# NXSTAGE MEDICAL, INC.

## FORM 10-Q
(Quarterly Report)

Filed 11/03/16 for the Period Ending 09/30/16

| | |
|---|---|
| Address | 350 MERRIMACK STREET<br>LAWRENCE, MA 01843 |
| Telephone | 978-687-4700 |
| CIK | 0001333170 |
| Symbol | NXTM |
| SIC Code | 3845 - Electromedical and Electrotherapeutic Apparatus |
| Industry | Advanced Medical Equipment & Technology |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

# 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, 2016

**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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

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

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

There were 64,756,107 shares of the registrant's common stock outstanding as of the close of business on October 31, 2016 .

**NXSTAGE MEDICAL, INC.**
**QUARTERLY REPORT ON FORM 10-Q**
**FOR THE QUARTER ENDED SEPTEMBER 30, 2016**
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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, 2016 | December 31, 2015 |
|---|---|---|
| | (In thousands, except share data) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 60,817 | $ 59,065 |
| Accounts receivable, net | 30,581 | 25,195 |
| Inventory | 46,877 | 38,391 |
| Prepaid expenses and other current assets | 5,875 | 6,254 |
| Total current assets | 144,150 | 128,905 |
| Property and equipment, net | 65,004 | 66,711 |
| Field equipment, net | 20,450 | 20,744 |
| Deferred cost of revenues | 33,972 | 33,068 |
| Intangible assets, net | 10,202 | 11,744 |
| Goodwill | 42,710 | 42,710 |
| Other assets | 2,623 | 2,992 |
| Total assets | $ 319,111 | $ 306,874 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 14,755 | $ 10,767 |
| Accrued expenses | 29,335 | 27,266 |
| Current portion of long-term debt | 330 | 315 |
| Other current liabilities | 4,105 | 4,394 |
| Total current liabilities | 48,525 | 42,742 |
| Deferred revenues | 50,969 | 51,362 |
| Long-term debt | 1,445 | 1,664 |
| Other long-term liabilities | 16,829 | 17,367 |
| Total liabilities | 117,768 | 113,135 |
| Commitments and contingencies (Note 9) | | |
| Noncontrolling interests subject to put provisions | 116 | 219 |
| Stockholders' equity: | | |
| Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of September 30, 2016 and December 31, 2015 | — | — |
| Common stock: par value $0.001, 100,000,000 shares authorized; 65,638,390 and 64,873,038 shares issued as of September 30, 2016 and December 31, 2015, respectively | 65 | 64 |
| Additional paid-in capital | 626,040 | 612,487 |
| Accumulated deficit | (406,004) | (402,830) |
| Accumulated other comprehensive loss | (4,328) | (4,031) |
| Treasury stock, at cost: 922,630 and 822,059 shares as of September 30, 2016 and December 31, 2015, respectively | (15,827) | (13,864) |
| Total NxStage Medical, Inc. stockholders' equity | 199,946 | 191,826 |
| Noncontrolling interests not subject to put provisions | 1,281 | 1,694 |
| Total stockholders' equity | 201,227 | 193,520 |
| Total liabilities and stockholders' equity | $ 319,111 | $ 306,874 |

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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| | (In thousands, except per share data) | | | |
| Revenues | $ 91,951 | $ 86,521 | $ 273,365 | $ 246,319 |
| Cost of revenues | 52,770 | 51,803 | 159,244 | 150,611 |
| Gross profit | 39,181 | 34,718 | 114,121 | 95,708 |
| Operating expenses: | | | | |
| Selling and marketing | 16,024 | 14,445 | 47,394 | 43,511 |
| Research and development | 8,278 | 6,752 | 23,393 | 19,248 |
| Distribution | 7,063 | 6,514 | 21,131 | 19,140 |
| General and administrative | 7,792 | 8,642 | 24,334 | 26,139 |
| Total operating expenses | 39,157 | 36,353 | 116,252 | 108,038 |
| Income (loss) from operations | 24 | (1,635) | (2,131) | (12,330) |
| Other expense: | | | | |
| Interest expense, net | (244) | (312) | (773) | (795) |
| Other (expense) income, net | (346) | 235 | (987) | 536 |
| | (590) | (77) | (1,760) | (259) |
| Net loss before income taxes | (566) | (1,712) | (3,891) | (12,589) |
| Provision for income taxes | 324 | 290 | 1,007 | 870 |
| Net loss | (890) | (2,002) | (4,898) | (13,459) |
| Less: Net loss attributable to noncontrolling interests | (724) | (315) | (1,724) | (787) |
| Net loss attributable to stockholders of NxStage Medical, Inc. | $ (166) | $ (1,687) | $ (3,174) | $ (12,672) |
| Net loss per share, basic and diluted | $ (0.00) | $ (0.03) | $ (0.05) | $ (0.20) |
| Weighted-average shares outstanding, basic and diluted | 64,638 | 63,528 | 64,414 | 63,215 |
| Other comprehensive loss, net of tax | (78) | (829) | (297) | (1,759) |
| Total comprehensive loss | (968) | (2,831) | (5,195) | (15,218) |
| Less: Comprehensive loss attributable to noncontrolling interests | (724) | (315) | (1,724) | (787) |
| Total comprehensive loss attributable to stockholders of NxStage Medical, Inc. | $ (244) | $ (2,516) | $ (3,471) | $ (14,431) |

See accompanying notes to these condensed consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| | (In thousands) | |
| Cash flows from operating activities: | | |
| Net loss | $ (4,898) | $ (13,459) |
| Adjustments to reconcile net loss to net cash flow from operating activities: | | |
| Depreciation and amortization | 23,974 | 23,240 |
| Stock-based compensation | 7,688 | 9,590 |
| Other | (886) | 748 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (5,501) | (6,560) |
| Inventory | (22,026) | (10,977) |
| Prepaid expenses and other assets | 621 | (85) |
| Accounts payable | 3,930 | (613) |
| Accrued expenses and other liabilities | 3,015 | (64) |
| Deferred revenues | (924) | (204) |
| Net cash provided by operating activities | 4,993 | 1,616 |
| Cash flows from investing activities: | | |
| Proceeds from sales of marketable securities | — | 403 |
| Cash paid for acquisitions, net of cash acquired | (513) | — |
| Purchases of property and equipment | (6,796) | (7,153) |
| Net cash used in investing activities | (7,309) | (6,750) |
| Cash flows from financing activities: | | |
| Issuance of shares under stock incentive plans, net of payroll taxes paid | 3,677 | 3,643 |
| Investment by noncontrolling interest holder | 1,210 | 471 |
| Proceeds from loans and lines of credit | — | 1,275 |
| Repayments on loans and lines of credit | (225) | (60) |
| Repayments on capital leases | (1,153) | (1,051) |
| Net cash provided by financing activities | 3,509 | 4,278 |
| Foreign exchange effect on cash and cash equivalents | 559 | (720) |
| Increase (decrease) in cash and cash equivalents | 1,752 | (1,576) |
| Cash and cash equivalents, beginning of period | 59,065 | 52,884 |
| Cash and cash equivalents, end of period | $ 60,817 | $ 51,308 |

See accompanying notes to these condensed consolidated financial statements.

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

## 1. Nature of Operations, 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, 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. We also operate several recently opened NxStage Kidney Care dialysis centers, independently and in some instances as joint ventures, that treat end-stage renal disease (ESRD) patients directly. Although small in scale, these centers provide us with valuable experience as a service provider 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, including skilled nursing facilities. More specifically, at NxStage Kidney Care we offer a range of treatment options, including home hemodialysis, peritoneal dialysis and in-center hemodialysis, including with our System One. These centers also help us to devise best practices for successful home dialysis programs and provide sites for future clinical trials. 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 23 countries have been treated with our products.

### *Basis of Presentation*

The accompanying condensed consolidated financial statements as of September 30, 2016 and December 31, 2015 and for the three and nine months ended September 30, 2016 and 2015 , 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, 2015 ( 2015 Annual Report) and updated, as necessary, in this Quarterly Report on Form 10-Q. Operating results for any interim period are not necessarily indicative of results for the entire year or future periods. The December 31, 2015 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 2015 Annual Report.

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

### *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 single customer represented more than 10% of accounts receivable at September 30, 2016 . One customer represented 12% of accounts receivable at December 31, 2015 .

***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, 2015 | $ | 389 |
| Provision | | 371 |
| Usage | | (393) |
| Balance at September 30, 2016 | $ | 367 |

***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, ranging from eight to fourteen years . Long-lived assets, including intangible assets, are tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying value of an asset or asset group to the future undiscounted cash flows over the asset's remaining depreciable life. If an asset or asset group is considered impaired, the impairment recognized is the amount by which the carrying value of the long-lived asset(s) exceeds the fair value of the long-lived asset(s), which is determined using estimated discounted cash flows to be generated from such assets or other methods, if appropriate. During the three and nine months ended September 30, 2016 and 2015 , no significant impairment was recognized. Future events and circumstances may indicate that certain long-lived tangible assets in the Services segment, primarily leasehold improvements at our NxStage Kidney Care dialysis centers, may not be recoverable. As of September 30, 2016 , our estimate of future undiscounted cash flows indicated that such carrying amounts were expected to be recovered. However, it is reasonably possible that the estimate of undiscounted cash flows may change in the near term resulting in the need to recognize an impairment at the clinic level for at least some portion of those assets. Estimating future net cash flows requires significant estimates and judgment. Changes in market conditions, including delays in CMS certification, slower than expected patient growth or unfavorable payor mix would negatively impact our estimated future net cash flows in the near term, which could result in impairment charges.

**Recent Accounting Pronouncements**

***Recently Implemented Accounting Pronouncements***

In April 2015, the FASB issued ASU No. 2015-5, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): "Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." Under this standard, if a cloud computing arrangement includes a software license, the software license element of the arrangement should be accounted for consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the arrangement should be accounted for as a service contract. The update was effective for us beginning January 1, 2016. The adoption of this standard did not impact our financial statements.

In September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): "Simplifying the Accounting for Measurement-Period Adjustments". The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and sets forth new disclosure requirements related to the adjustments. The new standard was effective for us beginning January 1, 2016. The adoption of this standard did not impact our financial statements.

***Recent Accounting Pronouncements Not Yet Adopted***

In May 2014, the FASB issued ASU 2014-09: "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 entity 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 revenue 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, with early adoption permitted no earlier than the original effective date of the standard, which is the first quarter of fiscal 2017 for us. 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. We are continuing to evaluate the future impact and method of adoption of ASU 2014-09 and related amendments for our consolidated financial statements and related disclosures. We intend to adopt ASU 2014-09 and related amendments effective January 1, 2018.

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 will be effective for us beginning January 1, 2017. The adoption of this update is not expected to have an impact on our financial statements.

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 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 is effective for us beginning January 1, 2017 and early adoption is permitted. We intend to adopt this standard as of January 1, 2017. We are currently evaluating the method of adoption and the potential impact this standard will have on our financial statements and related disclosure.

## 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, 2016 | December 31, 2015 |
|---|---|---|
| Purchased components | $ 16,595 | $ 15,294 |
| Work in process | 12,209 | 10,080 |
| Finished goods | 18,073 | 13,017 |
| Total | $ 46,877 | $ 38,391 |

## 4. Property and Equipment and Field Equipment

Accumulated depreciation on property and equipment was $45.5 million and $36.9 million at September 30, 2016 and December 31, 2015 , respectively. Accumulated depreciation on field equipment was $47.2 million and $44.1 million at September 30, 2016 and December 31, 2015 , respectively.

## 5. Intangible Assets

Accumulated amortization of intangible assets was $24.4 million and $22.9 million at September 30, 2016 and December 31, 2015 , 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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Options to purchase common stock | 1,096 | 631 | 682 | 756 |
| Unvested restricted stock units | 382 | 411 | 359 | 350 |
| Total | 1,478 | 1,042 | 1,041 | 1,106 |

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

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

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Payroll, compensation and related benefits | $ 14,186 | $ 14,061 |
| Distribution expenses | 4,107 | 3,465 |
| General and administrative expenses | 2,448 | 2,309 |
| Other manufacturing costs | 2,307 | 2,097 |
| Other | 6,287 | 5,334 |
| Total | $ 29,335 | $ 27,266 |

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

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Capital lease obligations | $ 2,041 | $ 2,184 |
| Deferred revenue, current portion | 1,273 | 1,363 |
| Other | 791 | 847 |
| Total | $ 4,105 | $ 4,394 |

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

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| Capital lease obligations | $ 10,862 | $ 10,815 |
| Lease incentive obligations | 3,247 | 3,743 |
| Benefit plan obligations | 1,804 | 1,681 |
| Other | 916 | 1,128 |
| Total | $ 16,829 | $ 17,367 |

**8. Segment Disclosures**

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

Our System One segment includes revenues from the sale and rental of the System One and PureFlow SL dialysate preparation equipment and the sale of disposable products to customers, including NxStage Kidney Care, in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home or a home-like setting, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. Some of our largest customers in the home market provide outsourced renal dialysis services to some of our customers in the critical care market. Sales of products to both markets are made primarily through dedicated sales forces and distributed directly to the customer, or the patient, with certain products sold through distributors.

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 2015 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, 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 | 5,578 | 500 | 1,134 | 1,113 | — | 8,325 |
| **Three Months Ended September 30, 2015** | | | | | | |
| Revenues from external customers | $ 61,910 | $ 19,440 | $ 3,418 | $ 1,753 | $ — | $ 86,521 |
| Intersegment revenues | 910 | — | — | — | (910) | — |
| Revenues | 62,820 | 19,440 | $ 3,418 | 1,753 | (910) | 86,521 |
| Segment profit (loss) | 16,036 | 3,762 | (15,567) | (5,866) | — | (1,635) |
| Depreciation and amortization | 5,129 | 551 | 1,222 | 865 | — | 7,767 |
| **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 | 16,033 | 1,489 | 3,361 | 3,091 | — | 23,974 |
| **Nine Months Ended September 30, 2015** | | | | | | |
| Revenues from external customers | $ 179,760 | $ 55,870 | $ 7,122 | $ 3,567 | $ — | $ 246,319 |
| Intersegment revenues | 2,060 | — | — | — | (2,060) | — |
| Revenues | 181,820 | 55,870 | $ 7,122 | 3,567 | (2,060) | 246,319 |
| Segment profit (loss) | 42,528 | 9,094 | (46,233) | (17,719) | — | (12,330) |
| Depreciation and amortization | 15,627 | 1,571 | 3,641 | 2,401 | — | 23,240 |

Substantially all of our revenues are derived from the sale of the System One and related products that 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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| DaVita | 21% | 20% | 20% | 20% |
| Fresenius | 18% | 16% | 18% | 17% |

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

**9. Commitments and Contingencies**

Significant commitments and contingencies at September 30, 2016 are consistent with those discussed in Note 10 to the consolidated financial statements in our 2015 Annual Report.

**10. Income Taxes**

The provision for income taxes of $0.3 million during both the three months ended September 30, 2016 and 2015 , and $1.0 million and $0.9 million during the nine months ended September 30, 2016 and 2015 , respectively, relates to the profitable operations of certain foreign subsidiaries.

As of September 30, 2016 , we had a liability for unrecognized tax benefits included in the balance sheet of approximately $0.5 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, 2016 .

**11. 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, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Cost of revenues | $ 314 | $ 227 | $ 1,056 | $ 734 |
| Selling and marketing | 781 | 1,127 | 2,562 | 3,657 |
| Research and development | 344 | 427 | 1,148 | 1,355 |
| General and administrative | 855 | 1,219 | 2,922 | 3,844 |
| Total | $ 2,294 | $ 3,000 | $ 7,688 | $ 9,590 |

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

The Company granted options to purchase 20,351 shares of common stock during the three months ended September 30, 2016 and options to purchase 1,334,351 and 1,061,554 shares of common stock during the nine months ended September 30, 2016 and 2015 , 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, 2016 and 2015 was $5.89 and $6.13 per option, respectively.

The Company awarded 23,380 and 34,660 restricted stock units during the three months ended September 30, 2016 and 2015 , respectively, and 219,846 and 173,841 restricted stock units during the nine months ended September 30, 2016 and 2015 , 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, 2016 and 2015 was $17.34 and $16.59 per unit, respectively.

In March 2016, the Compensation Committee of our Board of Directors approved the grant of up to 434,850 restricted stock units subject to the achievement of certain Company financial performance metrics for the year ending December 31, 2016 . The restricted stock units, if earned, vest over a requisite service period of three years and have an average fair value of $15.57 per unit.

**12. Stockholders' Equity**

We received 100,571 and 43,506 shares of common stock that were surrendered in payment for the exercise of stock options during the nine months ended September 30, 2016 and 2015 , respectively.

**13. Noncontrolling Interest**

As of September 30, 2016 , we have 7 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, together with our joint venture partners, 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 is complex, involves uncertainties, and requires significant judgment on various matters. At September 30, 2016 and December 31, 2015 , total assets of our VIEs were $12.5 million and $11.0 million , and total liabilities and noncontrolling interests of our VIEs were $10.9 million and $10.2 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 exercisable at the third-party owners' discretion given specific facts and circumstances as outlined in each subsidiary's operating agreement. 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, 2016 the Company's noncontrolling interests subject to put provisions were $0.1 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, 2016 and 2015 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Balance at beginning of period | $ 1,722 | $ 1,087 | $ 1,694 | $ 1,088 |
| Capital contributions by noncontrolling interest | 231 | — | 531 | 263 |
| Sales of noncontrolling interests | — | — | 679 | 208 |
| Net loss attributable to noncontrolling interest in consolidated subsidiary | (672) | (315) | (1,623) | (787) |
| Balance at end of period | $ 1,281 | $ 772 | $ 1,281 | $ 772 |

**14 . 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 a duration of up to twelve months and are designated as cash flow hedges. The counterparties to these foreign exchange forward contracts are creditworthy financial institutions; therefore, we do not consider the risk of counterparty nonperformance to be material. As of September 30, 2016 and December 31, 2015 , the notional amount of our outstanding contracts that are designated as cash flow hedges was $23.0 million and $22.1 million , respectively. The fair value of these contracts is recorded on the balance sheet within prepaid expenses and other current assets or accrued expenses depending on the gain (loss) position. The fair value of these contracts was a net liability of $1.0 million and $1.1 million at September 30, 2016 and December 31, 2015 , 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, 2016 and 2015 . 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, 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 |
| Three Months Ended September 30, 2015 | | | |
| Foreign exchange forward contracts | $ (1,093) | $ (547) | Cost of revenues |
| Nine Months Ended September 30, 2015 | | | |
| Foreign exchange forward contracts | $ (1,824) | $ (1,231) | Cost of revenues |

**15. Accumulated Other Comprehensive (Loss) Income**

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

| | Unrealized gain (loss) on derivative instruments | Other (2) | Total |
|---|---|---|---|
| **Balance, net of tax, as of December 31, 2015** | $ (1,483) | $ (2,548) | $ (4,031) |
| Other comprehensive loss before reclassifications | (1,338) | (389) | (1,727) |
| Loss reclassified to earnings (1) | 1,430 | — | 1,430 |
| Total other comprehensive income (loss) | 92 | (389) | (297) |
| **Balance, net of tax, as of September 30, 2016** | $ (1,391) | $ (2,937) | $ (4,328) |

(1) Reclassifications of gains (losses) on derivative instruments are included in cost of revenues on the condensed consolidated statement of comprehensive loss. See Note 14 , *Derivative Instruments and Hedging* for further information.

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

**16. 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, 2016 .

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

| September 30, 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) | $ 34,793 | $ — | $ — | $ 34,793 |
| Foreign exchange forward contracts (2) | — | 59 | — | 59 |
| **Liabilities** | | | | |
| Foreign exchange forward contracts (2) | $ — | $ 1,024 | $ — | $ 1,024 |

| December 31, 2015 | 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) | $ 34,776 | $ — | $ — | $ 34,776 |
| Foreign exchange forward contracts (2) | — | 51 | — | 51 |
| **Liabilities** | | | | |
| Foreign exchange forward contracts (2) | $ — | $ 1,192 | $ — | $ 1,192 |

(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, 2016 and December 31, 2015 . 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.

**17. 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, | |
|---|---|---|
| | 2016 | 2015 |
| **Noncash Investing and Financing Activities:** | | |
| Transfers from inventory to field equipment | $ 14,629 | $ 11,776 |
| Transfers from field equipment to deferred cost of revenues | 10,396 | 9,251 |
| Payment of corporate bonus in common stock | — | 1,103 |
| Market value of shares received in payment for exercise of stock options | 1,963 | 745 |
| Construction-in-process financed by construction liability | 187 | 1,332 |
| Property and equipment acquired under capital lease | 127 | 354 |

**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, 2015 , included in our 2015 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 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;
- 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; 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 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. For convenience, we use the term “products business” to refer collectively to our System One segment, In-Center segment, and Other category.

**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 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 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 expires at the end of 2016 and is similarly designed to have evergreen renewals unless we and Fresenius choose to modify the terms with an amendment or new agreement providing for purchases under a different structure.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Gambro AB (a subsidiary of Baxter International, Inc.) accounted for 19% and 42% of our In-Center segment revenues for the three months ended September 30, 2016 and 2015 , respectively, and 22% and 40% for the nine months ended September 30, 2016 and 2015 , respectively, with all of Gambro's sales of our products being to DaVita. We expect to see a decline in our In-Center revenue as a result of an expected reduction in blood tubing sales to Gambro over the remainder of this year, compared to 2015. Henry Schein accounted for 33% and 22% of our In-Center segment revenues for the three months ended September 30, 2016 and 2015 , respectively, and 27% and 21% for the nine months ended September 30, 2016 and 2015 , respectively.

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, 2016 , we had $3.9 million reserved against trade accounts receivable for future distributor rebates and recorded $2.9 million and $2.7 million during the three months ended September 30, 2016 and 2015 , respectively, and $10.1 million and $7.8 million during the nine months ended September 30, 2016 and 2015 , respectively, as a reduction of revenues in connection with distributor rebates. For the In-Center segment, as of September 30, 2016 , we had $2.7 million reserved against trade accounts receivable for future estimated distributor rebates and recorded $1.8 million in both the three months ended September 30, 2016 and 2015 , and $5.2 million and $5.9 million during the nine months ended September 30, 2016 and 2015 , respectively, as a reduction of revenues in connection with distributor rebates.

Our Services segment revenues are derived from open centers treating patients and will fluctuate based on payor mix, patient volume and timing of certain payments. Sales of the System One and related products to our NxStage Kidney Care dialysis centers are included in System One segment revenues, and more specifically home market revenues, which are then eliminated upon consolidation. Supporting the startup and ongoing operation of our NxStage Kidney Care dialysis centers requires significant capital and operating expenditures and management resources. Currently, our Services segment generates negative gross margins and operating losses as we open and start-up these new centers. We expect these losses to continue in the near term but improve as the centers and the overall segment matures. However, if we experience unanticipated costs or difficulties in advancing this market development initiative, we may be required to recognize an impairment of certain long-lived assets within our Services segment.

**Financial Performance**

The table below provides a summary of the financial results for the products business (which includes the results of our System One segment, In-Center segment and Other category) and Services segment and in total (in thousands, except percentages). For detail below this summary level, please see further segment discussion below.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| **Products Business (System One Segment, In-Center Segment & Other)** | | | | |
| Revenues | $ 90,035 | $ 85,678 | $ 268,271 | $ 244,812 |
| Gross profit | $ 43,455 | $ 38,397 | $ 126,888 | $ 106,884 |
| Gross margin percentage | 48% | 45% | 47% | 44% |
| Income from operations | $ 6,615 | $ 4,231 | $ 17,820 | $ 5,389 |
| **Services** | | | | |
| Revenues | $ 3,846 | $ 1,753 | $ 10,647 | $ 3,567 |
| Gross profit | $ (4,067) | $ (3,679) | $ (12,170) | $ (11,176) |
| Gross margin percentage | n/a | n/a | n/a | n/a |
| Loss from operations | $ (6,384) | $ (5,866) | $ (19,354) | $ (17,719) |
| **Eliminations** | | | | |
| Elimination of intersegment revenues | $ (1,930) | $ (910) | $ (5,553) | $ (2,060) |
| Elimination of intersegment gross profit | $ (207) | $ — | $ (597) | $ — |
| **Total Company** | | | | |
| Revenues | $ 91,951 | $ 86,521 | $ 273,365 | $ 246,319 |
| Gross profit | $ 39,181 | $ 34,718 | $ 114,121 | $ 95,708 |
| Gross margin percentage | 43% | 40% | 42% | 39% |
| Income (loss) from operations | $ 24 | $ (1,635) | $ (2,131) | $ (12,330) |

For several years, we have focused on operating and financial improvements. During the three and nine months ended September 30, 2016 these efforts resulted in revenues increasing by 6% to $92.0 million and by 11% to $273.4 million , respectively, versus the prior year comparable periods with sales in the home and critical care markets each driving growth. Driving continued improvements will remain an area of focus in 2016 and beyond within our products business and, at the same time, we expect to continue making significant investments in our Services segment. We expect that these investments will have a negative impact on our total operating performance in the near term and may offset performance improvements we expect in our products business.

**Comparison of the Three and Nine Months Ended September 30, 2016 and 2015**

*Revenues*

Our revenues for the three and nine months ended September 30, 2016 and 2015 were as follows (in thousands, except percentages):

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| System One segment | | | | | | | | |
| Home | $ 53,759 | 58 % | $ 46,473 | 54 % | $ 154,397 | 56 % | $ 134,760 | 55 % |
| Critical Care | 18,182 | 20 % | 16,347 | 19 % | 56,694 | 21 % | 47,060 | 19 % |
| Total System One segment | 71,941 | 78 % | 62,820 | 73 % | 211,091 | 77 % | 181,820 | 74 % |
| In-Center segment | 14,493 | 16 % | 19,440 | 22 % | 47,990 | 18 % | 55,870 | 23 % |
| Other | 3,601 | 4 % | 3,418 | 4 % | 9,190 | 3 % | 7,122 | 3 % |
| Products subtotal | 90,035 | 98 % | 85,678 | 99 % | 268,271 | 98 % | 244,812 | 100 % |
| Services segment | 3,846 | 4 % | 1,753 | 2 % | 10,647 | 4 % | 3,567 | 1 % |
| Elimination of intersegment revenues | (1,930) | (2)% | (910) | (1)% | (5,553) | (2)% | (2,060) | (1)% |
| Total | $ 91,951 | 100 % | $ 86,521 | 100 % | $ 273,365 | 100 % | $ 246,319 | 100 % |

In the home market, revenues increased $7.3 million , or 16% and $19.6 million , or 15% for the three and nine months ended September 30, 2016 versus the prior year comparable periods, respectively, driven primarily by the increase in the number of patients prescribed to use the System One both in the U.S. and internationally. We expect future demand for our products and revenue growth in the home market to be strong as we further penetrate this market, both in the U.S. and internationally, and leverage the annuity nature of our business. We further expect that our System One segment revenue will be

susceptible to fluctuations in equipment sales, changes in inventory levels at our international distributors and changes in currency exchange rates.

Critical Care market revenues increased $1.8 million , or 11% and $9.6 million , or 20% during the three and nine months ended September 30, 2016 versus the prior year comparable period, respectively, driven by higher sales of System One disposables and equipment. 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 the critical care market may fluctuate due to timing of sales and the overall capital spending environment of our customers.

In-Center segment revenues decreased $4.9 million , or 25% , and $7.9 million , or 14% for the three and nine months ended September 30, 2016 , versus the prior year comparable period, respectively, due to changing demand for our blood tubing sets from Gambro offset in part by variations in inventory management policies at both our distributors and end users. We anticipate In-Center segment revenues will continue to decrease over the remainder of this year as compared to last year due to changing demand for our blood tubing sets from Gambro.

Other revenues for the three and nine months ended September 30, 2016 and 2015 relate to dialyzers sold to Asahi. The increase in revenues was due to increased 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, 2016 and 2015 relate to dialysis services provided to patients at our recently opened NxStage Kidney Care dialysis centers. We expect future revenues will fluctuate based on payor mix, patient volume and timing of certain payments.

*Gross Profit (Loss)*

Our gross profit (loss) (in thousands, except as percentages of revenues) for the three and nine months ended September 30, 2016 and 2015 were as follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| System One segment | $ 38,680 | 54% | $ 32,942 | 52% | $ 111,427 | 53% | $ 92,727 | 51% |
| In-Center segment | 4,381 | 30% | 5,628 | 29% | 14,066 | 29% | 15,003 | 27% |
| Other | 394 | 11% | (173) | n/a | 1,395 | 15% | (846) | n/a |
| Products subtotal | 43,455 | 48% | 38,397 | 45% | 126,888 | 47% | 106,884 | 44% |
| Services segment | (4,067) | n/a | (3,679) | n/a | (12,170) | n/a | (11,176) | n/a |
| Elimination of intersegment gross profit | (207) | n/a | — | n/a | $ (597) | n/a | $ — | n/a |
| Gross profit | $ 39,181 | 43% | $ 34,718 | 40% | $ 114,121 | 42% | $ 95,708 | 39% |

Gross profit as a percentage of revenues for the System One segment improved versus the same period last year primarily driven by contractual price improvements, currency exchange rates and product mix , offset in part by increased service costs. We expect to sustain gross profit as a percentage of revenue 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 increased for the three and nine months ended September 30, 2016 , versus the prior year comparable period, driven primarily by product mix. We expect gross profit as a percentage of revenues will decrease as a result of lower volumes and changes in pricing and 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 first half of 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 the startup and 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 fluctuate based on payor mix, patient volume and 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 (in thousands, except as percentages of revenues) for the three and nine months ended September 30, 2016 and 2015 were as follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| System One segment | $ 12,180 | 17% | $ 10,927 | 17% | $ 35,604 | 17% | $ 32,558 | 18% |
| In-Center segment | 1,527 | 11% | 1,331 | 7% | 4,606 | 10% | 4,410 | 8% |
| Services segment | 2,317 | n/a | 2,187 | n/a | 7,184 | n/a | 6,543 | n/a |
| Total Selling and marketing | $ 16,024 | 17% | $ 14,445 | 17% | $ 47,394 | 17% | $ 43,511 | 18% |

Selling and marketing expenses increased $1.6 million , or 11% , and $3.9 million , or 9% for the three and nine months ended September 30, 2016 versus the prior year comparable period, respectively, but remained relatively consistent as a percentage of revenues.

Selling and marketing expenses for the System One segment increased due to increased personnel and personnel-related costs but decreased slightly as a percentage of revenues due to our ability to continue to leverage our infrastructure. Selling and marketing for the In-Center segment remained relatively consistent in dollar value and increased as a percentage of revenue.

Selling and marketing expenses for our Services segment increased $0.1 million , or 6% , and $0.6 million , or 10% for the three and nine months ended September 30, 2016 versus the prior year comparable period, respectively, due to increased expenses for 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 startup and 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 (in thousands, except as percentages of revenues) for the three and nine months ended September 30, 2016 and 2015 were as follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| Research and development | $ 8,278 | 9% | $ 6,752 | 8% | $ 23,393 | 9% | $ 19,248 | 8% |

Research and development expenses increased for the three and nine months ended September 30, 2016 versus the prior year comparable period. The increase was primarily due to increased personnel and personnel-related costs and increased project related spending.

For the near term, we expect research and development expenses will increase but remain consistent as a percentage of revenues as we seek to further develop and enhance the System One through our investment in our next-generation hemodialysis system, and invest in our peritoneal dialysis product development program to expand our product portfolio.

*Distribution*

Our distribution expenses (in thousands, except as percentages of revenues) for the three and nine months ended September 30, 2016 and 2015 were as follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| System One segment | $ 6,672 | 9% | $ 5,979 | 10% | $ 19,826 | 9% | $ 17,641 | 10% |
| In-Center segment | 391 | 3% | 535 | 3% | 1,305 | 3% | 1,499 | 3% |
| Total Distribution | $ 7,063 | 8% | $ 6,514 | 8% | $ 21,131 | 8% | $ 19,140 | 8% |

Distribution expenses increased $0.5 million , or 8% , and $2.0 million , or 10% for the three and nine months ended September 30, 2016 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 (in thousands, except as percentages of revenues) for the three and nine months ended September 30, 2016 and 2015 were as follows:

| | Three Months Ended September 30, | | | | Nine Months Ended September 30, | | | |
|---|---|---|---|---|---|---|---|---|
| | 2016 | | 2015 | | 2016 | | 2015 | |
| General and administrative | $ 7,792 | 8% | $ 8,642 | 10% | $ 24,334 | 9% | $ 26,139 | 11% |

General and administrative expenses decreased by $0.9 million , or 10% and $1.8 million , or 7% for the three and nine months ended September 30, 2016 versus the prior year comparable period, respectively . The decrease was primarily due to the suspension of the medical device tax, offset by increased personnel related costs and professional service fees. We expect general and administrative expenses as a percentage of revenue to decline modestly compared to prior periods as we continue to leverage our infrastructure, and as a result of the suspension of the medical device tax.

*Other Expense*

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

Other (expense) income, net in each period includes foreign currency gains and losses. Other income (expense), net during the three and nine months ended September 30, 2015 includes unrealized holding gains of $0.3 million and realized gains of $0.4 million recognized from corporate equity instruments designated as short term trading securities.

*Provision for Income Taxes*

The provision for income taxes of $0.3 million during both the three months ended September 30, 2016 and 2015 , and $1.0 million and $0.9 million during the nine months ended September 30, 2016 and 2015 , respectively, relates to the profitable operations of certain foreign subsidiaries.

**Liquidity and Capital Resources**

We have operated at a loss since our inception in 1998. As of September 30, 2016 , our accumulated deficit was $406.0 million and we had cash and cash equivalents of $60.8 million , with substantially all of that cash located in the U.S., and working capital of $95.6 million .

Over the long term we expect to generate positive cash flow. 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 planned investments in NxStage Kidney Care. If we determine that additional investment in these or any other initiatives would be beneficial, we may choose to access the credit or capital markets to provide additional liquidity. However, we may not be successful in securing such additional financing.

Our ongoing cash requirements include funding normal working capital needs including inventory and field equipment assets. Field equipment assets include System One equipment rented to customers in the home market and our "service pool" of equipment, which is equipment owned and maintained by us that is swapped for equipment owned or rented by our customers that needs repair or maintenance. While a majority of our home market customers have committed to purchase, rather than rent, the significant majority of their future System One equipment requirements thereby reducing our working capital cash requirements, we may be unable to continue to expand or sustain this level of equipment placements that are purchased rather than rented. Additionally, 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 a transaction of this type and is secured by substantially all of our assets. As of September 30, 2016 , 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 $27 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 $1.8 million at September 30, 2016 for costs associated

with these plans. The expense recorded in connection with these plans was not significant during the period ended September 30, 2016 or 2015 .

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2016 | 2015 |
| Net cash provided by operating activities | $ 4,993 | $ 1,616 |
| Net cash used in investing activities | (7,309) | (6,750) |
| Net cash provided by financing activities | 3,509 | 4,278 |
| Foreign exchange effect on cash and cash equivalents | 559 | (720) |
| Net cash flow | $ 1,752 | $ (1,576) |

*Net cash provided by operating activities* . Net cash flows from operating activities improved by $3.4 million during the nine months ended September 30, 2016 , versus the prior year comparable period, driven by improved net loss after adjustments for non-cash items such as depreciation and amortization and stock-based compensation partially offset by higher working capital requirements including timing of accounts receivable collections, and payments to our vendors. We expect working capital to fluctuate due to various factors including inventory requirements and timing of payments from our customers and to our vendors.

Cash flow from deferred revenues fluctuates based on timing of equipment sales. Amortization of deferred revenues into revenues relating to sales of home equipment was $13.4 million and $13.1 million during the nine months ended September 30, 2016 and 2015 , 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, primarily for the build-out of NxStage Kidney Care dialysis centers, coupled with expenditures for our manufacturing facilities as a result of our efforts to rationalize and expand our manufacturing operations, along with purchases of equipment for research and development and information technology. For the nine months ended September 30, 2016 , cash used in investing activities also includes $0.5 million related to our 2015 acquisition of controlling interest in a dialysis center.

The decrease of $0.4 million in purchases of property and equipment was driven primarily by spending associated with our NxStage Kidney Care dialysis centers and our manufacturing facilities. Capital expenditures for our Kidney Care centers were $3.2 million and $3.4 million during the nine months ended September 30, 2016 and 2015 , respectively.

*Net cash provided by financing activities* . During the nine months ended September 30, 2016 and 2015 we received $3.7 million and $3.6 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 and 2015 , we received $1.2 million and $0.5 million , respectively, in investments by noncontrolling interest holders. During the nine months ended September 30, 2015 we received $1.3 million in proceeds from a term loan. Cash provided by financing activities during both 2016 and 2015 was reduced by cash used to pay our 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 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, 2016 are described in Note 2 to the consolidated financial statements included in our 2015 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, 2016 are consistent with those described in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our 2015 Annual Report.

**Recent Accounting Pronouncements**

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements included in our 2015 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 2015 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, 2016 .

**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, 2016 . 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, 2016 , 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, 2016 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 dialysis market may not expand sufficiently to support our growth prospects.***

While we believe our largest growth opportunity currently is within the home dialysis market, home dialysis 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 dialysis 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. One Medicare contractor without such a local coverage determination, Noridian Healthcare Solutions, has issued a Medicare coverage article discussing considerations for hemodialysis frequency. Certain language in the coverage article is unclear or inconsistent with long-standing Medicare policy, including that reiterated in recent Medicare payment rules, but it may suggest a limitation to coverage of more frequent hemodialysis, even with medical justification. In partnership with other provider, patient, and professional organizations, we have actively engaged Noridian and the Centers for Medicare and Medicaid Services on this question. Many clinics have reported that they have continued to bill, and be paid for, additional treatments under this article; however, certain clinics have chosen at least at this time not to bill for more frequent dialysis sessions and this has impacted new patient access at those clinics. It remains unclear how this article will be implemented and what its impact will be in the long term.

In October 2016, the Centers for Medicare & Medicaid Services (CMS) 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, CMS 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.

***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. Efforts by the Centers for Medicare and Medicaid Services and commercial insurance payors to exert downward pressure on payment rates for dialysis services 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 led many European and other foreign countries to adopt healthcare reform proposals and medical cost containment measures, including government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing

systems, and payors limiting access to treatments based on cost-benefit analysis. Any of these measures, including the uncertainty in the medical community regarding their nature and effect, could have an adverse effect on our customers' purchasing decisions regarding our products and treatments, as well as limit the prices we may charge for our products.

***We sell a limited number of products.***

We derive most of our revenues from the sale or rental of the System One and the related products used with the System One, with the remainder of our revenues largely coming from the sale of a few key disposable products, including blood tubing sets and needles. Although we are working on initiatives that should diversify our future revenues, including our next-generation hemodialysis system, 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 these two customers 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, 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 market 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 expires at the end of 2016 and is similarly designed to have evergreen renewals unless we and Fresenius choose to modify the terms with an amendment or new agreement providing for purchases under a different structure.

***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. Although we are working towards achieving profitability, we continue to invest in our operations, in particular with respect to our NxStage Kidney Care dialysis centers and product pipeline, to drive future growth. Accordingly, while we expect to leverage our future operating expenses, we expect those expenses to continue to increase as we grow our business, and we cannot ensure the timing, extent or sustainability of our future profitability.

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

As health care providers and participants in federal health care programs, our NxStage Kidney Care dialysis centers must comply with complex regulations that are, in some instances, 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 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, we may also have to repay amounts received from government 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. Several 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 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 on the ground 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.

Before any NxStage Kidney Care dialysis center may bill and receive payment for dialysis services provided to patients covered by Medicare and certain private insurers, it must enroll in the Medicare Program. 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. Our NxStage Kidney Care dialysis centers may be unable to obtain Medicare certification in a timely manner, if at all.

Our NxStage Kidney Care dialysis centers are focused on supporting home therapy and developing innovative care delivery models with our products and solutions within the home and across the renal care market. Our customers may, however, perceive these centers to be directly competing with their business which could and may have already negatively impacted 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 2015 Annual Report entitled “Business - Our Competition.” Our competitors may have a significant competitive advantage 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 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 anticipate that demand for our blood tubing sets will continue to decrease over the remainder of this year as compared to last year. 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 the loss of our blood tubing set and needle business to competitors in the dialysis industry.

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 next generation hemodialysis system, 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 and 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 rent rather than purchase our equipment or enter into other less-capital intensive purchase structures with us, 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 currency exchange rates would reduce revenues or increase our costs which would reduce our operating profit.

***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, an equipment rental model that requires us to effectively manage our System One and PureFlow SL field equipment. While a majority of our home market customers currently purchase rather than rent our equipment, this may change due to pressures within the healthcare industry to reduce capital spending and other factors. Increases in our rental or service swap equipment would increase our ongoing cash requirements to fund working capital. In addition, our gross margins may be negatively impacted if we have excess equipment deployed and unused in the field. If we are unable to successfully track, service and redeploy equipment, we could incur increased costs, realize increased cash requirements and have material write-offs of equipment. This would negatively impact our working capital requirements and future profitability.

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

From time to time, we are threatened with individual actions involving our business, including without limitation products liability, employment, intellectual property, commercial and tort claims. The manufacture and marketing of medical devices, in particular, has an attendant risk of product liability claims. If any of our employees or products is found to have caused or

contributed to injuries or deaths, we could be held liable for substantial damages. Any claims made against us could adversely affect our reputation 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 us with 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.***

We operate manufacturing facilities in Germany, Italy and Mexico, and purchase components, products and supplies from foreign vendors. We also sell our products internationally. 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 could adversely affect our financial results and our ability to maintain mutually beneficial and profitable relationships with foreign vendors and distributors, and increase our costs to attract and retain international personnel;
- costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods;
- difficulty managing operations in multiple locations;
- local regulations that may restrict or impair our ability to conduct our operations, 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 business relies 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. 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 don't comply with applicable laws in the sale and marketing of our products or fulfill any responsibilities they may have to protect the intellectual property rights underlying our products, 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.

**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 may be 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 these regulatory requirements become increasingly more stringent, it may become more difficult and costly for us to 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 2015 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. 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. Product recalls may materially divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers, and potentially adversely impact our financial results.

From time to time we have chosen to voluntarily recall certain products that we believed were mislabeled or otherwise defective. In October 2015, we notified our customers about a voluntary recall to mitigate the potential risks associated with a software anomaly affecting approximately 15% of System One cyclers. There have been no serious injuries reported in connection with this anomaly. We reported this software anomaly to the FDA and other regulatory authorities and have concluded our discussions with them. Our remediation efforts are well under way and we expect to complete these during 2016. Remediation costs are expected to be less than $1 million over the total period of remediation.

***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 2015 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 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 providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all prescribing decisions, including the decision as to whether to order dialysis services more frequently than three times per week. In addition, our NxStage Kidney Care dialysis centers are directly subject to these laws with respect to the reimbursement claims they file with government payors. Potential false or fraudulent claim risk can arise from promoting and billing for services the government deems excessive or not medically necessary, as well as from other billing improprieties and from failure to timely return any identified overpayments. We are making every effort, including adhering strictly to guidelines in any local coverage determinations issued by Medicare contractors with jurisdiction over claims from any of our NxStage Kidney Care dialysis centers, to ensure that billing by our NxStage Kidney Care dialysis centers is proper and that physicians who order NxStage Kidney Care dialysis services fully document medical need for patients for whom more frequent than thrice weekly therapy is ordered. Nevertheless, we cannot provide assurance that the government will regard any billing errors that may be made as inadvertent or that the government will not examine our role in providing information to our customers, physicians and patients concerning the benefits and potential coverage of more frequent therapy. Likewise, our financial relationships with customers, physicians, patients or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial, and given the possibility of exclusion from participation in government health care programs, potentially crippling to the line of business involved. Moreover, 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 have begun to market the System One and certain of our other products internationally. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after a device has been CE marked. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business. Furthermore, reimbursement provided for our products in other jurisdictions could change, positively or negatively. If reimbursements were to be negatively changed, such as in the United Kingdom where we sell our products directly, our ability to sell our products could be impaired.

***We must comply with import and export laws.***

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. If there are modifications to the Generalized System of Preferences or cancellation of the Nairobi Protocol tariff classifications that apply to our products such that our products would be subject to duties, our profitability would also 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 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, premixed dialysate and sterile bags, as well as sterilization services. Some of our most critical single-source supply relationships are with Membrana GmbH and Laboratorios PiSA S.A. de C.V.

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

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

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

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

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

supplier could lead to supply delays or interruptions which would damage our business and impair our reputation, at least in the near term.

***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, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes, anti-union behavior, or other labor disputes at our manufacturing facilities. Some of our key single-source suppliers also have labor agreements in place, but nonetheless may be subject to similar risks related to labor disputes. Any such activity likely would cause production delays and prevent us from delivering our production commitments to customers, which could adversely affect our reputation and cause our business and operating results to suffer.

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

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

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenues;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time consuming if it is possible to do so.

***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.***

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

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

- developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers and distributors;
- disruptions in product supply for any reason, 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;
- litigation involving our company or our general industry;
- announcements of technical innovations or new products by our competitors;
- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture and supply our products to commercial standards;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- 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 company securities may engender class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

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

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

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

As part of our growth strategy, we may acquire other businesses and technologies and pursue additional business opportunities. To finance such activity, we may issue equity securities, which may dilute our existing stockholders, and incur debt, which may place restrictions on our business operations. Such financing activity may reduce the market value of our common shares and other securities, in particular if the initiatives being funded are not viewed favorably by our stockholders and are ultimately unsuccessful. We cannot assure you that additional financing will 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.

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

| Exhibit Number | Description |
|---|---|
| 31.1* | Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) or 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002. |
| 32.2** | Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002. |
| 101.INS* | XBRL Instance Document |
| 101.SCH* | XBRL Taxonomy Extension Schema |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase |

* Filed herewith.

** Furnished herewith.

**SIGNATURES**

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

NXSTAGE MEDICAL, INC.

By: /s/ Matthew W. Towse

Matthew W. Towse

*Chief Financial Officer*
*(Duly authorized officer and principal financial officer)*

November 3, 2016

**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, 2016 (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 3, 2016

**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, 2016 (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 3, 2016

**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, 2016 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 3, 2016

**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, 2016 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 3, 2016