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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 September 30, 2017

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 66,232,226 shares of the registrant's common stock outstanding as of the close of business on November 2, 2017.

NXSTAGE MEDICAL, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2017
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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)

	September 30, 2017	December 31, 2016
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,979	$ 59,632
Accounts receivable, net	30,245	32,286
Inventory	50,668	46,845
Prepaid expenses and other current assets	8,039	6,136
Total current assets	151,931	144,899
Property and equipment, net	62,212	61,561
Field equipment, net	23,793	22,309
Deferred cost of revenues	31,125	33,165
Intangible assets, net	8,169	9,688
Goodwill	42,748	42,648
Other assets	5,376	2,937
Total assets	$ 325,354	$ 317,207
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,871	$ 14,177
Accrued expenses	28,625	30,985
Current portion of long-term debt	99	328
Other current liabilities	4,602	3,770
Total current liabilities	46,197	49,260
Deferred revenues	47,422	49,001
Long-term debt	551	1,305
Other long-term liabilities	17,994	15,568
Total liabilities	112,164	115,134
Commitments and contingencies (Notes 1 and 10)		
Noncontrolling interests subject to put provisions	650	50
Stockholders' equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of September 30, 2017 and December 31, 2016	—	—
Common stock: par value $0.001, 100,000,000 shares authorized; 67,231,121 and 65,883,026 shares issued as of September 30, 2017 and December 31, 2016, respectively	67	65
Additional paid-in capital	653,431	631,219
Accumulated deficit	(419,324)	(407,601)
Accumulated other comprehensive loss	(1,895)	(6,101)
Treasury stock, at cost: 1,034,188 and 936,360 shares as of September 30, 2017 and December 31, 2016, respectively	(18,955)	(16,184)
Total NxStage Medical, Inc. stockholders' equity	213,324	201,398
Noncontrolling interests not subject to put provisions	(784)	625
Total stockholders' equity	212,540	202,023
Total liabilities and stockholders' equity	$ 325,354	$ 317,207

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands, except per share data)			
Revenues	$ 97,295	$ 91,951	$ 290,340	$ 273,365
Cost of revenues	56,688	52,770	167,377	159,244
Gross profit	40,607	39,181	122,963	114,121
Operating expenses:				
Selling and marketing	16,984	16,024	50,595	47,394
Research and development	11,222	8,278	29,757	23,393
Distribution	8,065	7,063	23,394	21,131
General and administrative	12,619	7,792	31,237	24,334
Total operating expenses	48,890	39,157	134,983	116,252
(Loss) income from operations	(8,283)	24	(12,020)	(2,131)
Other expense:				
Interest expense, net	(168)	(244)	(595)	(773)
Other income (expense), net	26	(346)	(565)	(987)
	(142)	(590)	(1,160)	(1,760)
Net loss before income taxes	(8,425)	(566)	(13,180)	(3,891)
Provision for (benefit from) income taxes	469	324	(166)	1,007
Net loss	(8,894)	(890)	(13,014)	(4,898)
Less: Net loss attributable to noncontrolling interests	(449)	(724)	(1,291)	(1,724)
Net loss attributable to NxStage Medical, Inc.	$ (8,445)	$ (166)	$ (11,723)	$ (3,174)
Add: Accretion to redemption value of noncontrolling interests	(481)	—	(481)	—
Net loss attributable to common stockholders	$ (8,926)	$ (166)	$ (12,204)	$ (3,174)
Net loss per share, basic and diluted	$ (0.14)	$ (0.00)	$ (0.19)	$ (0.05)
Weighted-average shares outstanding, basic and diluted	66,082	64,638	65,723	64,414
Other comprehensive (loss) income:				
Unrealized (loss) income on derivative instruments, net of income taxes	(661)	(5)	2,376	92
Other income (loss)	268	(73)	1,830	(389)
Total other comprehensive (loss) income	(393)	(78)	4,206	(297)
Total comprehensive loss	(9,287)	(968)	(8,808)	(5,195)
Less: Comprehensive loss attributable to noncontrolling interests	(449)	(724)	(1,291)	(1,724)
Total comprehensive loss attributable to NxStage Medical, Inc.	$ (8,838)	$ (244)	$ (7,517)	$ (3,471)

See accompanying notes to these condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2017	2016
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (13,014)	$ (4,898)
Adjustments to reconcile net loss to net cash flow from operating activities:		
Depreciation and amortization	25,321	23,974
Stock-based compensation	8,684	7,688
Other	1,183	(886)
Changes in operating assets and liabilities:		
Accounts receivable	2,443	(5,501)
Inventory	(18,154)	(22,026)
Prepaid expenses and other assets	604	621
Accounts payable	(1,886)	3,930
Accrued expenses and other liabilities	(1,286)	3,015
Deferred revenues	(1,906)	(924)
Net cash provided by operating activities	1,989	4,993
Cash flows from investing activities:		
Cash paid for acquisitions, net of cash acquired	(100)	(513)
Purchase of cost method investment	(2,500)	—
Purchases of property and equipment	(7,550)	(6,796)
Net cash used in investing activities	(10,150)	(7,309)
Cash flows from financing activities:		
Issuance of shares under stock incentive plans, net of payroll taxes paid	11,019	3,677
Investment by noncontrolling interest holder	—	1,210
Proceeds from loans, lines of credit and capital lease obligations	452	—
Repayments on loans and lines of credit	(126)	(225)
Repayments on capital leases	(981)	(1,153)
Net cash provided by financing activities	10,364	3,509
Foreign exchange effect on cash and cash equivalents	1,144	559
Increase in cash and cash equivalents	3,347	1,752
Cash and cash equivalents, beginning of period	59,632	59,065
Cash and cash equivalents, end of period	$ 62,979	$ 60,817

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 and markets 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 valuable experience to better meet and anticipate the needs of both our customers and patients, while optimizing our product technology. In addition, 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. More specifically, at NxStage Kidney Care we offer a range of treatment options, including home hemodialysis, peritoneal dialysis and flexible in-center hemodialysis. These centers also help us to devise best practices for successful home dialysis programs and provide sites for future clinical trials of our products.

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 an Agreement and Plan of Merger (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 under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act") or the expiration or termination of the applicable waiting periods (and any extension thereof) under the HSR Act and other customary closing conditions.

Immediately prior to, and contingent upon, closing, each outstanding Company stock option, restricted stock unit, restricted share and performance share (collectively, the “Company Equity Awards”) will vest in full (with applicable performance conditions deemed satisfied at maximum levels). Such fully vested Company Equity Awards will be canceled and converted into cash at $30.00 per share for each share of our common stock underlying such Company Equity Awards (net of any applicable exercise price and subject to any applicable withholding tax).

The Merger Agreement may be terminated by us or Fresenius if it 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 of the Company and Fresenius. 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.

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. See "Risk Factors" in Part II Item 1A of this Quarterly Report for additional information.

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2017 and December 31, 2016 and for the three and nine months ended September 30, 2017 and 2016, 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, 2016 (2016 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, 2016 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 2016 Annual Report.

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

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 September 30, 2017. Two customers represented 12% and 10% of accounts receivable at December 31, 2016.

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, 2016	$	280
Provision		317
Usage		(328)
Balance at September 30, 2017	$	269

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 2017, 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 September 30, 2017, 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 third quarter of 2017. We recorded an impairment charge during the second quarter of 2017 of $0.3 million in cost of revenue to write-down certain center level assets within our Services segment.

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. We had $15.0 million of long-lived assets at our Services segment at September 30, 2017. 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 2016 and 2015 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.

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. Our Services reporting unit, with a goodwill of $1.1 million at September 30, 2017, has been identified as having a higher risk for impairment. Future events that could have a negative impact on the levels of excess fair value over carrying value of our Services reporting unit include, but are not limited to, changes in discount rates, slower than expected patient ramp, lower than expected reimbursement rates or operating income, increases in capital expenditures or unfavorable changes in working capital. Negative changes in one or more of these factors, among others, could results in a goodwill impairment charge of up to $1.1 million in the future.

Recent Accounting Pronouncements

Recently Implemented Accounting Pronouncements

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): "Simplifying the Measurement of Inventory." The update requires that an entity should measure in scope inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The amendments were effective for us beginning January 1, 2017. The adoption of this update did not have a material impact on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09: “Improvements to Employee Share-Based Payment Accounting,” which simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The new guidance was effective for us beginning January 1, 2017. We have elected to continue to estimate forfeiture rates. This new standard impacts our income tax footnote disclosures. We have tax effected federal net operating losses of $18.0 million and state net operating losses of $1.6 million that are attributable to excess tax deductions related to stock-based compensation from prior years. Upon adoption the cumulative excess tax deductions related to stock-based compensation that were previously unrecognized are being recognized as a deferred tax asset and are fully offset by a valuation allowance. Other than this change in our income tax footnote disclosures, the adoption does not have a material impact on our financial statements.

In January 2017, the FASB issued ASU No. 2017-04: "Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment". The purpose of this update is to reduce the cost and complexity of evaluating goodwill for impairment. It eliminates the need for entities to calculate the impaired fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. Under this update, an entity will perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge is recognized for the amount by which the carrying value exceeds the reporting unit's fair value. We elected to early adopt this update on a prospective basis for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The adoption of this update did not have a material impact on our financial statements.

In May 2017, the FASB issued ASU No. 2017-09: "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting". The purpose of this update is to reduce the diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. It will allow companies to make non-substantive changes to their share-based payment awards, without accounting for them as modifications. It does not change the accounting for modifications. Under this update, an entity will apply the modification accounting guidance only if the value (or calculated value or intrinsic value, if those measurement methods are used), vesting conditions or classification of the award as an equity or liability instrument changes. This update also clarifies that a modification to an award could be significant and therefore require disclosure, even if modification accounting is not required. The new guidance will be applied prospectively to awards modified on or after the adoption date. We elected to early adopt this update in the second quarter of 2017. The adoption of this update did not have a material impact on our financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued ASU No. 2014-9: “Revenue from Contracts with Customers.” 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 is effective for us beginning January 1, 2018. The new guidance allows for full retrospective adoption applied to all periods presented or a modified retrospective adoption with the cumulative effect of initially applying the new guidance recognized at the date of initial application. In 2016, we commenced our evaluation of the impact of the standard, by establishing a cross functional team and evaluating the anticipated impact on significant contracts from each of our business segments. We intend to use the modified retrospective adoption methodology. We are evaluating the potential impact of the standard on the related disclosures and are comparing our current policies and practices to the requirements of the standard. We have developed a project plan to develop processes and tools and to assess the internal control structure in order to adopt the standard on January 1, 2018. We believe that the standard will impact the timing of revenue recognition for our Services segment as the standard eliminates cash basis revenue recognition and instead requires revenues to be estimated and recognized upon transfer of the promised goods and services. The adoption of the standard is not expected to have a material impact on our other segments. We have periodically briefed our Audit Committee on our progress made towards adoption. Based on our evaluation to date, we anticipate being able to estimate the quantitative impacts of adopting the ASU in connection with the filing of our 2017 Form 10-K.

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 January 2017, the FASB issued ASU No. 2017-01: "Business Combinations (Topic 805): Clarifying the Definition of a Business" which changes the definition of a business to assist entities with evaluating when a set of transferred assets and activities is a business. The update is effective for us beginning January 1, 2018. Early adoption is permitted, including for interim or annual periods in which the financial statements have not been issued or made available for issuance. The adoption of this update is not expected to have a material impact on our financial statements.

3. Inventory

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

	September 30, 2017	December 31, 2016
Purchased components	$ 14,861	$ 14,967
Work in process	14,891	13,939
Finished goods	20,916	17,939
Total	$ 50,668	$ 46,845

4. Property and Equipment, and Field Equipment

Accumulated depreciation on property and equipment was $57.3 million and $47.2 million at September 30, 2017 and December 31, 2016, respectively. Accumulated depreciation on field equipment was $52.5 million and $48.4 million at September 30, 2017 and December 31, 2016, respectively.

5. Intangible Assets

Accumulated amortization of intangible assets was $26.5 million and $25.0 million at September 30, 2017 and December 31, 2016, respectively.

6. 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Options to purchase common stock	1,069	1,096	1,126	682
Unvested restricted stock	327	382	238	359
Total	1,396	1,478	1,364	1,041

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

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

	September 30, 2017	December 31, 2016
Payroll, compensation and related benefits	$ 12,637	$ 14,086
Distribution expenses	5,132	4,804
General and administrative expenses	1,830	4,415
Audit, legal and consulting fees	3,469	1,373
Other manufacturing costs	1,481	1,891
Other	4,076	4,416
Total	$ 28,625	$ 30,985

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

	September 30, 2017	December 31, 2016
Capital lease obligations	$ 2,154	$ 1,840
Deferred revenue, current portion	1,526	1,035
Other	922	895
Total	$ 4,602	$ 3,770

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

	September 30, 2017	December 31, 2016
Capital lease obligations	$ 11,595	$ 9,991
Lease incentive obligations	2,842	3,059
Benefit plan obligations	2,020	1,678
Other	1,537	840
Total	$ 17,994	$ 15,568

8. Debt and Capital Lease Obligations

Other Loan

In May 2017, we extinguished a loan with a balance of $0.9 million and simultaneously entered into a capital lease of certain property and equipment for the same amount. The capital lease obligation is payable over five years. This debt extinguishment and capital lease financing represent a noncash investing and financing activity.

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 of the System One and PureFlow SL dialysate preparation equipment and sales 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 2016 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 September 30, 2017						
Revenues from external customers	$ 73,479	$ 15,465	$ 3,392	$ 4,959	$ —	$ 97,295
Intersegment revenues	1,197	—	—	—	(1,197)	—
Revenues	74,676	15,465	3,392	4,959	(1,197)	97,295
Segment profit (loss)	18,799	2,131	(23,602)	(5,626)	15	(8,283)
Depreciation and amortization	5,539	564	1,088	1,318	(26)	8,483
Three Months Ended September 30, 2016						
Revenues from external customers	$ 70,011	$ 14,493	$ 3,601	$ 3,846	$ —	$ 91,951
Intersegment revenues	1,930	—	—	—	(1,930)	—
Revenues	71,941	14,493	$ 3,601	3,846	(1,930)	91,951
Segment profit (loss)	19,828	2,463	(15,676)	(6,384)	(207)	24
Depreciation and amortization	6,015	500	1,134	1,232	(556)	8,325
Nine Months Ended September 30, 2017						
Revenues from external customers	$ 220,950	$ 45,397	$ 9,127	$ 14,866	$ —	$ 290,340
Intersegment revenues	3,845	—	—	—	(3,845)	—
Revenues	224,795	45,397	9,127	14,866	(3,845)	290,340
Segment profit (loss)	60,021	6,152	(60,445)	(17,724)	(24)	(12,020)
Depreciation and amortization	16,601	1,633	3,252	3,888	(53)	25,321
Nine Months Ended September 30, 2016						
Revenues from external customers	$ 205,538	$ 47,990	$ 9,190	$ 10,647	$ —	$ 273,365
Intersegment revenues	5,553	—	—	—	(5,553)	—
Revenues	211,091	47,990	$ 9,190	10,647	(5,553)	273,365
Segment profit (loss)	55,997	8,155	(46,332)	(19,354)	(597)	(2,131)
Depreciation and amortization	17,362	1,489	3,361	3,441	(1,679)	23,974

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
DaVita	20%	21%	20%	20%
Fresenius	20%	18%	19%	18%

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 September 30, 2017 are consistent with those discussed in Note 10 to the consolidated financial statements in our 2016 Annual Report.

11. Income Taxes

We recognized a provision for income taxes during both the three and nine months ended September 30, 2017 and 2016 related to the profitable operations of certain foreign subsidiaries. However, the provision recognized during 2017 includes the impact of an allocation of U.S. tax expense between continuing operations and total other comprehensive (loss) income. Such allocation resulted in an increase to the provision for income taxes of $0.1 million during the three months ended September 30, 2017 and a decrease to the provision for income taxes of $1.1 million during the nine months ended September 30, 2017. This allocation has no impact on total comprehensive loss or total stockholders' equity for 2017. However, it did result in a net tax benefit from income taxes in continuing operations of $0.2 million during the nine months ended September 30, 2017.

As of September 30, 2017, we had a liability for unrecognized tax benefits included in the balance sheet of approximately $0.8 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 and nine months ended September 30, 2017.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of revenues	$ 335	$ 314	$ 902	$ 1,056
Selling and marketing	1,054	781	3,047	2,562
Research and development	437	344	1,154	1,148
General and administrative	1,534	855	3,581	2,922
Total	$ 3,360	$ 2,294	$ 8,684	$ 7,688

Stock Options and Restricted Stock Units

The Company granted options to purchase 7,480 and 20,351 shares of common stock during the three months ended September 30, 2017 and 2016, respectively, and options to purchase 675,358 and 1,334,351 shares of common stock during the nine months ended September 30, 2017 and 2016, respectively, which vest based on continued employment over a period of one to four years. The weighted-average fair value of options granted during the nine months ended September 30, 2017 and 2016 was $9.92 and $5.89 per option, respectively.

The Company awarded 20,970 and 23,380 restricted stock units during the three months ended September 30, 2017 and 2016, respectively, and 175,895 and 219,846 restricted stock units during the nine months ended September 30, 2017 and 2016, respectively, 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 nine months ended September 30, 2017 and 2016 was $27.23 and $17.34 per unit, respectively.

In March 2017, the Compensation Committee of our Board of Directors approved the grant of up to 231,384 restricted stock units subject to the achievement of certain Company financial performance metrics for the year ending December 31, 2017. In August 2017, in connection with the Board of Director's approval of the Merger Agreement, the Compensation Committee determined that all Company financial performance metric criteria shall be deemed fully satisfied. The restricted stock units vest over a requisite service period of three years and have a modified grant date fair value of $23.14 per unit.

13. Stockholders' Equity

We received 97,828 and 100,571 shares of common stock that were surrendered in payment for the exercise of stock options during the nine months ended September 30, 2017 and 2016, respectively.

14. Noncontrolling Interest

As of September 30, 2017, 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, and provide operating and capital funding as necessary for the entities to accomplish their operational and strategic objectives which transfer substantial power over and economic responsibility for the entities to us.

The analysis upon which these consolidation determinations rest are complex, involve uncertainties, and require significant judgment on various matters. At September 30, 2017 and December 31, 2016, total assets of our VIEs were $5.8 million and $8.0 million, and total liabilities and noncontrolling interests of our VIEs were $5.9 million and $7.2 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 September 30, 2017 the Company's noncontrolling interests subject to put provisions were $0.7 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 and nine months ended September 30, 2017 and 2016 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Balance at beginning of period	$ (145)	$ 1,722	$ 625	$ 1,694
Capital contributions by noncontrolling interest	—	231	—	531
Sales of noncontrolling interests	—	—	—	679
Accretion to redemption value of noncontrolling interests	481	—	481	—
Reclassification of noncontrolling interest subject to put provision	(744)	—	(744)	—
Net loss attributable to noncontrolling interest in consolidated subsidiary	(376)	(672)	(1,146)	(1,623)
Balance at end of period	$ (784)	$ 1,281	$ (784)	$ 1,281

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 September 30, 2017 and December 31, 2016, the notional amount of our outstanding contracts that are designated as cash flow hedges was $22.4 million and $18.6 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 $1.9 million at September 30, 2017 and a net liability of $1.8 million at December 31, 2016, 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 nine months ended September 30, 2017 and 2016. 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 September 30, 2017			
Foreign exchange forward contracts	$ 116	$ 733	Cost of revenues
Nine Months Ended September 30, 2017			
Foreign exchange forward contracts	$ 4,211	$ 254	Cost of revenues
Three Months Ended September 30, 2016			
Foreign exchange forward contracts	$ (386)	$ (381)	Cost of revenues
Nine Months Ended September 30, 2016			
Foreign exchange forward contracts	$ (1,338)	$ (1,430)	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 on derivative instruments	Other (2)	Total
Balance, net of tax, as of December 31, 2016	$ (2,285)	$ (3,816)	$ (6,101)
Other comprehensive income before reclassifications, net of $1,581 tax during 2017	2,630	1,830	4,460
Gain reclassified to earnings (1)	(254)	—	(254)
Total other comprehensive income, net of tax	2,376	1,830	4,206
Balance, net of tax, as of September 30, 2017	$ 91	$ (1,986)	$ (1,895)

(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 nine months ended September 30, 2017.

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

September 30, 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)	$ 34,945	$ —	$ —	$ 34,945
Foreign exchange forward contracts (2)	—	2,096	—	2,096
Liabilities				
Foreign exchange forward contracts (2)	$ —	$ 203	$ —	$ 203

December 31, 2016	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)	$ 34,804	$ —	$ —	$ 34,804
Liabilities				
Foreign exchange forward contracts (2)	$ —	$ 1,771	$ —	$ 1,771

(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 September 30, 2017 and December 31, 2016. 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.

In September 2017, we acquired a 2.5% equity ownership of a privately held dialysis services company in exchange for $2.5 million in cash. This investment is accounted for using the cost method as we are unable to exercise any significant influence over the company. The investment has been recorded at historical cost, classified within other assets on our condensed consolidated balance sheet, and is reviewed for events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. There have been no changes in circumstances or identified events that may have a significant adverse effect on the fair value.

18. Supplemental Cash Flow Information

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

	Nine Months Ended September 30,	
	2017	2016
Noncash Investing and Financing Activities:		
Transfers from inventory to field equipment	$ 13,709	$ 14,629
Transfers from field equipment to deferred cost of revenues	7,570	10,396
Market value of shares received in payment for exercise of stock options	2,771	1,963
Redemption of noncontrolling interest	481	—
PP&E financed by construction liability	109	187
Property and equipment acquired under capital lease	—	127

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, 2016, included in our 2016 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;
- the ability of our product pipeline and other initiatives to help us expand existing markets and enter new ones;
- achieving greater operating leverage and improved financial results in the future;
- expectations about the profitability of our products business and company as a whole;
- financial performance of our NxStage Kidney Care dialysis centers and our continued investments in them;
- estimates of the number of end-stage renal disease (ESRD) patients that could be treated at home and with the System One;
- our strategic initiatives to grow home hemodialysis adoption, expand globally, enhance our product offerings, expand into high growth adjacencies and enter the peritoneal dialysis market and their ability to unlock market opportunity;
- access to home and more frequent hemodialysis;
- the market opportunity within and outside the U.S.;
- the development and commercialization of new products and improvements to existing products;
- 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 and the components of such revenue growth;
- expansion to new markets where our current and future technology has the ability to deliver value for our patients and customers;
- future financial results for our System One, In-Center and Services segments and total company;
- expectation of sustaining gross profit as a percentage of revenue in our System One segment above 50%;
- future selling and marketing, research and development, distribution, and general and administrative expenses;
- our manufacturing operations and supply chain;
- expectations with respect to our working capital levels and requirements;
- global economic conditions;
- the timing and cost of our remediation efforts concerning a software anomaly affecting certain System One cyclers;
- expectations with respect to achieving positive operating margins and positive cash flows;
- volatility of our stock price;
- expectations with respect to product reliability;
- anticipated benefits of manufacturing dialyzers for sale to Asahi Kasei Kuraray Medical Co. (Asahi) and future sales to Asahi;
- expected impact of changes to accounting standards and policies;
- the availability of, and impact of changes in, reimbursement for home and more frequent hemodialysis, including home nocturnal hemodialysis;
- the anticipated timing and likelihood of completion of the proposed merger of us with a subsidiary of Fresenius;
- the operation of our business during the pendency of the proposed merger;
- expectations for the business in the event the proposed merger is completed;
- the possibility that various closing conditions to the proposed merger may not be satisfied or waived in a timely manner or at all;
- the possibility that a material adverse effect occurs with respect to our business;
- risks related to disruption of management time from ongoing business operations due to the proposed merger;
- limitations placed on our ability to operate the business by the Merger Agreement;
- the risk that the proposed merger and its announcement could have an adverse effect on our ability to retain and hire key employees and maintain relationships with our suppliers and customers; 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 and markets 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 to 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 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 $4.1 million and $4.3 million of incremental costs for the three and nine months then ended September 30, 2017, respectively, for professional service fees and certain other costs related to the proposed merger. 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 concentrated. DaVita and Fresenius own and operate the two largest chains of dialysis centers in the U.S. Collectively, they provide treatment to more than approximately 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 any future growth. 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 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 23% and 33% of our In-Center segment revenues for the three months ended September 30, 2017 and 2016, respectively, and 22% and 27% for the nine months ended September 30, 2017 and 2016, respectively. Gambro AB (a subsidiary of Baxter International, Inc.) accounted for 17% and 19% of our In-Center segment revenues for the three months ended September 30, 2017 and 2016, respectively, and 21% and 22% for the nine months ended September 30, 2017 and 2016, respectively, with all of Gambro's sales of our product 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 September 30, 2017, we had $2.7 million reserved against trade accounts receivable for future distributor rebates and recorded $3.7 million and $2.9 million during the three months ended September 30, 2017 and 2016, respectively, and $11.5 million and $10.1 million during the nine months ended September 30, 2017 and 2016, respectively, as a reduction of revenues in connection with distributor rebates. For the In-Center segment, as of September 30, 2017, we had $2.5 million reserved against trade accounts receivable for future estimated distributor rebates and recorded $2.0 million and $1.8 million during the three months ended September 30, 2017 and 2016, respectively, and $5.0 million and $5.2 million during the nine months ended September 30, 2017 and 2016, 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. We currently have 20 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.

Financial Performance

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Products Business (System One Segment, In-Center Segment & Other)				
Revenues	$ 93,533	90,035	$ 279,319	$ 268,271
Gross profit	$ 44,333	$ 43,455	$ 133,988	$ 126,888
Gross margin percentage	47%	48%	48%	47%
(Loss) income from operations	$ (2,672)	$ 6,615	$ 5,728	$ 17,820
Services Segment				
Revenues	$ 4,959	$ 3,846	$ 14,866	$ 10,647
Gross profit	$ (3,741)	$ (4,067)	$ (11,001)	$ (12,170)
Gross margin percentage	n/a	n/a	n/a	n/a
Loss from operations	$ (5,626)	$ (6,384)	$ (17,724)	$ (19,354)
Eliminations				
Elimination of intersegment revenues	$ (1,197)	$ (1,930)	$ (3,845)	$ (5,553)
Elimination of intersegment gross profit	$ 15	$ (207)	$ (24)	$ (597)
Total Company				
Revenues	$ 97,295	$ 91,951	$ 290,340	$ 273,365
Gross profit	$ 40,607	$ 39,181	$ 122,963	$ 114,121
Gross margin percentage	42%	43%	42%	42%
(Loss) income from operations	$ (8,283)	$ 24	$ (12,020)	$ (2,131)

For several years, we have focused on operating and financial improvements. During the three and nine months ended September 30, 2017 these efforts resulted in revenues increasing by 6% to $97.3 million and by 6% to $290.3 million, respectively, 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 2017 and beyond within our products business. At the same time, we expect operating losses in our Services segment to improve in the long term, but continue to have a negative impact on our total operating performance in the near term.

Comparison of the Three and Nine Months Ended September 30, 2017 and 2016

Revenues

Our revenues for the three and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
System One segment								
Home	$ 55,852	57 %	$ 53,759	58 %	$ 165,949	57 %	$ 154,397	56 %
Critical Care	18,824	20 %	18,182	20 %	58,846	20 %	56,694	21 %
Total System One segment	74,676	77 %	71,941	78 %	224,795	77 %	211,091	77 %
In-Center segment	15,465	16 %	14,493	16 %	45,397	16 %	47,990	18 %
Other	3,392	3 %	3,601	4 %	9,127	3 %	9,190	3 %
Products subtotal	93,533	96 %	90,035	98 %	279,319	96 %	268,271	98 %
Services segment	4,959	5 %	3,846	4 %	14,866	5 %	10,647	4 %
Elimination of intersegment revenues	(1,197)	(1)%	(1,930)	(2)%	(3,845)	(1)%	(5,553)	(2)%
Total	$ 97,295	100 %	$ 91,951	100 %	$ 290,340	100 %	$ 273,365	100 %

Home product revenues increased $2.1 million, or 4% and $11.6 million, or 7% for the three and nine months ended September 30, 2017 versus the prior year comparable period, respectively, driven primarily by the increase in the number of patients prescribed to use the System One both in the U.S. and internationally along with contractual price improvements. These improvements were offset by lower equipment sales to NxStage Kidney Care as a result of completing the build out of our existing centers. 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 $0.6 million, or 4% and $2.2 million, or 4% during the three and nine months ended September 30, 2017 versus the prior year comparable period, respectively. 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 $1.0 million, or 7% and decreased $2.6 million, or 5% for the three and nine months ended September 30, 2017, versus the prior year comparable period, respectively. The changes are due to timing of sales of our blood tubing sets. Both periods benefited from increased needle sales, and were impacted by variations in inventory management policies at both our distributors and end users. Similarly, we expect In-Center segment revenues will continue to fluctuate as a result of these factors.

Other revenues for the three and nine months ended September 30, 2017 and 2016 relate to dialyzers sold to Asahi. The fluctuation in revenues was due to changes in volume. Sales to Asahi may fluctuate due to timing of sales, inventory management policies at Asahi and changes in currency exchange rates.

Service segment revenues for the three and nine months ended September 30, 2017 and 2016 relate to dialysis services provided to patients at our NxStage Kidney Care dialysis centers. We expect future revenues to increase modestly, but may fluctuate in the near term based on payor mix, and the timing of certain payments.

Gross Profit (Loss)

Our gross profit (loss) for the three and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
System One segment	$ 39,671	53%	$ 38,680	54%	$ 120,618	54%	$ 111,427	53%
In-Center segment	4,423	29%	4,381	30%	12,821	28%	14,066	29%
Subtotal	44,094	49%	43,061	50%	133,439	49%	125,493	48%
Other	239	7%	394	11%	549	6%	1,395	15%
Products subtotal	$ 44,333	47%	$ 43,455	48%	133,988	48%	126,888	47%
Services segment	(3,741)	n/a	(4,067)	n/a	(11,001)	n/a	(12,170)	n/a
Elimination of intersegment gross profit	15	n/a	(207)	n/a	$ (24)	n/a	$ (597)	n/a
Gross profit	$ 40,607	42%	$ 39,181	43%	$ 122,963	42%	$ 114,121	42%

Gross profit as a percentage of revenues for the System One segment decreased for the third quarter and improved for the year versus the same period last year. The quarterly decrease was primarily driven by increased product and service costs, offset in part by contractual price improvements. The year to date improvement was primarily driven by contractual price and product cost improvements, offset in part by increased service 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.

Gross profit as a percentage of revenues for the In-Center segment decreased as a percentage of revenue for the three and nine months ended September 30, 2017, versus the prior year comparable period, driven primarily by changes in pricing offset by favorable currency. We expect gross profit as a percentage of revenues will fluctuate as a result of changes in volume and changes product mix.

The Other category relates to costs associated with the manufacturing of dialyzers for sale to Asahi, which should provide us with long-term cost efficiencies through increased dialyzer production volumes. In the nine months ended September 30, 2016, we received reimbursements from Asahi for $0.7 million related to additional startup costs incurred in 2015 with the build out of the manufacturing facility in Germany which was recorded as a reduction of cost of revenues.

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; however, the margin percentage improved versus the prior year comparable periods due to continued revenue growth. We expect the Services segment gross margin will continue to be negatively impacted by costs associated with the operation of our NxStage Kidney Care dialysis centers, coupled with the impact of payor mix, and the timing of certain payments.

In aggregate, total company gross profit as a percentage of revenues will be negatively impacted by costs associated with our continued investment in our Services segment.

Selling and Marketing

Our selling and marketing expenses and selling and marketing expenses as a percentage of revenues for the three and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except as percentages of revenues):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
System One segment	$ 13,191	18%	$ 12,180	17%	$ 38,303	17%	$ 35,604	17%
In-Center segment	1,908	12%	1,527	11%	5,569	12%	4,606	10%
Products subtotal	15,099	16%	13,707	15%	43,872	16%	40,210	15%
Services segment	1,885	n/a	2,317	n/a	6,723	n/a	7,184	n/a
Total Selling and marketing	$ 16,984	17%	$ 16,024	17%	$ 50,595	17%	$ 47,394	17%

Selling and marketing expenses increased $1.0 million, or 6% and $3.2 million, or 7% for the three and nine months ended September 30, 2017 versus the prior year comparable period, respectively, but remained 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 increased due to increased personnel and personnel-related costs and increased further as a percentage of revenue for the nine month period primarily driven by lower revenues.

Selling and marketing expenses for our Services segment decreased $0.4 million, or 19% and $0.5 million, or 6% for the three and nine months ended September 30, 2017, respectively, versus the prior year comparable period. The decrease included

the recognition of severance and other post termination costs of $0.8 million during the nine months ended September 30, 2017. 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.

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 and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
Research and development	$ 11,222	12%	$ 8,278	9%	$ 29,757	10%	$ 23,393	9%

Research and development expenses increased for the three and nine months ended September 30, 2017 versus the prior year comparable period. The increase was primarily due to increased project related spending and increased personnel and personnel-related costs.

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

Distribution

Our distribution expenses for the three and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
System One segment	$ 7,681	10%	$ 6,672	9%	$ 22,294	10%	$ 19,826	9%
In-Center segment	384	2%	391	3%	1,100	2%	1,305	3%
Total Distribution	$ 8,065	8%	$ 7,063	8%	$ 23,394	8%	$ 21,131	8%

Distribution expenses increased $1.0 million, or 14% and $2.3 million, or 11% for the three and nine months ended September 30, 2017 versus the prior year comparable period, respectively, driven mainly by higher shipment volumes in the System One segment; however, it has remained relatively consistent as a percentage of revenues in both segments. 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 and nine months ended September 30, 2017 and 2016 were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
General and administrative	$ 12,619	13%	$ 7,792	8%	$ 31,237	11%	$ 24,334	9%

General and administrative expenses increased by $4.8 million, or 62% and $6.9 million, or 28% for the three and nine months ended September 30, 2017 versus the prior year comparable period, respectively. The increase was primarily due to professional service fees and other costs incurred in connection with the proposed merger. We recognized $3.6 million and $3.9 million of expenses incurred in connection with the proposed merger during the three and nine months ended September 30, 2017, respectively. We expect general and administrative expenses as a percentage of revenues will increase compared to prior periods, driven by costs associated with the proposed merger.

Other Expense

Interest expense, net remained relatively consistent for the three and nine months ended September 30, 2017 versus the prior year comparable period. 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 both the three and nine months ended September 30, 2017 and 2016 related to the profitable operations of certain foreign subsidiaries. However, the provision recognized during 2017 includes the impact of an allocation of U.S. tax expense between continuing operations and total other comprehensive (loss) income. Such allocation resulted in an increase to the provision for income taxes of $0.1 million during the three months ended September 30, 2017 and a decrease to the provision for income taxes of $1.1 million during the nine months ended September 30, 2017. This allocation has no impact on total comprehensive loss or total stockholders' equity for 2017. However, it did result in a net tax benefit from income taxes in continuing operations of $0.2 million during the nine months ended September 30, 2017.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of September 30, 2017, our accumulated deficit was $419.3 million and we had cash and cash equivalents of $63.0 million, with substantially all of that cash located in the U.S., and working capital of $105.7 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 continued investments in our existing NxStage Kidney Care dialysis centers.

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's 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 September 30, 2017, 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, we had approximately $24 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 $2.0 million at September 30, 2017 for costs associated with these plans. The expense recorded in connection with these plans was not significant during the nine months ended September 30, 2017 or 2016.

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

	Nine Months Ended September 30,	
	2017	2016
Net cash provided by operating activities	$ 1,989	$ 4,993
Net cash used in investing activities	(10,150)	(7,309)
Net cash provided by financing activities	10,364	3,509
Foreign exchange effect on cash and cash equivalents	1,144	559
Net cash flow	$ 3,347	$ 1,752

Net cash provided by operating activities. Net cash flows from operating activities decreased by $3.0 million during the nine months ended September 30, 2017, versus the prior year comparable period, driven by changes in working capital

requirements including timing of payments to our vendors and other accrued expenses, offset by in part by the timing of accounts receivable collections. 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 decreased by $1.0 million during the nine months ended September 30, 2017, versus the prior year comparable period. Amortization of deferred revenues into revenues relating to sales of home equipment was $13.3 million and $13.4 million during the nine months ended September 30, 2017 and 2016, 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 the build-out of NxStage Kidney Care dialysis centers, coupled with expenditures for our manufacturing facilities as a result of our efforts to maintain and expand our manufacturing operations, along with purchases of information technology. For the nine months ended September 30, 2017, cash used in investing activities includes $2.5 million equity investment in a dialysis services company accounted for using the cost method. Cash used in investing activities include payments related to an acquisition of a dialysis center during each of the nine months ended September 30, 2017 and 2016.

The increase of $0.8 million in purchases of property and equipment was driven primarily by spending associated with our manufacturing facilities. Capital expenditures for our NxStage Kidney Care centers were $1.9 million and $3.2 million during the nine months ended September 30, 2017 and 2016, respectively.

Net cash provided by financing activities. During the nine months ended September 30, 2017 and 2016 we received $11.0 million and $3.7 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. During the nine months ended September 30, 2016 we received $1.2 million in investments by noncontrolling interest holders. Cash provided by financing activities during both 2017 and 2016 was also reduced by cash used to pay our debt and capital lease 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 US 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 and nine months ended September 30, 2017 are described in Note 2 to the consolidated financial statements included in our 2016 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 and nine months ended September 30, 2017 are consistent with those described in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our 2016 Annual Report.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements included in our 2016 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 2016 Annual Report. There have been no material changes to our market risks or to our management of such risks during the three and nine months ended September 30, 2017 other than those discussed below.

Foreign Currency Exchange Risk

We enter into foreign exchange forward contracts on peso and euro denominated expenses to reduce our exposure to foreign currency exchange rate fluctuations from our foreign manufacturing and service operations located in Mexico and Europe.

Our foreign exchange forward contracts are entered into with large financial institutions and have durations of up to twelve months. These contracts are designated as cash flow hedges intended to offset the effect of exchange rate fluctuations on

forecasted manufacturing and service costs. The effective portion of changes in the fair value of derivatives designated and qualifying as cash flow hedges is recorded in accumulated other comprehensive (loss) income and is subsequently reclassified into earnings in the period in which the hedged forecasted transaction affects earnings. As of September 30, 2017, the notional amount of our outstanding contracts that are designated as cash flow hedges increased to approximately $22.4 million, as we accelerated our entry into certain planned foreign exchange forward contracts due to favorable exchange rates. Based on our analysis, a hypothetical adverse foreign exchange rate movement of 10% against our contracts would have resulted in a net loss in fair value of these contracts of approximately $2.7 million.

Item 4. ***Controls and Procedures***

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2017. 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 September 30, 2017, 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 and nine months ended September 30, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 this Quarterly 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 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, seven 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 approximately 90% of 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 are actively engaged in the comment process for the proposed local coverage determinations. Comment letters are due on various dates during November and December 2017. If the proposed local coverage determinations were adopted in their current form, they would adversely affect our business by significantly restricting patient access to home and more frequent hemodialysis.

In October 2016, the Centers for Medicare & Medicaid Services issued its final rule to update the payment policies and rates under the end-stage renal disease prospective payment system for 2017. Among other things, the Centers for Medicare & Medicaid Services increased the home and self-dialysis training add-on payment and reiterated its policy of paying for appropriately medically justified hemodialysis treatments provided in excess of three treatments per week. The proposed rule issued for 2018 does not change either of these favorable payment policies.

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 proposed rule for the end-stage renal disease prospective payment system, which proposes an increase to the base reimbursement rate of 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 that had imposed a 2.3% excise tax on domestic sales of certain medical devices, including our products, which reduced our profitability. In December 2015, this tax was suspended for two years, but will continue to have a negative financial impact when it is imposed again starting in 2018, 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. During 2017, we face uncertainty regarding potential federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all provisions of recent U.S. health care reforms. Such changes may negatively impact our prospects for revenue growth, increase our costs or benefit our competitors. Absent additional clarity on the terms of any such changes, the impact on our business is uncertain.

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, including a system for peritoneal dialysis, and our NxStage Kidney Care dialysis centers, 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 have a significant adverse impact on our business.

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 announcement of our merger agreement 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 our product pipeline and NxStage Kidney Care dialysis centers, to drive future growth. Accordingly, we cannot ensure the 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, 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.

Joint ventures have become common vehicles 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 has been growing governmental scrutiny of joint ventures and other financial arrangements with physicians or 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 them pursuant to any prohibited referrals, and incur the types of penalties 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 provide us with valuable experience to better meet and anticipate the needs of both our customers and patients, and optimize 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 market is mature and we face competition from many sources, including those that are listed in the section of our 2016 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 a broader bundle of 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 Fresenius which is the world’s largest provider of dialysis services and products and may at any time reduce its promotion of our dialysis products to its dialysis patients in favor of other, including its own, dialysis products.

Further consolidation within the highly competitive dialysis industry may exacerbate these risks.

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. 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 market 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 market requirements, such as our peritoneal dialysis system and next generation critical care system. Otherwise, we may lose revenues or market share to our competitors, which may be difficult to regain. Developing innovative products and bringing them to market is a highly costly, lengthy and uncertain process, and we may experience delays in 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 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;
- we may be unable to manufacture sufficient quantities of the new product for development or commercialization activities in a timely and cost-effective manner; and
- market demand for the new product may fall below expectations.

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, reducing our gross profit, or render our products overly expensive, 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, 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 United States 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 United States. 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 materially impact our 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 United Kingdom and Canada.

During June 2016, the referendum by UK voters to exit the European Union ("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 that may be material in the near-term.

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. Furthermore, current and prospective employees may experience uncertainty regarding their future roles in connection with our proposed merger with Fresenius, which might adversely affect our ability to retain, recruit and motivate key personnel.

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 devices 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.

Foreign markets are particularly 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 United States 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 classified as drugs rather than medical devices, which require us to demonstrate compliance with separate regulations applicable to drug manufacturers and distributors. These complex regulations may impose additional approval, manufacturing, surveillance and reporting requirements. Compliance with these additional requirements may increase our costs of doing business in new foreign markets and delay 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 2016 Annual Report entitled “Business - Government Regulation.” Noncompliance with applicable regulations can result in, among other things:

- violation letters;
- fines, injunctions, and civil penalties;
- recall or seizure of products;
- administrative detention, which is the detention by regulatory authorities of medical devices believed to be adulterated or misbranded;
- operating restrictions, partial suspension or total shutdown of production;
- failure of the government to grant pre-market clearance or pre-market approval for devices;
- withdrawal of marketing clearances or approvals; and
- criminal prosecution.

Such enforcement measures would require unanticipated expenditures to address or defend such actions and may adversely affect our business.

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 European Union 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.

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. From time to time we have chosen to voluntarily recall certain products that we believed were mislabeled or otherwise defective. Product recalls may materially divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our financial results.

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 2016 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 harm our business.

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 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 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 to purchase, order or use our products or services, or to refer patients to our NxStage Kidney Care dialysis centers, we could be subject to a claim under the federal healthcare program Anti-Kickback Statute, the Federal False Claims Act, the federal patient inducement prohibition or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws. 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 deems 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, raising 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 European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business. Furthermore, reimbursement provided for our products in other jurisdictions could change, positively or negatively. If reimbursements were to be negatively changed, such as in the United Kingdom 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 into the United States disposable medical supplies from our manufacturing facilities and vendors located outside the United States. We have manufacturing facilities in Mexico, Germany and Italy and export various components and assemblies related to those operations. To a lesser but increasing degree, we also export finished goods from the United States to foreign countries. The import and export of these items are subject to extensive and complex laws and regulations. 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, fiscal and tax policies which may include comprehensive tax reform and 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, both domestically and 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, or if the United States imposes tariffs or border-adjusted taxes on imports to the United States of goods manufactured outside the United States, 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 a material 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 United States 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 impair our business, at least in the near term.

Our dependence upon these and other single-source suppliers of raw materials, components, finished goods and sterilization services exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation, or customers switching to competitive products. Any interruption in supply could be particularly damaging to our customers using the System One to treat chronic end-stage renal disease who need access to the System One and related disposables to continue their therapy.

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

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 reputation and cause our business and operating results to suffer.

Commodity 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 have resulted in significant price increases for this material, and similar periods of rising resin prices may occur in the future. Our contracts with customers restrict our ability to immediately pass on these price increases, and future pricing to customers may be insufficient to accommodate increasing resin costs. In addition, our overall cost reduction plans may not sufficiently offset the impact of increased resin costs, which could result in declining margins and operating results.

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 material 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 an issued patent, and any patents that are issued may not provide meaningful protection against competitors or competitive technologies.

Our products could infringe the intellectual property rights of others.

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 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 proprietary 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. In addition, others may independently discover or reverse engineer trade secrets and proprietary information, and in such cases we may be unable to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position.

Many of our employees have worked at other medical device companies focused on the development of dialysis products, including our competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against these claims, litigation could result in substantial costs and harm to our reputation and be a distraction to management.

Risks Related to our Common Stock

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 have caused the market price of our common stock to fluctuate include:

- timing of market launch and market acceptance of our products;
- timing of achieving profitability from operations;
- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts' expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;
- developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers and distributors;
- disruptions in product supply for any reason, 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 United States and foreign countries;
- changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments, or the willingness of Medicare contractors to pay for more than three treatments a week where medically justified;
- 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 significantly harm our profitability and reputation.

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

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

our board of directors, which in turn may delay or prevent changes in our current management team that stockholders may favor. These provisions include:

- a prohibition on stockholder actions by written consent;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "stockholders rights plan" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- advance notice requirements for nominations of directors or stockholder proposals;
- the requirement that board vacancies be filled by a majority of our directors then in office; and
- the prohibition on a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

As part of our growth strategy, we may acquire other businesses and technologies and pursue additional business opportunities. To finance such activity, we may issue equity securities, which may dilute our existing stockholders, and incur debt, which may place restrictions on our business operations. Such financing activity may reduce the market value of our common shares and other securities, in particular if the initiatives being funded are not viewed favorably by our stockholders 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 proposed acquisition of the Company (the "Merger") by Fresenius Medical Care Holdings, Inc. ("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 Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (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 announcement and 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, which may reflect a market assumption that the proposed Merger will be consummated. Any of these events could harm our business, results of operations and financial condition 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.

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 materially and adversely affect our financial condition and results of operations, as well as the price per share for our common stock.

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 and 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. We may incur unexpected costs, charges or expenses resulting from the proposed Merger. 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 without Fresenius's consent. Such restrictions will be in place until either the Merger is consummated or the Merger Agreement is terminated. These restrictions may prevent us from, pursuing attractive business opportunities (if any) that arise prior to the consummation of the Merger. For these and other reasons, the pendency of the Merger could adversely affect our business and results of operations.

Any disruptions to our business while the Merger is pending that have a material adverse impact to our financial results could result in future borrowings

While the Merger is pending, a significant reduction in revenues and the consequent impact on our results of operations could negatively impact our cash on hand. Accordingly, we may need to draw on our current line of credit or obtain financing from other sources in order to fund operations and capital expenditures.

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

Uncertainty over the effects of the proposed Merger may make it more difficult to attract and retain qualified employees. 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. In addition, whether or not the proposed Merger is consummated, while it is pending we will continue to incur costs, fees, expenses and charges related to the proposed Merger, which may materially and adversely affect our financial condition and results of operations.

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

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* 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)

November 8, 2017

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 September 30, 2017 (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: November 8, 2017

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 September 30, 2017 (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: November 8, 2017

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 September 30, 2017 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: November 8, 2017

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 September 30, 2017 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: November 8, 2017