NxStage Medical, Inc.
Form 10-Q
August 09, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2007

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 of Incorporation)	*(I.R.S. Employer Identification No.)*
439 S. Union Street 5th Floor, Lawrence, MA	**01843**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant s Telephone Number, Including Area Code: **(978) 687-4700**

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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (Check One):

Large accelerated filer o Accelerated filer þ Non-accelerated filer 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 29,995,126 shares of the registrant s common stock issued and outstanding as of the close of business on August 5, 2007.

NXSTAGE MEDICAL, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2007
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PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements (Unaudited)***

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

	June 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,045,621	$ 49,958,540
Short-term investments	10,921,716	11,843,275
Accounts receivable, net	6,009,991	4,301,557
Inventory	15,143,662	10,419,030
Prepaid expenses and other current assets	479,166	1,014,688
Total current assets	74,600,156	77,537,090
Property and equipment, net	4,018,133	3,025,560
Field equipment, net	23,685,353	20,615,952
Deferred cost of revenues	9,081,431	139,893
Other assets	1,784,195	406,285
Total assets	$ 113,169,268	$ 101,724,780
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 9,565,724	$ 5,918,437
Accrued expenses	5,371,904	4,104,058
Current portion of long-term debt	2,800,000	2,800,000
Total current liabilities	17,737,628	12,822,495
Deferred rent obligation	618,214	648,604
Deferred revenue	13,323,698	228,542
Long-term debt	3,216,668	4,616,667
Total liabilities	34,896,208	18,316,308
Commitments and contingencies		
Stockholders equity:		
Undesignated preferred stock: par value $0.001, 5,000,000 shares authorized; zero shares issued and outstanding as of June 30, 2007 and December 31, 2006		

Common stock: par value $0.001, 100,000,000 shares authorized: 29,989,461 and 27,806,543 shares issued and outstanding as of June 30, 2007 and December 31, 2006, respectively	29,990	27,807
Additional paid-in capital	226,544,271	206,848,097
Accumulated deficit	(148,515,867)	(123,640,441)
Accumulated other comprehensive income	214,666	173,009
Total stockholders equity	78,273,060	83,408,472
Total liabilities and stockholders equity	$ 113,169,268	$ 101,724,780

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	**2006**	**2007**	**2006**
Revenues	$ 10,031,184	$ 4,546,273	$ 18,405,177	$ 7,946,995
Cost of revenues	11,511,184	6,003,629	21,428,345	10,860,883
Gross profit (deficit)	(1,480,000)	(1,457,356)	(3,023,168)	(2,913,888)
Operating expenses:				
Selling and marketing	5,119,820	3,758,537	9,851,400	6,951,520
Research and development	1,418,441	1,576,295	2,854,247	3,355,189
Distribution	2,997,348	1,518,685	5,341,789	2,808,284
General and administrative	2,525,834	2,149,016	5,192,856	4,123,745
Total operating expenses	12,061,443	9,002,533	23,240,292	17,238,738
Loss from operations	(13,541,443)	(10,459,889)	(26,263,460)	(20,152,626)
Other income (expense):				
Interest income	831,831	607,921	1,735,791	1,203,328
Interest expense	(172,689)	(535,863)	(347,757)	(693,503)
	659,142	72,058	1,388,034	509,825
Net loss	$ (12,882,301)	$ (10,387,831)	$ (24,875,426)	$ (19,642,801)
Net loss per share, basic and diluted	$ (0.43)	$ (0.46)	$ (0.84)	$ (0.90)
Weighted-average shares outstanding, basic and diluted	29,933,141	22,440,529	29,488,097	21,815,098

See accompanying notes to these condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2007	**2006**
Cash flows from operating activities:		
Net loss	$ (24,875,426)	$ (19,642,801)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of equipment	89,674	26,959
Depreciation and amortization	3,016,893	1,227,571
Amortization/write-off of debt discount		281,666
Stock-based compensation	1,497,078	1,270,266
Changes in operating assets and liabilities:		
Accounts receivable	(1,713,265)	(2,053,482)
Inventory	(16,690,885)	(9,871,716)
Prepaid expenses and other current assets	537,830	31,489
Deferred cost of revenues	(2,704,499)	
Accounts payable	3,621,379	2,203,906
Accrued expenses	484,699	1,054,087
Deferred rent obligation	(30,390)	(19,865)
Deferred revenue	10,095,156	
Net cash used in operating activities	(26,671,756)	(25,491,920)
Cash flows from investing activities:		
Purchases of property and equipment	(1,394,421)	(802,046)
Sales (purchases) of short-term investments, net	921,559	(29,463,588)
Increase in other assets	(586,967)	(421,311)
Net cash used in investing activities	(1,059,829)	(30,686,945)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	19,938,683	51,380,309
Proceeds from stock option and purchase plans	1,262,594	727,019
Proceeds from exercise of warrants		502,901
Net repayments on loans and lines of credit	(1,399,999)	(37,107)
Net cash provided by financing activities	19,801,278	52,573,122
Foreign exchange effect on cash and cash equivalents	17,388	44,084
Decrease in cash and cash equivalents	(7,912,919)	(3,561,659)
Cash and cash equivalents, beginning of period	49,958,540	61,223,377

Cash and cash equivalents, end of period	$ 42,045,621	$ 57,661,718
Supplemental Disclosure		
Cash paid for interest	$ 342,211	$ 750,840
Noncash Investing Activities		
Transfers from inventory to field equipment	$ 11,987,427	$ 7,391,692
Noncash Financing Activities		
Deferred compensation and paid-in capital	$ 1,517	$ 1,984

See accompanying notes to these condensed consolidated financial statements.

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

1. Description of Business

Operations

NxStage Medical, Inc. (the Company) is a medical device company that develops, manufactures and markets products for the treatment of kidney failure and fluid overload. The Company s primary product, the NxStage System One (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 clinics. The System One is cleared by the United States Food and Drug Administration (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, and fluids used in conjunction with therapy.

The Company has experienced and continues to experience negative operating margins and cash flow from operations and it expects to continue to incur net losses in the foreseeable future. The Company believes that it has sufficient cash and availability under its equipment line of credit to meet its funding requirements at least through 2007. There can be no assurance as to the availability of additional financing or the terms upon which additional financing may be available in the future if, and when, it is needed. If the Company is unable to obtain additional financing when needed, it may be required to delay, reduce the scope of, or eliminate one or more aspects of its business development activities, which could harm the growth of its business. As of June 30, 2007, the Company had approximately $53.0 million of unrestricted cash and short-term investments.

Basis of Presentation

The condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries. In the opinion of management, the interim financial statements reflect all adjustments consisting of normal, recurring adjustments necessary for a fair presentation of the results for interim periods. Operating results for the three and six month periods ended June 30, 2007 are not necessarily indicative of results that may ultimately be achieved for the entire year ending December 31, 2007. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes included in the Company s Annual Report on Form 10-K for the year ended December 31, 2006.

2. Summary of Significant Accounting Policies

(a) 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.

(b) Revenue Recognition

The Company recognizes revenue from product sales and services when earned in accordance with Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Emerging Issues Task Force, (EITF) 00-21, *Revenue Arrangements with Multiple Deliverables(EITF 00-21).* 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.

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Chronic Care Market

Prior to 2007, the Company derived revenue in the chronic care market from short-term rental arrangements with its customers as its principal business model in the chronic care market. These rental arrangements, which combine the use of the System One with a specified number of disposable products supplied to customers for a fixed amount per month, are recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to a binding customer purchase order and fixed payment terms. In the chronic care market, rental arrangements continue to represent the majority of the arrangements the Company has with its customers.

Beginning in 2007, the Company entered into long-term customer contracts to sell the System One and PureFlow SL equipment along with the right to purchase disposable products and service on a monthly basis. Some of these agreements include other terms such as development efforts, training, market collaborations, limited market exclusivity and volume discounts. The equipment and related items provided to the Company s customers in these arrangements are considered a multiple-element sales arrangement pursuant to EITF 00-21. When a sales arrangement involves multiple elements, the deliverables included in the arrangement are evaluated to determine whether they represent separate units of accounting. 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 are deferred, and are recognized as revenue on a straight-line basis over the expected term of the Company s obligation to supply disposables and service, which is five to 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.

The Company entered into a National Service Provider Agreement and a Stock Purchase Agreement with DaVita, Inc. on February 7, 2007. Pursuant to EITF 00-21, the Company considers these agreements a single arrangement. In connection with the Stock Purchase Agreement, DaVita purchased 2,000,000 shares of the Company s common stock for $10.00 per share, which represented a premium of $1.50 per share, or $3.0 million. The Company has recorded the $3.0 million premium as deferred revenue and will recognize this revenue ratably over seven years, consistent with its equipment service obligation to DaVita. During the three and six months ended June 30, 2007, the Company recognized revenue of $107,000 and $179,000 associated with the $3.0 million premium, respectively.

Critical Care Market

In the critical care market, the Company structures sales as direct product sales or as a disposables-based program in which a customer acquires the equipment through the purchase of a specific quantity of disposables over a specific period of time. 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. Under a disposables-based program, the customer is granted the right to use the equipment for a period of time, during which the customer commits to purchase a minimum number of disposable cartridges or fluids at a price that includes a premium above the otherwise average selling price of the cartridges or fluids to recover the cost of the equipment and provide for a profit. Upon reaching the contractual minimum purchases, ownership of the equipment transfers to the customer. Revenue under these arrangements is recognized over the term of the arrangement as disposables are delivered. During the reported periods, the majority of our critical care revenue is derived from direct product sales.

Our contracts provide for training, technical support and warranty services to our customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranties, the revenue is recognized ratably over the warranty period.

(c) Foreign Currency Translation and Transactions

Assets and liabilities of the Company s foreign operations are translated in accordance with Statement of Financial Accounting Standards (SFAS) No. 52, *Foreign Currency Translation"*. In accordance with SFAS No. 52, assets and liabilities of the Company s foreign operations are translated into U.S. dollars at current exchange rates, and income and expense items are translated at average rates of exchange prevailing during the year. Gains and losses realized from transactions, including intercompany balances not considered permanent investments, denominated in foreign currencies are included in the consolidated statements of operations and were not material for the periods presented.

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(d) Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly-liquid investments purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents include amounts invested in commercial paper and money market funds. Cash equivalents are stated at cost plus accrued interest, which approximates market value. Short-term investments represent commercial paper with an original maturity date of more than 90 days, but less than 180 days. Short-term investments have been classified as held-to-maturity and carried at amortized cost because the Company has the intent and ability to hold the investments to maturity.

(e) Fair Value of Financial Instruments and Concentration of Credit Risk

Financial instruments consist principally of cash and cash equivalents, accounts receivable, accounts payable and long-term debt. The estimated fair value of these instruments approximates their carrying value due to the short period of time to their maturities. The fair value of the Company s debt is estimated based on the current rates offered to the Company for debt with the same remaining maturities. The carrying amount of long-term debt approximates fair value.

(f) Inventory

Inventory is stated at the lower of cost or market (net realizable value). The Company regularly reviews its inventory quantities on hand and related cost and records a provision for any excess or obsolete inventory based on its estimated forecast of product demand and existing product configurations. The Company also reviews its inventory value to determine if it reflects lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margins and other factors in evaluating net realizable value. The medical device industry is characterized by rapid development and technological advances that could result in obsolescence of inventory. Additionally, the Company s estimates of future product demand may prove to be inaccurate.

Inventories at June 30, 2007 and December 31, 2006 are as follows:

	June 30, 2007	**December 31, 2006**
Purchased components	$ 7,177,250	$ 2,864,892
Finished units	7,966,412	7,554,138
	$ 15,143,662	$ 10,419,030

Inventory is shown net of a valuation reserve of approximately $425,000 and $492,000 at June 30, 2007 and December 31, 2006, respectively.

(g) Property and Equipment and Field Equipment

Property and equipment is carried at cost less accumulated depreciation. A summary of the components of property and equipment is as follows:

	June 30, 2007	**December 31, 2006**
Machinery, equipment and tooling	$ 3,291,328	$ 2,572,332
Leasehold improvements	1,112,496	987,307
Computer and office equipment	1,168,178	958,916
Furniture	493,595	408,694
Construction-in-process	730,928	436,902
	6,796,525	5,364,151
Less accumulated depreciation and amortization	(2,778,392)	(2,338,591)
Property and equipment, net	$ 4,018,133	$ 3,025,560

Depreciation expense for property and equipment was $224,000 and $167,000 for the three months ended June 30, 2007 and 2006, respectively, and $427,000 and $316,000 for the six months ended June 30, 2007 and 2006, respectively.

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Field equipment is carried at cost less accumulated depreciation as follows:

	June 30, 2007	December 31, 2006
Field equipment	$ 28,797,513	$ 24,101,844
Less accumulated depreciation and amortization	(5,112,160)	(3,485,892)
Field equipment, net	$ 23,685,353	$ 20,615,952

Depreciation expense for field equipment was $1,352,000 and $563,000 for the three months ended June 30, 2007 and 2006, respectively, and $2,591,000 and $912,000 for the six months ended June 30, 2007 and 2006, respectively.

The estimated service lives of property and equipment and field equipment are as follows:

	Estimated Useful Life
Leasehold improvements	Lesser of 5 years or lease term
Computer and office equipment	3 years
Machinery, equipment and tooling	5 years
Furniture	7 years
Field equipment	5 years

(h) Deferred Cost of Revenues

Costs relating to equipment sold for which deferral of revenue is required are capitalized and amortized ratably over the same period in which the associated revenue is being recognized. Deferred costs relating to equipment sold at June 30, 2007 and December 31, 2006 totaled $9.1 million and $0.1, respectively, and are separately presented in the accompanying condensed consolidated balance sheets. Amortization of deferred costs charged to cost of revenue was $211,000 and $290,000 for the three and six months ended June 30, 2007 and $12,000 and 41,000 for the three and six months ended June 30, 2006, respectively.

(i) 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 Company periodically assesses the adequacy of its recorded liability and adjusts the amount as necessary. Changes in the Company s product warranty reserve are as follows:

Balance at December 31, 2006	$ 172,244
Provision	194,310
Usage	(160,972)
Balance at June 30,, 2007	$ 205,582

(j) Distribution Expenses

Distribution expenses consist of the costs incurred in shipping products to customers and are charged to operations as incurred. Shipping and handling costs billed to customers are included in revenues and totaled $39,000 and $5,000 for the three months ended June 30, 2007 and 2006, respectively, and $48,000 and $21,000 for the six months ended June 30, 2007 and 2006, respectively.

(k) Research and Development Costs

Research and development costs are charged to operations as incurred.

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(l) Income Taxes

The Company accounts for federal and state income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes* . Under the liability method specified by SFAS No. 109, a deferred tax asset or liability is determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates. The Company s provision for income taxes represents the amount of taxes currently payable, if any, plus the change in the amount of net deferred tax assets or liabilities. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis.

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes"*, which clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with SFAS No. 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 on January 1, 2007. The adoption of FIN 48 did not have a material impact on the Company s financial position or results of operations. Upon adoption and as of June 30, 2007, the Company had no unrecognized tax benefits recorded.

The Company files federal, state and foreign tax returns. The Company has accumulated significant losses since its inception in 1998. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of the Company s tax years remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company recognizes interest and penalties for uncertain tax positions in income tax expense. Upon adoption and as of June 30, 2007, the Company had no interest and penalty accrual or expense.

(m) Share-based Compensation Cost

On January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment* , using a combination of the prospective and the modified prospective transition methods. Under the prospective method, the Company will not recognize the remaining compensation cost for any stock option awards which had previously been valued using the minimum value method, which was allowed until the Company s initial filing with the SEC for the sale of securities (i.e., stock options granted prior to July 19, 2005). Under the modified prospective method, the Company has (a) recognized compensation expense for all share-based payments granted after January 1, 2006 and (b) recognized compensation expense for awards granted to employees between July 19, 2005 and December 31, 2005 that remained unvested at December 31, 2005.

The captions in the Company s consolidated statement of operations for the three and six months ended June 30, 2007 and 2006 include share-based compensation as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Cost of revenue	$ 43,276	$ 16,251	$ 84,061	$ 27,501
Selling and marketing	242,064	138,689	451,270	253,055
Research and development	41,116	28,828	82,239	56,864
General and administrative	410,529	591,092	880,508	932,846
Total	$ 736,985	$ 774,860	$ 1,497,078	$ 1,270,266

(n) Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements"*, which addresses the measurement of fair value where such measure is required for recognition or disclosure purposes under GAAP.

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Among other provisions, SFAS No. 157 includes (1) a new definition of fair value, (2) a fair value hierarchy used to classify the source of information used in fair value measurements, (3) new disclosure requirements of assets and liabilities measured at fair value based on their level in the hierarchy, and (4) a modification of the accounting presumption that the transaction price of an asset or liability equals its initial fair value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 (i.e., beginning in 2008 for NxStage). The Company is currently evaluating the expected impact of SFAS No. 157 on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. The Company is currently evaluating if it will elect the fair value option for any of its eligible financial instruments and other items.

(o) Reclassifications

Certain reclassifications were made to prior periods to conform to current year presentation.

3. Stockholders Equity

Common and Preferred Stock

On February 7, 2007, the Company sold 2,000,000 shares of its common stock to DaVita in a private placement at a price of $10.00 per share and with aggregate net proceeds of approximately $20.0 million. The shares sold to DaVita represented, at the time of issuance, approximately seven percent (7%) of the Company s issued and outstanding shares of common stock.

On June 14, 2006, the Company completed a follow-on public offering of 6,325,000 shares of its common stock at a price of $8.75 per share and with aggregate net proceeds of approximately $51.4 million. On November 1, 2005, the Company completed its initial public offering of 6,325,000 shares of its common stock at a price of $10.00 per share and with aggregate net proceeds of approximately $56.5 million. In connection with the initial public offering, all shares of all series of the Company s outstanding preferred stock were automatically converted into an aggregate of 12,124,840 shares of common stock.

Warrants

At June 30, 2007, warrants to purchase a total of 73,460 shares of common stock were outstanding. These warrants have a weighted average exercise price of $8.17 and expire in December 2011. There were no grants or warrant exercises during the six months ended June 30, 2007.

2005 Stock Purchase Plan and Employee Stock Purchase Plan

The Company grants options and restricted stock to its employees under the Company s 2005 Stock Incentive Plan. As of June 30, 2007, the Company has reserved 3,153,724 shares of common stock for issuance upon exercise of stock options, 49,478 shares for issuance under the 2005 Purchase Plan and 73,460 shares for issuance upon exercise of warrants.

The Company s 2005 Employee Stock Purchase Plan (the 2005 Purchase Plan) originally authorized the issuance of up to 50,000 shares of common stock to participating employees through a series of periodic offerings. An incremental 50,000 shares was approved by the Company s stockholders on May 30, 2007. Each six-month offering period begins in January or July. The first offering under the 2005 Purchase Plan began on January 3, 2006 and ended on June 30, 2006. An employee becomes eligible to participate in the 2005 Purchase Plan once he or she has been employed for at least three months and is regularly employed for at least 20 hours per week for more than three months in a calendar year. The price at which employees can purchase common stock in an offering is 95 percent of the closing price of the common stock on the NASDAQ Global Market on the day the offering terminates, unless otherwise determined by the Board or Compensation Committee.

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4. Net Loss per Share

The Company calculates net loss per share based on the weighted-average number of shares of common stock outstanding, excluding unvested shares of restricted common stock. For the periods ended June 30 2007 and 2006; 3,227,184 and 2,769,570, respectively, shares of common stock equivalents were not included in the computation of net loss per share because the effect would have been anti-dilutive.

5. Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income"*, establishes standards for reporting comprehensive income (loss) and its components in the body of the financial statements. Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in equity, such as foreign currency translation adjustments, that are excluded from results of operations.

At June 30, 2007 and December 31, 2006, accumulated other comprehensive income (loss) consists of foreign currency translation adjustments.

6. Financing Arrangements

Debt

In December 2004, the Company entered into a debt agreement in the principal amount of $5.0 million, which was payable monthly over a three-year term and was secured by all the assets of the Company. Interest accrued at a rate of 7.0% annually and monthly principal and interest payments were made in advance. In addition, a final interest payment of $650,000 was due at the scheduled maturity date of December 2007, or earlier if the loan was prepaid in advance. This additional interest payment was accrued on a monthly basis using the interest method over the 36-month life of the loan and was included in accrued expenses in the accompanying condensed consolidated balance sheets. Concurrent with entering into a new equipment line of credit in May 2006, the Company repaid all outstanding borrowings under the agreement in the aggregate amount of $3.4 million, which included principal and accrued interest and the final interest payment of $650,000. This extinguishment of debt gave rise to the early recognition of approximately $434,000 of interest expense for the year ended December 31, 2006.

On May 15, 2006, the Company entered into an equipment line of credit agreement for the purpose of financing field equipment purchases and placements. The line of credit agreement provides for the availability of up to $20.0 million through December 31, 2007, and borrowings bear interest at the prime rate plus 0.5% (8.4% at June 30, 2007). Under the line of credit agreement, $10.0 million was available through December 31, 2006 and an additional $10.0 million is available from January 1, 2007 through December 31, 2007. The availability of the line of credit is subject to a number of covenants, including maintaining certain levels of liquidity, adding specified numbers of patients and operating within certain net loss parameters. The Company is also required to maintain operating and/or investment accounts with the lender in an amount at least equal to the outstanding debt obligation. Borrowings are secured by all assets of the Company other than intellectual property and are payable ratably over a three-year period from the date of each borrowing. At June 30, 2007, the Company had outstanding borrowings of $6.0 million and $11.6 million of borrowing availability under the equipment line of credit.

Annual maturities of principal under the Company s debt obligations at June 30, 2007 are as follows:

2007	$ 1,400,000
2008	2,800,000
2009	1,816,668
	$ 6,016,668

7. Segment and Enterprise Wide Disclosures

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information"*, establishes standards for reporting information regarding operating segments in annual financial statements. Operating segments are

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identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment. All revenues were generated in the United States and substantially all assets are located in the United States.

The Company sells products into two markets, critical care and chronic care in the United States. The critical care market consists of hospitals or facilities that treat patients that have suddenly, and possibly temporarily, lost kidney function. The chronic care market consists of dialysis centers and hospitals that provide treatment options for patients that have end-stage renal disease (ESRD). Revenues recognized in these markets were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Critical care market	$ 3,285,130	$ 1,881,198	$ 6,224,427	$ 3,464,795
Chronic care market	6,746,054	2,665,075	12,180,750	4,482,200
Total revenues	$ 10,031,184	$ 4,546,273	$ 18,405,177	$ 7,946,995

For the three and six months ended June 30, 2007, the Company had one customer who individually represented 30% and 27% of revenues, respectively, and 23% of accounts receivable as of June 30, 2007. For the three and six months ended June 30, 2006, the Company had one customer who individually represented 18% and 16% of revenues, respectively. One customer represented 17% of the Company s accounts receivable as of December 31, 2006.

8. Related-Party Transactions

Medisystems Corporation

Supply Agreement

The Company purchases completed cartridges, tubing and certain other components used in the System One disposable cartridge from Medisystems Corporation, an entity owned by David S. Utterberg, a 6.7% stockholder of the Company and member of the Company s Board of Directors. The Company purchased approximately $2.1 million and $3.8 million during the three and six months ended June 30, 2007, and $1.2 million and $1.9 million for the three and six months ended June 30, 2006, respectively, of goods and services from this related party. Amounts owed to Medisystems Corporation totaled $665,000 and $926,000 at June 30, 2007 and December 31, 2006, respectively, and are included in accounts payable in the accompanying condensed consolidated balance sheets. At June 30, 2007, the Company had commitments to purchase approximately $3.2 million of products from Medisystems Corporation.

On January 4, 2007, the Company entered into a seven-year Supply Agreement (the Medisystems Supply Agreement), with Medisystems that expires on December 31, 2013. Prior to entering into the Medisystems Supply Agreement, the Company purchased products from Medisystems through purchase orders. Pursuant to the terms of the Medisystems Supply Agreement, the Company will purchase no less than ninety percent (90%) of its North American requirements for disposal cartridges, or Medisystems products, for use with its System One from Medisystems. The Supply Agreement was approved by the Company s Audit Committee and Board of Directors.

Stock Purchase Agreement

On June 4, 2007, the Company entered into a Stock Purchase Agreement with David S. Utterberg to purchase all of the issued and outstanding shares of Medisystems Services Corporation, a Nevada corporation, Medisystems Corporation, a Washington corporation, Medisystems Europe S.p.A, a company organized under the laws of Italy, and Medimexico s. de R.L. de C.V., a company organized under the laws of Mexico, (referred to collectively as the Medisystems Entities), all of which entities are owned directly or indirectly by Mr. Utterberg, in exchange for 6,500,000 shares of the Company (the Stock Purchase), and a Consulting Agreement with David S. Utterberg and DSU Medical, Inc. (DSU), a company owned by Mr. Utterberg, to provide consulting, advisory and related services to the Company for two years following the consummation of the Stock Purchase. Under the terms of the Consulting Agreement, the Company will pay Mr. Utterberg $200,000 annually, plus reasonable expenses and Mr.

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Utterberg and DSU will agree (i) not to compete with the Company and will not encourage or solicit any of the Company s employees, customers or suppliers, and (ii) will assign to the Company certain inventions and proprietary rights received during the term of the Consulting Agreement and will grant certain exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid licenses for such inventions and proprietary rights. In the event the Stock Purchase is consummated, Mr. Utterberg will own approximately 23.4% of the outstanding common stock of the Company and will continue to be a director of the Company.

The consummation of the Stock Purchase is subject to a number of conditions, including, among other things, the termination of applicable waiting periods under the Hart-Scott-Rodino Act, the approval by our stockholders of the issuance of shares of our common stock to Mr. Utterberg in connection with the Stock Purchase, and the effectiveness of our registration and proxy statement/prospectus on Form S-4, as determined by the SEC, seeking stockholder approval of this stock issuance. None of these conditions has yet been satisfied. We filed our registration and proxy statement/prospectus on Form S-4 seeking stockholder approval in connection with the Stock Purchase with the SEC on July 27, 2007. This registration and proxy statement/prospectus on Form S-4 has not yet been declared effective by the SEC.

Consistent with the Company s Audit Committee Charter and Related Person Transaction Policy, the Stock Purchase Agreement and Consulting Agreement were each approved by the Company s Audit Committee and Board of Directors.

As of June 30, 2007, the Company has capitalized approximately $1.2 million of direct costs incurred in conjunction with the pending Medisystems Stock Purchase. These costs are included in other assets in the accompanying condensed consolidated balance sheets.

9. Commitments and Contingencies

On March 1, 2007, the Company entered into a long-term agreement with the Entrada Group (Entrada), to establish manufacturing and service operations in Mexico, initially for its cycler and PureFlow SL disposables and later for its PureFlow SL hardware. The agreement obligates Entrada to provide the Company with manufacturing space, support services and a labor force through 2012. Subject to certain exceptions, the Company is obligated for the facility fees through the term of the agreement. The agreement may be terminated upon material breach, generally following a 30-day cure period.

In the second quarter of 2007, the Company started to experience an increased incidence of reported dialysate leaks associated with System One cartridges. The reported incidence of leaks is higher than the Company has historically observed. In early August 2007, the Company sent a letter to patients and customers informing them of the increased incidence in leaks and reminding them of existing System One labeling responsive to the risk of leaks. The Company has characterized this notification as a voluntary recall.

These cartridge leaks have resulted in dissatisfaction with the System One for certain of our customers and could impair our future growth and patient retention. The incremental leaks have also been associated with increased cycler service costs, which have imposed additional service pool requirements, and could impair the Company s ability to meet future demand. If the incidence of leaks persists or increases or if patient satisfaction declines, the Company may incur additional costs, however the Company deems any loss to the approximate $2.5 million of affected inventory to be improbable at this time, therefore no amount has been accrued to date. Additionally, costs related to the return or replacement of cartridges, and costs incurred to rework inventory on-hand and/or returned by customers, may also be incurred and could be material to the Company. The Company has not incurred any material costs to date in connection with this matter.

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

Special Note Regarding Forward Looking Statements

The following discussion should be read with our unaudited condensed consolidated financial statements and notes included in Part I, Item 1 of this Quarterly Report for the three and six months ended June 30, 2006 and 2005, 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, 2006, 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 and the sufficiency of our cash for future operations. Words such as we expect, anticipate, target, project, believe, goals, estimate, potential, pre expect, might, could, intend, variations of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. 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 risk factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report, as well as in the 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.

Overview

We are a medical device company that develops, manufactures and markets innovative systems for the treatment of end-stage renal disease, or ESRD, acute kidney failure and fluid overload. Our primary product, the System One, is a small, portable, easy-to-use hemodialysis system designed to provide physicians and patients improved flexibility in how hemodialysis therapy is prescribed and delivered. We believe the largest market opportunity for our product is the home hemodialysis market for the treatment of ESRD.

From our inception in 1998 until 2002, our operations consisted primarily of start-up activities, including designing and developing the System One, recruiting personnel and raising capital. Historically, research and development costs have been our single largest operating expense. However, with the launch of the System One in the home chronic care market, selling and marketing costs became our largest operating expense in 2005 and this trend continued during the three and six months ended June 30, 2007 as we expanded our United States sales force to penetrate our markets and grow revenues.

Our overall strategy since inception has been to (a) design and develop new products for the treatment of kidney failure, (b) establish that the products are safe, effective and cleared for use in the United States, (c) further enhance the product design through field experience from a limited number of customers, (d) establish reliable manufacturing and sources of supply, (e) execute a market launch in both the chronic and critical care markets and establish the System One as a preferred system for the treatment of kidney failure, (f) obtain the capital necessary to finance our working capital needs and build our business and (g) achieve profitability. The evolution of NxStage, and the allocation of our resources since we were founded, reflects this plan. We believe we have largely completed steps (a) through (d), and we plan to continue to pursue the other strategic objectives described above.

We sell our products in two markets: the chronic care market and the critical care market. We define the chronic care market as the market devoted to the treatment of patients with ESRD and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. We offer a different configuration of the System One for each market. The United States Food and Drug Administration, or FDA, has cleared both configurations for hemodialysis, hemofiltration and ultrafiltration. Our products may be used by our

customers to treat patients suffering from either condition, although the site of care, the method of delivering care and the duration of care are sufficiently different that we have separate marketing and sales efforts dedicated to each market.

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

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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 in the chronic care market and commenced full commercial introduction in the chronic care market in September 2004 in the United States. 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 our System One in June 2005 for hemodialysis in the home.

In March 2006, we received clearance from the FDA to market our PureFlow SL module as an alternative to the bagged fluid presently used with our System One in the chronic care market. This accessory to the System One allows for the automated preparation of high purity dialysate in the patient s home using ordinary tap water and dialysate concentrate. The PureFlow SL is designed to help patients with ESRD more conveniently and effectively manage their home hemodialysis therapy by eliminating the need for bagged fluids. In July 2006, we released the PureFlow SL for commercial use and began shipping the PureFlow SL product. Our experience suggests that our chronic care home patients will predominantly use our PureFlow SL module at home and will use bagged fluid for travel and outside of the home. Bagged fluids will continue to be used in the critical care market.

Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. Reimbursement claims for the System One therapy are typically submitted by the dialysis clinic 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. Expanding Medicare reimbursement over time to cover more frequent therapy could accelerate our market penetration and revenue growth in the future.

Our System One is produced through internal and outsourced manufacturing. We purchase many of the components and subassemblies included in the System One, as well as the disposable cartridges used in the System One, from third-party manufacturers, some of which are single source suppliers. In addition to outsourcing with third-party manufacturers, we assemble, package and label a quantity of disposable products in our leased facilities in Lawrence, Massachusetts and North Andover, Massachusetts as well as in our facilities in Mexico provided to us by the Entrada Group. NxStage GmbH & Co. KG, our wholly-owned German subsidiary, is the sole manufacturer of the dialyzing filter that is a component of the disposable cartridge used in the System One and the ultrafilter used in the PureFlow SL.

We market the System One through a direct sales force in the United States primarily to dialysis clinics and hospitals, and we expect revenues to continue to increase in the near future. Our revenues were $10.0 million for the three months ended June 30, 2007, a 121% increase from revenues of $4.5 million in the three months ended June 30, 2006, and a 20% increase from revenues of $8.4 million in the first quarter of 2007. Our revenues were $18.4 million for the six months ended June 30, 2007, a 132% increase from revenues of $7.9 million in the six months ended June 30, 2006. We have increased the number of sales representatives in our combined sales force from 27 at June 30, 2006 to 31 at June 30, 2007. During the remainder of 2007, we expect to add additional sales and marketing personnel as needed for the remainder of 2007. As of June 30, 2007, 1,615 ESRD patients were using the System One at 265 dialysis clinics, compared to 663 ESRD patients at 126 dialysis clinics as of June 30, 2006, and compared to 1,022 ESRD patients at 174 dialysis clinics as of December 31, 2006. In addition, as of June 30, 2007, 93 hospitals were using the System One for critical care therapy, compared to 58 and 77 hospitals as of June 30, 2006 and December 31, 2006, respectively.

The following table sets forth the amount and percentage of revenues derived from each market for the periods indicated:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2007		2006		2007		2006	
Chronic care	6,746,054	67.3%	2,665,075	58.6%	12,180,750	66.2%	4,482,200	56.4%

Critical care	$ 3,285,130	32.7%	$ 1,881,198	41.4%	$ 6,224,427	33.8%	$ 3,464,795	43.6%
Total	$ 10,031,184	100.0%	$ 4,546,273	100.0%	$ 18,405,177	100.0%	$ 7,946,995	100.0%

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We have not been profitable since inception, and we expect to incur net losses for the foreseeable future as we expand our sales efforts and grow our operations. Our accumulated deficit at June 30, 2007 was $148.5 million. Our goal is to increase our sales volume and revenues to gain scale of operation and to drive product cost reductions, which we believe, when combined with other design improvements, will allow us to reach profitability. We expect our revenues in the chronic care market to increase faster than those in the critical care market and believe they will continue to represent the majority of our revenues.

2007 Recent Developments

Medisystems

On January 4, 2007, the Company entered into a seven-year supply agreement, with Medisystems Corporation pursuant to which Medisystems will supply no less than 90% of our North American requirements for disposable cartridges for use with the System One. The agreement may be terminated upon material breach, generally following a 120-day cure period. Medisystems is a related party to NxStage. David Utterberg, the president and sole stockholder of Medisystems, is a director and stockholder of NxStage.

On June 4, 2007, we entered into a stock purchase agreement with Mr. Utterberg, who is a member of our board of directors and owns approximately 6.7% of our outstanding common stock, pursuant to which we will acquire all of the outstanding equity of four entities, referred to as the Medisystems Entities, and each Medisystems Entity will become a direct or indirect wholly-owned subsidiary of ours. Mr. Utterberg will receive 6,500,000 shares of our common stock, subject to a post-closing working capital adjustment as consideration for the stock purchase.

The consummation of the stock purchase is subject to a number of conditions, including, among other things, the termination of applicable waiting periods under the Hart-Scott-Rodino Act, the approval by our stockholders of the issuance of shares of our common stock to Mr. Utterberg in connection with the stock purchase, and the effectiveness of our registration and proxy statement/prospectus on Form S-4, as determined by the SEC, seeking stockholder approval of this stock issuance. None of these conditions has yet been satisfied. We filed our registration and proxy statement/prospectus on Form S-4 seeking stockholder approval in connection with the Stock Purchase with the SEC on July 27, 2007. This registration and proxy statement/prospectus on Form S-4 has not yet been declared effective by the SEC.

Membrana

In January 2007, we entered into a long-term supply agreement with Membrana, pursuant to which Membrana has agreed to supply, on an exclusive basis, capillary membranes for use in the filters used with the System One for ten years. In exchange, for Membrana s agreement to pricing reductions based on volumes ordered, we have agreed to purchase a base amount of membranes per year. The agreement may be terminated upon a material breach, generally following a 60-day cure period.

DaVita

On February 7, 2007, we entered into a National Service Provider Agreement and a Stock Purchase Agreement with DaVita, Inc. Pursuant to the National Service Provider Agreement, we granted DaVita certain market rights for the System One and related supplies for home hemodialysis therapy. We granted DaVita exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the U.S. ESRD patient population, and limited exclusivity in the majority of all other U.S. geographies, subject to DaVita s meeting certain requirements, including patient volume commitments and new patient training rates. Under the agreement, we can continue to sell to other clinics in the majority of geographies. 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 limits, but does not prohibit, the sale by us 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 the U.S. chronic dialysis patient population and that also supplies dialysis products. Therefore, our ability to sell the System One for chronic home patient hemodialysis therapy to Fresenius is presently limited.

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Under the National Service Provider Agreement, DaVita committed to purchase all of its existing System One equipment as of February 7, 2007 (for a total purchase price of approximately $5.0 million) and to buy a significant percentage of its future System One equipment needs. The agreement has a term of three years, terminating on December 31, 2009, and DaVita has the option of renewing the agreement for four additional periods of six months if DaVita meets certain patient volume targets. In connection with the National Service Provider Agreement, on February 7, 2007, DaVita also purchased, pursuant to a Stock Purchase Agreement, 2,000,000 shares of our common stock for a purchase price of $10.00 per share, a premium of $1.50 per share over the then-current closing price of our common stock. As of August 6, 2007, DaVita had sold all of its NxStage common stock purchased under that agreement.

Entrada

On March 13, 2007, we entered into a long-term agreement with the Entrada Group, or Entrada, to establish manufacturing and service operations in Mexico, initially for our cycler and PureFlow SL disposables and later for our PureFlow SL hardware. The agreement obligates Entrada to provide us with manufacturing space, support services and a labor force through 2012.

Product Reliability Issue

In the second quarter of 2007, we started to experience an increased incidence of reported dialysate leaks associated with our System One cartridges. The reported incidence of leaks is higher than we have historically observed. When the System One is used in accordance with its instructions, these leaks present no risk to patient health. System One device labeling anticipates the potential for leaks to occur and specifically warns against leaks and alerts users of the need to observe treatments in order to detect leaks. Four patients with reported leaks, that were unobserved by these patients or their partners until after their treatments were terminated, reported hypotension, or low blood pressure, resolved by a fluid bolus, with no lasting clinical effect. In early August 2007, we sent a letter to our patients and customers informing them of the increased incidence in leaks and reminding them of existing System One labeling alerting users of the potential for leaks and instructing them to observe treatments in order to detect any leaks. We have characterized this notification as a voluntary recall. In response to the reported increase in incidence of leaks, we are also currently developing a test to better evaluate the susceptibility of our cartridges to leaks prior to release, with the goal of reducing the chance for pinhole-sized leaks in our cartridges.

These cartridge leaks have resulted in dissatisfaction with our System One for certain of our customers and could impair our future growth and patient retention. The incremental leaks have also been associated with increased cycler service costs, which have imposed additional service pool requirements, and could impair our ability to meet future demand. If the incidence of leaks persists or increases or if patient satisfaction declines, we may incur additional costs, however we deem any loss to the approximate $2.5 million of affected inventory to be improbable at this time, therefore no amount has been accrued to date. Additionally, costs related to the return or replacement of cartridges, and costs incurred to rework inventory on-hand and/or returned by customers, may also be incurred and could be material. We have not incurred any material costs to date in connection with this matter. We are working to address the product leaks quickly, but they still remain an issue with our customer base.

Statement of Operations Components

Revenues

Our product consists of the System One, an electromechanical device used to circulate the patient s blood during therapy (the cycler); a single-use, disposable cartridge, which contains a preattached dialyzer, and dialysate fluid used in our therapy, sold either in premixed bags or prepared with our PureFlow SL module. We distribute our products in two markets: the chronic care market and the critical care market. We define the chronic care market as the market devoted to the treatment of ESRD patients in the home and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. We offer a different configuration of the System One for each market. The FDA has cleared both configurations for hemodialysis, hemofiltration and ultrafiltration. Our product may be used by our customers to treat patients suffering from either condition and we have separate marketing and sales efforts dedicated to each market.

We derive our revenue from the sale and rental of equipment and the sale of the related disposable products. In the critical care market, we generally sell the System One and disposables to hospital customers. In the chronic care

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market, customers rent or purchase the machine and then purchase the related disposable products based on a specific patient prescription. We generally recognize revenue when a product has been delivered to our customer, or, in the chronic care market, for those customers that rent the System One, we recognize revenue on a monthly basis in accordance with a contract under which we supply the use of a cycler and the amount of disposables needed to perform a set number of dialysis therapy sessions during a month. For customers that purchase the System One in the chronic care market, we recognize revenue from the equipment sale ratably over the expected service obligation period, while disposable product revenue is recognized upon delivery.

Our rental contracts with dialysis centers for ESRD patients generally include terms providing for the sale of disposable products to accommodate up to 26 treatments per month per patient and the purchase or monthly rental of System One cyclers and, in the majority of instances, our PureFlow SL module. These contracts typically have a term of one year and are cancelable at any time by the dialysis clinic with 30 days notice. Under these contracts, if home hemodialysis is prescribed, supplies are shipped directly to patient homes and paid for by the treating dialysis clinic. We also include vacation delivery terms, providing for the free shipment of products to a designated vacation destination. We derive an insignificant amount of revenues from the sale of ancillary products, such as extra lengths of tubing. Over time, as more chronic patients are treated with the System One and more systems are placed in patient homes under monthly agreements that provide for the rental of the machine and the purchase of the related disposables, we expect this recurring revenue stream to continue to grow.

In the first quarter of 2007, we entered into long-term contracts with three larger dialysis chains, including DaVita, which was our largest customer during the three months ended June 30, 2007. Revenues from DaVita represented approximately 30% of our revenues during the three months ended June 30, 2007, and we expect revenue from DaVita will continue to account for a significant portion of our revenues for the remainder of 2007. Each of these agreements has a term of at least three years, and may be cancelled upon a material breach, subject to certain curing rights. These contracts provide the customer the option to purchase as well as rent the System One equipment, and, in the case of the DaVita contract, DaVita has agreed to purchase rather than rent a significant percentage of its future System One equipment needs. It is not clear what percentage of our customers, if any, will migrate to this model, and we expect, at least in the near term, that the majority of our customers will continue to rent the System One in the chronic care market.

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, production overhead 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 the products.

We are currently operating at negative gross profit as we continue to build a base of recurring revenue and reduce product costs. We expect the cost of revenues as a percentage of revenues to decline over time for several reasons. First, we continue to realize increased sales volume and realization of economies of scale that are bringing improved purchasing terms and prices, and we are realizing economies of scale that are providing us with broader options and efficiencies in indirect manufacturing overhead costs. Second, we have introduced, and are continuing to introduce, several process and product design changes, such as our new PureFlow SL module, that are expected to have inherently lower cost than our current products. Third, through our relationship with the Entrada Group, we opened a facility that will move the manufacture of certain of our products, including the System One cycler and certain disposables, to lower labor cost markets. Fourth, we are working to improve product reliability. And finally, we continue to look for opportunities to vertically integrate the manufacture of our products that will lead to lower cost, such as with the pending Medisystems acquisition.

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

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to instruct their patients in the operation of the System One. 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 chronic care market and as we add additional sales and marketing personnel.

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. We expect limited research and development expense increases in the foreseeable future as we continue to improve and enhance our core products.

Distribution. Distribution expenses include the freight cost of delivering our products to our customers or our customers patients, depending on the market and the specific agreement with our customers, and salary, benefits and stock-based compensation for distribution personnel. 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 from customers back to our service center for repair if the product is under warranty, and the related expense of shipping a replacement product to our customers. We expect that distribution expenses will increase at a lower rate than revenue due to expected efficiencies gained from increased business volume, improvements in product reliability, and the continued penetration of our PureFlow SL module in the chronic market, which significantly reduces the weight and quantity of monthly disposable shipments.

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 for 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. Rent, utilities and depreciation expense are allocated to operating expenses based on personnel and square footage usage. We expect that general and administrative expenses will increase in the near term as we add additional administrative support for our growing business.

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,	
	2007	**2006**	**2007**	**2006**
Revenues	100%	100%	100%	100%
Cost of revenues	115	132	116	137
Gross profit (deficit)	(15)	(32)	(16)	(37)
Operating expenses:				
Selling and marketing	51	83	54	87
Research and development	14	35	16	42
Distribution	30	33	29	35
General and administrative	25	47	28	52
Total operating expenses	120	198	127	216
Loss from operations	(135)	(230)	(143)	(253)

Other income (expense):				
Interest income	9	13	10	15
Interest expense	(2)	(12)	(2)	(9)
	7	1	8	6
Net loss	(128)%	(229)%	(135)%	(247)%

Comparison of Three and Six Months Ended June 30, 2007 to Three and Six Months Ended June 30, 2006

Revenues

Our revenues for the three and six months ended June 30, 2007 and 2006 were as follows:

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	Three Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Revenues	$ 10,031	$ 4,546	$ 5,485	121%

	Six Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Revenues	$ 18,405	$ 7,947	$ 10,458	132%

The increase in revenues for both the three and six months ended June 30, 2007 as compared to the same periods in 2006 was attributable to increased sales and rentals of the System One in both the critical care and chronic care markets, primarily as a result of increased sales and marketing efforts as we continue our commercial launch of the System One. Revenues in the chronic care market increased to $6.7 million in the three months ended June 30, 2007 compared to $2.7 million in the three months ended June 30, 2006, an increase of 153%, while revenues in the critical care market increased 75% to $3.3 million in the three months ended June 30, 2007, compared to $1.9 million in the three months ended June 30, 2006. Revenues in the chronic care market increased to $12.2 million during the six months ended June 30, 2007 compared to $4.5 million during the six months ended June 30, 2006, an increase of 172%, while revenues in the critical care market increased 80% to $6.2 million during the six months ended June 30, 2007, compared to $3.5 million during the six months ended June 30, 2006.

Cost of Revenues and Gross Profit (Deficit)

	Three Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Cost of revenues	$ 11,511	$ 6,004	$ 5,507	92%
Gross profit (deficit)	$ (1,480)	$ (1,457)	$ 23	2%
Gross profit (deficit) percentage	(15%)	(32%)		

	Six Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Cost of revenues	$ 21,428	$ 10,861	$ 10,567	97%
Gross profit (deficit)	$ (3,023)	$ (2,914)	$ 109	4%

Gross profit (deficit) percentage	(16%)	(37%)

The increase in cost of revenues was attributable primarily to our increased revenues. We ended June 30, 2007 with 1,615 patients compared to 663 patients ending June 30, 2006, contributing to an increase in material cost of revenues of $4.6 million for the quarter ending June 30, 2007 compared to the same quarter in 2006. In addition, cost of revenues increased during the three months ended June 30, 2007 as compared to the three months ended June 30, 2006 because of a larger employee base that resulted in additional salaries, health benefits and payroll taxes of $647, 000, increased inbound freight costs of $427,000 to support our higher production volume, offset by $392,000 of favorable materials cost due to volume based supplier contacts. We added 593 net patients during the six months ended June 30, 2007 to arrive at 1,615 patients compared to 663 patients ending June 30, 2006, contributing to an additional material cost of revenues of $8.5 million compared to the same period in 2006. In addition, cost of revenues increased during the six months ended June 30, 2007 as compared to the six months ended June 30, 2006 because of a larger employee base which resulted in additional salaries, health benefits and payroll taxes of $1.5 million, and increased inbound freight costs of $825,000 to support our higher production volume, offset by $615,000 of favorable materials cost due to volume based supplier contracts. We continue to see incremental improvement in our direct product costs; however, this is currently being offset somewhat by an increase in disposables per patient due to product reliability issues. We expect that over time as our reliability improves, the disposables per patient will decline.

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Selling and Marketing

	Three Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Selling and marketing	$ 5,120	$ 3,759	$ 1,361	36%
Selling and marketing as a percentage of revenues	51%	83%		

	Six Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Selling and marketing	$ 9,851	$ 6,952	$ 2,899	42%
Selling and marketing as a percentage of revenues	54%	87%		

The increase in selling and marketing expenses was the result of several factors. For the three months ended June 30, 2007 compared to the same period in 2006, approximately $1.1 million of the increase was due to additional salaries, health benefits and payroll taxes resulting from increased headcount and $236,000 related to a higher level of sales and marketing activity in both the chronic and critical care markets. We increased our combined sales force from 27 sales representatives as of June 30, 2006 to 31 sales representatives as of June 30, 2007. For the six months ended June 30, 2007 compared to the same period in 2006, approximately $2.4 million of the increase was due to additional salaries, health benefits and payroll taxes resulting from increased headcount and $524,000 related to a higher level of sales and marketing activity in both the chronic and critical care markets. We anticipate that selling and marketing expenses will continue to increase in absolute dollars as we broaden our marketing initiatives to increase public awareness of the System One in the chronic care market and as we add additional sales and marketing personnel.

Research and Development

	Three Months Ended June 30, 2007	June 30, 2006	Decrease	Percentage Decrease
	(In thousands, except percentages)			
Research and development	$ 1,418	$ 1,576	$ (158)	(10)%
Research and development as a percentage of revenues	14%	35%		

	Six Months Ended June 30,	Percentage

	June 30, 2007	2006	Decrease	Increase
	(In thousands, except percentages)			
Research and development	$ 2,854	$ 3,355	$ (501)	(15)%
Research and development as a percentage of revenues	16%	42%		

The decrease in research and development expenses during the three months ended June 30, 2007 compared to the same period in 2006 was attributable to $71,000 resulting from lower clinical trial activities, decrease in salary, benefits and payroll taxes of $51,000 as a result of decreased headcount, and a $30,000 decrease in consulting costs relating to the development of the Pure Flow SL module. The decrease in research and development expenses during the six months ended June 30, 2007 compared to the same period in 2006 was attributable to $247,000 of lower development costs associated with our PureFlow SL module, decreased salary, benefits and payroll taxes of $175,000 as a result of decreased headcount, and a decrease of $54,000 resulting from lower clinical trial activities. We expect research and development expenses will increase in the foreseeable future as we seek to further enhance our System One and related products, and their reliability, but we do not expect that research and development expenses will increase as rapidly as other expense categories as we have substantially completed basic development of the System One. We expect research and development expenses to continue to decline as a percentage of revenues.

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Distribution

	Three Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Distribution	$ 2,997	$ 1,519	$ 1,478	97%
Distribution as a percentage of revenues	30%	33%		

	Six Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
Distribution	$ 5,342	$ 2,808	$ 2,534	90%
Distribution as a percentage of revenues	29%	35%		

The increase in distribution expenses for the three and six month periods ended June 30, 2007 compared to the same period in 2006 was due to increased volume of shipments of disposable products to a growing number of patients in the chronic care market, and due to product reliability issues. We expect that distribution expenses will increase at a lower rate than revenues in the second half of 2007 due primarily to expected shipping efficiencies gained from increased business volume and density of customers, the reduction of higher cost deliveries associated with bagged fluid due to the commercial launch of our PureFlow SL module, which began in July 2006, and the use of an outsourced logistics provider located in the central part of the continental United States.

General and Administrative

	Three Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			
General and administrative	$ 2,526	$ 2,149	$ 377	18%
General and administrative as a percentage of revenues	25%	47%		

	Six Months Ended June 30, 2007	June 30, 2006	Increase	Percentage Increase
	(In thousands, except percentages)			

General and administrative	$ 5,193	$ 4,124	$ 1,069	26%
General and administrative as a percentage of revenues	28%	52%		

The increase in general and administrative expenses during the three months ended June 30, 2007 compared to the same period in 2006 was primarily due to an increase of $506,000 of professional fees and corporate expenses offset by $158,000 in lower salary and benefits. The increase in general and administrative expenses during the six months ended June 30, 2007 compared to the same period in 2006 was primarily due to an increase of $910,000 of professional fees and corporate expenses and $112,000 in higher salary and benefits. We expect that general and administrative expenses will continue to increase in the near term as we add support structure for our growing business and as a result of costs related to operating a public company.

Interest Income and Interest Expense

Interest income is derived primarily from U.S. government securities, certificates of deposit, commercial paper and money market accounts. For the three and six month periods ended June 30, 2007, interest income increased by $224,000 and $532,000, respectively, due to increased cash and investment balances resulting from our follow-on public offering in June 2006 and our sale of stock to DaVita in February 2007.

For the three and six month periods ended June 30, 2007, interest expense decreased by $363,000 and $346,000, respectively, based on the repayment of certain long-term debt arrangements in the three and six month periods ended June 30, 2006.

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Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of June 30, 2007, our accumulated deficit was $148.5 million and we had cash, cash equivalents and short-term investments of approximately $53.0 million. On February 7, 2007, we issued and sold 2,000,000 shares of common stock to DaVita in which we received net proceeds, after deducting legal expenses, of approximately $19.9 million. On June 14, 2006, we closed a follow-on public offering in which we received net proceeds after deducting underwriting discounts, commissions and expenses of approximately $51.4 million from the sale and issuance of 6,325,000 shares of common stock.

On May 15, 2006, we entered into an equipment line of credit agreement for the purpose of financing field equipment purchases and placements. The line of credit agreement provides for the availability of up to $20.0 million through December 31, 2007, and borrowings bear interest at the prime rate plus 0.5% (8.4% as of June 30, 2007). Under the line of credit agreement, $10.0 million is available through December 31, 2006 and a further $10.0 million is available from January 1, 2007 through December 31, 2007. The availability of the line of credit is subject to a number of covenants, including maintaining certain levels of liquidity, adding specified numbers of patients and operating within net loss parameters. We are also required to maintain operating and/or investment accounts with the lender in an amount at least equal to the outstanding debt obligation. Borrowings are secured by all of our assets other than intellectual property and are payable ratably over a three-year period from the date of each borrowing. At June 30, 2007, we had outstanding borrowings of $6.0 million and $11.6 million of borrowings available under the equipment line of credit.

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

	Six Months Ended June 30,	
	2007	**2006**
Net cash used in operating activities	$ (26,672)	$ (25,492)
Net cash used in investing activities	(1,981)	(1,223)
Net cash provided by (used in) financing activities	19,801	52,573
Effect of exchange rate changes on cash	17	44
Net cash flow	$ (8,835)	$ 25,902

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 include increases in accounts receivable and increased inventory requirements for production and placements of the System One, offset by increases in deferred accounts payable and accrued expenses. Non-cash transfers from inventory for the placement of rental units with our customers represented $12.0 million and $7.4 million, respectively, during the six months ended June 30, 2007 and 2006.

Net Cash Used in Investing Activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, primarily for research and development, information technology, manufacturing operations and capital improvements to our facilities. Excluded from these figures is the net cash provided by short-term investments and marketable securities of $0.9 million during the six months ended June 30, 2007 and net cash used of $29.5 million of short-term investments during the six months ended June 30, 2006.

Net Cash Provided By Financing Activities. Net cash provided by financing activities reflected $19.9 million of net proceeds received from the issuance of common stock to DaVita in February 2007, and $1.3 million of proceeds from the exercise of stock options and warrants during the six months ended June 30, 2007, offset by the net repayment of debt of $1.4 million and $37,000 during the six months ended June 30, 2007 and 2006, respectively.

We expect to continue to incur net losses for the foreseeable future. We expect that our current cash position, and the availability under our equipment line of credit, is sufficient to support operations at least through 2007. In the longer term, we expect to fund the working capital needs of our operations with revenue generated from product

placements and sales, but these resources may prove insufficient. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to sell additional equity or issue debt securities. Any sale of additional

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equity or issuance of debt securities may 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 this 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 could harm the growth of our business. We anticipate that the pending acquisition with Medisystems, if consummated, will have a positive effect on our working capital.

The following table summarizes our contractual commitments as of June 30, 2007 (unaudited) and the effect those commitments are expected to have on liquidity and cash flow in future periods:

	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
			(In thousands)		
Equipment line of credit	$ 6,017	$ 2,800	$ 3,217	$	$
Operating leases	3,909	753	1,567	1,543	46
Purchase obligations(1)	40,674	22,401	10,131	2,442	5,700
Total	$ 50,600	$ 25,954	$ 14,915	$ 3,985	$ 5,746

(1) Purchase obligations include purchase commitments for System One components, primarily for equipment 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 U.S. generally accepted accounting principles. 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 set forth below. This summary should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q.

Revenue Recognition

We recognize revenues from product sales and services when earned in accordance with Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition"*, and Emerging Issues Task Force, 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.

Chronic Care Market

Prior to 2007, we derived revenue in the chronic care market from short-term rental arrangements with our customers as our principal business model in the chronic care market. These rental arrangements, which combine the use of the System One with a specified number of disposable products supplied to customers for a fixed amount per month, are recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to a binding customer purchase order and fixed payment terms. Rental arrangements continue to represent the majority of the arrangements we have with our customers in the chronic care market.

Beginning in 2007, we entered into long-term customer contracts to sell System One and PureFlow SL equipment along with the right to purchase disposable products and service on a monthly basis. Some of these agreements

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include other terms such as development efforts, training, market collaborations, limited market exclusivity, and volume discounts. The equipment and related items provided to our customers in these arrangements are considered a multiple-element sales arrangement pursuant to EITF 00-21. When a sales arrangement involves multiple elements, the deliverables included in the arrangement are evaluated to determine whether they represent separate units of accounting. We have determined that we cannot account for the sale of equipment as a separate unit of accounting. Therefore, 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 obligation to supply disposables and service, which is five to seven years. We have 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.

We entered into a national service provider agreement and a stock purchase agreement with DaVita on February 7, 2007. Pursuant to EITF 00-21, we consider these agreements a single arrangement. In connection with the stock purchase agreement, DaVita purchased 2,000,000 shares of our common stock for $10.00 per share, which represented a premium of $1.50 per share, or $3.0 million over the current market price. We have recorded the $3.0 million premium as deferred revenue and will recognize this revenue ratably over seven years, consistent with our equipment service obligation to DaVita. During the three and six months ended June 30, 2007, we recognized revenue of $107,000 and $179,000, respectively, associated with the $3.0 million premium.

Critical Care Market

In the critical care market, sales are structured as direct product sales or as a disposables-based program in which a customer acquires the equipment through the purchase of a specific quantity of disposables over a specific period of time. We recognize revenues from direct product sales at the later of the time of shipment or, if applicable, delivery in accordance with contract terms. Under a disposables-based program, the customer is granted the right to use the equipment for a period of time, during which the customer commits to purchase a minimum number of disposable cartridges or fluids at a price that includes a premium above the otherwise average selling price of the cartridges or fluids to recover the cost of the equipment and provide for a profit. Upon reaching the contractual minimum purchases, ownership of the equipment transfers to the customer. Revenues under these arrangements are recognized over the term of the arrangement as disposables are delivered. During the reported periods, the majority of our critical care revenues were derived from direct product sales.

Our contracts provide for training, technical support and warranty services to our 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.

Inventory Valuation

Inventories are valued at the lower of cost or estimated market. We regularly review our inventory quantities on hand and related cost and record a provision for excess or obsolete inventory primarily based on an estimated forecast of product demand for each of our existing product configurations. We also review our inventory value to determine if it reflects lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margins and other factors in evaluating net realizable value. The medical device industry is characterized by rapid development and technological advances that could result in obsolescence of inventory.

Field Equipment

We amortize field equipment using the straight-line method over an estimated useful life of five years. We review the estimated useful life of five years periodically for reasonableness. Factors considered in determining the reasonableness of the useful life include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns, actual equipment disposal rates, and the impact of planned design improvements. We believe the five year useful life is appropriate as of June 30, 2007.

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Related-Party Transactions

Medisystems Corporation

Supply Agreement

We purchase completed cartridges, tubing and certain other components used in the System One disposable cartridge from Medisystems Corporation, an entity owned by David S. Utterberg, a member of our Board of Directors and the owner of approximately 6.7% of our outstanding common stock. We purchased approximately $2.1 million and $3.8 million during the three and six months ended June 30, 2007, and $1.2 million and $1.9 million for the three and six months ended June 30, 2006, respectively, of goods and services from this related party. Amounts owed to Medisystems Corporation totaled $665,000 and $926,000 at June 30, 2007 and December 31, 2006, respectively, and are included in accounts payable in the accompanying condensed consolidated balance sheets. At June 30, 2007, we had commitments to purchase approximately $3.2 million of products from Medisystems Corporation.

On January 4, 2007, we entered into a supply agreement with Medisystems that expires on December 31, 2013. Prior to entering into the supply agreement, we purchased products from Medisystems through purchase orders. Pursuant to the terms of the supply agreement, we will purchase no less than ninety percent (90%) of our North American requirements for disposal cartridges, or Medisystems products, for use with its System One from Medisystems.

Stock Purchase Agreement

On June 4, 2007, we entered into a stock purchase agreement with Mr. Utterberg to purchase all of the issued and outstanding shares of the Medisystems Entities in exchange for 6,500,000 shares of our common stock, which we refer to as the stock purchase, and agreed to enter into a consulting agreement with Mr. Utterberg and DSU, a company owned by Mr. Utterberg, upon the consummation of the stock purchase, to provide us with consulting, advisory and related services for two years following the consummation of the Stock Purchase. Under the terms of the Consulting Agreement, we will pay Mr. Utterberg $200,000 annually, plus reasonable expenses and Mr. Utterberg and DSU will agree (1) not to compete with us and will not encourage or solicit any of our employees, customers or suppliers, and (2) will assign to us certain inventions and proprietary rights received during the term of the Consulting Agreement and will grant certain exclusive, worldwide, perpetual, royalty-free irrevocable, sublicensable, fully paid licenses for such inventions and proprietary rights. In the event the Stock Purchase is consummated, Mr. Utterberg will own approximately 23.4% of our outstanding common stock and will continue to be a member of our Board of Directors.

The consummation of the stock purchase is subject to a number of conditions, including, among other things, the termination of applicable waiting periods under the Hart-Scott-Rodino Act, the approval by our stockholders of the issuance of shares of our common stock to Mr. Utterberg in connection with the stock purchase, and the effectiveness of our registration and proxy statement/prospectus on Form S-4, as determined by the SEC, seeking stockholder approval of this stock issuance. None of these conditions has yet been satisfied. We filed our registration and proxy statement/prospectus on Form S-4 seeking stockholder approval in connection with the Stock Purchase with the SEC on July 27, 2007. This registration and proxy statement/prospectus on Form S-4 has not yet been declared effective by the SEC.

Consistent with our Audit Committee Charter and Related Person Transaction Policy, the Stock Purchase Agreement and Consulting Agreement were each approved by our Audit Committee and Board of Directors. The Supply Agreement was also approved by the Audit Committee and Board of Directors.

As of June 30, 2007, we have capitalized approximately $1.2 million of direct costs incurred in conjunction with the pending Medisystems stock purchase. These costs are included in other assets in the accompanying condensed consolidated balance sheets.

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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 above.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements"*, which addresses the measurement of fair value where such measure is required for recognition or disclosure purposes under GAAP. Among other provisions, SFAS No. 157 includes (i) a new definition of fair value, (ii) a fair value hierarchy used to classify the source of information used in fair value measurements, (iii) new disclosure requirements of assets and liabilities measured at fair value based on their level in the hierarchy, and (iv) a modification of the accounting presumption that the transaction price of an asset or liability equals its initial fair value. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 (i.e., beginning in 2008 for NxStage). We are currently evaluating the impact of SFAS No. 157 on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115,* which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective as of the beginning of an entity s first fiscal year that begins after November 15, 2007. We are currently evaluating if we will elect the fair value option for any of our eligible financial instruments and other items.

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

During the three and six months ended June 30, 2007, 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, 2006. 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, 2006.

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, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2007, 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 Securities Exchange Act) occurred during the fiscal quarter ended June 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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 substantially all of our future revenues from the rental or sale of our System One and the sale of our related disposable products used with the System One.

Since our inception, we have devoted substantially all 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. We expect that the rental or sale of the System One and the sale of related products will account for substantially all of our revenues for the foreseeable future. Most of our related products cannot be used with any other dialysis systems and, therefore, we will derive little or no revenues from related products unless we sell or otherwise place the System One. To the extent that the System One is not a successful product or is withdrawn from the market for any reason, we do not have other products in development that could replace revenues from the System One.

We cannot accurately predict the size of the home hemodialysis market, and it may be smaller or slower to develop than we expect.

Although home hemodialysis treatment options are available, adoption 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 2004, 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; USRDS data indicates approximately 2,000 patients were receiving home-based hemodialysis in 2004. 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. Our long-term growth will depend on the number of patients who adopt home-based hemodialysis and how quickly they adopt it, and we do not know whether the number of home-based dialysis patients will be greater or fewer than the number of patients performing peritoneal dialysis or how many peritoneal dialysis patients will switch to home-based hemodialysis. We received our home use clearance for the System One from the FDA in June 2005 and we will need to devote significant resources to developing the market. We cannot be certain that this market will develop, how quickly it will develop or how large it will be.

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

We believe that the chronic care market is the largest market opportunity for our System One hemodialysis system. Historically, we have typically billed the dialysis clinic for the rental of the equipment and the sale of the related disposable cartridges and treatment fluids. In our recent DaVita 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 equipment needs. It is not clear what percentage of our future chronic customers will purchase rather than rent System One equipment. However, it is possible that a significant percentage of our chronic customers will continue to rent rather than purchase System One equipment and that, as a result, we will generate a significant percentage of our revenues and cash flow from the use of the System One over time rather than upfront from the sale of the System One equipment. In this event, we will need significant amounts of working capital to manufacture System One equipment for rental to dialysis clinics.

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We only recently began marketing our System One to dialysis clinics for the treatment of ESRD, and we have not achieved widespread market acceptance of our product. We may not be able to generate sufficient cash flow to meet our capital needs. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to sell additional equity or issue debt securities. Any sale of additional equity or issuance of debt securities may 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 this 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 could harm the growth of our business.

We have limited operating experience, a history of net losses and an accumulated deficit of $148.5 million at June 30, 2007. We cannot guarantee if, when and the extent that we will become profitable, or that we will be able to maintain profitability once it is achieved.

Since inception, we have incurred losses every quarter and at June 30, 2007, we had an accumulated deficit of approximately $(148.5) million. We expect to incur increasing operating expenses as we continue to grow our business. Additionally, in the chronic care market, the cost of manufacturing the System One and related disposables currently exceeds the market price. We cannot provide assurance that we will be able to lower the cost of manufacturing the System One and related disposables below the current chronic care market price, 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 in part upon achieving a sufficient scale of operations, obtaining better purchasing terms and prices, achieving efficiencies in manufacturing overhead costs, implementing design and process improvements to lower our costs of manufacturing our products and achieving efficient distribution of our products.

In March 2006, we received clearance from the FDA to market our PureFlow SL module as an alternative to the bagged fluid presently used with our System One in the chronic care market, and we commercially launched the PureFlow SL module in July 2006. This accessory to the System One allows for the preparation of high purity dialysate in the patient s home using ordinary tap water and dialysate concentrate. The PureFlow SL is designed to help patients with ESRD more conveniently and effectively manage their home hemodialysis therapy by eliminating the need for bagged fluids. Since its launch, PureFlow SL penetration has reached approximately 58% of all of our chronic patients. The product is still early in its commercial launch and we continue to work to improve product reliability and user experience, based upon customer feedback. Any failure to further improve reliability and user experience, and thereby gain rapid market acceptance of the PureFlow SL module, including converting our installed base of patients currently using bagged fluid, could adversely affect our ability to achieve profitability.

We compete against other dialysis equipment manufacturers with much greater financial resources and better established products and customer relationships, which may make it difficult for us to penetrate the market and achieve significant sales of our products.

Our System One competes directly against equipment produced by Fresenius Medical Care AG, Baxter Healthcare, Gambro AB, B. Braun and others, each of which markets one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure.

To date, only one other company has had a hemodialysis product specifically cleared for home use, Aksys Ltd., announced in January the withdrawal of its product from the market. Products sold by our other competitors have also been used in the home, in particular Fresenius systems. Each of these competitors offers products that have been in use for a longer time than our System One 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. Most of these companies manufacture additional complementary products enabling them to offer a 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, is subject to an import hold imposed by the FDA on its acute and chronic dialysis machines. It is not clear what the chronic and acute market impact will be when the import hold is lifted. We believe the overall impact of the import hold has been positive to us, however, we

are not sure of the magnitude of the impact this import hold has had on revenues.

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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 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 safety, convenience or effectiveness or are offered at lower prices than our System One. Our ability to successfully market the System One 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 the System One.

Our success will depend on our ability to achieve market acceptance of our System One.

Our products have limited product and brand recognition and have only been used at a limited number of dialysis clinics and hospitals. In the chronic care market, we will 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. Each of these constituencies will 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 the System One for a number of reasons including:

- the failure by us to demonstrate to patients, operators of dialysis clinics, nephrologists, dialysis nurses and others that our product is equivalent or superior to existing therapy options or, that the cost or risk associated with use of our product is not greater than available alternatives;

- 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 dialysis clinics;

- 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, safer, easier to use or less expensive than ours;

- 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 continued availability of satisfactory reimbursement from healthcare payors, including Medicare.

Current Medicare reimbursement rates limit the price at which we can market the System One, and adverse changes to reimbursement could affect the adoption of the System One.

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our System One. As a result of legislation passed by the U.S. Congress more than 30 years ago, Medicare provides comprehensive and well-established reimbursement in the United States for ESRD. With over 80% of U.S. ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer s decision to use the System One and limits the fee for which we can rent the System One and sell the related disposable cartridges and treatment fluids. Current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification 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 may be slowed. Changes in Medicare reimbursement rates could negatively affect demand for our products and the prices we charge for them.

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

As the commercial launch of the System One continues, we will need to expand our regulatory, 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 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 performance typically experienced in the early stages of a product s life cycle, our ability to grow our business and achieve profitability could be impaired.

Our System One is still early in its product launch, and our PureFlow SL module was only introduced during the third quarter of 2006. We continue to experience product reliability issues that are higher than we expect long-term, which lead us to incur increased service and distribution costs, as well as 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 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, and have achieved some improvements to date. If we are unable to continue to improve product reliability, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

Most recently, in the second quarter of 2007, we started to experience an increased incidence of reported dialysate leaks associated with our System One cartridges. The reported incidence of leaks is higher than we have historically observed. When the System One is used in accordance with its instructions, these leaks present no risk to patient health. System One device labeling anticipates the potential for leaks to occur and specifically warns against leaks and alerts users of the need to observe treatments in order to detect leaks. Four patients with reported leaks, that were unobserved by these patients or their partners until after their treatments were terminated, reported hypotension, or low blood pressure, resolved by a fluid bolus, with no lasting clinical effect. In early August 2007, we sent a letter to our patients and customers informing them of the increased incidence in leaks and reminding them of existing System One labeling alerting users of the potential for leaks and instructing them to observe treatments in order to detect any leaks. We have characterized this notification as a voluntary recall. In response to the reported increase in incidence of leaks, we are also currently developing a test to better evaluate the susceptibility of our cartridges to leaks prior to release, with the goal of reducing the chance for pinhole-sized leaks in our cartridges.

These cartridge leaks have resulted in dissatisfaction with our System One for certain of our customers and could impair our future growth and patient retention. The incremental leaks have also been associated with increased cycler service costs, which have imposed additional service pool requirements, and could impair our ability to meet future demand. If the incidence of leaks persists or increases or if patient satisfaction declines, we may incur additional costs, however we deem any loss to the approximately $2.5 million of affected inventory to be improbable at this time, therefore no amount has been accrued to date. Additionally, costs related to the return or replacement of cartridges, and costs incurred to rework inventory on-hand and/or returned by customers may also be incurred and could be material. We have not incurred any material costs to date in connection with this matter. We are working to address the product leaks quickly, but they still remain an issue with our customer base.

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

Because the majority of our chronic 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.

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Our agreement with DaVita confers certain geographic market rights to DaVita and limits our ability to sell the System One to Fresenius, both of which may present a barrier to adoption of the System One.

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Fresenius controls approximately 33% of the U.S. dialysis clinics and is the largest worldwide manufacturer of dialysis systems. DaVita controls approximately 27% of the U.S. dialysis clinics, and has entered into a preferred supplier agreement with Gambro pursuant to which Gambro will provide a significant majority of DaVita s dialysis equipment and supplies for a period of at least 10 years. 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.

Our recent agreement with DaVita confers certain market rights for the System One and related supplies for home hemodialysis therapy. DaVita is granted exclusive rights in a small percentage of geographies, which geographies collectively represent less than 10% of the U.S. ESRD patient population, and limited exclusivity in the majority of all other U.S. geographies, subject to DaVita s meeting certain requirements, including patient volume commitments and new patient training rates. Under the agreement, we can continue to sell to other clinics in the majority of geographies. 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 limits, but does 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 U.S. chronic dialysis patients and that also supplies dialysis products. Therefore, our ability to sell the System One for chronic home patient hemodialysis therapy to Fresenius is presently limited.

It is not yet clear what impact this agreement may have on the market acceptance for our product. It is also not yet clear to what extent DaVita will purchase the System One from us. For the three months ended June 30, 2007, sales to DaVita represented 30% of our total revenues. Although we expect that DaVita will continue to be a significant customer of ours, the agreement imposes no purchase obligations upon DaVita and we cannot be certain whether DaVita will continue to purchase and/or rent the System One from us in the future. We believe that any future decision by DaVita to stop or limit the use of the System One would adversely affect our business, at least in the near term.

If kidney transplantation becomes a viable treatment option for more patients with ESRD, the market for our System One 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 the most recent 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 System One.

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

We sell the System One 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 hemodialysis systems or dialysis systems designed specifically for use in the 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 and ease of operation.

We are subject to the risk of costly and damaging product liability claims and may not be able to maintain sufficient product liability insurance to cover claims against us.

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If our System One 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. As is the case with a number of other medical device companies, it is likely that product liability claims will be brought against us. Since their introduction into the market, our products have been subject to three voluntary recalls and one voluntary product withdrawal. Our first voluntary recall occurred in February 2001 in Canada and related to a software glitch that we detected in our predecessor system, which could have increased the likelihood of a clotted filter during treatment. There were no patient injuries associated with this recall, and the software glitch was remedied with a subsequent software release. The second voluntary recall occurred in April 2004 in the United States relating to pinhole-sized dialysate leaks in our cartridges. Although System One device labeling anticipates the potential for leaks to occur, and therefore specifically warns against leaks and alerts users of the need to check for leaks while performing treatments, the incidence of leaks was higher than we had historically experienced. There were no patient injuries associated with this recall; we subsequently switched suppliers and instituted additional testing requirements to minimize the chance for pinhole-sized leaks in our cartridges. Our third voluntary recall occurred in the United Sates in August 2007 and also related to pinhole-sized leaks in our cartridges. Four patients with reported leaks, that were unobserved by these patients or their partners until the end of their treatments, reported hypotension, or low blood pressure, resolved by a fluid bolus, with no lasting clinical effect. No other patient injuries were reported in connection with this recall. In response to this increased incidence in leaks, we are developing a test to better evaluate the susceptibility of cartridges to leaks prior to release, with the goal of reducing the chance for pinhole-sized leaks in our cartridges. The voluntary market withdrawal occurred in the United States in May 2002 when we suspended sales of our predecessor system while we addressed issues involving limited instances of contaminated hemofiltration fluids compounded by a pharmacy and supplied by a third-party. Six patients exposed to contaminated fluids reported fevers and/or chills, with no lasting clinical effect. We subsequently modified our cartridge to allow for an additional filter to remove contaminants from fluids used with our product. Our products may be subject to further recalls or withdrawals, which could increase the likelihood of product liability claims. We have also received several reports of operator error from both patients in the home hemodialysis setting and nurses in the critical care setting. We have sought to address many potential sources of operator error with product design changes to simplify the operator process. In addition, we have made improvements in our training materials and product labeling. However, instances of operator error cannot be eliminated and could also increase the likelihood of product liability claims.

Although we maintain insurance, including product liability insurance, we cannot provide assurance that any claim that may be brought against us will not result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product 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 claim brought against us, with or without merit, could result in the increase of our product liability insurance rates 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, 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 have had limited sales, marketing, customer service and distribution experience. We need to expand our sales and marketing, customer service and distribution infrastructures to be successful in penetrating the dialysis market.

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We currently market and sell the System One through our own sales force, and we have had limited experience in sales, marketing and distribution of dialysis products. As of June 30, 2007, we had 107 employees in our sales, marketing and distribution organization, including 31 direct sales representatives. We plan to expand our sales, marketing, customer service and distribution infrastructures. We cannot provide assurance that we will be able to retain or attract experienced personnel to our early-stage company and build an adequate sales and marketing, customer service and distribution staff or that the cost will not be prohibitive.

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

In addition to our operations in Lawrence, Massachusetts, we operate manufacturing facilities in Rosdorf, Germany and Fresnillo, Mexico and we 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. These risks include fluctuations in foreign currency exchange rates that may increase the U.S. dollar cost of the disposables we purchase from foreign third-party suppliers, costs associated with sourcing and shipping goods internationally, difficulty managing operations in multiple locations and local regulations that may restrict or impair our ability to conduct our operations.

Risks Related to the Proposed Acquisition of the Medisystems Entities and Other Possible Business Combinations

We may not complete the acquisition of the Medisystems entities and, the failure to do so, could harm our common stock price and future business and operations.

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg to purchase his issued and outstanding shares of Medisystems Services Corporation, a Nevada corporation, Medisystems Corporation, a Washington corporation, Medisystems Europe S.p.A., a company organized under the laws of Italy, and Medimexico s. de R.L. de C.V., a company organized under the laws of Mexico, which we refer to collectively as the Medisystems entities. The proposed acquisition of the Medisystems entities is subject to a number of closing conditions, including approval of our stockholders, and may not be completed. If the acquisition is not completed, we may be subject to the following risks:

- the price of our common stock may decline;
- we will not realize our expected benefits of the acquisition;
- under certain circumstances we will be required to pay Mr. Utterberg a termination fee of up to $600,000 in reasonable documented expenses incurred by him in connection with the acquisition; and
- the costs incurred by us related to the acquisition, such as legal, accounting and certain financial advisory fees, must be paid even if the acquisition is not completed.

The market price of our common stock may decline as a result of the acquisition.

The market price of our common stock may decline as a result of the acquisition for a number of reasons including if:

- we do not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by financial or industry analysts;
- the effect of the acquisition on our business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on our business and prospects from the acquisition.

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Our stockholders may not realize a benefit from the acquisition commensurate with the ownership dilution they will experience in connection with the acquisition.

As consideration for the acquisition of the Medisystems entities, we expect to issue 6,500,000 shares of our common stock, or approximately 21.7% of our outstanding common stock as of June 29, 2007. If we are unable to realize the strategic and financial benefits currently anticipated from the acquisition, our stockholders will have experienced substantial dilution of their ownership interest without receiving commensurate benefit.

We may face challenges in integrating Medisystems business with NxStage s and, as a result, may not realize the expected benefits of the proposed acquisition.

Even though NxStage s and Medisystems businesses are relatively distinct, integrating the operations and personnel of Medisystems and NxStage will require a significant investment of management s time and effort as well as the investment of capital, particularly with respect to information systems. The successful integration of Medisystems and NxStage will require, among other things, coordination of certain manufacturing operations and sales and marketing operations and the integration of Medisystems operations into the NxStage organization. The diversion of the attention of NxStage s and Medisystems senior management and any difficulties encountered in the process of combining the companies could cause the disruption of, or a loss of momentum in, the activities of the combined businesses.

The inability to successfully integrate the operations and personnel of Medisystems and NxStage, or any significant delay in achieving integration, could have a material adverse effect on the combined businesses after the completion of the acquisition, and, as a result, on the market price of NxStage s common stock.

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, in addition to our proposed acquisition of Medisystems, other businesses and 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; and
- potential loss of key employees of the acquired company;

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.

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Purchase accounting treatment of acquisitions could decrease our net income in the foreseeable future, which could have a material and adverse effect on the market value of our common stock.

Under accounting principles generally accepted in the United States of America, we would account for acquisitions using the purchase method of accounting. Under purchase accounting, we would record the consideration issued in connection with the acquisition and the amount of direct transaction costs as the cost of acquiring the company or business. We would allocate that cost to the individual assets acquired and liabilities assumed, including various identifiable intangible assets such as acquired technology, acquired trade names and acquired customer relationships based on their respective fair values. Intangible assets generally will be amortized over a three to fifteen year period. Goodwill and certain intangible assets with indefinite lives are not subject to amortization but are subject to at least an annual impairment analysis, which may result in an impairment charge if the carrying value exceeds their implied fair value. These potential future amortization and impairment charges may significantly reduce net income, if any, and therefore may adversely affect the market value of our common stock.

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 System One and related products, including the disposables required for its use, are all 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 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 the System One. We cannot provide assurance that such clearances or approvals would 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 the System One 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

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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.

Complex medical devices, such as the System One, 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 could 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. Recalls, involving the System One, depending upon the nature and scope of the recall, may be particularly harmful to our business and financial results, because the System One is our primary product. Our August 2007 voluntary recall relating to the increased incidence of reported cartridge leaks has not, as of the date of this report, caused us to incur material costs. If the incidence of leaks persists or increases or if patient satisfaction declines, this may change.

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 U.S.

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manufacturing facility 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. 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 treatment for ESRD could affect the adoption of our System One and the level of our future product revenues.

In the United States, all patients who suffer from ESRD, regardless of age, are eligible for coverage under Medicare, after a requisite coordination period if other insurance is available. As a result, more than 80% of patients with ESRD are covered by Medicare. Although we rent and sell our products to hospitals, dialysis centers and other healthcare providers and not directly to patients, the reimbursement rate for ESRD treatments is an important factor in a potential customer s decision to purchase the System One. The dialysis centers that purchase our product rely on adequate third-party payor coverage and reimbursement to maintain their ESRD facilities. The CMS provides the composite rate for dialysis services, which is subject to regional variation and varies depending upon whether the facility is hospital-based or an independent clinic. The composite rate is intended to cover most items and services related to the treatment of ESRD, but does not include payment for physician services or separately billable laboratory services or drugs. Changes in Medicare reimbursement rates could negatively affect demand for our products and the prices we charge for them.

Most ESRD patients who use our product for dialysis therapy in the home treat themselves six times per week. CMS rules, however, limit the number of hemodialysis treatments paid for by Medicare to three a week, unless there is medical justification for the additional treatments. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis. 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.

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 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.

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Although we have not initiated any marketing efforts in jurisdictions outside of the United States and Canada, we intend in the future to market our products in other markets. In order to market our products in the European Union or 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 effect 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 System One operations 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. U.S. Federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of 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. 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. 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 System One to a customer, we could be subject to a claim under the Medicare/ Medicaid anti-kickback 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,

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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.

Although we have not initiated any marketing efforts in jurisdictions outside of the United States and Canada, we intend in the future 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 the System One 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.

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 depend on the services of our senior executives and certain key engineering, scientific, clinical and marketing personnel, the loss of whom could negatively affect our business.

Our success depends upon the skills, experience and efforts of our senior executives and other key personnel, including our chief executive officer, certain members of our engineering staff, our marketing executives and managers, our manufacturing executives and managers and our clinical educators. Much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. Virtually all of our employees have agreements which impose obligations that may prevent a former employee of ours from working for a competitor for a period of time; however, these clauses may not be enforceable, or enforceable only in part, or the company may choose not to seek enforcement. We do not maintain key man life insurance on any of our senior executives, other than our chief executive officer.

We obtain some of the components, subassemblies and completed products included in the System One from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenues.

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We depend on single source suppliers for some of the components and subassemblies we use in the System One. KMC Systems, Inc. is our only contract manufacturer of the System One cycler, although we are considering a plan to develop alternative manufacturing capabilities for this product; B. Braun Medizintechnologie GmbH is our only supplier of bicarbonate-based dialysate used with the System One; Membrana GmbH is our only supplier of the fiber used in our filters; PISA is our primary supplier of lactate-based dialysate; and Medisystems Corporation is the only supplier of our disposable cartridge and several cartridge components. Medisystems is a related party to NxStage. David Utterberg, the chief executive officer and sole stockholder of Medisystems, is a member of our board of directors and, at June 30, 2007, held approximately 6.7% of our common stock. We also obtain certain other components included in the System One 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 B. Braun, for bicarbonate, and Membrana, for fiber, we are contractually prevented from obtaining an alternative source of supply, except in certain limited instances. In the case of Medisystems, we are contractually prevented from obtaining an alternative source of supply for more than 10% of our North American requirements, except in certain limited instances. 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 and, potentially, further FDA clearance or approval of any modification, thereby causing further costs and delays.

Certain of our products are recently developed or are transitioning to other locations and 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 are also expanding our manufacturing capacity which requires us to relocate our manufacturing operations to other locations. 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 and related disposables. We are, therefore, more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature.

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

We purchase components and subassemblies from third-party suppliers, including some of our 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 to us 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 these suppliers. If we inaccurately forecast demand for components or subassemblies, our ability to manufacture and commercialize the System One 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 could lead to disruptions in product supply, which could permanently impair our customer base and reputation.

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:

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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 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, 2007, we had 48 pending patent applications, including foreign, international and U.S. applications, and 27 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.

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.

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

In order to protect our proprietary technology and processes, we 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 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;
- disruptions in product supply for any reason, including product recalls of the failure of third party suppliers to 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;
- regulatory developments in the United States and foreign countries;

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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;

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 existing stockholders, our stock price could decline.

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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 29,989,461 shares of common stock outstanding as of June 30, 2007. 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 299,895 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 29, 2007, subject to certain conditions, holders of an aggregate of approximately 13,511,174 shares of 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 29, 2007, 3,203,202 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, 2007, 3,153,724 shares were subject to outstanding options, of which 1,879,783 were exercisable and which can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and the restrictions imposed on our affiliates under Rule 144.

Our costs have increased significantly as a result of operating as a public company, and our management is required to devote substantial time to comply with public company regulations.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as new rules subsequently implemented by the SEC and the NASDAQ Global Market, have imposed various new requirements on public companies, including changes in corporate governance practices. Our management and other personnel now need to devote a substantial amount of time to these new requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2006, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Global Market, SEC or other regulatory authorities.

We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.

We anticipate that we will retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to investors. Investors seeking cash dividends should not invest in our common stock.

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 46% of our outstanding common stock. As a result, these stockholders, if acting together, will have the ability to determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any

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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.

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

We held our Annual Meeting of Stockholders on May 30, 2007 and our stockholders voted to:

(i) Elect the individuals named below to hold office until our 2008 Annual Meeting of Stockholders:

Nominees	Votes For	Votes Withheld
Jeffrey H. Burbank	26,294,345	121,944
Philippe O. Chambon	26,285,597	130,692
Daniel A. Giannini	26,294,605	121,684
Craig W. Moore	26,292,005	124,284
Reid S. Perper	26,294,605	121,684
Peter P. Phildius	26,294,605	121,684
David S. Utterberg	25,714,360	701,949

(ii) Ratify the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2007, which matter was approved by a vote of 26,375,311 shares voting for, 37,525 shares voting against and 3,453 shares abstaining

(iii) Approve the amendment of our 2005 Employee Stock Purchase Plan to increase the number of shares of common stock which may be issued pursuant to the plan by an additional 50,000, which matter was approved by a vote of 23,602,366 shares voting for, 130,177 shares voting against and 21,556 shares abstaining.

Item 6. ***Exhibits***

Exhibit Number	
10.1	Stock Purchase Agreement, dated June 4, 2007, by and between the Registrant and David S. Utterberg.
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, 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 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002.

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Exhibit Number	
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.

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SIGNATURES

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

NXSTAGE MEDICAL, INC.

By: /s/ Robert S. Brown
Robert S. Brown
Chief Financial Officer
(Duly authorized officer and principal financial and accounting officer)
August 9, 2007