NxStage Medical, Inc.
Form 10-Q
August 07, 2009

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, DC 20549**
**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended June 30, 2009**

**OR**

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

**For the transition period from to**

**Commission file number: 000-51567**

**NxStage Medical, Inc.**

*(Exact Name of Registrant as Specified in Its Charter)*

| **Delaware** | **04-3454702** |
|---|---|
| *(State or Other Jurisdiction of Incorporation or Organization)* | *(I.R.S. Employer Identification No.)* |
| **439 S. Union St., 5th Floor, Lawrence, MA** | **01843** |
| *(Address of Principal Executive Offices)* | *(Zip Code)* |

**(978) 687-4700**

(*Registrant s Telephone Number, Including Area Code)*

*(Former Name, Former Address, and Former Fiscal year, If Changed Since Last Report)*

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

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

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

There were 46,662,945 shares of the registrant s common stock issued and outstanding as of the close of business on August 3, 2009.

**NXSTAGE MEDICAL, INC.**
**QUARTERLY REPORT ON FORM 10-Q**
**FOR THE QUARTER ENDED JUNE 30, 2009**
**TABLE OF CONTENTS**

Table of Contents

**NXSTAGE MEDICAL, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and per share data)**
**(Unaudited)**

| | June 30, 2009 | December 31, 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 24,455 | $ 26,642 |
| Accounts receivable, net | 9,510 | 11,886 |
| Inventory | 28,781 | 30,862 |
| Prepaid expenses and other current assets | 2,123 | 2,011 |
| Total current assets | 64,869 | 71,401 |
| Property and equipment, net | 10,852 | 12,254 |
| Field equipment, net | 25,864 | 30,445 |
| Deferred cost of revenues | 24,017 | 23,711 |
| Intangible assets, net | 29,606 | 31,004 |
| Goodwill | 42,698 | 42,698 |
| Other assets | 1,059 | 553 |
| Total assets | $ 198,965 | $ 212,066 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 14,414 | $ 17,183 |
| Accrued expenses | 8,998 | 10,746 |
| Current portion of long-term debt | 59 | 9,110 |
| Total current liabilities | 23,471 | 37,039 |
| Deferred revenue | 33,692 | 29,634 |
| Long-term debt | 36,597 | 21,054 |
| Other long-term liabilities | 1,955 | 1,892 |
| Total liabilities | 95,715 | 89,619 |
| Commitments and contingencies | | |
| Stockholders equity: | | |
| Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; no shares issued and outstanding as of June 30, 2009 and December 31, 2008 | | |
| Common stock: par value $0.001, 100,000,000 shares authorized; 46,658,515 and 46,548,585 shares issued and outstanding as of June 30, 2009 and December 31, 2008, respectively | 47 | 47 |
| Additional paid-in capital | 360,765 | 355,266 |
| Accumulated deficit | (257,990) | (233,247) |
| Accumulated other comprehensive income | 428 | 381 |

| | | |
|---|---|---|
| Total stockholders equity | 103,250 | 122,447 |
| Total liabilities and stockholders equity | $ 198,965 | $ 212,066 |

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

**NXSTAGE MEDICAL, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except per share data)**
**(Unaudited)**

| | Three Months Ended June30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Revenues | $ 36,398 | $ 31,616 | $ 70,133 | $ 62,621 |
| Cost of revenues | 27,581 | 27,201 | 54,261 | 54,188 |
| Gross profit | 8,817 | 4,415 | 15,872 | 8,433 |
| Operating expenses: | | | | |
| Selling and marketing | 7,411 | 7,263 | 14,642 | 14,098 |
| Research and development | 2,271 | 2,362 | 4,673 | 4,488 |
| Distribution | 3,525 | 3,335 | 7,209 | 6,730 |
| General and administrative | 4,749 | 4,884 | 9,704 | 9,699 |
| Total operating expenses | 17,956 | 17,844 | 36,228 | 35,015 |
| Loss from operations | (9,139) | (13,429) | (20,356) | (26,582) |
| Other expense: | | | | |
| Interest income | 14 | 94 | 25 | 307 |
| Interest expense | (3,337) | (1,081) | (4,372) | (1,891) |
| Change in fair value of financial instruments | | 2,086 | | 2,086 |
| Other (expense) income, net | (14) | (144) | 79 | (293) |
| | (3,337) | 955 | (4,268) | 209 |
| Net loss before income taxes | (12,476) | (12,474) | (24,624) | (26,373) |
| Provision for income taxes | 39 | 60 | 119 | 105 |
| Net loss | $ (12,515) | $ (12,534) | $ (24,743) | $ (26,478) |
| Net loss per share, basic and diluted | $ (0.27) | $ (0.32) | $ (0.53) | $ (0.70) |
| Weighted-average shares outstanding, basic and diluted | 46,575 | 38,770 | 46,565 | 37,772 |

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2009** | **2008** |
| Cash flows from operating activities: | | |
| Net loss | $ (24,743) | $ (26,478) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 10,229 | 9,087 |
| Stock-based compensation | 3,877 | 3,280 |
| Change in fair value of financial instruments | | (2,086) |
| Other | 1,197 | 125 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 2,494 | (1,709) |
| Inventory | (2,179) | (24,060) |
| Prepaid expenses and other assets | 700 | 1,048 |
| Accounts payable | (2,788) | (639) |
| Accrued expenses and other liabilities | (144) | (1,080) |
| Deferred revenue | 672 | 6,399 |
| Net cash used in operating activities | (10,685) | (36,113) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (566) | (1,786) |
| Maturities of short-term investments | | 1,100 |
| Decrease in other assets | (582) | 116 |
| Net cash used in investing activities | (1,148) | (570) |
| Cash flows from financing activities: | | |
| Net proceeds from private placement sale of common stock | | 24,747 |
| Proceeds from stock option and purchase plans | 148 | 2 |
| Proceeds from loans and lines of credit | 39,895 | 5,000 |
| Net repayments on loans and lines of credit | (30,506) | (30) |
| Net cash provided by financing activities | 9,537 | 29,719 |
| Foreign exchange effect on cash and cash equivalents | 109 | 111 |
| Decrease in cash and cash equivalents | (2,187) | (6,853) |
| Cash and cash equivalents, beginning of period | 26,642 | 33,245 |
| Cash and cash equivalents, end of period | $ 24,455 | $ 26,392 |

| | | |
|---|---|---|
| **Noncash Investing Activities** | | |
| Transfers from inventory to field equipment and deferred cost of revenues | $ 3,225 | $ 13,389 |
| Transfers from field equipment to deferred cost of revenues | $ 1,712 | $ 998 |

See accompanying notes to these condensed consolidated financial statements.

Table of Contents

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

**1. Nature of Operations**

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

The Company has experienced negative operating margins and cash flows from operations and it expects to continue to incur net losses in the foreseeable future. The Company believes, based on current projections, that it has the required resources to fund operating requirements at least through 2010. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of, complementary businesses, services or technologies.

**Basis of Presentation**

The accompanying condensed consolidated financial statements as of June 30, 2009 and for the three and six months ended June 30, 2009, and related notes, are unaudited but, in management s opinion, include all adjustments, consisting of normal recurring adjustments that the Company considers necessary for fair statement of the interim periods presented. The Company has prepared its unaudited, condensed consolidated financial statements following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under these rules, the Company has condensed or omitted certain footnotes and other financial information that are normally required by generally accepted accounting principles in the United States, or GAAP. The Company s accounting policies are described in the notes to the consolidated financial statements in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and updated, as necessary, in this Quarterly Report on Form 10-Q. Operating results for the three and six months ended June 30, 2009 are not necessarily indicative of results for the entire fiscal year or future periods. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries at June 30, 2009. The December 31, 2008 condensed consolidated balance sheet contained herein was derived from audited financial statements, but does not include all disclosures required by GAAP. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

**2. Summary of Significant Accounting Policies**

***Principles of Consolidation***

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made to prior year s financial statements to conform to the 2009 presentation.

***Use of Estimates***

The preparation of the Company s condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of

contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Revenue Recognition***

The Company recognizes revenue from product sales and services when earned in accordance with Staff Accounting Bulletin No. 104, or SAB 104, *Revenue Recognition,* and Emerging Issues Task Force Issue No. 00-21, or EITF 00-21, *Revenue Arrangements with Multiple Deliverables.* Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured. The Company s revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate

Table of Contents

units.

Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors revenue is recognized at the time of sale if a reasonable estimate of future returns or refunds can be made. If a reasonable estimate of future returns or refunds cannot be made, the Company recognizes revenue using the sell-through method. Under the sell-through method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

*System One Segment*

The Company derives its revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

Under the rental arrangements, which combine the use of the System One and PureFlow SL hardware with a specified number of disposable products supplied to customers for a fixed price per month, revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

For customers that purchase the System One and PureFlow SL hardware, the Company recognizes equipment revenue upon delivery if the equipment has stand-alone value and the fair value of the undelivered items, typically the disposables and, in some instances service, can be determined. If the fair value of the undelivered items can be determined, they are accounted for separately as delivered. If the fair value of any of the undelivered items cannot be determined, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and recognized as revenue on a straight-line basis over the expected term of the Company s remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery.

In the critical care market, the Company structures sales of the System One as direct product sales. The Company recognizes revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

The Company s contracts for the System One in the critical care market provide for training, technical support and warranty services to its customers. The Company recognizes training and technical support revenue when the related services are performed. In the case of extended warranty, the revenue is recognized ratably over the warranty period.

*In-Center Segment*

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. The Company s distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

In addition to contractually determined volume discounts, the Company offers rebates based on sales to specific end customers and discount incentives for early payment. The Company recognizes these sales incentives in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (Including) Reseller of the Vendors Products.* Sales incentives are recorded as a reduction of sales and trade accounts receivable, based on the Company s best estimate of the amount of probable future rebate or discount on current sales.

***Concentration of Credit Risk***

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2009** | **2008** | **2009** | **2008** |
| Customer A | 22% | 22% | 21% | 19% |
| Customer B | 35% | 40% | 36% | 41% |

Sales to Customer A are primarily in the System One segment and sales to Customer B are to one of the Company s significant distributors in the In-Center segment. Half of all Customer B sales are to Customer A.

One customer represented 22% of accounts receivable at June 30, 2009. Two customers represented 26% and 10% of accounts receivable at December 31, 2008.

***Warranty Costs***

For a period of one year following the delivery of products to its critical care customers, the Company provides for product repair or replacement if it is determined that there is a defect in material or manufacture of the product. For sales into the critical care market, the Company accrues estimated warranty costs at the time of shipment based on contractual rights and historical experience. Warranty expense is included in cost of revenues in the consolidated statements of operations. The following is a rollforward of the Company s warranty accrual (in thousands):

| | |
|---|---|
| Balance at December 31, 2008 | $ 235 |
| Provision | 120 |
| Usage | (179) |
| Balance at June 30, 2009 | $ 176 |

Table of Contents

***Net Loss per Share***

Basic earnings per share is computed by dividing income available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period. The computation of diluted earnings per share is similar to basic earnings 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.

Options to purchase 0.1 million and 0.5 million shares of common stock for the three months ended June 30, 2009 and 2008, respectively, and 0.1 million shares of common stock for the six months ended June 30, 2009 were not included in the computation of diluted net loss per share as their effect would have been anti-dilutive.

***Subsequent Events***

Events occurring subsequent to June 30, 2009 have been evaluated through August 7, 2009, the date the Company filed its Quarterly Report on Form 10-Q.

***Recent Accounting Pronouncements***

Effective January 1, 2009, the Company adopted Statement of Financial Accounting Standards, or SFAS, No. 141(R), *Business Combinations*, or SFAS 141(R), a replacement of SFAS No. 141. SFAS 141(R) provides that, upon initially obtaining control, an acquirer shall recognize 100 percent of the fair values of acquired assets, including goodwill and assumed liabilities, with only limited exceptions, even if the acquirer has not acquired 100 percent of its target. As a consequence, the step acquisition model will be eliminated. Additionally, SFAS 141(R) changes current practice, in part, as follows: (1) contingent consideration arrangements will be fair valued at the acquisition date and included on that basis in the purchase price consideration; (2) transaction costs will be expensed as incurred, rather than capitalized as part of the purchase price; (3) pre-acquisition contingencies, such as legal issues, will generally have to be accounted for in purchase accounting at fair value; (4) in-process research and development will be capitalized and either amortized over the life of the product or written off if the project is abandoned or impaired; (5) changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense; and (6) in order to accrue for a restructuring plan in purchase accounting, the requirements in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, would have to be met at the acquisition date.

Since SFAS 141(R) is applicable to future acquisitions completed after January 1, 2009 and the Company did not have any business combinations subsequent to January 1, 2009 to date, the adoption of SFAS 141(R) did not have an impact on the Company s consolidated financial statements. SFAS 141(R) amends SFAS No. 109, *Accounting for Income Taxes*, such that adjustments made to valuation allowances on deferred taxes and acquired tax contingencies associated with acquisitions that closed prior to the effective date of SFAS 141(R) would also follow the provisions of SFAS 141(R). Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting, whether the business combination was accounted for under SFAS 141 or SFAS 141(R), will be recognized in current period income tax expense.

Effective January 1, 2009, the Company adopted Emerging Issues Task Force, or EITF, Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity s Own Stock*, or EITF 07-5. EITF 07-5 requires the application of a two-step approach in evaluating whether an equity-linked financial instrument (or embedded feature) is indexed to a Company s own stock, including evaluating the instrument s contingent exercise and settlement provisions, and must be applied to all instruments outstanding on the date of adoption. The adoption of EITF 07-5 did not have an impact on the Company s consolidated financial statements.

Effective April 1, 2009, the Company adopted Financial Accounting Standards Board, or FASB, Staff Position No. 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*, or FSP 157-4. FSP 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157, *Fair Value Measurements*, or SFAS 157. FSP 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of FSP 157-4 did not have an impact on the Company s consolidated financial statements.

Effective April 1, 2009, the Company adopted FASB Staff Position No. 107-1 and Accounting Principles Board, or APB, No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, or FSP 107-1. FSP 107-1 amends SFAS 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements and also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. The adoption of this standard has resulted in the enhanced disclosure of the fair values attributable to debt instruments within this interim report. Since FSP 107-1 addresses disclosure requirements, the adoption of this FSP did not impact the Company s financial position, results of operations or cash flows.

Table of Contents

Effective June 30, 2009, the Company adopted the provisions of SFAS No. 165, *Subsequent Events*, or SFAS 165. SFAS 165 provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. The adoption of SFAS 165 has resulted in enhanced disclosures around subsequent events within this interim report. Since SFAS 165 primarily addresses disclosure requirements, the adoption of this standard did not impact the Company s financial position, results of operations or cash flows.

In April 2009, the FASB issued FASB Staff Position No. 115-2 and SFAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* or FSP 115-2. FSP 115-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. The Company adopted FSP 115-2 on April 1, 2009. The adoption of FSP 115-2 did not have an impact on the Company s consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*, or SFAS 168. SFAS 168 replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, to establish the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with GAAP. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have an impact on our financial position, results of operations or cash flows.

In June 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140*, or SFAS 166. SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor s continuing involvement in transferred financial assets. Specifically, among other aspects, SFAS 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. SFAS 166 is effective for transfer of financial assets occurring on or after January 1, 2010. The Company has not determined the effect the adoption of SFAS 166 will have on its consolidated financial statements, but the effect will be limited to future transactions.

**3. Inventory**

Inventories, stated at lower of cost or market, consist of the following (in thousands):

| | June 30, 2009 | December 31, 2008 |
|---|---|---|
| Purchased components | $ 15,368 | $ 15,296 |
| Work in process | 1,494 | 1,402 |
| Finished goods | 11,919 | 14,164 |
| | $ 28,781 | $ 30,862 |

**4. Property and Equipment and Field Equipment**

Accumulated depreciation on property and equipment was $8.6 million and $7.1 million at June 30, 2009 and December 31, 2008, respectively. Accumulated depreciation on field equipment was $21.8 million and $17.5 million at June 30, 2009 and December 31, 2008, respectively.

**5. Intangible Assets**

Accumulated amortization of intangible assets was $4.9 million and $3.5 million at June 30, 2009 and December 31, 2008, respectively.

**6. Debt**

In June 2009, the Company closed a $40.0 million term loan and security agreement with Asahi Kasei Kuraray Medical, or Asahi. Borrowings bear interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by all of the Company s assets other than cash, bank accounts, accounts receivable, field equipment, and inventory. The term loan may be prepaid, without penalty, at the Company s option. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of the Company s common stock, with the number of shares to be determined based upon the average closing stock price of the Company s common stock during the thirty business days preceding the maturity date. Under no circumstance would the Company be obligated to issue more than 10% of the number of its shares of common stock outstanding on the maturity date to Asahi in satisfaction of this obligation; provided that the Company and Asahi may mutually agree, in each of its own sole discretion, to increase the 10% limitation up to 20%.

Table of Contents

Borrowings under the term loan and security agreement were recorded at their estimated fair value at issuance, net of a $3.7 million discount. The discount will be recorded to interest expense over the term of the agreement, through May 31, 2013, on a straight-line basis.

The Company used $30.0 million of the proceeds from the term loan and security agreement to pay off the Company s debt obligation owed under its credit and security agreement with GE Capital Corporation, or GE, including $2.0 million of prepayment and other transactions fees which were recorded to interest expense during the three months ended June 30, 2009.

**7. Comprehensive Loss**

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Net loss | $ (12,515) | $ (12,534) | $ (24,743) | $ (26,478) |
| Foreign currency translation adjustment | 107 | 410 | 47 | 373 |
| Comprehensive loss | (12,408) | $ (12,124) | (24,696) | $ (26,105) |

**8. Segment Disclosures**

After careful evaluation of the business activities regularly reviewed by the Company s chief operating decision-maker for which separate discrete financial information is available, management determined that the Company has two reporting segments, System One and In-Center. Beginning in the first quarter of 2009, the Company allocated previously unallocated cost of revenues to its System One and In-Center segments. Prior year segment information has been changed to conform to the current presentation.

The accounting policies of the reportable segments are the same as those described in Note 2, Summary of Significant Accounting Policies. The profitability measure employed by the Company and its chief operating decision maker for making decisions about allocating resources to segments and assessing segment performance is segment (loss) profit, which consists of sales, less cost of sales, direct selling and marketing and distribution expenses.

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

Within the System One segment, the Company derives revenue from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. Within the System One segment, the Company sells a similar technology platform of the System One with different features. Some of the Company s largest customers in the home market provide outsourced renal dialysis services to some of the Company s customers in the critical care market. Sales of product to both markets are made through dedicated sales forces and products are distributed directly to the customer, or the patient.

Within the In-Center segment, the Company sells blood tubing sets and needles for hemodialysis and needles for apheresis primarily for the treatment of ESRD patients at dialysis centers. Nearly all In-Center products are sold through national distributors.

Table of Contents

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

| | System One | In-Center | Unallocated | Total |
|---|---|---|---|---|
| Three Months Ended June 30, 2009 | | | | |
| Revenues from external customers | $ 20,446 | $15,952 | | $ 36,398 |
| Segment (loss) profit | (5,000) | 2,881 | (7,020) | (9,139) |
| Segment assets | 70,775 | 17,397 | 110,793 | 198,965 |
| Three Months Ended June 30, 2008 | | | | |
| Revenues from external customers | $ 16,235 | $15,381 | $ | $ 31,616 |
| Segment (loss) profit | (7,304) | 1,121 | (7,246) | (13,429) |
| Segment assets | 85,785 | 17,433 | 119,375 | 222,593 |
| Six Months Ended June 30, 2009 | | | | |
| Revenues from external customers | $ 39,268 | $30,865 | $ | $ 70,133 |
| Segment (loss) profit | (10,615) | 4,637 | (14,378) | (20,356) |
| Segment assets | 70,775 | 17,397 | 110,793 | 198,965 |
| Six Months Ended June 30, 2008 | | | | |
| Revenues from external customers | $ 31,102 | $31,519 | $ | $ 62,621 |
| Segment (loss) profit | (15,138) | 2,743 | (14,187) | (26,582) |
| Segment assets | 85,785 | 17,433 | 119,375 | 222,593 |

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

| | June 30, 2009 | December 31, 2008 |
|---|---|---|
| Total segment assets | $ 88,172 | $ 96,904 |
| Corporate assets: | | |
| Cash and cash equivalents | 24,455 | 26,642 |
| Property and equipment, net | 10,852 | 12,254 |
| Intangible assets, net | 29,606 | 31,004 |
| Goodwill | 42,698 | 42,698 |
| Prepaid and other assets | 3,182 | 2,564 |
| Total assets | $ 198,965 | $ 212,066 |

**9. Income Taxes**

The Company s provision for income taxes of $39,000 and $60,000 for the three months ended June 30, 2009 and 2008, respectively, and $119,000 and $105,000 for the six months ended June 30, 2009 and 2008, respectively, relates to the profitable operations of certain foreign entities.

**10. Stock-Based Compensation**

The captions in the Company s condensed consolidated statements of operations for the three and six months ended June 30, 2009 and 2008 include stock-based compensation as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2009 | 2008 | 2009 | 2008 |
| Cost of revenues | $ 370 | $ 309 | $ 664 | $ 564 |

| | | | | |
|---|---|---|---|---|
| Selling and marketing | 787 | 660 | 1,451 | 1,209 |
| Research and development | 176 | 169 | 313 | 293 |
| General and administrative | 859 | 656 | 1,449 | 1,214 |
| | $ 2,192 | $ 1,794 | $ 3,877 | $ 3,280 |

***Stock Options***

The Company grants stock options to employees, officers and directors under its current stock plans. The Company granted options to purchase 129,000 and 294,250 shares of common stock during the three months ended June 30, 2009 and 2008,

Table of Contents

respectively, and options to purchase 1,657,430 and 1,491,400 shares of common stock during the six months ended June 30, 2009 and 2008, respectively. The weighted-average fair value of options granted during the six months ended June 30, 2009 and 2008 was $1.21 and $2.92 per option, respectively.

***Performance-Based Plans***

In March 2009, the Company committed to grant up to 1,591,250 restricted stock units to certain employees and executive officers based on the Company s financial performance for the year ended December 31, 2009, which the Company refers to as the 2009 Performance Share Plan. The grants are being recognized as compensation expense, adjusted as necessary based on the number of awards expected to vest, over the requisite service period of three years using the graded vesting method in accordance with FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Options or Award Plans*.

In March 2009, the Company approved its 2009 corporate bonus plan, or the 2009 Bonus Plan. Payout under the 2009 Bonus Plan will be based on the Company s financial performance for the year ended December 31, 2009 and may be paid in cash, or in restricted stock units, at the discretion of the Compensation Committee of the Company s Board of Directors. The estimated payout under the 2009 Bonus Plan is being recognized as compensation expense during 2009 and has been classified as a liability on the Company s condensed consolidated balance sheet.

The Company recorded $0.4 million and $0.6 million in stock-based compensation expense during the three and six months ended June 30, 2009, respectively, in connection with the 2009 Performance Share Plan and 2009 Bonus Plan. As of June 30, 2009, unrecognized compensation expense of $1.5 million for the 2009 Bonus Plan and the 2009 Performance Share Plan is expected to be recognized over a period of approximately 2.5 years.

**11. Stockholders Equity**

On May 22, 2008, the Company entered into Securities Purchase Agreements relating to a private placement of shares of its common stock and warrants to purchase shares of its common stock.

The warrants to purchase shares of common stock issued on May 28, 2008 were classified as a current liability on the Company s balance sheet for the year ended December 31, 2008. The fair value of these warrants upon issuance was $3.3 million and at June 30, 2008 was $2.1 million. These amounts were determined using the Black-Scholes option pricing model and calculated using the following assumptions: 65% volatility; expected term of 5 years; 3.2% risk-free interest rate; and 0% dividend. The fair value of these warrants represents a noncash financing activity. The Company recognized $1.2 million in other income during the three months ended June 30, 2008 related to changes in the fair value of these warrants.

In connection with this private placement, the Company entered into an obligation on May 22, 2008 to sell 4.0 million shares and warrants to purchase 0.8 million shares of its common stock which met the definition of a derivative instrument under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. The fair value of this derivative instrument at issuance was $1.3 million and at June 30, 2008 was $2.2 million. These amounts were determined using the Black-Scholes option pricing model and calculated using the following assumptions: 76% volatility; expected term of 71 to 32 days; 1.9% risk-free interest rate; and 0% dividend. The fair value of this derivative instrument represents a noncash financing activity. The Company recognized $0.9 million in other income during the three months ended June 30, 2008 related to changes in the fair value of this derivative instrument.

The exercise price of the warrants to purchase shares of the Company s common stock issued in connection with this private placement was fixed at $5.50 per share on December 31, 2008 based on the Company s achievement of over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, the fair value of these warrants of $1.9 million at December 31, 2008 was reclassified from a current liability to equity on January 1, 2009. The reclassification on January 1, 2009 represents a noncash financing activity.

**12. Related-Party Transactions**

On June 4, 2007, the Company entered into a stock purchase agreement with David S. Utterberg, a director and significant stockholder of the Company, under which the Company agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and certain affiliated entities, which the Company refers to as the MDS Entities. The acquisition of the MDS Entities, which the Company refers to as the Medisystems Acquisition, was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage. In consideration for the Medisystems Acquisition, the Company issued Mr. Utterberg 6.5

million shares of common stock, which the Company refers to as the Acquisition Shares. As a result of the Medisystems Acquisition and the issuance of the Acquisition Shares to Mr. Utterberg, Mr. Utterberg s aggregate ownership of the Company s outstanding common stock increased to approximately 20%. In addition, the Company may be required to issue additional shares of common stock to Mr. Utterberg since, pursuant to the terms of the stock purchase agreement, Mr. Utterberg and the Company have agreed to indemnify each other in the event of certain breaches or failures, and any such indemnification amounts must be paid in shares of the Company s common stock, valued at the time of payment. However, the Company will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of the Company s common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. An aggregate of 0.5 million of the Acquisition Shares remain in escrow to cover potential indemnification claims the Company may have against Mr. Utterberg. In connection with the Medisystems Acquisition and as a result of Medisystems Corporation, one of the MDS Entities, becoming a direct wholly-owned subsidiary of the Company,

Table of Contents

the Company acquired rights under an existing license agreement between Medisystems and DSU Medical Corporation, or DSU, a Nevada corporation, which is wholly-owned by Mr. Utterberg. The Company refers to this agreement as the License Agreement. Additionally, as a condition to the parties obligations to consummate the Medisystems Acquisition, Mr. Utterberg and DSU entered into a consulting agreement with the Company dated October 1, 2007, which the Company refers to as the Consulting Agreement.

Under the License Agreement, Medisystems Corporation received an exclusive, irrevocable, sublicensable, royalty-free, fully paid license to certain DSU patents, or the Licensed Patents, in exchange for a one-time payment of $2.7 million. The Licensed Patents fall into two categories, those patents that are used exclusively by the MDS Entities, referred to as the Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, referred to as the Class B patents. Pursuant to the terms of the License Agreement, Medisystems Corporation has a license to (a) the Class A patents, to practice in all fields for any purpose and (b) the Class B patents, solely with respect to certain defined products for use in the treatment of extracorporeal fluid treatments and/or renal insufficiency treatments. The License Agreement further provides that the rights of Medisystems Corporation under the agreement are qualified by certain sublicenses previously granted to third parties. The Company has agreed that Mr. Utterberg retains the right to the royalty income under one of these sublicenses.

The Company assumed a $2.8 million liability owed to DSU as a result of the acquisition of the MDS Entities. The amount owed represented consideration owed to DSU by the MDS Entities for the termination of a royalty-bearing sublicense agreement of $0.1 million and the one-time payment for the establishment of the royalty-free license agreement of $2.7 million. The Company paid $2.0 million of the liability owed during the quarter ended March 31, 2008 and the remaining liability of $0.6 million, net of receivable from DSU for reimbursements of costs related to the acquisition of $0.2 million, during the quarter ended September 30, 2008.

Under the Consulting Agreement, Mr. Utterberg and DSU agreed to provide consulting, advisory and related services for a period of two years following the consummation of the Medisystems Acquisition. In addition, under the terms of the Consulting Agreement, Mr. Utterberg and DSU have agreed during the term of the agreement not to compete with the Company during the term of the Consulting Agreement in the field defined in the Consulting Agreement and not to encourage or solicit any of the Company s employees, customers or suppliers to alter their relationship with the Company. The Consulting Agreement further provides that (a) Mr. Utterberg and DSU assign to the Company certain inventions and proprietary rights received by him/it during the term of the agreement and (b) the Company grants Mr. Utterberg and DSU an exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid license under such assigned inventions and proprietary rights for any purpose outside the inventing field, as defined in the Consulting Agreement. Under the terms of the Consulting Agreement, Mr. Utterberg and DSU will receive an aggregate of $0.2 million per year, plus expenses, in full consideration for the services and other obligations provided for under the terms of the Consulting Agreement. The Consulting Agreement also requires Mr. Utterberg and the Company to indemnify each other in the event of certain breaches and failures under the agreement and requires that any such indemnification liability be satisfied with shares of common stock, valued at the time of payment. However, the Company will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of the Company s common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. The Company paid Mr. Utterberg and DSU $50,000 during both the three months ended June 30, 2009 and 2008 and $100,000 during both the six months ended June 30, 2009 and 2008.

Finally, in connection with the Medisystems Acquisition, the Company agreed that if Mr. Utterberg is no longer a director of the Company, the Company s Board of Directors will nominate for election to the Company s Board of Directors any director nominee proposed by Mr. Utterberg, subject to certain conditions.

On May 22, 2008, the Company entered into Securities Purchase Agreements relating to a private placement of shares of its common stock and warrants to purchase shares of its common stock. The private placement took place in two closings, on May 28, 2008 and August 1, 2008, and raised $25.0 million and $18.0 million, respectively, in gross proceeds. Participants in the private placement consist of unaffiliated and affiliated accredited institutional investors. One of these investors, the Sprout Group, is affiliated with one of the Company s Board members, Dr. Philippe O. Chambon. The Sprout Group purchased 1.0 million shares and warrants to purchase 0.2 million shares of the

Company s common stock at a price similar to that of unaffiliated investors. Under applicable rules of the NASDAQ Global Market, the second closing of the private placement, which included all shares issued to the Sprout Group and other affiliated accredited institutional investors, was subject to stockholder approval, which was obtained at a special meeting on July 31, 2008.

The Securities Purchase Agreements entered into with OrbiMed Advisors, LLC, or OrbiMed, in connection with the private placement required that the Company appoint one individual nominated by OrbiMed to its Board of Directors upon the earlier of the second closing of the private placement or sixty days after the first closing of the private placement. The appointment of Mr. Jonathan Silverstein, a general partner of OrbiMed, on July 23, 2008, to the Board satisfied this requirement. OrbiMed purchased an aggregate of 5.6 million shares and warrants to purchase 1.1 million shares of the Company s common stock in connection with the private placement at a price similar to that of unaffiliated investors.

**13. Fair Value Measurements**

At June 30, 2009, the Company had $12.8 million in money market funds, included in cash and cash equivalents, measured at fair value on a recurring basis using level 1 inputs as defined in SFAS No. 157, *Fair Value Measures*.

Table of Contents

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, prepaids and other current and non-current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

The carrying amount of the Company s long-term debt approximates fair value. The fair value of the Company s long-term debt was estimated using inputs derived principally from market observable data, including current rates offering to the Company for debt of the same or similar remaining maturities. Within the hierarchy of fair value measurements, these are level 2 inputs as defined in SFAS No. 157, *Fair Value Measures*.

**14. Significant Revenue Contracts**

***National Service Provider Agreement and a Stock Purchase Agreement with DaVita***

In February 2007, the Company entered into a National Service Provider Agreement and a Stock Purchase Agreement with DaVita, a significant customer, which pursuant to EITF 00-21, the Company considers to be a single arrangement.

In connection with the National Service Provider Agreement, the Company agreed to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The National Service Provider Agreement included other terms such as development efforts, training, market collaborations, limited market exclusivity and volume discounts. The sales of the equipment and other items included in the arrangement are considered multiple-element sales arrangements pursuant to EITF 00-21. The Company has determined that it cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under this arrangement are deferred and recognized as revenue on a straight-line basis over the expected term of the Company s obligation to supply disposables and service pursuant to the agreement which is seven years. The Company has deferred both the unrecognized revenue and direct costs relating to the delivered equipment, which costs are being amortized over the same period as the related revenue.

In connection with the Stock Purchase Agreement, DaVita purchased 2.0 million shares of the Company s common stock for $10.00 per share, which on the date of the purchase represented a premium over the market price of $1.50 per share, or $3.0 million. The Company has recorded the $3.0 million premium as deferred revenue and is recognizing this revenue ratably over seven years, consistent with its equipment service obligation to DaVita.

***Asahi Strategic Business Alliance***

In May 2009, the Company entered into a series of agreements with Asahi Kasei Kuraray Medical, or Asahi, a leading medical supply company headquartered in Japan. The signed agreements between the partners are multi-faceted and include a Term Loan and Security Agreement, or Loan Agreement, Technology and Trademark License Agreement, or License Agreement, a Dialyzer Production Agreement, a Supply and Purchase Agreement and a Collaboration Agreement. Pursuant to EITF 00-21, the Company considers these separate agreements to be a single arrangement.

Under the terms of the Loan Agreement, Asahi agreed to provide the Company with $40 million of debt financing. The four year loan bears interest at 8% annually, with 50% of the interest deferred to maturity. The Company estimated the fair value of the loan at issuance using quoted prices for similar debt instruments, level 2 measurements within the fair value hierarchy. The fair value of the loan of $36.3 million was recorded by the Company, net of a $3.7 million discount. The discount will be amortized over the term of the loan into interest expense on a straight-line basis. In accordance with the terms of the License Agreement, the Company granted Asahi a royalty-free license to its Streamline blood tubing set technology and production technology to make and sell the Company s current dialyzer design. The Company estimated the fair value of the license using an income approach, namely the relief from royalty approach, which requires assumptions related to future cash flows, assumed royalty rates and a discount rate, level 3 measurements within the fair value hierarchy. The fair value of the license of $3.7 million was recorded to deferred revenue and will be recognized as revenue over the estimated life of the underlying patents, of six to seven years. The deferral of the consideration allocated to the license represents a noncash operating activity.

Under the term of the Dialyzer Production Agreement in which the Company agreed to manufacturer dialyzers for Asahi, the Company will recognize revenue from product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

***Kimal Strategic Business Alliance***

In March 2009, the Company signed a five year exclusive distribution agreement with Kimal plc, or Kimal. Pursuant to the agreement the Company will sell Kimal the NxStage System One and certain other products for use or resale in the UK and Ireland.

The Company has determined that it cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under this arrangement are deferred and recognized as revenue on a straight-line basis over shorter of the economic life of the equipment or the expected term of the Company s obligation to supply disposables pursuant to the agreement which is five years. The Company has deferred both the unrecognized revenue and direct costs relating to the delivered equipment, which costs are being amortized over the same period as the related revenue.

Table of Contents

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

**Special Note Regarding Forward Looking Statements**

The following discussion should be read with our unaudited condensed consolidated financial statements and notes included in Part I, Item 1 of this Quarterly Report, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2008, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC. This Quarterly Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, revenues, cost of revenues, distribution expenses, sales and marketing expenses, general and administrative expenses, research and development expenses, the impact of the acquisition of Medisystems Corporation, our liquidity and capital resources, and the sufficiency of our cash for future operations. Words such as expect, anticipate, target, project, believe, estimate, potential, predict, may, will, might, could, intend, variations of these terms or the negative of and similar expressions are intended to identify these forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II. We undertake no obligation to revise or update publicly any forward-looking statement for any reason. Readers should carefully review the factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report and in Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as in other documents filed by us with the SEC, as they may be amended from time to time, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

**Recent Events**

In June 2009, we entered into a five year distribution agreement with Gambro Renal Products, Inc., or Gambro, pursuant to which we will supply blood tubing sets, including our ReadySet and the Streamline product lines, to Gambro. Gambro, in turn, will exclusively supply the blood tubing sets to DaVita, Inc., or DaVita, for use with specific dialysis machines, subject to certain conditions.

In May 2009, we entered into a series of agreements with Asahi Kasei Kuraray Medical Co., Ltd., or Asahi, a leading medical supply company headquartered in Japan. The agreements are multi-faceted and include a Term Loan and Security Agreement, or Term Loan, pursuant to which Asahi agreed to provide us with $40 million of debt financing. The Term Loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal matures in four years from the effective date, and is payable in one balloon payment at maturity. The Term Loan is secured by all of our assets other than cash, bank accounts, accounts receivable, field equipment, and inventory and may be prepaid, without penalty, at our option. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions. We used $30.0 million of the proceeds to pay off the entire debt obligation, including prepayment and other transaction fees, owed under our credit and security agreement with GE Capital Corporation, or GE. Remaining proceeds will be used for operating purposes.

In May 2009, we signed a five year exclusive distribution agreement with Kimal plc, or Kimal, a distributor of medical device technology across the United Kingdom and international healthcare markets, for the promotion, sale, delivery and service of the System One and certain of our other products in the UK and Ireland. The agreement marks our first international expansion for the System One outside of the United States and Canada. Under the terms of the agreement, the System One and PureFlow SL dialysate preparation system will be available to dialysis centers and

hospitals throughout the UK and Ireland exclusively through Kimal, which also has the option to make our blood tubing sets and needles available to their customers in these regions.

**Overview**

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

Table of Contents

We report the results of our operations in two segments: the System One segment and the In-Center segment.

In the System One segment we derive our revenues from the sale and rental of equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home, and the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. In the In-Center segment, we derive our revenues from the sale of needles and blood tubing sets primarily used for in-center dialysis treatments.

Within the System One segment, we offer a similar technology platform of the System One for the home and critical care markets with different features. The FDA has cleared the System One for hemodialysis, hemofiltration and ultrafiltration. We offer primarily needles and blood tubing sets in the In-Center segment. Our products are predominantly used by our customers to treat patients suffering from ESRD or acute kidney failure. We have marketing and sales efforts dedicated to each market, although nearly all sales in the In-Center segment are made through distributors.

We received clearance from the FDA in July 2003 to market the System One for treatment of renal failure and fluid overload using hemodialysis as well as hemofiltration and ultrafiltration. In the first quarter of 2003, we initiated sales of the System One in the critical care market to hospitals and medical centers in the United States. In late 2003, we initiated sales of the System One for the treatment of patients with ESRD. At the time of these early marketing efforts, our System One was cleared by the FDA under a general indication statement, allowing physicians to prescribe the System One for hemofiltration, hemodialysis and/or ultrafiltration at the location, time and frequency they considered in the best interests of their patients. Our original indication did not include a specific home clearance, and we were not able to promote the System One for home use at that time. The FDA cleared the System One in June 2005 for hemodialysis in the home. We are presently pursuing a nocturnal indication for the System One under an FDA-approved investigational device exemption, or IDE, study started in the first quarter of 2008. We recently completed enrollment in our IDE study and expect to have it completed and submitted to the FDA by the first quarter of 2010.

Our business expanded significantly in late 2007 in connection with the October 1, 2007 acquisition of Medisystems Corporation and certain affiliated entities, or Medisystems Acquisition. With that acquisition, we acquired our needle and blood tubing set product lines for use predominantly in hemodialysis performed in-center as well as apheresis. The In-Center segment is significantly more mature than our System One segment. Medisystems Corporation and certain affiliated entities, which the Company refers to as the MDS Entities, have been selling products to dialysis centers for the treatment of ESRD since 1981, and they have achieved leading positions in the United States market for both blood tubing sets and needles. Our blood tubing set products include the ReadySet High Performance Blood Tubing set, or ReadySet, and the Streamline Airless Blood Tubing set, or Streamline. ReadySet has been on the market since 1993. Streamline is our next generation blood tubing product designed to provide improved patient outcomes and lower costs to dialysis centers. This product is early in its market launch and adoption has been somewhat limited to date. Our needle product line includes AV fistula needle sets incorporating safety features including MasterGuard Anti-Stick Needle Protectors and MasterGuard technology and ButtonHole needle sets. Our AV fistula needle sets with MasterGuard Anti-Stick Needle Protector were commercially introduced in 1995 and our ButtonHole needle sets were commercially introduced in 2002.

Our customers, who include dialysis centers and hospitals, receive reimbursement for the dialysis treatments provided with our products typically from Medicare and, to a lesser degree, from private insurers. Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. Reimbursement claims for dialysis therapy using the System One or our blood tubing sets and needles are typically submitted by the dialysis center or hospital to Medicare and other third-party payors using established billing codes for dialysis treatment or, in the critical care setting, based on the patient s primary diagnosis. Medicare presently limits reimbursement for chronic hemodialysis to three treatments per week, absent a finding of medical justification. Because most of our System One home dialysis patients are treated more than three times a week, expanding Medicare reimbursement over time to more predictably cover more frequent therapy may be critical to the market penetration of the System One in the home market and to our revenue growth in the future. As a result of 2008 MIPPA legislation, CMS has announced that, in 2011, it will implement a new bundled payment for dialysis treatment. We expect to obtain further insight into the

bundled payment structure through CMS proposed rulemaking process in late 2009. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

The manufacture of our products is accomplished through a complementary combination of outsourcing and internal production. Specifically, we manufacture our System One Cycler and PureFlow SL hardware, and assemble, package and label our PureFlow SL disposables, within our Fresnillo, Mexico facility. We manufacture components used in our System One cartridge assembly, and assemble the System One disposable cartridge and some blood tubing sets and other ancillary products, in Tijuana, Mexico. We manufacture our dialyzers in Rosdorf, Germany and manufacture components for some blood tubing sets, dialyzers and System One cartridges in Modena, Italy. We outsource the manufacture of our premixed dialysate, needles and some blood tubing sets.

In our System One segment, we market the System One in the home and critical care markets through a direct sales force in the United States primarily to dialysis centers, for ESRD hemodialysis patients, and hospitals. In our In-Center segment, we market our blood tubing and needle products primarily through distributors, although we also have a small dedicated sales force for that business. Nearly all In-Center sales are made to customers in the United States, with very limited amounts sold internationally through distributors. In May 2009, we announced our first international distribution agreement for the System One with Kimal. With the exception of very limited early sales of the System One in Canada, to date all System One segment revenues have been derived from sales within the United States. Under our agreement with Kimal, we will now begin selling the System One, as well as Streamline and ButtonHole needles, in the United Kingdom and Ireland.

Table of Contents

Since inception, we have incurred losses every quarter and at June 30, 2009, we had an accumulated deficit of approximately $258.0 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable. Our ability to become profitable is dependent principally upon implementing design and process improvements to lower the costs of manufacturing our products, obtaining better purchasing terms and prices, growing revenue, increasing reliability of our products, improving our field equipment utilization, achieving efficiencies in manufacturing and supply chain overhead costs, achieving efficiencies in the distribution of our products and achieving a sufficient scale of operations.

We have experienced negative operating margins and cash flows from operations and expect to continue to incur net losses in the foreseeable future. We believe, based on current projections, that we have the required resources to fund operating requirements at least through 2010. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of complementary businesses, services or technologies.

**Statement of Operations Components**

***Revenues***

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

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

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

In early 2007, we began entering into long-term contracts with customers in the home market that provide for the purchase as well as the rental of the System One equipment, including the cycler and PureFlow SL. The term of these agreements varies but is generally at least three years, and may be cancelled upon a material breach, subject to certain curing rights. Under our 2007 contract with DaVita, our largest customer, DaVita agreed to purchase rather than rent a significant percentage of its future System One equipment needs. In the home market, we expect, at least in the near term, that the majority of dialysis providers will choose to rent rather than purchase the System One.

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

Table of Contents

Our In-Center segment revenues are highly concentrated in several significant purchasers. Revenues from Henry Schein our primary distributor, represented approximately 80% of our In-Center segment revenues during both the three and six months ended June 30, 2009. Revenues from our two other significant distributors over each of the same periods were approximately 18% of our In-Center segment revenues. Sales to DaVita, through Henry Schein, represent a significant percentage of these revenues. DaVita has contractual purchase commitments under two agreements with us covering the In-Center segment: one for needles and one for blood tubing sets. DaVita s purchase obligations with respect to needles expire in January 2013. Our agreement with DaVita governing the sale of blood tubing sets expires in September 2009. In June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines to DaVita. In connection with the sale of its United States dialysis clinic business to DaVita, Gambro and DaVita entered into a long-term product supply agreement under which DaVita agreed to purchase a significant majority of its product requirements from Gambro. Our In-Center segment revenues are subject to fluctuation as a result of changes in sales volumes and variations in inventory management policies with both our distributors and end users. We regularly monitor the amount of inventory held by distributors to ensure it is not excessive when compared to end user demand.

Our distribution contracts for our In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events. In addition to contractually determined volume discounts, we offer rebates based on sales to specific end customers and discount incentives for early payment. Our sales revenues are presented net of these rebates, incentives, discounts and returns. As of June 30, 2009, we had $2.0 million reserved against trade accounts receivable for future sales incentives. We recorded $2.4 million and $4.9 million during the three and six months ended June 30, 2009, respectively, as a reduction of sales in connection with sale incentives.

Our agreement with Henry Schein, our primary distributor for the In-Center segment, which expired in July 2009, has been extended for a period of one month. We and Henry Schein have provided notice of intent to renew the agreement and we are currently in discussions with Henry Schein to renew the agreement. However, we have no assurance that we will be able to negotiate a renewal. If we are unable to negotiate a renewal, we will need to seek alternative distribution relationships or to sell our In-Center segment products directly to end users. Our agreements with our other primary two distributors for the In-Center segment are scheduled to expire in July 2011 and February 2012, respectively. Our agreement with Gambro expires in July 2014.

DaVita continues to be our most significant customer for both segments. We have long-term agreements covering products sales to DaVita in both the System One and In-Center segments; however, the initial term of our agreement for the home market with DaVita is scheduled to expire in December 2009. The loss of any of this business, at least in the near term, would have an adverse effect on our business.

***Cost of Revenues***

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

***Operating Expenses***

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

*Research and Development.* Research and development expenses consist primarily of salary, benefits and stock-based compensation for research and development personnel, supplies, materials and expenses associated with

product design and development, clinical studies, regulatory submissions, reporting and compliance and expenses incurred for outside consultants or firms who furnish services related to these activities.

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

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

Table of Contents

***Results of Operations***

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2009** | **2008** | **2009** | **2008** |
| Revenues | 100% | 100% | 100% | 100% |
| Cost of revenues | 76% | 86% | 77% | 87% |
| Gross profit | 24% | 14% | 23% | 13% |
| Operating expenses: | | | | |
| Selling and marketing | 20% | 23% | 21% | 23% |
| Research and development | 6% | 7% | 7% | 7% |
| Distribution | 10% | 11% | 10% | 11% |
| General and administrative | 13% | 15% | 14% | 15% |
| Total operating expenses | 49% | 56% | 52% | 56% |
| Loss from operations | (25%) | (42%) | (29%) | (43%) |
| Other expense: | | | | |
| Interest income | | | | 1% |
| Interest expense | (9%) | (3%) | (6%) | (3%) |
| Change in fair value of financial instruments | | 6% | | 3% |
| Other (expense) income, net | | (1%) | | |
| | (9%) | 2% | (6%) | 1% |
| Provision for income taxes | | | | |
| Net loss | (34%) | (40%) | (35%) | (42%) |

***Comparison of the Three and Six Months Ended June 30, 2009 and 2008***

*Revenues*

Our revenues for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended | | | | Six Months Ended | | | |
|---|---|---|---|---|---|---|---|---|
| | **June 30, 2009** | | **June 30, 2008** | | **June 30, 2009** | | **June 30, 2008** | |
| System One segment | | | | | | | | |
| Home | $ 15,205 | 42% | $ 11,850 | 37% | $ 29,559 | 42% | $ 22,396 | 36% |
| Critical Care | 5,241 | 14% | 4,385 | 14% | 9,709 | 14% | 8,706 | 14% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Total System One segment | 20,446 | 56% | 16,235 | 51% | 39,268 | 56% | 31,102 | 50% |
| In-Center segment | 15,952 | 44% | 15,381 | 49% | 30,865 | 44% | 31,519 | 50% |
| Total | $ 36,398 | 100% | $ 31,616 | 100% | $ 70,133 | 100% | $ 62,621 | 100% |

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

In the home market, revenues increased $3.4 million, or 28%, and $7.2 million, or 32%, for the three and six months ended June 30, 2009, respectively, versus the prior year comparable period as a result of an increase in the number of patients prescribed to use and centers offering the System One. Critical care market revenues increased $0.9 million, or 20%, and $1.0 million, or 12%, for the three and six months ended June 30, 2009, respectively, versus the prior year comparable period as a result of higher disposable sales volumes. Higher disposable revenue is a result of the increase in the installed base of System One units. Future demand for our products for both the home and critical care markets is expected to remain strong due to the life-sustaining, non-elective nature of dialysis therapy. Revenues in the home market are expected to continue to increase as we further penetrate the market place. However, in the critical care market, we continue to expect, at least in the short-term, to see a shift to a more conservative capital spending environment as hospitals face pressure to reduce capital spending.

In-Center segment revenues increased $0.6 million, or 4%, for the three months ended June 30, 2009 and decreased $0.7 million, or 2%, for the six months ended June 30, 2009, respectively, versus the prior year comparable period. The fluctuations in revenues for both periods were primarily a result of changes in distributor inventory levels and lower sales volumes. We expect future demand

Table of Contents

will be susceptible to fluctuation as a result of changes in sales volumes and variations in inventory management policies with both our distributors and end users. In addition, during the third and fourth quarter of 2009, we expect to see some fluctuation in revenues as we transition a portion of our blood tubing set business from Henry Schein to Gambro.

*Cost of Revenues and Gross Profit*

Our cost of revenues for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended | | | Six Months Ended | | |
|---|---|---|---|---|---|---|
| | June 30, 2009 | June 30, 2008 | % Change | June 30, 2009 | June 30, 2008 | % Change |
| System One segment | $ 15,792 | $ 14,296 | 10% | $ 30,558 | $ 28,021 | 9% |
| In-Center segment | 11,789 | 12,905 | (9%) | 23,703 | 26,167 | (9%) |
| Total Cost of revenue | $ 27,581 | $ 27,201 | 1% | $ 54,261 | $ 54,188 | 0% |

Gross profit for the System One segment increased $2.7 million, or 140%, from $1.9 million for the three months ended June 30, 2008 to $4.7 million for the three months ended June 30, 2009. Gross profit increased $5.6 million, or 183%, from $3.1 million for the six months ended June 30, 2008 to $8.7 million for the six months ended June 30, 2009. The increase in gross profit for both periods was a result of increased revenues and lower overall costs of manufacturing as we continue to realize the benefits of certain cost saving initiatives such as the transition of manufacturing to lower cost labor markets, improvements in product design and reliability and the favorable impact of foreign currency rates versus the United States dollar.

Gross profit for the In-Center segment increased $1.7 million, or 68%, from $2.5 million for the three months ended June 30, 2008 to $4.2 million for the three months ended June 30, 2009. Gross profit increased $1.8 million, or 34%, from $5.4 million for the six months ended June 30, 2008 to $7.2 million for the six months ended June 30, 2009. The increase in gross profit for both periods was due to lower manufacturing costs as we continue to realize the benefits of certain cost savings initiatives.

We expect the cost of revenues as a percentage of revenues to continue to decline over time for three general reasons. First, we expect to introduce additional process improvements and product design changes that have inherently lower cost than our current products. Second, we expect to continue to improve product reliability, which would reduce service costs. Finally, we anticipate that increased volume and realization of economies of scale will lead to better purchasing terms and prices and efficiencies in manufacturing and supply chain overhead costs. We cannot, however, guarantee that our expectations will be achieved with respect to our cost reduction plans.

*Selling and Marketing*

Our selling and marketing expenses for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended | | | Six Months Ended | | |
|---|---|---|---|---|---|---|
| | June 30, 2009 | June 30, 2008 | % Change | June 30, 2009 | June 30, 2008 | % Change |
| System One segment | $ 6,495 | $ 6,304 | 3% | $ 12,817 | $ 12,240 | 5% |
| In-Center segment | 916 | 959 | (4%) | 1,825 | 1,858 | (2%) |
| Total Selling and marketing | $ 7,411 | $ 7,263 | 2% | $ 14,642 | $ 14,098 | 4% |

The increase in selling and marketing expenses was primarily the result of higher personnel and personnel-related costs due to expanded sales and marketing and customer service functions. We anticipate that selling and marketing expenses will continue to increase as we broaden our marketing initiatives to increase public awareness of the System One in the home market and other products, particularly Streamline, in the in-center market, and as we add additional sales support and marketing personnel, but decrease as a percent of revenues as we continue to leverage our existing structure.

*Research and Development*

Our research and development expenses for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended | | | Six Months Ended | | |
|---|---|---|---|---|---|---|
| | **June 30, 2009** | **June 30, 2008** | **% Change** | **June 30, 2009** | **June 30, 2008** | **% Change** |
| Research and development | $ 2,271 | $ 2,362 | (4%) | $ 4,673 | $ 4,488 | 4% |

Table of Contents

The decrease in research and development expenses for the three months ended June 30, 2009 was primarily a result of timing of research and development project spending and decreased clinical trials expenses resulting from the completion of enrollment in our nocturnal IDE study which began in the first quarter of 2008. The increase in research and development expenses for the six months ended June 30, 2009 was primarily the result of increased clinical trial costs due to increased patient registration in our nocturnal IDE study and FREEDOM study and increased personnel and personnel related costs due to increased headcount. We expect research and development expenses will increase in absolute dollars but remain relatively constant as a percentage of sales in the foreseeable future as we seek to further enhance our System One and related products, and their reliability, and with the increased activity associated with our nocturnal IDE study and FREEDOM study.

*Distribution*

Our distribution expenses for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended June 30, 2009 | June 30, 2008 | % Change | Six Months Ended June 30, 2009 | June 30, 2008 | % Change |
|---|---|---|---|---|---|---|
| System One segment | $ 3,159 | $ 2,939 | 7% | $ 6,508 | $ 5,979 | 9% |
| In-Center segment | 366 | 396 | (8%) | 701 | 751 | (7%) |
| Total Distribution | $ 3,525 | $ 3,335 | 6% | $ 7,209 | $ 6,730 | 7% |

The increase in distribution expenses was primarily a result of increased shipments of products to the growing number of patients in the System One segment offset by a decrease in the In-Center segment primarily due to shipping efficiencies. Distribution expenses were 10% of revenues for both the three and six months ended June 30, 2009 versus 11% for both the three and six months ended June 30, 2008. We expect that distribution expenses will continue to increase at a lower rate than revenues due to expected efficiencies gained from increased business volume, better pricing obtained from carriers following recent price negotiations and increased volume, customer adoption of our PureFlow SL hardware, which significantly reduces the weight and quantity of monthly disposable shipments, and improved reliability of System One equipment. We cannot predict the estimated impact, if any, of fuel costs on future distribution costs.

*General and Administrative*

Our general and administrative expenses for the three and six months ended June 30, 2009 and 2008 were as follows (in thousands, except percentages):

| | Three Months Ended June 30, 2009 | June 30, 2008 | % Change | Six Months Ended June 30, 2009 | June 30, 2008 | % Change |
|---|---|---|---|---|---|---|
| General and administrative | $ 4,749 | $ 4,884 | (3%) | $ 9,704 | $ 9,699 | 0% |

General and administrative expenses as a percentage of revenues decreased to 13% of revenues for the three months ended June 30, 2009 versus 15% of revenues for the three months ended June 30, 2008 and decreased to 14% of revenues for the six months ended June 30, 2009 versus 15% of revenues for the six months ended June 30, 2008. The decrease was due to our continued initiative to leverage our overhead structure. We expect that general and administrative expenses will remain relatively flat in the near term as we continue to leverage our existing structure.

*Other Income and Expense*

Interest income decreased $0.1 million, or 85%, for the three months ended June 30, 2009 and decreased $0.3 million, or 92%, for the six months ended June 30, 2009, versus the prior year comparable periods due to lower

interest rates on investments. Interest income is derived primarily from investments in money market funds.

Interest expense increased $2.3 million, or 209%, for the three months ended June 30, 2009 and increased $2.5 million, or 131%, for the six months ended June 30, 2009, versus the prior year comparable periods due primarily to prepayment and other transaction fees of $2.0 million incurred during the three months ended June 30, 2009 to pay off the entire debt obligation owed under our credit and security agreement with GE. Interest expense was derived primarily from borrowings under our credit and security agreement with GE that we entered into in November 2007, subsequently amended in March 2009 and terminated in June 2009.

The change in fair value of the derivative instruments issued in connection with the May 22, 2008 private placement resulted in the recognition of $2.1 million of other income for the three months ended June 30, 2008. These instruments included the warrants to purchase 1.1 million shares of NxStage common stock issued on May 28, 2008 and the obligation to issue a second tranche of the Company s common stock and warrants to purchase shares of common stock in a second closing. The obligation was settled on August 1, 2008. The fair value of the warrants to purchase shares of the Company s common stock was reclassified from a current liability to equity on January 1, 2009.

Table of Contents

Other expense of $14,000 and other income of $79,000 for the three and six months ended June 30, 2009, respectively, and other expense of $144,000 and $293,000 for the three and six months ended June 30, 2008, respectively, is derived primarily from foreign currency gains and losses.

*Provision for Income Taxes*

The provision for income taxes of $39,000 and $119,000 for the three and six months ended June 30, 2009, respectively, and $60,000 and $105,000 for the three and six months ended June 30, 2008, respectively, relates to the profitable operations of certain of our foreign entities.

**Liquidity and Capital Resources**

We have operated at a loss since our inception in 1998. As of June 30, 2009, our accumulated deficit was $258.0 million and we had cash and cash equivalents of $24.5 million.

Our primary ongoing cash requirements will be to fund operating activities, product development and debt service. Our primary sources of liquidity are cash on hand and ongoing revenues. At June 30, 2009, we had $24.5 million of cash and cash equivalents and working capital of $41.4 million. A significant factor affecting the management of our ongoing cash requirements is our ability to execute upon cost reduction initiatives to lower product cost. We have the flexibility under our current term loan and security agreement with Asahi, to seek up to $40.0 million in additional borrowings at market interest rates to fund our growth objectives, if necessary. However, based on the current credit market, the interest rates obtained may be less favorable than historical interest rates and the interest rates available to us under our current credit facility.

In May 2009, we entered into a series of agreements with Asahi Kasei Kuraray Medical, or Asahi, a leading medical supply company headquartered in Japan. The signed agreements between the partners are multi-faceted and include a Term Loan and Security Agreement, or Term Loan, in which Asahi agreed to provide us with $40 million of debt financing. The Term Loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal matures in four years from the effective date, and is payable in one balloon payment at maturity. The Term Loan is secured by all of our assets other than cash, bank accounts, accounts receivable, field equipment, and inventory and may be prepaid, without penalty, at our option. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions. We used $30.0 million of the proceeds to pay off the entire debt obligation, including prepayment and other transaction fees, owed under our credit and security agreement with GE. We intend to use the remaining proceeds for operating purposes.

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. The plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of $1.5 million as other long-term liabilities at June 30, 2009 for costs associated with these plans. The expense recorded in connection with these plans was not significant for the three or six months ended June 30, 2009.

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2009** | **2008** |
| Net cash used in operating activities | $ (10,685) | $ (36,113) |
| Net cash used in investing activities | (1,148) | (570) |
| Net cash provided by financing activities | 9,537 | 29,719 |
| Effect of exchange rate changes on cash | 109 | 111 |
| Net cash flow | $ (2,187) | $ (6,853) |

*Net Cash Used in Operating Activities.* For each of the periods above, net cash used in operating activities was attributable primarily to net losses after adjustment for non-cash charges, such as depreciation, amortization and stock-based compensation expense. Significant uses of cash from operations for the six months ended June 30, 2009 include cash used to reduce accounts payable and accrued expenses primarily due to the timing of vendor payments, inventory purchases and $1.9 million of prepayment and other transactions fees incurred in connection with the termination of the term loan and security agreement with GE. These uses of cash were offset by decreases in accounts receivable as a result of our continued focus on cash collections and the timing of payments from large customers. Significant uses of cash from operations for the six months ended June 30, 2008 include increases in accounts receivable and inventory purchases of System One and PureFlow SL hardware as we began closing out our outside manufacturing contracts. Non-cash transfers from inventory to field equipment and deferred costs for the placement of rental units and sales to our customers represented $3.2 million and $13.4 million during the six months ended June 30, 2009 and 2008, respectively. Non-cash transfers from field equipment to deferred costs for sales of units to customers represented $1.7 million and $1.0 million for the six months ended June 30, 2009 and 2008, respectively.

*Net Cash Used in Investing Activities.* Net cash used in investing activities reflected purchases of property and equipment of $0.6 million and $1.8 million for the six months ended June 30, 2009 and 2008, respectively, primarily for research and development,

Table of Contents

information technology, manufacturing operations and capital improvements to our facilities. Net maturities of short-term investments were $1.1 million for the six months ended June 30, 2008. This activity varies from period to period based upon our cash availability and requirements.

*Net Cash Provided by Financing Activities.* Net cash provided by financing activities during the six months ended June 30, 2009 included $40.0 million of borrowings under our term loan and security agreement with Asahi offset by $0.1 million in fees paid in connection with the Asahi debt issuance, $30.0 million in repayments of borrowings under our credit and security agreement with GE and $0.5 million amendment fee paid in connection with the March 16, 2009 amendment to our credit and security agreement with GE. Net cash provided by financing activities during the six months ended June 30, 2008 included $5.0 million of additional borrowings under our credit and security agreement with GE and $24.7 million net proceeds from the sale of 5.6 million shares of our common stock and warrants to purchase 1.1 million shares of our common stock.

We have experienced negative operating margins and cash flows from operations and expect to continue to incur net losses in the foreseeable future. We believe that we have the required resources to fund operating requirements at least through 2010. Future capital requirements will depend on many factors, including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of, complementary businesses, services or technologies.

As of June 30, 2009, our financial contractual obligations described in our annual report on Form 10-K for the year ended December 31, 2008 have not materially changed, with the exception of our debt obligations. In May 2009, we borrowed $40.0 million under our term loan and security agreement with Asahi and paid off the entire debt obligation owed under our credit and security agreement with GE.

The following table summarizes our contractual commitments as of June 30, 2009 and the effect those commitments are expected to have on liquidity and cash flow in future periods (in thousands):

| | Total | Less Than One Year | 1-3 Years | 3-5 Years | More Than 5 Years |
|---|---|---|---|---|---|
| Debt obligations | $ 40,246 | $ 59 | $ 76 | $ 40,111 | |
| Operating leases | 4,772 | 1,748 | 2,899 | 125 | |
| Purchase obligations (1) | 53,283 | 26,999 | 20,740 | 3,168 | 2,376 |
| Total | $ 98,301 | $ 28,806 | $ 23,715 | $ 43,404 | $ 2,376 |

(1) Purchase obligations include purchase commitments for System One components, primarily for equipment, blood tubing sets, needles, and fluids pursuant to

contractual agreements with several of our suppliers. Certain of these commitments may be extended and/or canceled at our option.

**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.

A summary of those accounting policies and estimates that we believe are most critical to fully understanding and evaluating our financial results is described in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and updated, as necessary, in this Quarterly Report on Form 10-Q. This summary should be read in conjunction with our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q.

***Revenue Recognition***

We recognize revenue from product sales and services when earned in accordance with Staff Accounting Bulletin No. 104, or SAB 104, *Revenue Recognition,* and Emerging Issues Task Force Issue No. 00-21, or EITF 00-21, *Revenue Arrangements with Multiple Deliverables.* Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured. Our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Table of Contents

Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors, revenue is recognized at the time of sale if a reasonable estimate of future returns or refunds can be made. If a reasonable estimate of future returns or refunds cannot be made, we recognize revenue using the sell-through method. Under the sell-through method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

*System One Segment*

We derive revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

Under the rental arrangements, which combine the use of the System One and PureFlow SL hardware with a specified number of disposable products supplied to customers for a fixed price per month, revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

For customers that purchase the System One and PureFlow SL hardware, we recognize equipment revenue upon delivery if the equipment has stand-alone value and the fair value of the undelivered items, typically the disposables and, in some instances service, can be determined. If the fair value of the undelivered items can be determined, they are accounted for separately as delivered. If the fair value of any of the undelivered items cannot be determined, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery.

In the critical care market, we structure sales of the System One as direct product sales. We recognize revenue from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms.

Our contracts for the System One in the critical care market provide for training, technical support and warranty services to its customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranty, the revenue is recognized ratably over the warranty period.

*In-Center Segment*

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. Our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

In addition to contractually determined volume discounts, we offer rebates based on sales to specific end customers and discount incentives for early payment. We recognize these sales incentives in accordance with Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration given by a Vendor to a Customer (Including) Reseller of the Vendors Products.* Sales incentives are recorded as a reduction of sales and trade accounts receivable, based on our best estimate of the amount of probable future rebate or discount on current sales.

**Related-Party Transactions**

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg, one of our directors and a significant stockholder, under which we agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and certain affiliated entities, which we refer to as the MDS Entities. The acquisition of the MDS Entities, which we refer to as the Medisystems Acquisition was completed on October 1, 2007 and, as a result, each of the MDS Entities is a direct or indirect wholly-owned subsidiary of NxStage. In addition, as a result of completion of the Medisystems Acquisition, the supply agreement, dated January 2007, with Medisystems Corporation, under which Medisystems Corporation agreed to provide cartridges for use with the System One, was terminated with no resulting gain or loss recognized. In consideration for the Medisystems Acquisition, we issued Mr. Utterberg 6.5 million shares of our common stock, which we refer to as the Acquisition Shares. As a result of the Medisystems Acquisition and the issuance of the Acquisition Shares to Mr. Utterberg, Mr. Utterberg s aggregate ownership of our outstanding common stock increased to approximately 20%. In addition, we may be required to

issue additional shares of our common stock to Mr. Utterberg. Pursuant to the terms of the stock purchase agreement, Mr. Utterberg and we have agreed to indemnify each other in the event of certain breaches or failures, and any such indemnification amounts must be paid in shares of our common stock, valued at the time of payment. However, we will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of our common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. An aggregate of 0.5 million of the Acquisition Shares remain in escrow to cover potential indemnification claims we may have against Mr. Utterberg. In connection with the Medisystems Acquisition and as a result of Medisystems Corporation, one of the MDS Entities, becoming a direct wholly-owned subsidiary of ours, we acquired rights under an existing license agreement between Medisystems Corporation and DSU Medical Corporation, or DSU, a Nevada corporation, which is wholly-owned by Mr. Utterberg. We refer to this agreement as the License Agreement. Additionally, as a condition to the parties obligations to consummate the Medisystems Acquisition, Mr. Utterberg and DSU entered into a consulting agreement with us dated October 1, 2007, which we refer to as the Consulting Agreement.

Table of Contents

Under the License Agreement, Medisystems Corporation received an exclusive, irrevocable, sublicensable, royalty-free, fully paid license to certain DSU patents, or the licensed patents, in exchange for a one-time payment of $2.7 million. The licensed patents fall into two categories, those patents that are used exclusively by the MDS Entities, referred to as the Class A patents, and those patents that are used by the MDS Entities and other companies owned by Mr. Utterberg, referred to as the Class B patents. Pursuant to the terms of the License Agreement, Medisystems Corporation has a license to (1) the Class A patents, to practice in all fields for any purpose and (2) the Class B patents, solely with respect to certain defined products for use in the treatment of extracorporeal fluid treatments and/or renal insufficiency treatments. The License Agreement further provides that the rights of Medisystems Corporation under the agreement are qualified by certain sublicenses previously granted to third parties. We have agreed that Mr. Utterberg retains the right to the royalty income under one of these sublicenses.

Under the Consulting Agreement, Mr. Utterberg and DSU will provide consulting, advisory and related services to us for a period of two years following the consummation of the Medisystems Acquisition. In addition, under the terms of the Consulting Agreement, Mr. Utterberg and DSU have agreed not to compete with NxStage during the term of the Consulting Agreement in the field defined in the Consulting Agreement and not to encourage or solicit any of our employees, customers or suppliers to alter their relationship with us during the term of the agreement. The Consulting Agreement further provides that (1) Mr. Utterberg and DSU assign to us certain inventions and proprietary rights received by him/it during the term of the agreement and (2) we grant Mr. Utterberg and DSU an exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid license under such assigned inventions and proprietary rights for any purpose outside the inventing field, as defined in the Consulting Agreement. Under the terms of the Consulting Agreement, Mr. Utterberg and DSU will receive an aggregate of $200,000 per year during the term of the agreement, plus expenses, in full consideration for the services and other obligations provided for under the terms of the Consulting Agreement. The Consulting Agreement also requires Mr. Utterberg and NxStage to indemnify each other in the event of certain breaches and failures under the agreement and requires that any such indemnification liability be satisfied with shares of our common stock, valued at the time of payment. However, we will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of our common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. We paid Mr. Utterberg and DSU $50,000 during both the three months ended June 30, 2009 and 2008 and $100,000 during both the six months ended June 30, 2009 and 2008, respectively.

We assumed a $2.8 million liability owed to DSU as a result of the acquisition of the MDS Entities. The amount owed represents consideration owed to DSU by the MDS Entities for the termination of a royalty-bearing sublicense agreement of $0.1 million and the one-time payment for the establishment of the royalty-free license agreement of $2.7 million. We paid $2.0 million of the liability owed during the quarter ended March 31, 2008 and the remaining liability of $0.6 million, net of receivable from DSU for reimbursements of costs related to the acquisition of $0.2 million, during the quarter ended September 30, 2008.

As of March 31, 2008, we had a receivable for reimbursement of costs related to the acquisition in the amount of $0.4 million from Mr. Utterberg and DSU. During the quarter ended September 31, 2008, approximately $0.2 million was collected and the remaining was offset against amounts owed by us to DSU.

In connection with the Medisystems Acquisition, we also agreed that if Mr. Utterberg is no longer a director of NxStage, our Board of Directors will nominate for election to our Board of Directors any director nominee proposed by Mr. Utterberg, subject to certain conditions.

On May 22, 2008, we entered into Securities Purchase Agreements relating to a private placement of shares of our common stock and warrants to purchase shares of our common stock. The private placement took place in two closings, on May 28, 2008 and August 1, 2008, and raised $25.0 million and $18.0 million, respectively, in gross proceeds. Participants in the private placement consist of unaffiliated accredited institutional investors and affiliated accredited institutional investors. One of these investors, the Sprout Group, is affiliated with one of our Board members, Dr. Philippe O. Chambon. Under applicable rules of the NASDAQ Global Market, the second closing of the private placement, which included all shares issued to the Sprout Group and other affiliated accredited institutional investors, was subject to stockholder approval, which was obtained at a special meeting on July 31, 2008.

Consistent with the requirements of our Audit Committee Charter, these transactions were reviewed and approved by our Audit Committee, which is comprised solely of independent directors, as well as our Board of Directors.

The Securities Purchase Agreement entered into with OrbiMed Advisors, LLC, or OrbiMed, in connection with the private placement required that we appoint one individual nominated by OrbiMed to our Board of Directors upon the earlier of the second closing of the private placement or sixty days after the first closing of the private placement. The appointment of Mr. Jonathan Silverstein, a general partner of OrbiMed on July 23, 2008, to the Board satisfied this requirement. OrbiMed purchased an aggregate of 5.6 million shares and warrants to purchase 1.1 million shares of our common stock in connection with the private placement at a price similar to that of unaffiliated investors.

**Off-Balance Sheet Arrangements**

Since inception we have not engaged in any off-balance sheet financing activities except for leases which are properly classified as operating leases and disclosed in the Liquidity and Capital Resources section in the Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

Table of Contents

**Recent Accounting Pronouncements**

Effective January 1, 2009, we adopted Statement of Financial Accounting Standards, or SFAS, No. 141(R), *Business Combinations*, or SFAS 141 (R), a replacement of SFAS No. 141. SFAS 141(R) provides that, upon initially obtaining control, an acquirer shall recognize 100 percent of the fair values of acquired assets, including goodwill and assumed liabilities, with only limited exceptions, even if the acquirer has not acquired 100 percent of its target. As a consequence, the step acquisition model will be eliminated. Additionally, SFAS 141(R) changes current practice, in part, as follows: (1) contingent consideration arrangements will be fair valued at the acquisition date and included on that basis in the purchase price consideration; (2) transaction costs will be expensed as incurred, rather than capitalized as part of the purchase price; (3) pre-acquisition contingencies, such as legal issues, will generally have to be accounted for in purchase accounting at fair value; (4) in-process research and development will be capitalized and either amortized over the life of the product or written off if the project is abandoned or impaired; (5) changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense; and (6) in order to accrue for a restructuring plan in purchase accounting, the requirements in SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, would have to be met at the acquisition date.

Since SFAS 141(R) is applicable to future acquisitions completed after January 1, 2009 and we did not have any business combinations subsequent to January 1, 2009 to date, the adoption of SFAS 141(R) did not have an impact on our consolidated financial statements. SFAS 141(R) amends SFAS No. 109, *Accounting for Income Taxes*, such that adjustments made to valuation allowances on deferred taxes and acquired tax contingencies associated with acquisitions that closed prior to the effective date of SFAS 141(R) would also follow the provisions of SFAS 141(R). Thus, all changes to valuation allowances and liabilities for uncertain tax positions established in acquisition accounting, whether the business combination was accounted for under SFAS 141 or SFAS 141(R), will be recognized in current period income tax expense.

Effective January 1, 2009, we adopted Emerging Issues Task Force, or EITF, Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) Is Indexed to an Entity s Own Stock*, or EITF 07-5. EITF 07-5 requires the application of a two-step approach in evaluating whether an equity-linked financial instrument (or embedded feature) is indexed to a Company s own stock, including evaluating the instrument s contingent exercise and settlement provisions, and must be applied to all instruments outstanding on the date of adoption. The adoption of EITF 07-5 did not have an impact on our consolidated financial statements.

Effective April 1, 2009, we adopted Financial Accounting Standards Board, or FASB, Staff Position No. 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*, or FSP 157-4. FSP 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157, *Fair Value Measurements*, or SFAS 157. FSP 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. The adoption of FSP 157-4 had no impact on our consolidated financial statements.

Effective April 1, 2009, we adopted FASB Staff Position No. 107-1 and Accounting Principles Board, or APB, 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, or FSP 107-1. FSP 107-1 amends SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements and also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. The adoption of this standard has resulted in enhanced disclosures of fair values within this interim report. Since FSP 107-1 addresses disclosure requirements, the adoption of this FSP did not impact our financial position, results of operations or cash flows.

Effective June 30, 2009, we adopted the provisions of SFAS No. 165, *Subsequent Events*, or SFAS 165. SFAS 165 provides guidance to establish general standards of accounting for and disclosures of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS 165 also requires entities to disclose the date through which subsequent events were evaluated as well as the rationale for why that date was selected. This disclosure should alert all users of financial statements that an entity has not evaluated subsequent events after that date in the set of financial statements being presented. The adoption of SFAS 165 has resulted in

enhanced disclosures around subsequent events within this interim report. Since SFAS 165 primarily addresses disclosure requirements, the adoption of this standard did not impact our financial position, results of operations or cash flows.

In April 2009, the FASB issued FASB Staff Position No. 115-2 and SFAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments,* or FSP 115-2. FSP 115-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. We adopted FSP 115-2 on April 1, 2009. The adoption of FSP 115-2 did not have an impact on our consolidated financial statements.

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*, or SFAS 168. SFAS 168 replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, to establish the FASB Accounting Standards Codification as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with GAAP. SFAS 168 is effective for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have an impact on our financial position, results of operations or cash flows.

Table of Contents

In June 2009, the FASB issued SFAS No. 166, *Accounting for Transfers of Financial Assets, an amendment of FASB Statement No. 140*, or SFAS 166. SFAS 166 prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor s continuing involvement in transferred financial assets. Specifically, among other aspects, SFAS 166 amends SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, or FIN 46(R), to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. SFAS 166 is effective for transfer of financial assets occurring on or after January 1, 2010. We have not determined the effect the adoption of SFAS 166 will have on our consolidated financial statements, but the effect will be limited to future transactions.

Table of Contents

**Item 3.** ***Quantitative and Qualitative Disclosures About Market Risk***

During the six months ended June 30, 2009, there were no material changes in our market risk exposure. For quantitative and qualitative disclosures about market risk affecting NxStage, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. As of the date of this report, there have been no material changes to the market risks described in our Annual Report on Form 10-K for December 31, 2008.

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

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2009. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1943, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

## PART II OTHER INFORMATION

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

In addition to the factors discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report, the following are some of the important risk factors that could cause our actual results to differ materially from those projected in any forward-looking statements.

**Risks Related to our Business**

***We expect to derive a significant percentage of our future revenues from the rental or sale of our System One and a limited number of other products.***

Since our inception, we have devoted a substantial amount of our efforts to the development of the System One and the related products used with the System One. We commenced marketing the System One and the related disposable products to the critical care market in February 2003. We commenced marketing the System One for chronic hemodialysis treatment in September 2004. Prior to the Medisystems Acquisition, nearly 100% of our revenues were derived from the rental or sale of our System One and the sale of related disposables. Although the Medisystems Acquisition broadened our product offerings, we expect that in 2009 and in the foreseeable future, we will continue to derive a significant percentage of our revenues from the System One, and that we will derive the remainder of our revenues from the sale of a few key disposable products acquired in the Medisystems Acquisition, including blood tubing sets and needles. To the extent that any of our primary products is not commercially successful or is withdrawn from the market for any reason, our revenues will be adversely impacted, and we do not have other significant products in development that could readily replace these revenues.

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

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

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered five or more times a week, the market adoption of our System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider supply costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for Medicare patients, at least in part by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. Presently, we understand that a number of our customers are unable to obtain such additional reimbursement, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times per week. Both of these facts will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to grow our revenue in the future. As a result of 2008 MIPPA legislation, CMS has announced that, in 2011, it will implement a new bundled payment for dialysis treatment. We expect to obtain further insight into the bundled payment structure through the CMS proposed

rulemaking process in late 2009. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

New regulations particularly impacting home hemodialysis technologies can also negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. In 2008, the Centers for Medicare and Medicaid Services, or CMS, released new Conditions for Coverage applicable to our customers. These Conditions for Coverage impose water testing requirements on our patients using our PureFlow SL product. These water testing requirements increase the burden of our therapy for our patients and may impair market adoption, especially for our PureFlow SL product. To the extent additional regulations are introduced unique to the home environment, market adoption could be even further impaired.

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

***We require significant capital to build our business, and financing may not be available to us on reasonable terms, if at all.***

Table of Contents

We have experienced negative operating margins and cash flows from operations and we expect to continue to incur net losses in the foreseeable future. In addition, our System One home market relies heavily upon a rental sales model whereby approximately half of our sales to customers in the home market include the rental rather than the purchase of System One equipment. This sales model requires significant amounts of working capital to manufacture System One equipment for rental to dialysis clinics. Our agreement with DaVita signed in early 2007 departs from the rental model, which helps us to conserve cash flow. In our 2007 agreement, DaVita agreed to purchase all of its System One equipment then being rented from us and to buy a significant percentage of its future System One equipments needs. The initial term of that agreement, however, expires in December 2009.

We believe that we have the required resources to fund operating requirements at least through 2010. Future capital requirements will depend on many factors including the rate of revenue growth, continued progress on improving gross margins, the expansion of selling and marketing activities and research and development activities, the timing and extent of expansion into new geographies or territories, the timing of new product introductions and enhancement to existing products, the continuing market acceptance of products, availability of credit and potential investments in, or acquisitions of complementary businesses, services or technologies. There is no assurance that additional debt or equity capital will be available to us on favorable terms, if at all.

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

***We have limited operating experience, a history of net losses and an accumulated deficit of $258.0 million at June 30, 2009. We cannot guarantee if, when and the extent to which we will become profitable, or that we will be able to maintain profitability if it is achieved.***

Since inception, we have incurred losses every quarter and, at June 30, 2009, we had an accumulated deficit of approximately $258.0 million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, while we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins will continue to improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability should it occur, or the extent to which we will be profitable. Our ability to become profitable is dependent principally upon implementing design and process improvements to lower our costs of manufacturing our products, accessing lower labor cost markets for the manufacture of our products, growing revenue, increasing the reliability of our products, improving our field equipment utilization, achieving efficiencies in manufacturing and supply chain overhead costs, achieving efficient distribution of our products, achieving a sufficient scale of operations, and obtaining better purchasing terms and prices.

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

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Collectively, these entities provide treatment to more than 60% of United States dialysis patients. Additionally, DaVita has certain dialysis supplies purchase obligations to Gambro under a long-term preferred supplier agreement. Each of Fresenius and DaVita may choose to offer their dialysis patients only the dialysis equipment manufactured by them or their affiliates, to offer the equipment they contractually agreed to offer or to otherwise limit access to the equipment manufactured by competitors. With less than 40% of United States dialysis patients cared for by independent dialysis clinics, our market adoption, at least within the United States, will be more constrained without the presence of one or both of DaVita and Fresenius as customers for our System One and In-Center products.

DaVita is our most significant customer for both of the System One and In-Center segments. In February 2007, we entered into an agreement with DaVita which conferred certain market rights for the System One and related supplies for home hemodialysis therapy. Under that agreement, DaVita was granted exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the United States ESRD patient population, and limited exclusivity in the majority of all other United States geographies, subject to DaVita s meeting certain requirements, including patient volume commitments and new patient training rates. If certain minimum patient

numbers or training rates are not achieved, DaVita can lose all or part of its preferred geographic rights. The agreement further limited, but does did not prohibit, the sale by NxStage of the System One for chronic home patient hemodialysis therapy to any provider that is under common control or management of a parent entity that collectively provides dialysis services to more than 25% of United States chronic dialysis patients and that also supplies dialysis products. The agreement therefore limited our ability to sell the System One for chronic home patient hemodialysis therapy to Fresenius. The initial term of that agreement expires in December 2009, and we have no assurance that it will be extended or renewed.

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

DaVita is our most significant customer. Sales through distributors to DaVita of products accounted for nearly half of In-Center segment revenues for both the three and six months ended June 30, 2009, and direct sales to DaVita accounted for approximately 38% of our System One segment revenues for both the three and six months ended June 30, 2009, and nearly half of our home hemodialysis patients. Our national service provider agreement with DaVita for the home business does not impose minimum purchase requirements, and the initial term expires in December 2009. We cannot guarantee we will be able to negotiate an extension to this agreement with DaVita on favorable terms, if at all, or the extent to which DaVita will purchase our products. Although we expect that DaVita will continue to be a significant customer in the home market, we cannot be certain that DaVita will continue to

Table of Contents

purchase and/or rent the System One or add additional System One patients in the future. Our contract for needles with DaVita, expiring in December 2013, includes certain minimum order requirements; however, these can be reduced significantly under certain circumstances. Our contract for blood tubing set with DaVita will expire in September 2009. However, in June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines to DaVita. The partial or complete loss of DaVita as a customer for any of these product lines would adversely affect our business, at least in the near term. Further, given the significance of DaVita as a customer, any change in DaVita s ordering or clinical practices can have a significant impact on our revenues, especially in the near term.

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

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

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

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

Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter Healthcare, JMS and others. Our System One in the critical care market competes against Gambro AB, Fresenius Medical Care AG, Baxter Healthcare, B. Braun and others. Our System One in the home market is currently the only system specifically indicated for the use in the home market in the United States. Our competitors each market one or more FDA-cleared medical device for the treatment of acute or chronic kidney failure. Each of these competitors offers products that have been in use for a longer time than our System One, and in some instances many of our Medisystems products, and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy and, Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage. Finally, one of our competitors, Gambro AB, had been subject to an import hold imposed by the FDA on its acute and chronic dialysis machines. Since the import hold has lifted, competition from Gambro has increased, which could impair our performance in the future in the critical care market.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our products, including our System One. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices. Fresenius and Baxter have each made public statements that they are either contemplating or actively developing new and/or improved systems

for home hemodialysis. Fresenius made these statements in connection with their recent acquisition of Renal Solutions, Inc., and Baxter made them in connection with the announcement of a research and development collaboration with DEKA Research & Development Corporation and HHD, LLC. We are unable to predict when products from these or other companies may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it would adversely affect our sales and growth. Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of ESRD and/or in the treatment of acute kidney failure or fluid overload. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

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

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

Table of Contents

***The success and growth of our business will depend upon our ability to achieve expanded market acceptance of our System One and In-Center products.***

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

- the failure by us to demonstrate to operators of dialysis clinics, hospitals, nephrologists, dialysis nurses, patients and others that our products are equivalent or superior to existing therapy options;
- competition from products sold by companies with longer operating histories and greater financial resources, more recognizable brand names and better established distribution networks and relationships with hospitals or dialysis clinics;
- the failure by us to continue to improve product reliability and the ease of use of our products;
- limitations on the existing infrastructure in place to support home hemodialysis, including without limitation, home hemodialysis training nurses, and the willingness, cost associated with, and ability of dialysis clinics to build that infrastructure;
- the ownership and operation of some dialysis providers by companies that also manufacture and sell competitive dialysis products;
- the introduction of competing products or treatments that may be more effective, easier to use or less expensive than ours;
- regulations that impose additional burden on patients and their caregivers, such as the recently adopted Medicare conditions for coverage which impose additional water testing requirements in connection with the use of our PureFlow SL;
- the number of patients willing and able to perform therapy independently, outside of a traditional dialysis clinic, may be smaller than we estimate; and
- the availability of satisfactory reimbursement from healthcare payors, including Medicare and any negative impact of the bundle payment method to be introduced by the CMS in 2011.

In addition, the future growth of our business depends, to a lesser degree, upon the successful launch and market acceptance of our latest generation blood tubing set product, Streamline. Streamline is designed to be a high-quality, high-performance blood tubing set that is expected to yield valuable savings and improved patient outcomes for those clinics that adopt it for use. Market penetration of this product is limited to date, and it is not possible to predict whether and to what extent current and future customers will elect to use this product instead of more established or competitive blood tubing sets. If we are unable to convert customers to the Streamline product and receive more widespread commercial acceptance of this product, our ability to achieve our growth and profitability objectives could be impaired.

***Our business and results of operations may be negatively impacted by general economic and financial market conditions and such conditions may increase other risks that affect our business.***

The world s financial markets are currently experiencing significant turmoil, resulting in reductions in available credit, increased costs of credit, increased volatility in security prices, rating downgrades of investments and reduced valuations of securities generally. These events have materially and adversely impacted the availability of financing to a wide variety of businesses and the resulting uncertainty has led to reductions in capital investments, overall spending levels and future product plans and sales projections. In general, we believe demand for our products in the home and in-center market will not be substantially affected by the current market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, revenues in the in-center market could be impacted due to changes in sales volumes and inventory management policies with both our distributors and end customers. In addition, during the third and fourth quarter of 2009, we expect to see some fluctuation in revenues as we transition a portion of our blood tubing set business from Henry Schein to Gambro. Finally, the impact of tightened credit markets on hospitals could continue to impair the manner and pace in which we sell equipment in the critical care market or delay equipment placements. Hospitals facing pressure to reduce capital spending may choose to rent equipment rather than purchase it outright, or to enter into other less-capital intensive purchase structures with us, which may, in turn, have a negative impact on our cash flows.

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

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our products. As a result of legislation passed by the United States Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the United States for ESRD. With over 80% of United States ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One or our other products and limits the fee for which we can rent or sell our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for

Table of Contents

by Medicare to three times a week, unless there is medical justification provided by the patient s physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for the additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis, based on documentation provided by our customers. If daily therapy is prescribed, a clinic s decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic s patients. Medicare is switching from intermediaries to Medicare authorized contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. We understand that a number of our customers are unable to obtain additional reimbursement for more frequent therapy, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times a week. Both of these facts will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to more predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to our revenue growth in the future. Additionally, any adverse changes in the rate paid by Medicare for ESRD treatments in general would likely negatively affect demand for our products in the home market and the prices we charge to them. As a result of 2008 MIPPA legislation, CMS has announced that, in 2011, it will implement a new bundled payment for dialysis treatment. We expect to obtain further insight into the bundled payment structure through CMS proposed rulemaking process in late 2009. It is not possible at this time to determine what impact this will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

***As we continue to commercialize the System One, Streamline and our other products, we may have difficulty managing our growth and expanding our operations successfully.***

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

***If we are unable to improve on the product reliability of our System One product or maintain strong product reliability for our other products, our ability to maintain or grow our business and achieve profitability could be impaired.***

We continue to experience product reliability issues associated with our System One and PureFlow SL that are higher than we expect long-term, and have led us to incur increased service and distribution costs, as well as to increase the size of our field equipment base. This, in turn, negatively impacts our gross margins and increases our working capital requirements. Additionally, product reliability issues associated with any of our product lines can also lead to decreases in customer satisfaction and our ability to grow or maintain our revenues. We continue to work to improve product reliability for all products, and have achieved some improvements to date. If we are unable to continue to improve product reliability of our System One, PureFlow SL products and Streamline products, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

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

Because a significant percentage of our System One home care business continues to rely upon an equipment rental model, our ability to manage System One equipment is important to minimizing our working capital requirements. In addition, our gross margins may be negatively impacted if we have excess equipment deployed, and unused, in the

field. If we are unable to successfully track, service and redeploy equipment, we could (1) incur increased costs, (2) realize increased cash requirements and/or (3) have material write-offs of equipment. This would negatively impact our working capital requirements and future profitability.

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

While kidney transplantation is the treatment of choice for most ESRD patients, it is not currently a viable treatment for most- patients due to the limited number of donor kidneys, the high incidence of kidney transplant rejection and the higher surgical risk associated with older ESRD patients. According to USRDS data, in 2004, approximately 17,000 patients received kidney transplants in the United States. The development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants or any other advances in kidney transplantation could limit the market for our products. The development of viable medical or other solutions for renal replacement may also limit the market for our products.

***If we are unable to convince additional hospitals and healthcare providers of the benefits of our products for the treatment of acute kidney failure and fluid overload, we will not be successful in increasing our market share in the critical care market.***

We sell the System One in the critical care market for use in the treatment of acute kidney failure and fluid overload associated with, among other conditions, congestive heart failure. Physicians currently treat most acute kidney failure patients using conventional

Table of Contents

hemodialysis systems or dialysis systems designed specifically for use in the intensive care unit, or ICU. We will need to convince hospitals and healthcare providers that using the System One is as effective as using conventional hemodialysis systems or ICU-specific dialysis systems for treating acute kidney failure and that it provides advantages over conventional systems or other ICU-specific systems because of its significantly smaller size, ease of operation and clinical flexibility. In addition, the impact of tightened credit markets on hospitals could impair the manner in which we sell products in the critical care market. Hospitals facing pressure to reduce capital spending may choose to delay capital equipment purchases or seek alternative financing options. One of our competitors in the critical care market, Gambro AB, had been subject to an FDA import hold that was lifted in late 2007. Since the import hold has lifted, competition from Gambro has increased, which could impair our performance in the future in the critical care market.

***We could be subject to costly and damaging product liability and professional liability claims and may not be able to maintain sufficient product liability and professional liability insurance to cover claims against us.***

If any of our employees or products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. Claims of this nature may also adversely affect our reputation, which could damage our position in the market. While we maintain insurance, including professional liability, product and excess liability claims may be brought against us that could result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. In addition, due to the recent tightening of global credit and the disruption in the financial markets, there may be a disruption in our insurance coverage or delay or disruption in the payment of claims by our insurance providers. Our insurance policies also have various exclusions, and we may be subject to a product or professional liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance.

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

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

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

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

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

***We currently rely upon Kawasumi, a third-party manufacturer, to manufacture a significant percentage of our blood tubing set products using our supplied components and all of our needles. Kawasumi s contractual obligation to manufacture blood tubing sets expires in January 2010, with opportunities for extension, and its obligation to supply needles expires in February 2011. In the event these agreements are not renewed or extended upon favorable terms, if at all, or in the event we are unable to sufficiently expand our manufacturing capabilities,***

***or obtain alternative third party supply prior to the expiration of these agreements, our growth and ability to meet customer demand would be impaired.***

Historically, we have relied upon a third-party manufacturer, Kawasumi, to manufacture a significant percentage of our blood tubing set products using our supplied components. Kawasumi has a strong history of manufacturing high-quality product for us. In May 2008, we negotiated a new agreement with Kawasumi extending their obligation to supply blood tubing sets to us through January 31, 2010, with opportunities to extend the term beyond that date. We cannot be certain that this agreement will be renewed or extended on favorable terms, if at all, that we would be able to manufacture independently the volume of products currently manufactured by Kawasumi, and therefore, whether we would have sufficient capacity to meet all of our customer demand, that we would be able to manufacture products at the same cost at which we currently purchase products from Kawasumi or that we could find a third party to supply blood tubing sets on favorable terms, if at all, the failure of any of which could impair our business. We also depend solely on Kawasumi for all of our finished goods needles. Kawasumi s obligation to supply needles to us expires in February 2011. In the event this agreement is not renewed or extended on favorable terms, if at all, and we are unable to manufacture comparable needles for ourselves prior to the contract expiration, or if we are unable to obtain comparable needles from another third party on favorable terms, if at all, the revenues and profitability of our business will be impaired.

Table of Contents

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

We sell the majority of our In-Center products through distributors, which collectively accounted for substantially all of In-Center revenues for the three and six months ended June 30, 2009, with our primary distributor, Henry Schein, accounting for approximately 80% of In-Center revenues for both the three and six months ended June 30, 2009. Our distribution agreement with Henry Schein, originally scheduled to expire in July 2009, was extended through August 2009. We are presently in negotiations to renew the agreement, however; we cannot be certain that this agreement will be renewed on favorable terms, if at all. In June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines, to DaVita. During the third and fourth quarter of 2009, we expect to see some fluctuation in revenues as we transition a portion of our blood tubing set business from Henry Schein to Gambro.

***Unless we can demonstrate sufficient product differentiation in our blood tubing set business through Streamline or products that we introduce in the future, we will continue to be susceptible to further pressures to reduce product pricing and more vulnerable to the loss of our blood tubing set business to competitors in the dialysis industry.***

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

***The activities of our business involve the import of finished goods into the United States from foreign countries, subject to customs inspections and duties, and the export of components and certain other products from other countries into Germany, Mexico and Thailand. If we misinterpret or violate these laws, or if laws governing our exemption from certain duties changes, we could be subject to significant fines, liabilities or other adverse consequences.***

We import into the United States disposable medical supplies from Germany, Thailand and Mexico. We also import into the United States disposable medical components from China, Germany and Italy and export components and assemblies into Mexico, Thailand and Italy. The import and export of these items are subject to extensive laws and regulations with which we will need to comply. To the extent we fail to comply with these laws or regulations, or fail to interpret our obligations accurately, we may be subject to significant fines, liabilities and a disruption to our ability to deliver product, which could cause our combined businesses and operating results to suffer. To the extent there are modifications to the Generalised System of Preferences or cancellation of the Nairobi Protocol Classification such that our products would be subject to duties, our profitability would also be negatively impacted. The current Swine Flu Virus, or similar pandemics, could also impair our ability to import or export goods internationally. At present, there is no impact from the Swine Flu Virus on our supply chain, nor has there been any suggestion that such an impact would occur. However, there can be no assurance that should the pandemic worsen, our supply chain would not be impaired.

***The success of our business depends on the services of each of our senior executives as well as certain key engineering, scientific, manufacturing, clinical and marketing personnel, the loss of whom could negatively affect the combined businesses.***

Our success has always depended upon the skills, experience and efforts of our senior executives and other key personnel, including our research and development and manufacturing executives and managers. Much of our expertise is concentrated in relatively few employees, the loss of whom for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the future resignation of any employee. We maintain key person insurance for only one of our executives, Jeffrey Burbank, our Chief Executive

Officer.

***We have filed a resale registration statement covering shares of our common stock that we recently sold in a private placement. If the holders of these shares are unable to sell the shares under the registration statement, we may be obligated to pay them damages, which could harm our financial condition.***

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

**Risks Related to the Regulatory Environment**

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

Our products are medical devices subject to extensive regulation in the United States, and in foreign markets we may wish to enter. To market a medical device in the United States, approval or clearance by the FDA is required, either through the pre-market approval process or the 510(k) clearance process. We have obtained the FDA clearances necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In

Table of Contents

addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications for our products. Presently, we are pursuing a nocturnal indication for the System One under an IDE study started in the first quarter of 2008. We cannot provide assurance that this or other clearances or approvals will be forthcoming, or, if forthcoming, what the timing and expense of obtaining such clearances or approvals might be. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products.

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

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

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

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

- untitled letters, warning letters, fines, injunctions and civil penalties;
- administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;
- customer notification, or orders for repair, replacement or refund;
- voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

refusal to review pre-market notification or pre-market approval submissions;

rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and

criminal prosecution.

***Our products are subject to market withdrawals or product recalls after receiving FDA clearance or approval, and market withdrawals and product recalls could cause the price of our stock to decline and expose us to product liability or other claims or could otherwise harm our reputation and financial results.***

Medical devices can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. These could lead to a government mandated or voluntary recall by us. The FDA has the authority to require the recall of our products in the event a product presents a reasonable probability that it would cause serious adverse health consequences or death. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers.

Table of Contents

***If we or our contract manufacturers fail to comply with FDA s Quality System regulations, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.***

Our finished goods manufacturing processes, and those of some of our contract manufacturers, are required to comply with the FDA s Quality System Regulations, or QSRs, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its QSRs through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. Our manufacturing facility formerly located in Lawrence, MA U.S. has previously had three FDA QSR inspections. The first resulted in one observation, which was rectified during the inspection and required no further response from us. Our last two inspections, including our most recent inspection in March 2006, resulted in no observations. Medisystems has been inspected by the FDA on eight occasions, and all inspections resulted in no action indicated. We cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities.

We cannot provide assurance that any future inspections would have the same result. If one of our manufacturing facilities or those of any of our contract manufacturers fails to take satisfactory corrective action in response to an adverse QSR inspection, FDA could take enforcement action, including issuing a public warning letter, shutting down our manufacturing operations, embargoing the import of components from outside of the United States, recalling our products, refusing to approve new marketing applications, instituting legal proceedings to detain or seize products or imposing civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer.

***Changes in reimbursement for acute kidney failure could negatively affect the adoption of our critical care products and the level of our future critical care product revenues.***

Unlike Medicare reimbursement for ESRD, Medicare only reimburses healthcare providers for acute kidney failure and fluid overload treatment if the patient is otherwise eligible for Medicare, based on age or disability. Medicare and many other third-party payors and private insurers reimburse these treatments provided to hospital inpatients under a traditional diagnostic-related group, or DRG, system. Under this system, reimbursement is determined based on a patient s primary diagnosis and is intended to cover all costs of treating the patient. The presence of acute kidney failure or fluid overload increases the severity of the primary diagnosis and, accordingly, may increase the amount reimbursed. For care of these patients to be cost-effective, hospitals must manage the longer hospitalization stays and significantly more nursing time typically necessary for patients with acute kidney failure and fluid overload. If we are unable to convince hospitals that our System One provides a cost-effective treatment alternative under this diagnosis related group reimbursement system, they may not purchase our product. In addition, changes in Medicare reimbursement rates for hospitals could negatively affect demand for our products and the prices we charge for them.

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In both the United States and foreign countries, there have been legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The federal government and some states have enacted healthcare reform legislation, and further federal and state proposals are likely. We cannot predict the exact form this legislation may take, the probability of passage, or the ultimate effect on us. Our business could be adversely affected by future healthcare reforms or changes in Medicare.

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

Historically, we have not sold or marketed the System One outside the United States and Canada. In May 2009, we announced our first international distribution agreement for the System One with Kimal, granting Kimal distribution rights for the System One as well as Streamline and ButtonHole needles in the United Kingdom and the Republic of Ireland. We may look to other markets for the System One in the future as well. Our In-Center products are presently sold in the United States as well as in several other countries, through distributors. We presently have CE marking as well as Canadian regulatory authority to sell our System One as well as certain other products in Canada and Europe. However, in order to market directly our products in other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from

country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States, which could negatively affect our overall market penetration.

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

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

Table of Contents

Health and Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. At this time, we are not a HIPAA covered entity and consequently are not directly subject to HIPAA. However, we have entered into several business associate agreements with covered entities that contain commitments to protect the privacy and security of patients health information and, in some instances, require that we indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability and/or our reputation and business could be harmed. In addition, conduct by a person that is not a covered entity could potentially be prosecuted under aiding and abetting or conspiracy laws if there is an improper disclosure or misuse of patient information.

Many state laws apply to the use and disclosure of health information, which could affect the manner in which we conduct our business. Such laws are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA. Such state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

***We are subject to federal and state laws prohibiting kickbacks and false and fraudulent claims which, if violated, could subject us to substantial penalties. Additionally, any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.***

The Medicare/ Medicaid anti-kickback laws, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. In addition, several states require us to report and disclose the value, nature, purpose and particular recipient of any fee, payment, subsidy or economic benefit which we may from time to time provide to certain physicians or health care providers. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs; we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on our company. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If one of our sales representatives were to offer an inappropriate inducement to purchase our products to a customer, we could be subject to a claim under the Medicare/ Medicaid anti-kickback laws or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable state anti-kickback laws, or healthcare provider sunshine laws.

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

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

To date, our marketing efforts have been confined nearly exclusively to the United States. We have had limited activities in Canada with our System One, and in certain other jurisdictions with our In-Center products sold through distributors. In May 2009, we announced an international distribution agreement with Kimal, whereby we will

commence promotion and sales of our System One, as well as Streamline and ButtonHole needles, in the United Kingdom and Ireland. We may, in the future, seek to market our products in other markets. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business. Further, reimbursement provided to our products in other jurisdictions could change, positively or negatively. In the event reimbursement were to be negatively changed, such as, for example, in the United Kingdom, our ability to sell our products could be impaired.

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

We are subject to the United States Foreign Corrupt Practices Act which generally prohibits United States companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices occur from time-to-time in the PRC. We can make no assurance,

Table of Contents

however, that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

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

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

**Risks Related to Operations**

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

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

Finding alternative sources for these components and subassemblies would be difficult in many cases and may entail a significant amount of time and disruption. In the case of Membrana, for fiber, we are contractually prevented from obtaining an alternative source of supply for our System One products. In the case of other suppliers, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our System One or other products and, potentially, further FDA clearance or approval of any modification, thereby causing further costs and delays.

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

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

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

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

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

***and negatively impact our ability to deliver our products on a timely basis.***

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

Table of Contents

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

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

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

We continue to develop new products and make improvements to existing products. We have also relocated the manufacture of certain of our products to Mexico. As such, we and certain of our third-party manufacturers, have limited manufacturing experience with certain of our products, including key products such as the PureFlow SL, related disposables and our Streamline. We are, therefore, more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature.

**Risks Related to Intellectual Property**

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

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

prevent our competitors from duplicating our products;

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

permit us to gain or maintain a competitive advantage.

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

As of June 30, 2009, we had 44 pending patent applications, including foreign, international and U.S. applications, and 41 U.S. and international issued patents. Under our license agreement with DSU Medical Corporation, we also license approximately 37 pending patent applications, including foreign, international and U.S. applications, and approximately 78 U.S. and international issued patents. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. We cannot provide assurance that any pending or future patent applications we hold will result in an issued patent or that if patents are issued to us, that such patents will provide meaningful protection against competitors or against competitive technologies. The issuance of a patent is not conclusive as to its validity or enforceability. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. Competitors may also be able to design around our patents. Our patents and patent applications cover particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, it would likely have an adverse effect on our sales.

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

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

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

Table of Contents

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

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

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

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

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

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

**Risks Related to our Common Stock**

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

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

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

future debt or equity financings;

developments or disputes with key vendors or customers;

disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across the border, or the failure of third party suppliers to produce needed products or components;

reports by officials or health or medical authorities, the general media or the FDA regarding the potential benefits of the System One or of similar dialysis products distributed by other companies or of daily or home dialysis;

announcements by the FDA of non-clearance or non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;

product recalls;

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

regulatory developments in the United States and foreign countries;

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

litigation involving our company or our general industry or both;

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

Table of Contents

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; and

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

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

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

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

a prohibition on actions by our stockholders by written consent;

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

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

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

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

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

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. We have 46,658,515 shares of common stock outstanding as of June 30, 2009. Shares held by our affiliates may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which approximates 466,585 shares, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

At June 30, 2009, subject to certain conditions, holders of an aggregate of approximately 24,280,888 shares of our common stock have rights with respect to the registration of these shares of common stock with the Securities and

Exchange Commission, or SEC. If we register their shares of common stock following the expiration of the lock-up agreements, they can sell those shares in the public market.

As of June 30, 2009, 11,526,017 shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan and outstanding stock options. As of June 30, 2009, 6,955,967 shares were subject to outstanding options, of which 3,356,022 were exercisable and which can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144.

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

Our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 68% of our outstanding common stock. David S. Utterberg, one of our directors, holds approximately 18% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

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

entrenching our management and/or Board;

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

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

Table of Contents

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

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

- difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;
- potential disruption of our ongoing business and distraction of management;
- potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;
- difficulty in incorporating acquired technology and rights into our products and technology;
- unanticipated expenses and delays in completing acquired development projects and technology integration;
- management of geographically remote units both in the United States and internationally;
- impairment of relationships with partners and customers;
- customers delaying purchases of our products pending resolution of product integration between our existing and our newly acquired products;
- entering markets or types of businesses in which we have limited experience;
- potential loss of key employees of the acquired company; and
- inaccurate assumptions of acquired company s product quality and/or product reliability.

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

Table of Contents

**Item 4. Submission of Matters to a Vote of Security Holders**

On July 31, 2008, we held a Special Meeting of Stockholders. Matters voted on and the results of such voting are as follows:

1. The election of eight members to our board of directors.

| | Votes For | Withhold |
|---|---|---|
| Jeffrey H. Burbank | 34,679,010 | 96,355 |
| Philippe O. Chambon | 34,076,613 | 698,752 |
| Daniel A. Giannini | 34,684,138 | 91,227 |
| Earl R. Lewis | 32,419,422 | 2,355,943 |
| Craig W. Moore | 34,081,857 | 693,508 |
| Reid S. Perper | 34,678,645 | 96,720 |
| Jonathan T. Silverstein | 34,681,005 | 94,360 |
| David S. Utterberg | 34,674,584 | 100,781 |

2. To amend our 2005 Stock Incentive Plan to, among other tings, increase the number of shares of our common stock that may be issued pursuant to the plan by an additional 4,100,000 shares.

| | |
|---|---|
| Votes For | 25,924,298 |
| Votes Against | 4,601,059 |
| Abstain | 4,010 |

3. To amend our 2005 Employee Stock Purchase Plan to increase the number of shares of our common stock that may be issued pursuant to the plan by an additional 500,000 shares.

| | |
|---|---|
| Votes For | 30,341,584 |
| Votes Against | 186,050 |
| Abstain | 1,733 |

4. To ratify the selection by our Audit Committee of Ernst & Young LLP as our independent registered public accounting firm for the 2009 fiscal year.

| | |
|---|---|
| Votes For | 34,687,586 |
| Votes Against | 78,894 |
| Abstain | 8,885 |

Table of Contents

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

| Exhibit Number | |
|---|---|
| 10.45+ | Supply Agreement with Laboratorios PiSA dated April 10, 2009 |
| 10.46+ | Extracorporeal Disposables Distribution Agreement with Gambro Renal Products, Inc. dated June 15, 2009 |
| 10.47 | Term Loan and Security Agreement effective June 5, 2009 by and between the registrant, EIR Medical, Inc., Medisystems Services Corporation, Medisystems Corporation, as Borrowers, and Medimexico s. de R.L. de C.V., NxStage Verwaltungs GmbH, NxStage GmbH & Co. KG and Medisystems Europe S.p.A., as Guarontors and Asahi Kasei Kuraray Medical, Co., Ltd., as the Lender |
| 10.48+ | Technology and Trademark License Agreement effective June 15, 2009 by and between the Registrant and Asahi Kasei Kuraray Medical Co., Ltd. |
| 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. |

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

Table of Contents

**SIGNATURES**

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

NXSTAGE MEDICAL, INC.

By: /s/ Robert S. Brown
Robert S. Brown
*Chief Financial Officer*
*(Duly authorized officer and principal financial and accounting officer)*

August 7, 2009