 31, 2018 and 2017, respectively.

Net cash used in investing activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, related to expenditures for our manufacturing facilities as a result of our efforts to maintain and expand our manufacturing operations, coupled with the build-out of NxStage Kidney Care dialysis centers, along with purchases of information technology.

The decrease of $0.5 million in purchases of property and equipment was driven primarily by decreased spending associated with our NxStage Kidney Care dialysis centers. Capital expenditures for our NxStage Kidney Care centers were $0.1 million and $0.6 million during the three months ended March 31, 2018 and 2017, respectively.

Net cash (used in) provided by financing activities. During the three months ended March 31, 2018 and 2017 we used $0.3 million and received $4.7 million, respectively, of net cash flows from stock plan activities. Proceeds from stock incentive plans are subject to fluctuation based primarily on the number of options exercised and, to a lesser extent, the weighted-average exercise price. Cash provided by financing activities during both 2018 and 2017 was also reduced by cash used to pay our capital lease and debt obligations.

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 U.S. 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 these condensed consolidated financial statements for the three months ended March 31, 2018 are described in Note 2 to the consolidated financial statements included in our 2017 Annual Report 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 months ended March 31, 2018 are consistent with those described in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our 2017 Annual Report, except for changes to revenue recognition from the adoption of ASC 606 (see Note 2).

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements included in our 2017 Annual Report 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 2017 Annual Report. There have been no material changes to our market risks or to our management of such risks during the three months ended March 31, 2018.

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 March 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, 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 March 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We implemented internal controls to ensure we adequately evaluated our contracts and properly assessed the impact of ASC 606 to facilitate its adoption on January 1, 2018. There were no significant changes to our internal control over financial reporting due to the adoption of this standard.

PART II - OTHER INFORMATION

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

We face a number of risks and uncertainties that are difficult to predict and many of which are outside of our control. In this section, we describe what we believe are the material risks to our business and future development. This is not an exhaustive list of risks affecting our business. There may be other risks that are not currently known to us or that we currently believe are immaterial but turn out to be material in the future. If any of these risks were to materialize, it could adversely affect our business, financial condition, results of operation, reputation and growth prospects, and cause actual results to differ materially from those projected in any of our forward-looking statements. In that case, the value of our common stock could decline substantially.

Investors should carefully consider the risk factors described below together with the other cautionary statements included in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in our 2017 Annual Report.

Risks Related to our Business

The home hemodialysis market may not expand sufficiently to support our growth prospects.

While we believe our largest growth opportunity with our existing products is within the home hemodialysis market, home hemodialysis therapies have not been extensively adopted. With our current technology, we believe that approximately 10-15% of end-stage renal disease patients in the U.S. would be appropriate candidates for home hemodialysis. However, only 2% of U.S. chronic dialysis patients receive hemodialysis treatments at home.

Our growth requires that we continue to shift patients' and the medical community's understanding and view of home hemodialysis and will require further increases in the number of patients who adopt home hemodialysis from current levels, physicians who are willing to prescribe home hemodialysis, and dialysis centers that are willing to support home hemodialysis growth. Most dialysis centers presently do not have the infrastructure to support a significant home hemodialysis patient population, including the availability of home hemodialysis training nurses, and may not be motivated to invest in home hemodialysis programs due, in part, to certain Medicare reimbursement policies. We will need to continue to devote significant resources to expanding the home hemodialysis market, but these efforts ultimately may not be successful.

Medicare reimbursement policies may limit patient access to our home hemodialysis products.

Medicare regulations that, directly or indirectly, have a disproportionate impact on home hemodialysis therapy may limit patient access to our home hemodialysis products. In 2011, the Centers for Medicare and Medicaid Services implemented a prospective payment system for dialysis treatment. Under this prospective payment system, the Centers for Medicare and Medicaid Services generally makes a single bundled payment to the dialysis center for each dialysis treatment that covers all renal dialysis services, inclusive of home dialysis and most drugs frequently administered to dialysis patients. This payment system replaced the former system which paid centers 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. A stated goal of the new prospective payment system was to encourage home dialysis. To date, this reimbursement structure has not had a positive impact on the adoption of home or more frequent hemodialysis or the price of 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 rates of training 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.

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, have been prescribed to dialyze more than three times per week to attain the clinical benefits of more frequent dialysis. Given the increased provider costs associated with providing more frequent dialysis, access to our home hemodialysis products will be impacted by whether dialysis centers receive or pursue adequate reimbursement for the additional dialysis treatments. Reimbursement for more frequent hemodialysis requires medical justification provided by the dialysis center based on information from the patient's physician, which increases the center's administrative burden. In addition, there is no national standard for what constitutes medical justification, thus reimbursement for more frequent hemodialysis varies due to differing Medicare contractor policies and center billing practices. Dialysis centers may be unwilling to support more frequent home hemodialysis in the absence of predictable Medicare reimbursement for additional treatments per week based on submitted claims for medical justification.

Currently, only four of the twelve Medicare contractor jurisdictions have issued formal local coverage determinations that describe medical justification for more frequent hemodialysis. In the remaining jurisdictions, medical justification is determined on a case-by-case basis. Recently, however, all Medicare contractors have issued proposed local coverage determinations setting forth a limited set of medical conditions that would constitute medical justification for more frequent hemodialysis in their respective jurisdictions. The proposed local coverage determinations are nearly identical across Medicare contractors and would cover all existing dialysis units. We believe the proposed local coverage determinations are inconsistent with long-standing Medicare policy, including that reiterated in recent Medicare payment rules, current clinical literature and locally accepted standards of care. In partnership with other provider, patient, and professional organizations, we have been actively engaged in the comment process for the proposed local coverage determinations. If the proposed local coverage determinations were adopted in their current form, they would adversely affect our business, financial condition and results of operation by significantly restricting patient access to home and more frequent hemodialysis.

Measures to reduce healthcare costs may hurt our business.

Our customers are healthcare providers who depend upon reimbursement by government and commercial insurance payors for dialysis treatments. 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 customer's decision to use the System One or our other products and limits the prices we may charge for our products. The Centers for Medicare and Medicaid Services issued the 2018 final rule for the end-stage renal disease prospective payment system, which increased the base reimbursement rate by less than 1% over 2017 rates. Commercial insurance payors may also exert downward pressure on payment rates for dialysis services. A reduction in reimbursement rates for dialysis treatments may adversely affect our customers' businesses and cause them to enact cost reduction measures that may include reducing the scope of their home hemodialysis programs.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the availability of and reimbursement for healthcare services. For example, in 2010, comprehensive U.S. health care reform legislation was passed imposing a 2.3% excise tax on domestic sales of certain medical devices, including our products. This tax was suspended for 2016 and 2017, and, as part of the Tax Reform, the tax was again suspended for two years, beginning in January 2018. The tax will continue to have a negative impact when it is imposed again starting in 2020 unless permanently suspended or repealed. Rising healthcare costs have also led many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures, including government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing systems, and payors limiting access to treatments based on cost-benefit analysis. Any of these measures, including the uncertainty in the medical community regarding their nature and effect, could have an adverse effect on our customers' purchasing decisions regarding our products and treatments, as well as limit the prices we may charge for our products.

We sell a limited number of products.

We derive most of our revenues from sales of the System One and the related products used with the System One, with the remainder of our revenues largely coming from sales of a few key disposable products, including blood tubing sets and needles. Although we are working on initiatives that should diversify our future revenues, our present business continues to be exposed to risks that are concentrated in a small number of products. As a result, any event that adversely affects these products or the markets for these products could adversely affect our business, financial condition and results of operation.

Our relationships with DaVita and Fresenius are important to our business.

DaVita and Fresenius collectively provide treatment to over two-thirds of U.S. dialysis patients and are our two largest customers. Sales to them have driven a large portion of our historical revenue growth. Any adverse change in either customer's ordering or clinical practices, including in response to the establishment of our NxStage Kidney Care dialysis centers or the pendency of our Merger with Fresenius, would have an adverse impact on our revenues. In addition, these large dialysis providers have significant purchasing power, and we may be required to grant them favorable pricing and other terms for our products that reduce our gross margins and have an adverse effect on our operating results.

Our home market agreements with DaVita and Fresenius are intended to support the continued expansion of patient access to home hemodialysis with the System One, but like all our agreements with home customers, these agreements are not requirements contracts and they contain no minimum purchase volumes. Our home market agreement with DaVita extends through December 31, 2018, with monthly renewals thereafter unless terminated by either party with 30 days' prior notice. Our home market agreement with Fresenius continues to renew on a monthly basis unless we and Fresenius choose to modify the terms with an amendment or new agreement.

We may be unable to achieve or sustain profitable operations.

Since inception, we have incurred negative operating margins and losses every quarter. Currently, we have a significant accumulated deficit. We continue to invest in our operations, in particular with respect to research and development, to drive future growth. Accordingly, we cannot ensure the timing, extent or sustainability of our future profitability.

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

As health care providers and participants in federal health care programs, our NxStage Kidney Care dialysis centers must comply with complex regulations that are, in some instances, relatively new to our business, 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;
- prohibitions on submitting false claims for government or commercial insurance reimbursement;
- laws regulating the use and disclosure of patient health information; and
- laws regulating the storage and administration of pharmaceuticals and medical devices.

If we violate such laws and regulations, we may face criminal and civil sanctions, including fines and civil monetary penalties and exclusion from participation in Medicare, Medicaid and other government programs. If we are found to have submitted improper claims for reimbursement to the government or commercial insurers, we may also have to repay amounts received from government or commercial payors and pay additional damages and interest.

Physician joint ventures for the ownership and operation of dialysis centers is a common business structure within the dialysis services industry and are designed to improve the quality of care while managing healthcare costs by sharing clinical expertise, management experience and industry knowledge in an efficient manner. A few of our NxStage Kidney Care dialysis centers are structured as joint ventures in which physicians hold an interest. These physician owners may also provide medical director services and refer patients to our dialysis centers. There historically has been significant governmental scrutiny of joint ventures and other financial arrangements with physicians and physician groups. Although we seek to structure and operate our joint ventures in compliance with all regulatory requirements, the applicable laws are broadly written and it is often difficult to determine precisely how these laws will be applied in specific circumstances. Regulatory authorities may challenge our joint ventures or our operation of joint ventures on the grounds that they are intended to induce patient referrals and, if successful, may require that we restructure or terminate our joint ventures, repay to Medicare amounts received by the centers pursuant to any prohibited referrals, and incur the sorts of penalties or sanctions described in the preceding paragraph.

Our NxStage Kidney Care dialysis centers must maintain enrollment in the Medicare program in order to bill and receive payment for dialysis services provided to patients covered by Medicare and certain private insurers. Medicare enrollment requires, among other things, that a center successfully complete a certification process conducted by individual state agencies on behalf of the Centers for Medicare and Medicaid Services and that certification requirements be met on an ongoing basis. Our NxStage Kidney Care dialysis centers may be unable to obtain Medicare certification in a timely manner, if at all, or could lose certification upon resurvey if they are found to not meet applicable requirements. Our NxStage Kidney Care dialysis centers have provided us with valuable experience to better meet and anticipate the needs of both our customers and patients, while optimizing our product technology. Our customers may, however, perceive these centers to be directly competing with their business which could, and may have already, negatively impact product sales.

We face competition from many sources.

The dialysis therapy industry is highly dynamic and we face competition from many sources, including those that are listed in the section of our 2017 Annual Report entitled “Business - Our Competition.” Our competitors may have significant competitive advantages by:

- offering products and services that are more widely recognized by physicians, patients and providers;
- offering broader product lines which enable them to offer customers a single source for multiple products;
- having significantly more financial and human resources, more established service and customer support infrastructures and spending more on product development and marketing;
- having more established sales forces and distribution channels; and
- having more established relationships with the providers of dialysis therapy, including DaVita and Fresenius which may at any time reduce their promotion of our dialysis products to their dialysis patients.

Further consolidation within the highly competitive dialysis industry may exacerbate these risks. In addition, new, well-funded entrants may enter the dialysis industry, such as CVS Health, which recently announced its intent to enter this market.

Our in-center business is increasingly subject to pricing and other competitive pressures within the highly consolidated U.S. dialysis services industry. A meaningful portion of that business was lost when our needle purchase agreement with DaVita expired in December 2014 and we experienced reduced demand for our blood tubing sets from Baxter during 2016 and 2017.

While we believe our in-center products offer benefits over competing products, our customers often regard blood tubing sets and needles as commodities and we are vulnerable to large changes in purchasing patterns for these products. Unless we can successfully demonstrate to customers the differentiating features of our blood tubing sets and needles, we may continue to be susceptible to pressures to reduce our product pricing and more vulnerable to reduction in sales of our blood tubing sets and needles.

As we attain greater commercial success, our competitors are likely to develop products that offer features and functionality similar to the System One and our other products. 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.

The development of viable medical, pharmacological and technological advances in treating or preventing kidney failure may also limit the opportunity for our products and services. 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. This may change, however, with 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, and other advances in kidney transplantation.

We need to maintain strong product reliability to grow our business.

We need to maintain strong reliability for our existing products to achieve our growth and profitability objectives. Poor product reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. 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. From time to time, we may 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 increase our costs in the near-term.

We need to develop and commercialize new products to grow our business.

Our future growth requires that we develop and commercialize new products in a timely manner to address changing industry requirements. Otherwise, we may lose revenues to our competitors, which may be difficult to regain. Developing innovative products and bringing them to market requires significant investment without assurance of success. In addition, this is a highly costly, lengthy and uncertain process, and we may experience delays in developing or commercializing new products. Our efforts may not produce commercially viable products due to the many technological, regulatory, operational and other risks associated with product development, including:

- the new product may not perform as intended or may have safety concerns;
- the costs associated with obtaining regulatory approval or in satisfying applicable regulatory requirements may be prohibitive and, even in markets where these costs are not prohibitive, the associated efforts may significantly lengthen projected timelines for new product introduction;
- the FDA and other regulatory authorities may not approve the new product or the facilities in which it is manufactured in a timely manner or at all;
- payors may not reimburse the new product sufficiently or at all;
- competing products may be safer, more effective or easier to use; and
- we may be unable to manufacture sufficient quantities of the new product for development or commercialization activities in a timely and cost-effective manner.

General economic and financial market conditions may exacerbate our business risks.

Global macro-economic conditions and the world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. Our customers and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. As a result, they may choose to pay for System One equipment on a monthly basis versus upfront, which may reduce our cash flows, and have fewer personnel available to train new patients for home hemodialysis. Our international business is particularly vulnerable to global macro economic conditions. Furthermore, unfavorable changes in foreign exchange rates versus the U.S. dollar could increase our product costs, thus reducing our gross profit, or render our products overly expensive, thus reducing our revenues.

We may not effectively manage our growth.

Our business growth will strain our administrative and operational infrastructure unless we:

- increase our manufacturing capacity to meet customer demand;
- expand our sales and marketing and on-going development capabilities;
- improve our information technology infrastructure, operational, financial and management controls and reporting systems and procedures; and
- manage the increased complexity and scope of our relationships with various partners, distributors, suppliers, manufacturers and other organizations.

We may be unable to implement such changes in an efficient and timely manner, and in the process of expansion may discover deficiencies in our existing systems and controls.

We need to effectively manage our field equipment.

Our home market relies upon an equipment service swap model and, for some of our customers, a month-to-month equipment rental model that requires us to effectively manage our System One and PureFlow SL field equipment. While a majority of System One equipment sold in the home market is paid for upfront by our customer versus on a monthly basis, this may change due to pressures within the healthcare industry to reduce capital spending and other factors. Increases in our field equipment assets 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 and 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. Any investigation into alleged unlawful conduct could increase our expenses, damage our reputation, and divert management time and attention from operating our business. While we maintain insurance at levels deemed adequate by management, future claims may exceed our insurance coverage or may not be covered by any insurance.

Acquiring or developing businesses, technologies or products may present new challenges.

In the course of evaluating growth opportunities, we may acquire or develop businesses, technologies or products, as we did in 2007 with the acquisition of Medisystems and in 2013 with the introduction of our NxStage Kidney Care dialysis centers. We may also devote resources to potential acquisitions that are never completed or may fail to realize the anticipated benefits of such efforts. There are substantial risks and uncertainties associated with any growth or change in business lines or strategy that may prevent us from realizing the anticipated benefits of such opportunities or adversely affect our business, financial condition and results of operation, including:

- need for significant investment without assurance of success;
- potential disruption of our ongoing business;
- need for involvement of senior management to develop the acquired businesses, technologies or products, which will take away from the time they ordinarily spend on the remainder of our business;
- entry into markets or types of businesses in which we have limited experience;
- impairment of relationships with key partners, customers or suppliers of ours or any acquired business;
- addition of new complex compliance obligations;
- difficulty in managing geographically remote units both in the U.S. and internationally;
- 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 product and service offerings;
- unanticipated expenses and delays in completing acquired development projects and technology integration;

- difficulty in transitioning and integrating the operations and personnel of an acquired businesses, including with respect to differing and complex accounting and financial reporting systems;
- customers delaying purchases of our products pending resolution of product integration between our existing and our newly acquired products;
- loss of key employees of an acquired company; and
- inaccurate assumptions of an acquired company's product or service quality.

Further, any acquired technology or product may require additional development efforts prior to commercial sale, including clinical testing and approval by the FDA and applicable foreign regulatory authorities. All technology and product candidates are prone to risks of failure typical of medical device product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

We have international operations that introduce a number of risks and uncertainties.

Substantially all of our manufacturing is done outside the U.S. We operate manufacturing facilities in Germany, Italy and Mexico, and purchase components, products and supplies from foreign vendors. We also sell our products internationally, and are increasing our presence in international markets. We are subject to a number of risks and challenges that specifically relate to these international operations, including:

- foreign exchange risk, in particular with respect to the euro and peso, which has been amplified by the recent strength of the U.S. dollar and which could adversely affect our financial results and our ability to maintain mutually beneficial and profitable relationships with foreign vendors, distributors and customers, and increase our costs to attract and retain international personnel;
- expropriation and other restrictive government actions;
- changes in intellectual property legal protections and remedies;
- costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods;
- changes to U.S. and foreign trade policies, including enactment of tariffs or border-adjusted taxes on goods imported into the U.S.;
- difficulty managing operations in multiple locations;
- local regulations that may restrict or impair our ability to conduct our operations, increase compliance costs, and make it more expensive and complex to manage our workforce;
- fluctuations in local economic conditions;
- 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; and
- in certain locations, risks associated with local instability, including threats of violence, which could lead to disruptions in supply at our manufacturing facilities or key vendors.

These risks and uncertainties may adversely impact our international growth strategy in these markets and overall operating profits. Risks associated with our international operations may increase where we sell our products and services directly rather than through distributors, as we do in the UK and Canada.

During June 2016, the referendum by UK voters to exit the EU (Brexit) adversely impacted global markets and resulted in a sharp decline of the British pound sterling against our reporting currency, the US dollar. Continued volatility in or devaluation of the British pound sterling may adversely affect our results of operations by reducing our reported international sales and earnings and causing our UK customers to reduce their investment in healthcare. The further impact of Brexit on our international business will depend on any agreements the UK makes to retain access to EU markets. Although it is unknown what the terms of the UK's future relationship with the EU will be, the imposition of greater restrictions on imports and exports between the UK and EU countries and an increase in regulatory complexity could adversely affect our relationships with our customers, suppliers and employees in the UK.

Our in-center and international businesses rely heavily upon third-party distributors.

Substantially all of our blood tubing sets and needles are sold through distributors. We also use distributors to sell our products in most of our international markets. Relying on third-party distributors exposes us to many risks, including competitive pressure, compliance risks, credit risk and concentration. Relying on third-party distributors can also introduce choppiness into our revenues. From time to time, distributors may alter their purchasing patterns, and their subsequent inventories on hand, in order to obtain shipping efficiencies, earned or offered discounts, or in order to optimize their individual

cash flows. Furthermore, distributors may delay or defer purchase decisions with regards to our products or seek to terminate or renegotiate their relationships with us as a result of our proposed Merger with Fresenius, whether pursuant to the terms of their existing agreements with us or otherwise.

Distributors may sell products that compete with our products, and we may be unable to motivate them to focus their efforts on selling our products. The trend toward consolidation among distributors may yield greater purchasing leverage, which may increase the pricing pressures facing our business. If our distributors fail to comply with applicable laws in the sale and marketing of our products or fulfill any other responsibilities they may have, our revenues may decline and we may become involved in legal proceedings. Distributors may face financial difficulties, including bankruptcy, which could harm our collection of accounts receivable and financial results. Moving any of this business to other distributors would involve switching costs in the near-term that may be material relative to the value of the business involved.

We rely on the expertise of a concentrated group of employees.

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.

Risks Related to the Regulatory Environment

Our products and business are subject to extensive regulation.

We need regulatory approvals to market new products and, in some cases, modifications to existing marketed products. Regulatory approval pathways for medical products are complex, time consuming and difficult to define, and they may become more onerous through additional regulation. We may be unable to obtain the necessary approvals to market our new products and modifications to marketed products in a timely manner, if at all. Additionally, the costs and timelines associated with obtaining the necessary approvals for new products may be prohibitive.

Foreign markets are challenging as the regulatory approval procedure varies from country to country and requires that we comply with numerous regulatory requirements that differ from the FDA approval process and are not superseded by obtaining approval from the FDA or another country's regulatory authority. As regulatory requirements in the U.S. and internationally become increasingly more stringent, it may become more difficult, time consuming and costly for us to obtain future approvals for our products and expand into new markets.

In certain foreign markets, some of our products are regulated differently than they are in the United States, which has required us to demonstrate compliance with different regulations and has increased the cost of obtaining applicable regulatory approvals. As we introduce new products into foreign markets, new and complex regulations may impose additional approval, manufacturing, surveillance and reporting requirements for our products, beyond those we already have experience complying with. Compliance with these additional requirements may increase our costs of doing business in new foreign markets and delay or prevent our entry into such markets.

Following marketing approval, we must comply with numerous ongoing regulatory requirements, industry codes of conduct and consensus standards, including those described in the section of our 2017 Annual Report entitled “Business - Government Regulation.” Noncompliance with applicable regulations can result in, among other things:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Such enforcement measures would require unanticipated expenditures to address or defend such actions and may adversely affect our business, financial condition and results of operation.

New regulations, codes and standards are periodically adopted which may require us to change our existing product technologies, operating procedures or marketing practices in order to continue selling our products. For example, the EU regulatory bodies recently finalized new medical device regulations, which will take effect in 2020 after a three year transition period. These new regulations change several aspects of the existing regulatory framework, including requiring stricter regulation of notified bodies by national authorities and imposing more stringent post-market surveillance obligations. We face greater uncertainty as these stricter and more complex regulations are implemented and enforced in the coming years. In addition, regulatory authorities have been increasingly aggressive in their enforcement activities and scrutiny of medical device and healthcare companies. Any of these factors may expose us to increased compliance costs and the assessment of significant fines, as well as risks that we may be unable to satisfy the new regulations, codes or standards, or more expansive interpretations of existing regulations, and have to suspend, curtail or otherwise modify our selling and marketing efforts and other aspects of our operations.

Modifications to our marketed products may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the EU, we must notify our EU Notified Body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

It is important to our business that we build a pipeline of product offerings that address limitations of current dialysis and disposable products. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products for any number of reasons, including due to the cost associated with certain regulatory approval requirements, or these products may not be accepted by physicians or users.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to, among others:

- identify and anticipate physician and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical and clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with FDA and foreign regulations on marketing of new products or modified products; and
- provide adequate training to potential users of our products.

If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our products may be recalled from the market.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software 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. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. From time to time we have chosen to voluntarily recall certain products that we believed were mislabeled or otherwise defective. We also may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

If we or our suppliers fail to comply with ongoing FDA or foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain approval or clearance, and the manufacturing processes, reporting requirements, post-market clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our third-party suppliers are required to comply with the Quality System Requirements (QSR). The QSR covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements in the U.S. or experience delays in obtaining necessary regulatory approvals or clearances, this could delay production of our products and lead to fines, difficulties in obtaining regulatory approvals or clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the policies of the new administration and their impact on the regulation of our products in the U.S. remain uncertain. The outcome of the 2016 election and the forthcoming 2018 mid-term elections could result in significant legislative and regulatory reforms impacting the FDA's regulation of our products. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

We need to protect the privacy of patient health and other personal information.

In the course of performing our business we obtain, from time to time, confidential patient health information and other personal information. Federal and state laws, as well as the laws of foreign countries, protect the confidentiality of certain patient health information, in particular individually identifiable information, and other personal information, and restrict the use and disclosure of that information. A description of these laws is included in the section of our 2017 Annual Report entitled "Business - Government Regulation - Privacy and Security." Complying with the privacy and security requirements of such laws imposes 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 or other personal information against improper use and disclosure, we could lose customers and be exposed to liability, including potential civil and criminal penalties 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 adversely impact our business, financial condition and results of operations.

We must comply with fraud and abuse laws.

Various federal and state laws, as well as the laws of foreign countries, prohibit payments to induce the referral, purchase, order or use of healthcare products or services and require medical device companies to monitor and report certain payments to health care professionals. 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 dialysis providers, 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. If we were to offer or pay inappropriate inducements for the purchase, order or use of our products or services, or for the referral of patients to our NxStage Kidney Care dialysis centers, we could be subject to claims under various healthcare fraud and abuse laws, including the federal healthcare program Anti-Kickback Statute, the Federal False Claims Act, the Medicare and Medicaid beneficiary 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. A shifting and diverse regulatory environment increases the associated compliance risks since different jurisdictions may have different reporting requirements.

Other federal and state laws, as well as the laws of foreign countries, generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to government or commercial 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 addition, our NxStage Kidney Care dialysis centers are directly subject to these laws with respect to the reimbursement claims they file with government or commercial payors. Potential false or fraudulent claim risk can arise from promoting and billing for services the government or other third party payers deem excessive or not medically necessary, as well as from other billing improprieties and from failure to timely return any identified overpayments. We attempt to ensure that billing by our NxStage Kidney Care dialysis centers is proper and that physicians who order NxStage Kidney Care dialysis services document medical need for patients for whom more frequent than thrice weekly therapy is ordered. Nevertheless, the government may not regard any billing errors that may be made as inadvertent and may 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, raise the possibility of exclusion from participation in government health care programs, potentially crippling to the line of business involved. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time consuming response.

Foreign governments tend to impose strict price controls.

We market the System One and certain of our other products internationally. In some foreign countries, particularly in the EU, 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 U.S., 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. If reimbursements were to be negatively changed, such as in the UK or Canada where we sell our products directly, our ability to profitably sell our products could be impaired.

We must comply with import and export laws and regulations.

We import disposable medical supplies into the U.S. from our manufacturing facilities and vendors located outside the U.S. 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 U.S. to foreign countries. The import and export of these items are subject to extensive and complex laws and regulations. If 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. The U.S. federal government has called for substantial changes to trade policies which may include changes to existing trade agreements, including but not limited to the North American Free Trade Agreement. Changes to capital and exchange controls, expropriation or other restrictive government actions could adversely affect our business. We also are subject to changes in tax and tariff regulations abroad that could increase our costs and reduce our margins. If 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 expenses could increase and our profitability may be negatively impacted.

We must comply with anti-bribery laws.

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 or our executives 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 an adverse effect on our business, financial condition and results of operations.

We must comply with environmental and occupational safety laws.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials, and our NxStage Kidney Care dialysis centers produce medical waste in connection with providing dialysis services. 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 or occupational safety 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.

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 and sterile bags, as well as sterilization services. Some of our most critical single-source supply relationships are with Membrana and Laboratorios PiSA.

Membrana is our only supplier of the fiber used in our filters for System One products under an agreement that expires in December 2023, 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 U.S. and the performance of Asahi fiber in our System One has not yet been validated.

Laboratorios PiSA supplies substantially all of our 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. While we purchase premixed dialysate from another qualified supplier, any significant disruption in Laboratorios PiSA's ability to supply premixed dialysate to us would adversely impact 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 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 adversely impact our business, financial condition and results of operations and harm our reputation, at least in the near term.

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.

We may experience manufacturing disruptions.

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, high employee turnover, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes 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 business, financial condition and results of operations and harm our reputation.

Commodity and electronic component price increases may adversely affect our financial results.

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. Periods of rising prices for crude oil, natural gas and other petrochemical intermediates from which resin is produced can result in significant price increases for this material. Periods of rising resin prices may occur in the future. In addition, we believe electronic component demand is rising, which may cause lead times to increase and prices to rise, potentially impacting both delivery and cost.

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 material costs. In addition, our overall cost reduction plans may not sufficiently offset the impact of increased material costs, which could result in declining margins and operating results.

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.

Our business is dependent upon the security and uninterrupted operation of our information technology infrastructure.

We rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information, including confidential patient health information, and to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory, financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third-parties and are highly interconnected, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of installing, upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. In addition, these systems can require significant resources to ensure their continuous operation. Despite the precautionary measures we have taken to prevent breakdowns in our information

technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, we may be subject to remediation expenses, reputational harm, and litigation.

Risks Related to Intellectual Property

We have to protect our intellectual property.

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 issued patents, 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.

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 50 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 financial 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.

Disclosure of trade secrets and other confidential information may harm our business.

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 or trade secrets. In addition, others may independently discover or reverse engineer trade secrets and confidential information, and in such cases we may be unable to assert any trade secret rights against such party. Others also may be able to obtain patent protection covering trade secrets and prevent us from practicing those trade secrets. 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.

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 confidential 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 or be enjoined from manufacturing or selling products. Even if we are successful in defending against these claims, litigation could result in substantial financial costs and harm to our reputation and be a distraction to management and other key employees.

Risks Related to our Common Stock

Our stock price may fluctuate significantly.

Our current stock price may reflect a market assumption that our proposed Merger will occur, meaning that a failure to complete the Merger could result in a decline in the price of our common stock. Historically, there have been periods of volatility in the market price of our common stock, and if they were to recur could delay or prevent you from selling your common stock at or above the price you paid for it. Some of the factors that may have caused the market price of our common stock to fluctuate include:

- timing of commercial launch and 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, 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, medical or regulatory authorities or the general media regarding the potential benefits of the System One, similar dialysis products distributed by other companies, or more frequent or home dialysis;
- delays or failures to obtain marketing approval for new products or modifications to marketed products;
- product recalls and withdrawals;
- defaults under our material contracts, including without limitation our credit agreement;
- regulatory developments in the U.S. 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;
- regulatory changes that could affect our profitability, such as the imposition of import tariffs and border-adjusted taxes;
- litigation involving our company or our 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;
- 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. Periods of volatility in the market price of our securities may engender class action securities litigation against us. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could adversely affect our business, financial condition and results of operations and harm our reputation.

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 or are ultimately unsuccessful. Additional financing may not be available on terms favorable to us, or at all, particularly in light of the volatility in the financial markets and the valuations of securities generally.

Risks Related to the Proposed Merger

The proposed Merger is subject to a number of conditions beyond our control. Failure to complete the proposed Merger within the expected timeframe, or at all, could adversely affect our business, results of operations and our stock price.

The consummation of the Merger by Fresenius remains conditioned, among other things, on: (i) the absence of any governmental order or law preventing the Merger or making the consummation of the Merger illegal, (ii) receipt of regulatory approval under the HSR Act or the expiration or termination of the applicable waiting periods (and any extension thereof) under the HSR Act, and (iii) other customary closing conditions.

We cannot predict whether and when these remaining conditions will be satisfied. If one or more of these conditions is not satisfied, and as a result, we do not complete the proposed Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the proposed Merger. Certain costs associated with the proposed Merger have already been incurred or may be payable even if the proposed Merger is not consummated. Finally, disruptions to our business resulting from the pendency of the proposed Merger, including adverse changes in our relationships with our customers, partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the proposed Merger.

Our stock price may also fluctuate significantly based on announcements by Fresenius and other third parties or us regarding the Merger or based on market perceptions of the likelihood of us satisfying the closing conditions related to the Merger. Such announcements may lead to perceptions in the market that the Merger may not be completed, which could cause our stock price to fluctuate or decline. If we do not consummate the Merger, the price of our common stock may decline significantly from the current market price. Any of these events could adversely affect our business, financial condition and results of operations and could cause a decline in the price of our common stock.

The Merger consideration payable to holders of shares of our common stock will not be adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or in the event of any change in our stock price.

The Merger consideration payable to holders of shares of our common stock will not be adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or changes in the market price of, analyst estimates of, or projections relating to, our common stock. For example, if we experienced an improvement in our business, assets, liabilities, prospects, outlook, financial condition or results of operations prior to the consummation of the proposed Merger, there would be no adjustment to the amount of the proposed Merger consideration.

We may be unable to obtain the regulatory approvals required to complete the proposed Merger.

One of the conditions to consummation of the proposed Merger is receipt of regulatory approval under the HSR Act, or the expiration or termination of the applicable waiting periods (and any extension thereof) under the HSR Act. There can be no assurance that such regulatory approval to consummate the proposed Merger will be obtained. If such regulatory approval is obtained, there can be no assurance as to the timing of such approval, our ability to obtain the approval on satisfactory terms or in the absence of any litigation challenging such approval. In October 2017, we and Fresenius each received a Request for Additional Information and Documentary Material (also known as a Second Request) from the Federal Trade Commission. The effect of the Second Request is generally to extend the waiting period imposed by the HSR Act until after Fresenius and we have substantially complied with the Second Request. In addition, compliance with the Second Request is expected to add to our costs associated with working to close the proposed Merger and divert additional management time and attention from operating our business.

At any time before or after the consummation of the proposed Merger (and notwithstanding the termination of the waiting period under the HSR Act), the U.S. Department of Justice, Federal Trade Commission or any state or non-U.S. governmental entity could take such action, under antitrust laws or otherwise, as it deems necessary or desirable in the public interest. Such action could include seeking to enjoin the consummation of the proposed Merger and seeking the divestiture of substantial assets. Private parties may also seek to take legal action under antitrust laws under certain circumstances. If the proposed Merger does not receive, or timely receive, the required regulatory approval and clearance, or if another event occurs delaying or preventing the proposed Merger, such delay or failure to complete the proposed Merger may create uncertainty or otherwise have negative consequences that may adversely affect our business, financial condition and results of operations, as well as the price per share for our common stock, at least in the near term.

While the proposed Merger is pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business.

Whether or not the proposed Merger is consummated, the proposed Merger may have an adverse effect on our business and financial results. The pendency of the Merger diverts management's attention and our resources from ongoing business and operations. Our employees and other key personnel have uncertainties about the effect of the proposed Merger, and the uncertainties may impact our ability to retain, recruit and hire key personnel while the proposed Merger is pending or if it fails to close. While the proposed Merger is pending, we will continue to incur costs, fees, expenses and charges related to the proposed Merger, which may adversely affect our business, financial condition and results of operations. Furthermore, actions by our suppliers, customers and other business partners in response to the proposed Merger may be adversely impacting our sales, financial condition and results of operations.

In addition, the Merger Agreement generally requires us to operate in the ordinary course of business consistent with past practice, pending consummation of the Merger and restricts us from taking certain actions with respect to our business and financial affairs, if outside the ordinary course of our business, without Fresenius's consent. Such restrictions will be in place until either the Merger is consummated or the Merger Agreement is terminated. For these and other reasons, the pendency of the Merger could adversely affect our business, financial condition and results of operations.

The proposed Merger may impair our ability to attract and retain qualified employees.

Although, to date, the proposed Merger has not adversely impacted our ability to attract and retain qualified employees, as the period of time following the signing of the Merger Agreement continues to increase, our ability to continue to attract and retain qualified employees could be impaired. Furthermore, if key personnel depart because of such uncertainties, or because they do not wish to remain with the combined company after closing, our business and results of operations may be adversely affected.

Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

During March 2018, we repurchased 28,039 shares of our common stock at a price of $24.05 per share that were delivered in payment for the exercise of employee stock options.

Item 6. ***Exhibits***

Exhibit Number	Description
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.

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)

May 10, 2018

Exhibit 31.1

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

I, Jeffrey H. Burbank, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NxStage Medical, Inc. for the period ended March 31, 2018 (this "report");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jeffrey H. Burbank

Jeffrey H. Burbank
Chief Executive Officer
Date: May 10, 2018

Exhibit 31.2

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

I, Matthew W. Towse, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NxStage Medical, Inc. for the period ended March 31, 2018 (this "report");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Matthew W. Towse

Matthew W. Towse

Senior Vice President and Chief Financial Officer

Date: May 10, 2018

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of NxStage Medical, Inc. (the "Company") for the period ended March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Jeffrey H. Burbank, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey H. Burbank

Jeffrey H. Burbank
Chief Executive Officer
Date: May 10, 2018

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of NxStage Medical, Inc. (the "Company") for the period ended March 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Matthew W. Towse, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Matthew W. Towse

Matthew W. Towse

Senior Vice President and Chief Financial Officer

Date: May 10, 2018