WASHINGTON FEDERAL INC
Form 10-Q
August 11, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2008

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from __________ to __________

Commission file number 0–25454

WASHINGTON FEDERAL, INC.

(Exact name of registrant as specified in its charter)

Washington	**91-1661606**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

425 Pike Street Seattle, Washington 98101

(Address of principal executive offices and zip code)

(206) 624-7930

(Registrant s telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report.)

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

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

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

APPLICABLE ONLY TO CORPORATE ISSUERS

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

Title of class:	at August 8, 2008
Common stock, $1.00 par value	87,862,599

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

PART I

Item 1. Financial Statements (Unaudited)

The Condensed Consolidated Financial Statements of Washington Federal, Inc. and Subsidiaries filed as a part of the report are as follows:

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF FINANCIAL CONDITION

(UNAUDITED)

	June 30, 2008	September 30, 2007
	(In thousands, except share data)	
ASSETS		
Cash and cash equivalents	**$ 70,071**	$ 61,378
Available-for-sale securities, including encumbered securities of **$779,422** and $700,955, at fair value	**1,582,663**	1,515,688
Held-to-maturity securities, including encumbered securities of **$100,821** and $58,647, at amortized cost	**127,177**	138,373
Loans receivable, net	**9,425,874**	8,188,278
Interest receivable	**54,084**	49,611
Premises and equipment, net	**117,734**	74,807
Real estate held for sale	**20,902**	4,873
FHLB stock	**144,841**	132,397
Intangible assets, net	**222,248**	107,245
Other assets	**29,653**	12,767
	$ 11,795,247	$ 10,285,417
LIABILITIES AND STOCKHOLDERS EQUITY		
Liabilities		
Customer accounts		
Savings and demand accounts	**$ 7,160,466**	$ 5,979,049
Repurchase agreements with customers	**13,536**	17,736
	7,174,002	5,996,785
FHLB advances	**2,001,146**	1,760,979
Other borrowings	**1,115,600**	1,075,000
Advance payments by borrowers for taxes and insurance	**22,028**	31,824
Federal and state income taxes	**31,670**	38,032
Accrued expenses and other liabilities	**82,407**	64,670
	10,426,853	8,967,290
Stockholders equity		
Common stock, $1.00 par value, 300,000,000 shares authorized; **105,056,998** and 104,921,450 shares issued; **87,828,584** and 87,441,750 shares outstanding	**105,057**	104,921
Paid-in capital	**1,259,312**	1,254,490
Accumulated other comprehensive income (loss), net of taxes	**(17,193)**	(13,033)
Treasury stock, at cost; **17,228,414** and 17,479,700 shares	**(210,881)**	(213,934)
Retained earnings	**232,099**	185,683
	1,368,394	1,318,127
	$ 11,795,247	$ 10,285,417

SEE NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Quarter Ended June 30,		Nine Months Ended June 30,	
	2008	2007	**2008**	2007
	(In thousands, except per share data)			
INTEREST INCOME				
Loans	**$ 155,008**	$ 135,458	**$ 446,702**	$ 387,929
Mortgage-backed securities	**22,407**	18,677	**66,187**	56,216
Investment securities and cash equivalents	**3,066**	4,485	**11,035**	11,952
	180,481	158,620	**523,924**	456,097
INTEREST EXPENSE				
Customer accounts	**66,195**	63,712	**200,240**	178,697
FHLB advances and other borrowings	**33,622**	28,489	**104,154**	83,399
	99,817	92,201	**304,394**	262,096
Net interest income	**80,664**	66,419	**219,530**	194,001
Provision for loan losses	**13,216**	1,000	**23,716**	1,200
Net interest income after provision for loan losses	**67,448**	65,419	**195,814**	192,801
OTHER INCOME				
Gain on sale of loans	**32**		**433**	
Gain on sale of real estate	**3,164**		**11,876**	11
Other	**4,364**	5,230	**12,579**	11,644
	7,560	5,230	**24,888**	11,655
OTHER EXPENSE				
Compensation and fringe benefits	**14,127**	11,577	**38,252**	31,991
Occupancy	**2,916**	2,300	**7,992**	6,454
Other	**6,610**	3,340	**16,478**	8,779
	23,653	17,217	**62,722**	47,224
Gain (loss) on real estate acquired through foreclosure, net	**72**	(17)	**(182)**	139
Income before income taxes	**51,427**	53,415	**157,798**	157,371
Income taxes	**18,258**	19,150	**56,129**	56,239
NET INCOME	**$ 33,169**	$ 34,265	**$ 101,669**	$ 101,132
PER SHARE DATA				
Basic earnings	**$ 0.38**	$ 0.39	**$ 1.16**	$ 1.16
Diluted earnings	**.38**	.39	**1.16**	1.15
Cash dividends	**.210**	.210	**.630**	.620
Weighted average number of shares outstanding	**87,789,556**	87,309,444	**87,619,645**	87,364,179
Weighted average number of shares outstanding, including dilutive stock options	**87,811,275**	87,514,339	**87,756,491**	87,602,549

SEE NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended June 30, 2008	June 30, 2007
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	**$ 101,669**	$ 101,132
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of fees, discounts, premiums and intangible assets, net	**1,459**	445
Depreciation	**2,940**	2,345
Stock option compensation expense	**947**	831
Provision for loan losses	**23,716**	1,200
Gain on investment securities and real estate held for sale, net	**(11,695)**	(150)
Gain on sale of loans	**(448)**	
Decrease (increase) in accrued interest receivable	**466**	(1,751)
Increase (decrease) in income taxes payable	**(666)**	2,886
FHLB stock dividends	**(70)**	(68)
Decrease (increase) in other assets	**(14,783)**	2,423
Increase in accrued expenses and other liabilities	**6,495**	599
Net cash provided by operating activities	**110,030**	109,892
CASH FLOWS FROM INVESTING ACTIVITIES		
Loans originated:		
Single-family residential	**(644,514)**	(586,708)
Construction - speculative	**(187,576)**	(423,595)
Construction - custom	**(208,881)**	(264,729)
Land - acquisition & development	**(132,354)**	(331,874)
Land - consumer lot loans	**(19,998)**	(32,395)
Multi-family	**(82,615)**	(64,716)
Commercial real estate	**(27,571)**	(8,983)
Commercial & industrial	**(116,517)**	(8,505)
HELOC	**(40,829)**	(2,984)
Consumer	**(65,982)**	(2,048)
	(1,526,837)	(1,726,537)
Savings account loans originated	**(5,977)**	(3,757)
Loan principal repayments	**1,389,207**	1,303,605
Decrease in undisbursed loans in process	**(223,885)**	(59,199)
Loans purchased	**(683)**	(6,163)
Proceeds from sale of loans	**7,327**	
FHLB stock redemption	**748**	1,256
Available-for-sale securities purchased	**(301,854)**	(202,714)
Principal payments and maturities of available-for-sale securities	**178,474**	213,198
Available-for-sale securities sold	**72,030**	44,041
Principal payments and maturities of held-to-maturity securities	**11,316**	41,400
Net cash paid out for acquisition	**(166,859)**	(35,221)
Proceeds from sales of real estate held for sale	**30,544**	2,000
Premises and equipment purchased, net	**(5,370)**	(1,146)
Net cash used by investing activities	**(541,819)**	(429,237)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net increase in customer accounts	**430,463**	263,725

Net increase in borrowings	**70,330**	148,894
Proceeds from exercise of common stock options	**1,685**	3,434
Dividends paid	**(55,253)**	(54,126)
Proceeds from Employee Stock Ownership Plan	**4,804**	990
Treasury stock purchased, net		(7,542)
Decrease in advance payments by borrowers for taxes and insurance	**(11,547)**	(11,392)
Net cash provided by financing activities	**440,482**	343,983
Increase in cash and cash equivalents	**8,693**	24,638
Cash and cash equivalents at beginning of period	**61,378**	45,722
Cash and cash equivalents at end of period	**$ 70,071**	$ 70,360
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Non-cash investing activities		
Real estate acquired through foreclosure	**$ 34,076**	$ 4,066
Cash paid during the period for		
Interest	**299,363**	260,495
Income taxes	**57,743**	53,542
The following summarizes the non-cash activities relating to the First Mutual acquisition (2008) and the First Federal acquisition (2007):		
Fair value of assets and intangibles acquired, including goodwill	**$ (1,147,890)**	$ (576,750)
Fair value of liabilities assumed	**966,905**	480,033
Cash paid out for acquisition	**(180,985)**	**(96,717)**
Plus cash acquired	**14,126**	61,496
Net cash paid out for acquisition	**$ (166,859)**	**$ (35,221)**

SEE NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

QUARTER AND NINE MONTHS ENDED JUNE 30, 2008 AND 2007

(UNAUDITED)

NOTE A Basis of Presentation

The consolidated unaudited interim financial statements included in this report have been prepared by Washington Federal, Inc. (Company). The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect amounts reported in the financial statements. Actual results could differ from these estimates. In the opinion of management, all adjustments (consisting only of normal recurring accruals) necessary for a fair presentation are reflected in the interim financial statements. The September 30, 2007 Consolidated Statement of Financial Condition was derived from audited financial statements.

The information included in this Form 10-Q should be read in conjunction with Company s 2007 Annual Report on Form 10-K (2007 Form 10-K) as filed with the SEC. Interim results are not necessarily indicative of results for a full year.

Certain reclassifications have been made to the financial statements to conform prior periods to current classifications.

NOTE B Acquisitions

On February 1, 2008, the Company acquired 100% of the outstanding shares of First Mutual Bancshares, Inc. (First Mutual). The merger agreement provided for the merger of First Mutual with and into the Company, followed by the merger of First Mutual Bank, a federal savings bank and wholly owned subsidiary of First Mutual, into the Company s wholly owned subsidiary, Washington Federal Savings and Loan Association. As a result of the acquisition, Washington Federal added 169 employees and 12 branches primarily located on the rapidly growing eastside of Seattle. The acquisition was accounted for as a purchase transaction with the total cash consideration funded through internal sources. The all-cash purchase price was $180,985,000. The purchase price has been allocated to the underlying assets and liabilities based on estimated fair values at the date of acquisition. Results of operations are included from the date of acquisition. The Company acquired assets with an estimated fair value of $1,147,890,000 and assumed liabilities with an estimated fair value of $966,905,000. The acquisition produced goodwill of $110,382,000 and a core deposit intangible of $2,523,000.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

QUARTER AND NINE MONTHS ENDED JUNE 30, 2008 AND 2007

(UNAUDITED)

The balance of the Company s intangible assets was as follows:

	Goodwill	Servicing Rights Intangible	Core Deposit Intangible	Total
		(In thousands)		
Balance at September 30, 2006	$ 54,484	$	$ 1,775	$ 56,259
First Federal acquisition	47,923		4,882	52,805
Amortization			(1,819)	(1,819)
Balance at September 30, 2007	102,407		4,838	107,245
First Mutual acquisition	110,382	4,233	2,523	117,138
Additions		461		461
Amortization		(767)	(1,829)	(2,596)
Balance at June 30, 2008	$ 212,789	$ 3,927	$ 5,532	$ 222,248

The table below presents the estimated core deposit intangible asset amortization expense for the next five years:

Year ended September 30,	Amortization expense (In thousands)
2008	$ 2,441
2009	2,247
2010	1,031
2011	330
2012	330

<u>NOTE C - Dividends</u>

On July 25, 2008 the Company paid its 102nd consecutive quarterly cash dividend. Dividends per share amounted to 21.0 cents for the quarter ended June 30, 2008 and the same period one year ago.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

QUARTER AND NINE MONTHS ENDED JUNE 30, 2008 AND 2007

(UNAUDITED)

NOTE D Comprehensive Income

The Company s comprehensive income includes all items which comprise net income plus the unrealized gains (losses) on available-for-sale securities. Total comprehensive income for the quarters ended June 30, 2008 and 2007 totaled $9,703,000 and $18,476,000, respectively. Total comprehensive income for the nine months ended June 30, 2008 and 2007 totaled $97,508,000 and $88,885,000, respectively. The difference between the Company s net income and total comprehensive income for the nine months ended June 30, 2008 was $4,161,000, which equals the change in the net unrealized loss on available-for-sale securities of $6,577,000, less tax of $2,416,000.

NOTE E Allowance for Losses on Loans

The following table summarizes the activity in the allowance for loan losses for the quarters and nine months ended June 30, 2008 and 2007:

	Quarter Ended June 30,		Nine Months Ended June 30,	
	2008	2007	2008	2007
	(In thousands)			
Balance at beginning of period	$ 47,005	$ 27,997	$ 28,520	$ 24,993
Provision for loan losses	13,216	1,000	23,716	1,200
Charge-offs	(6,162)	(190)	(9,358)	(509)
Recoveries		3		3
Acquired reserves			11,181	3,123
Balance at end of period	$ 54,059	$ 28,810	$ 54,059	$ 28,810

NOTE F Available for Sale Investments

Securities not classified as held-to-maturity are considered to be available-for-sale. Gains and losses realized on the sale of these securities are based on the specific identification method. Unrealized gains and losses for available-for-sale securities are excluded from earnings and reported as a net amount in the accumulated other comprehensive income component of stockholders equity.

Management evaluates debt and equity securities for other than temporary impairment on a quarterly basis based on the securities current credit quality, interest rates, term to maturity and management s intent and ability to hold the securities until the net book value is recovered. Any other than temporary declines in fair value are recognized in the statements of operations.

As of June 30, 2008, the Company had an investment in agency preferred stock with a book value of $90,200,000 in its available for sale portfolio. In accordance with SFAS 115, these securities are carried at estimated fair value, which totaled $64,449,000 as of quarter end. The net unrealized loss is included in Other Comprehensive Gain (Loss) on the balance sheet. The Company has evaluated these securities for an other than temporary impairment (OTTI) and concluded that at this time, no such impairment exists. On an ongoing basis the Company will evaluate these securities to determine if and when such an OTTI occurs. At that point, any unrealized loss determined to be other than temporary would be recorded through the income statement.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

QUARTER AND NINE MONTHS ENDED JUNE 30, 2008 AND 2007

(UNAUDITED)

NOTE G New Accounting Pronouncement

Effective October 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48 (FIN 48), Accounting for Uncertainty in Income Taxes. As a result of the implementation of FIN 48 the Company did not record any cumulative effect adjustment to retained earnings.

As of October 1, 2007 the Company s liability for uncertain tax positions was $2.6 million. Included in the balance of unrecognized tax benefits at October 1, 2007, are $1.7 million of tax benefits that, if recognized, would affect the effective tax rate. The Company records interest and penalties related to uncertain tax positions in income tax expense. As of October 1, 2007 there was approximately $0.9 million of accrued interest and $0 of accrued penalties. There were no significant changes in components of the liability in the first three quarters of the current fiscal year.

Based on current information the Company does not expect any changes in the amount of unrecognized tax benefits over the next twelve months to have a significant impact on the results of operations or the financial position of the Company.

The Company s federal income tax returns for 2003 through 2007 are open tax years. State income tax returns are generally subject to examination for a period of three to five years after filing of the respective return. The state impact of any federal changes remains subject to examination by various states for a period of up to two years after formal notification to the states. The Company has various state income tax returns in the process of examination, administrative appeals or litigation. The Company s unrecognized tax benefits are related to state returns open from 1999 through 2007.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

PART I Financial Information

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations
FORWARD LOOKING STATEMENTS

In addition to historical information, this Quarterly Report on Form 10-Q includes certain forward-looking statements, as defined in the Securities Act of 1933 and the Securities Exchange Act of 1934, based on current management expectations. Actual results could differ materially from those management expectations. Such forward-looking statements include statements regarding the Company s intentions, beliefs or current expectations as well as the assumptions on which such statements are based. Stockholders and potential stockholders are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those contemplated by such forward-looking statements. Factors that could cause future results to vary from current management expectations include, but are not limited to: general economic conditions; legislative and regulatory changes; monetary fiscal policies of the federal government; changes in tax policies; rates and regulations of federal, state and local tax authorities; changes in interest rates; deposit flows; cost of funds; demand for loan products; demand for financial services; competition; changes in the quality or composition of the Company s loan and investment portfolios; changes in accounting principles; policies or guidelines and other economic, competitive, governmental and technological factors affecting the Company s operations, markets, products, services and fees. The Company undertakes no obligation to update or revise any forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results over time.

GENERAL

Washington Federal, Inc. (Company) is a savings and loan holding company. The Company s primary operating subsidiary is Washington Federal Savings.

INTEREST RATE RISK

The Company assumes a high level of interest rate risk as a result of its policy to originate and hold for investment fixed-rate single-family home loans, which are longer-term in nature than the short-term characteristics of its liabilities of customer accounts and borrowed money. At June 30, 2008, the Company had a negative one-year maturity gap of approximately 34% of total assets, a slight increase from the 33% negative one-year gap as of September 30, 2007. This increase was the result of the growth in single family residential loans, which are 30 year fixed rate, combined with a decrease in construction speculative loans and an increase in short term borrowings.

The interest rate spread increased to 2.69% at June 30, 2008 from 2.05% at September 30, 2007. The spread increased primarily due to two factors. First, falling short-term interest rates decreased the cost of customer deposits. Since the Federal Reserve began decreasing short-term rates in September 2007, market rates for short-term deposits have fallen. As a result, deposits are repricing to lower rates contributing to an increasing spread by reducing the rate paid on customer accounts. Second, the acquisition of First Mutual Bank (FMB) on February 1, 2008, which provided $1,042,959,000 of earning assets, at a weighted average rate of 7.23%. Additionally, the FMB acquisition brought $953,533,000 of paying liabilities, carrying a weighted average rate of 3.38%. As of the date of the FMB acquisition, FMB had a period end spread of 3.85%.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

PART I Financial Information

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

As of June 30, 2008, the weighted average rates on earning assets decreased by 20 basis points since September 30, 2007, while the weighted average rates on customer accounts and borrowings decreased by 84 basis points over the same period. As of June 30, 2008, the Company had grown total assets by $1,509,830,000, or 14.7%, from $10,285,417,000 at September 30, 2007. Cash and cash equivalents increased $8,693,000, or 14.2%, during the nine months ended June 30, 2008. Loans increased $1,237,596,000, or 15.1%, to $9,425,874,000 during the nine months ended June 30, 2008, as the Company grew long-term assets primarily through its acquisition of FMB. Cash and cash equivalents of $70,071,000 and stockholders equity of $1,368,394,000 provides management with flexibility in managing interest rate risk.

LIQUIDITY AND CAPITAL RESOURCES

The Company s net worth at June 30, 2008 was $1,368,394,000, or 11.60% of total assets. This was an increase of $50,267,000 from September 30, 2007 when net worth was $1,318,127,000, or 12.82% of total assets. The increase in the Company s net worth included $101,669,000 from net income and a $4,161,000 decrease in accumulated other comprehensive income as a result of a net decrease in market value of the Company s available-for-sale investments. The vast majority of the Company s available for sale investments are fixed rate. As a result of market interest rates increasing, the value of fixed rate investments generally decreased. Net worth was also reduced by $55,253,000 of cash dividend payments.

The Company had the option to pay either all cash for the acquisition of FMB or it could have issued up to 50% of the consideration in common stock. Based on relatively low market interest rates, a lower stock price than when the transaction was negotiated and management s evaluation of the current interest rate cycle, the Company elected to pay all cash for the FMB transaction.

The Company s percentage of net worth to total assets is over two times the minimum required under Office of Thrift Supervision regulations. Management believes this strong net worth position will help the Company manage its interest rate risk and enable it to compete more effectively for controlled growth through acquisitions, de novo expansion and increased customer deposits.

CHANGES IN FINANCIAL CONDITION

Available-for-sale and held-to-maturity securities: Available-for-sale securities increased $66,975,000, or 4.4%, during the nine months ended June 30, 2008, which included the purchase of $301,854,000 of available-for-sale investment securities. During the same period there were sales of $72,030,000 of available-for-sale securities. There were not any purchases or sales of held-to-maturity securities. As of June 30, 2008, the Company had net unrealized losses on available-for-sale securities of $17,193,000, net of tax, which were recorded as part of stockholders equity.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

PART I Financial Information

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

Loans receivable: During the quarter ended June 30, 2008, the balance of loans receivable increased 15.1% to $9,425,874,000 compared to $8,188,278,000 at September 30, 2007. This growth was due primarily to the FMB acquisition and is consistent with management s strategy to grow the loan portfolio to mitigate the decreasing weighted average rates on earning assets. The following table shows the loan portfolio by category for the last three quarters.

Loan Portfolio by Category

(In thousands)

	AS OF 12/31/07		AS OF 3/31/08		AS OF 6/30/08	
	AMOUNT	%	AMOUNT	%	AMOUNT	%
Single-family residential	$ 6,208,448	70.5%	$ 6,578,993	67.3%	$ 6,709,942	68.2%
Construction - speculative	668,292	7.6	630,531	6.4	548,376	5.6
Construction - custom	318,947	3.6	345,551	3.5	307,461	3.1
Land - acquisition & development	746,078	8.5	753,393	7.7	737,931	7.5
Land - consumer lot loans	158,475	1.8	213,543	2.2	214,674	2.2
Multi-family	564,195	6.4	696,301	7.1	692,963	7.0
Commercial real estate	103,018	1.2	278,018	2.8	264,599	2.7
Commercial & industrial	20,385	0.2	121,300	1.2	160,422	1.6
HELOC	16,821	0.2	59,712	0.6	68,638	0.7
Consumer	7,137	0.1	118,107	1.2	142,786	1.4
	8,811,796	100%	9,795,449	100%	9,847,792	100%
Less:						
ALL	29,370		47,005		54,059	
Loans in Process	387,913		385,544		330,556	
Deferred Net Origination Fees	38,699		38,183		37,303	
	455,982		470,732		421,918	
	$ 8,355,814		$ 9,324,717		$ 9,425,874	

The acquisition of FMB resulted in a slight diversification of the loan portfolio, decreasing single family residential from 70.5% of the portfolio at December 31, 2007, to 68.2% as of June 30, 2008, and increasing other categories such as commercial real estate, commercial and industrial loans, consumer loans and multi-family loans.

Non-performing assets: Non-performing assets increased significantly during the nine months ended June 30, 2008 to $85,107,000 from $15,931,000 at September 30, 2007, a 434% increase. This increase is attributable to the weakening housing market throughout our eight state branch network. Non-performing assets as a percentage of total assets was .72% at June 30, 2008 compared to .15% at September 30, 2007.

WASHINGTON FEDERAL, INC. AND SUBSIDIARIES

PART I Financial Information

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

During the last ten and twenty years the Company s average ratio of non-performing assets to total assets was .33% and .47%, respectfully. While our non-performing assets have increased significantly over the last 9 months based on current conditions in the real estate marketplace, the Company anticipates non-performing assets will continue to increase in the future based on current market conditions.

The following table sets forth information regarding restructured and nonaccrual loans and REO held by the Company at the dates indicated.

	June 30, 2008	September 30, 2007
	(In thousands)	
Restructured loans (1)	$ 2,663	$ 250
Nonaccrual loans:		
Single-family residential	21,783	9,820
Construction - speculative	28,668	2,446
Construction - custom	682	
Land - acquisition & development	8,743	1,809
Land - consumer lot loans		
Multi-family		148
Commercial real estate	1,862	253
Commercial & industrial	1,851	42
HELOC		
Consumer	641	
Total nonaccrual loans (2)	64,230	14,518
Total REO (3)	20,877	1,413
Total non-performing assets	$ 85,107	$ 15,931
Total non-performing assets and restructured loans	$ 87,770	$ 16,181
Total non-performing assets and restructured loans as a percentage of total assets	0.74%	0.16%

(1) Performing in accordance with restructured terms.

(2) The Company recognized interest income on nonaccrual loans of approximately $66,000 in the quarter ended June 30, 2008. Had these loans performed according to their original contract terms, the Company would have recognized interest income of approximately $2,480,000 for the quarter ended June 30, 2008.

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In addition to the nonaccrual loans reflected in the above table, at June 30, 2008, the Company had $81,837,000 of loans that were less than 90 days delinquent but which it had classified as substandard for one or more reasons. If these loans were deemed non-performing, the Company s ratio of total non-performing assets and restructured loans as a percent of total assets would have increased to 1.44% at June 30, 2008.

(3) Total REO (included in real estate held for sale on the Statement of Financial Condition) includes real estate held for sale acquired in settlement of loans or acquired from purchased institutions in settlement of loans.

Allocation of the allowance for loan losses: The following table shows the allocation of the Company s allowance for loan losses at the dates indicated.

	June 30, 2008		September 30, 2007	
	Amount	Loans to Total Loans [1]	Amount	Loans to Total Loans [1]
	(In thousands)			
Single-family residential	$ 15,072	68.2%	$ 10,083	69.4%
Construction - speculative	8,789	5.6	4,716	8.1
Construction - custom	931	3.1	1,163	3.8
Land - acquisition & development	9,675	7.5	4,506	8.6
Land - consumer lot loans	1,854	2.2	1,136	1.8
Multi-family	3,598	7.0	5,299	6.4
Commercial real estate	3,513	2.7	1,297	1.3
Commercial & industrial	2,136	1.6	320	0.3
HELOC	950	0.7		0.2
Consumer	7,541	1.4		0.1
	$ 54,059	100.0%	$ 28,520	100.0%

[1] The percentage is based on gross loans before allowance for loan losses, loans in process and deferred loan origination costs.

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Customer accounts: Customer accounts increased $1,177,217,000, or 19.6%, to $7,174,002,000 at June 30, 2008 compared with $5,996,785,000 at September 30, 2007. $744,182,000 of the deposit growth came through the FMB acquisition, the remaining $433,035,000 was organic growth. The following table shows the composition of our customer accounts as of the dates shown:

Deposits by Type

(In thousands)

	June 30, 2008		September 30, 2007	
	AMOUNT	%	AMOUNT	%
Checking (noninterest)	$ 131,502	1.8%	$ 88,732	1.5%
NOW (interest)	398,937	5.6	320,362	5.3
Savings (passbook/stmt)	191,361	2.7	198,876	3.3
Money Market	1,187,076	16.5	739,554	12.3
CD s	5,265,126	73.4	4,649,261	77.6
Total	$ 7,174,002	100.0%	$ 5,996,785	100.0%

FHLB advances and other borrowings: Total borrowings increased $280,767,000, or 9.9%, to $3,116,746,000 at June 30, 2008 compared with $2,835,979,000 at September 30, 2007. The increase in borrowings was due primarily to $180,985,000 in cash consideration paid for the FMB acquisition. Total short-term borrowings (due within 30 days) at June 30, 2008 were $315,000,000 compared with $275,000,000 at September 30, 2007. See Interest Rate Risk on page 10.

RESULTS OF OPERATIONS

Net Income: The quarter ended June 30, 2008 produced net income of $33,169,000 compared to $34,265,000 for the same quarter one year ago, a 3.2% decrease. The decrease for the quarter resulted primarily from the increase in the provision for loan losses.

Net income for the nine months ended June 30, 2008 was $101,669,000 compared to $101,132,000 for the same period one year ago, a 0.5% increase. The increase for the period resulted primarily from the growth in the balance sheet and growth in net interest income, both of which were offset by the significant increase in the provision for loan losses. See the Rate / Volume analysis below.

Net Interest Income: The largest component of the Company s earnings is net interest income, which is the difference between the interest and dividends earned on loans and other investments and the interest paid on customer deposits and borrowings. Net interest income is impacted primarily by two factors; first, the volume of earning assets and liabilities and second, the rate earned on those assets or the rate paid on those liabilities.

The following table sets forth certain information explaining changes in interest income and interest expense for the periods indicated compared to the same periods one year ago. For each category of interest-earning asset and interest-bearing liability, information is provided on changes attributable to (1) changes in volume (changes in volume multiplied by old rate) and (2) changes in rate (changes in rate multiplied by old volume). The change in interest income and interest expense attributable to changes in both volume and rate has been allocated proportionately to the change due to volume and the change due to rate.

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Rate / Volume Analysis:

	Comparison of Quarters Ended 6/30/08 and 6/30/07			Comparison of Nine Months Ended 6/30/08 and 6/30/07		
	Volume	Rate (In thousands)	Total	Volume	Rate (In thousands)	Total
Interest income:						
Loan portfolio	$ 26,807	$ (7,257)	$ 19,550	$ 68,512	$ (9,739)	$ 58,773
Mortgaged-backed securities	3,527	203	3,730	9,056	915	9,971
Investments(1)	(877)	(542)	(1,419)	(653)	(264)	(917)
All interest-earning assets	29,457	(7,596)	21,861	76,915	(9,088)	67,827
Interest expense:						
Customer accounts	11,943	(9,460)	2,483	29,720	(8,177)	21,543
FHLB advances and other borrowings	6,366	(1,233)	5,133	22,576	(1,821)	20,755
All interest-bearing liabilities	18,309	(10,693)	7,616	52,296	(9,998)	42,298
Change in net interest income	$ 11,148	$ 3,097	$ 14,245	$ 24,619	$ 910	$ 25,529

(1) Includes interest on cash equivalents and dividends on FHLB stock

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Provision for Loan Losses: The Company recorded a $13,216,000 provision for loan losses during the quarter ended June 30, 2008, while a $1,000,000 provision was recorded for the same quarter one year ago. Non-performing assets amounted to $85,107,000 or .72% of total assets at June 30, 2008 compared to $12,074,000 or .12% of total assets one year ago. The Company had net charge-offs of $6,162,000 for the quarter ended June 30, 2008 compared with $187,000 of net charge-offs for the same quarter one year ago. This significant increase in the provision for loan losses is in response to the overall deterioration in the housing market in the Company s eight western state territory, the material increase in net charge offs for the quarter and the added credit risk from the growth in the FMB portfolio.

The Company s believes that higher non-performing assets and charge-offs may continue going forward until the housing market begins to recover.

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The following table analyzes the Company s allowance for loan losses at the dates indicated.

	Quarter Ended June 30, 2008	Quarter Ended June 30, 2007	Nine Months Ended June 30, 2008	Nine Months Ended June 30, 2007
	(In thousands)			
Beginning balance	$ 47,005	$ 27,997	$ 28,520	$ 24,993
Charge-offs:				
Single-family residential	196		1,258	
Construction - speculative	2,206	190	3,767	452
Construction - custom				
Land - acquisition & development	3,041		3,125	23
Land - consumer lot loans	60		60	
Multi-family	25		25	34
Commercial real estate				
Commercial & industrial			14	
HELOC				
Consumer	634		1,109	
	6,162	190	9,358	509
Recoveries:				
Single-family residential				
Construction - speculative				
Construction - custom				
Land - acquisition & development				
Land - consumer lot loans				
Multi-family				
Commercial real estate				
Commercial & industrial		2		2
HELOC				
Consumer		1		1
		3		3
Net charge-offs	6,162	187	9,358	506
Provision for loan losses	13,216	1,000	23,716	1,200
Acquired reserves			11,181	3,123
Ending balance	$ 54,059	$ 28,810	$ 54,059	$ 28,810
Ratio of net charge-offs to average loans outstanding	0.07%	0.00%	0.11%	0.01%

Other Income: The quarter ended June 30, 2008 produced total other income of $7,560,000 compared to $5,230,000 for the same quarter one year ago, an increase of $2,330,000, primarily due to a $3,164,000 gain on the sale of real estate during the quarter.

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Other Expense: The quarter ended June 30, 2008 produced total other expense of $23,653,000 compared to $17,217,000 for the same quarter one year ago, a 37.4% increase. The increase in total other expense over the same comparable period one year ago was primarily the result of compensation and other direct costs related to the February 2008 acquisition of FMB, which operated historically with a significantly higher cost structure than Washington Federal. The Company has already reduced costs substantially and believes more savings may occur as the full integration occurs over time. Total other expense for the quarters ended June 30, 2008 and June 30, 2007 equaled .75% and .66%, respectively, of average assets. The number of staff, including part-time employees on a full-time equivalent basis, was 1,072 at June 30, 2008 and 898 at June 30, 2007; the increase primarily due to the acquisition of FMB.

Taxes: Income taxes decreased $892,000, or 4.7%, for the quarter ended June 30, 2008 when compared to the same period one year ago. This decrease was a result of lower pretax income. The effective tax rate for the quarter ended June 30, 2008 was 35.50%, compared to 35.85% for the same period one year ago.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Management believes that there have been no material changes in the Company s quantitative and qualitative information about market risk since September 30, 2007. For a complete discussion of the Company s quantitative and qualitative market risk, see Management s Discussion and Analysis of Financial Condition and Results of Operations in the Company s 2007 Form 10-K.

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PART I Financial Information

Item 4. Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the Company s President and Chief Executive Officer along with the Company s Executive Vice President and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures pursuant to the Securities Exchange Act of 1934 (Exchange Act) Rule 13a-15. Based upon that evaluation, the Company s President and Chief Executive Officer, along with the Company s Executive Vice President and Chief Financial Officer, concluded that the Company s disclosure controls and procedures are effective in timely alerting them to material information relating to the Company (including its consolidated subsidiaries) required to be included in the Company s periodic SEC filings. There have been no significant changes in the Company s internal controls or in other factors that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Disclosure controls and procedures are Company controls and other procedures that are designed to ensure that information required to be disclosed by the 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 the Company in the reports that it files under the Exchange Act is accumulated and communicated to the Company s management, including its President and Chief Executive Officer and Executive Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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PART II Other Information

Item 1. Legal Proceedings

From time to time the Company or its subsidiaries are engaged in legal proceedings in the ordinary course of business, none of which are considered to have a material impact on the Company s financial position or results of operations.

Item 1A. Risk Factors

Not applicable

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

The following table provides information with respect to purchases made by or on behalf of the Company of the Company s common stock during the three months ended June 30, 2008.

Period	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan (1)	Maximum Number of Shares That May Yet Be Purchased Under the Plan at the End of the Period
April 1, 2008 to April 30, 2008		$		2,888,314
May 1, 2008 to May 31, 2008				2,888,314
June 1, 2008 to June 30, 2008				2,888,314
Total				2,888,314

(1) The Company s only stock repurchase program was publicly announced by the Board of Directors on February 3, 1995 and has no expiration date. Under this ongoing program, a total of 21,956,264 shares have been authorized for repurchase.

Item 3. Defaults Upon Senior Securities

Not applicable

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PART II Other Information

Item 4. Submission of Matters to a Vote of Security Holders
Not applicable

Item 5. Other Information
Not applicable

Item 6. Exhibits

(a) Exhibits

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6 Stock-Based Compensation

Stock-based compensation was recognized as follows in the Condensed Statements of Operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Cost of revenue	$ 44,869	$ 35,632	$ 95,430	$ 70,700
General and administrative	254,329	1,023,645	450,175	1,225,892
Sales and marketing	108,532	131,339	220,493	271,604
Research and development	37,649	13,790	55,705	27,393
Total	$ 445,379	$ 1,204,406	$ 821,803	$ 1,595,589

As of June 30, 2017 we had $990,963 of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.4 years. As of June 30, 2017, we had $2,360,903 of unrecognized compensation cost related to unvested Restricted Stock Units (RSUs), which is expected to be recognized over a weighted-average period of 2.9 years.

The following table presents a summary of our stock-based compensation activity for the six months ended June 30, 2017:

	Stock Options	Restricted Stock Units
Outstanding beginning of period	1,482,204	159,646
Awards granted		70,984
Awards exercised/vested	(25,511)	(20,112)
Awards canceled	(11,750)	(4,318)
Outstanding end of period	1,444,943	206,200

7 Investments

Our investments consisted of corporate bonds that we have classified as available-for-sale and are summarized in the following tables:

	June 30, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,097,529	$ 2,711	$ 35,871	$ 6,064,369
International corporations	971,087	2,173	13,582	959,678
Total	$ 7,068,616	$ 4,884	$ 49,453	$ 7,024,047

	December 31, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,814,295	$ 385	$ 52,072	$ 6,762,608
International corporations	1,211,645	2,241	10,973	1,202,913
Total	$ 8,025,940	$ 2,626	$ 63,045	$ 7,965,521

Unrealized losses from the above investments for all periods presented are attributable to changes in interest rates. We do not believe any of these unrealized losses represent other-than-temporary impairments based on our evaluation of available evidence as of June 30, 2017.

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8 Fair Value Measurements

The fair value of our assets and liabilities subject to recurring fair value measurements are as follows:

	Fair Value at June 30, 2017			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Corporate bonds:				
U.S. corporations	$ 6,064,369	$	$ 6,064,369	$
International corporations	959,678		959,678	
Total	$ 7,024,047	$	$ 7,024,047	$

	Fair Value at December 31, 2016			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Corporate bonds:				
U.S. corporations	$ 6,762,608	$	$ 6,762,608	$
International corporations	1,202,913		1,202,913	
Total	$ 7,965,521	$	$ 7,965,521	$

Our corporate bonds are valued by a third-party custodian at closing prices from national exchanges or pricing vendors on the valuation date.

There were no transfers into or out of any Levels during the six months ended June 30, 2017 or the year ended December 31, 2016.

9 Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss, net of tax, for the three months ended June 30, 2017 and 2016 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balances at March 31, 2017	$	(31,669)
Gains, net		3,923
Reclassification realized in net earnings		1,417
Balances at June 30, 2017	$	(26,329)
Balances at March 31, 2016	$	(41,191)
Gains, net		2,054
Reclassification realized in net earnings		24,701
Balances at June 30, 2016	$	(14,436)

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The components of accumulated other comprehensive loss, net of tax, for the six months ended June 30, 2017 and 2016 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balances at December 31, 2016	$	(36,849)
Gains, net		6,047
Reclassification realized in net earnings		4,473
Balances at June 30, 2017	$	(26,329)
Balances at December 31, 2015	$	(55,285)
Gains, net		11,892
Reclassification realized in net earnings		28,957
Balances at June 30, 2016	$	(14,436)

10 Income Taxes

We recorded provisions for income tax (benefit) expense of $(8,360) and $16,123 for the three and six months ended June 30, 2017, respectively. Our effective tax rate was (2.4)% and 11.5% for the three and six months ended June 30, 2017, respectively. Our effective tax rates for the three and six months ended June 30, 2017 differed from the U.S. Federal statutory rate primarily due to research and development tax credits, domestic production activities deductions and a discrete items related to certain employee incentive stock options, partially offset by expense associated with employee incentive stock options, U.S. state tax expense and other permanent items.

We recorded provisions for income tax expense of $1,104,133 and $2,335,150 for the three and six months ended June 30, 2016, respectively. Our effective tax rate was 33.1% and 34.1% for the three and six months ended June 30, 2016, respectively. Our effective tax rates for the three and six months ended June 30, 2016 differed from the U.S. Federal statutory rate primarily due to discrete items recorded during the three months ended June 30, 2016, the domestic production activities deduction and research and development credits, partially offset by U.S. state tax expense.

As of June 30, 2017 and December 31, 2016, we have not identified or accrued for any uncertain tax positions. We are currently unaware of any uncertain tax positions that could result in significant payments, accruals or other material deviations in this estimate over the next 12 months.

We file tax returns in the United States Federal jurisdiction and many state jurisdictions. Our returns are not currently under examination by the Internal Revenue Service or other taxing authorities. The Company is subject to income tax examinations for our United States Federal and State income taxes for 2013 and subsequent years.

11 Segment, Customer and Geographic Information

We operate in one reportable segment which is the development, manufacture and sale of MRI compatible medical devices, related accessories and services for use by hospitals and acute care facilities during MRI procedures.

In the U.S., we sell our products through our direct sales force and outside of the U.S. we sell our products through distributors who resell our products to end users.

Revenue information by geographic region is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
United States	$ 4,842,913	$ 8,994,675	$ 9,159,807	$ 16,869,191
International	681,451	874,230	1,527,117	1,963,867
Total revenue	$ 5,524,364	$ 9,868,905	$ 10,686,924	$ 18,833,058

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Revenue information by type is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Devices:				
MRI Compatible IV Infusion Pump Systems	$ 3,279,228	$ 8,196,898	$ 6,281,839	$ 15,492,340
MRI Compatible Patient Vital Signs Monitoring Systems	399,322		789,024	
Total Devices Revenue	3,678,550	8,196,898	7,070,863	15,492,340
Disposable IV Sets and Services	1,845,814	1,672,007	3,616,061	3,340,718
Total revenue	$ 5,524,364	$ 9,868,905	$ 10,686,924	$ 18,833,058

Property and equipment, net, information by geographic region is as follows:

	June 30, 2017 (unaudited)	December 31, 2016
United States	$ 1,149,175	$ 1,112,382
International	560,351	343,767
Total property and equipment, net	$ 1,709,526	$ 1,456,149

Long-lived assets held outside of the United States consist principally of tooling, which is a component of property and equipment, net.

12 Commitments and Contingencies

Leases. In January 2014, we entered into a non-cancelable operating lease, commencing July 1, 2014, for a new manufacturing and headquarters facility in Winter Springs, Florida owned by Susi, LLC, an entity controlled by our President and CEO, Roger Susi. Pursuant to the terms of our lease for this property, the monthly base rent is $32,649, adjusted annually for changes in the consumer price index. Under the terms of the lease, we are responsible for property taxes, insurance and maintenance expenses. The term of the lease expires on May 31, 2019. Unless advance written notice of termination is timely provided, the lease will automatically renew for two successive terms of five years each beginning in 2019 and again in 2024, and thereafter, will be renewed for successive terms of one year each.

A summary of our non-cancelable operating lease commitments of June 30, 2017 is as follows:

Six months ending December 31, 2017	$	196,956
2018		392,599
2019		163,243
2020		
2021		
Total non-cancelable operating lease commitments	$	752,798

Rent expense under our operating leases was $101,520 and $101,180 for the three months ended June 30, 2017 and 2016, respectively, and $203,025 and $202,439 for the six month ended June 30, 2017 and 2016, respectively.

Leasehold improvements are amortized over the shorter of the initial lease term or the estimated useful life.

Purchase commitments. We had various purchase orders for goods or services totaling approximately $1,800,000 at June 30, 2017 and $3,700,000 at December 31, 2016. No amounts related to these purchase orders have been recognized in our balance sheet.

Legal matters. We may from time to time become party to various legal proceedings or claims that arise in the ordinary course of business.

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13 Common Stock

The table below summarizes our common stock activity (shares):

Balance, December 31, 2016	10,722,675
Option exercises	25,511
Vesting of restricted stock units, net of shares withheld for taxes	16,414
Treasury stock	(182,632)
Balance, June 30, 2017	10,581,968

14 Subsequent Event

On July 17, 2017, our Board of Directors approved a modification to the underwriters warrants originally issued pursuant to our initial public offering (IPO Warrants). This modification extends the expiration date of the IPO Warrants from July 17, 2017 to July 17, 2019 and revises the strike price from $8.125 to $10.05. The fair value of the amended IPO Warrants is $2.42 per share as measured using the Black-Scholes options pricing model. Related to this modification, we expect to recognize a $380,452 charge to earnings during our fiscal third quarter. As of July 17, 2017, IPO Warrants to purchase 181,600 shares of our common stock remain outstanding.

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

The following Management s Discussion and Analysis of Financial Condition (MD&A) supplements the MD&A in the Company s Annual Report filed on Form 10-K. The MD&A should be read in conjunction with the Risk Factors section of this Quarterly Report, our condensed financial statements and accompanying footnotes, the discussion of certain risks and uncertainties contained in Part II, Item 1A of this Quarterly Report, the Form 10-K and the cautionary information regarding forward-looking statements at the end of this section.

Some of the statements contained in this MD&A and elsewhere in this Quarterly Report are forward-looking statements that involve substantial risks and uncertainties. All statements other than historical facts contained in this report, including statements regarding our future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as believes, expects, anticipates, intends, estimates, may, will, continue, should, plan, predict, potential and other similar expressions. We have based these forward-looking statements on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Our actual results could differ materially from those anticipated in these forward-looking statements, which are subject to a number of risks, uncertainties and assumptions including, but not limited to the risks discussed in the Risk Factor section of this Quarterly Report.

Our Business

We develop, manufacture, market and distribute a Magnetic Resonance Imaging (MRI) compatible intravenous (IV) infusion pump system and a MRI compatible patient vital signs monitoring system and accessories and services relating to them.

We are a leader in the development of innovative MRI compatible medical devices and the only known provider of non-magnetic IV infusion pump systems that are specifically designed to be safe for use during MRI procedures. We were the first to develop an infusion delivery system that largely eliminates many of the dangers and problems present during MRI procedures. Standard infusion pumps contain magnetic and electronic components which can create radio frequency (RF) interference and are dangerous to operate in the presence of the powerful magnet that drives an MRI system. Our patented MRidium® MRI compatible IV infusion pump system has been designed with a non-magnetic ultrasonic motor, uniquely-designed non-ferrous parts and other special features in order to safely and predictably deliver anesthesia and other IV fluids during various MRI procedures. Our pump solution provides a seamless approach that enables accurate, safe and dependable fluid delivery before, during and after an MRI scan, which is important to critically-ill patients who cannot be removed from their vital medications, and children and infants who must generally be sedated in order to remain immobile during an MRI scan.

Each IV infusion pump system consists of an MRidium® MRI compatible IV infusion pump, non-magnetic mobile stand, proprietary disposable IV tubing sets and many of these systems contain additional optional upgrade accessories.

Our 3880 MRI compatible patient vital signs monitoring system (3880 Monitor) has been designed with non-magnetic components and other special features in order to safely and accurately monitor a patient s vital signs during various MRI procedures. The 3880 Monitor system operates dependably in magnetic fields up to 30,000 gauss, which means it can operate virtually anywhere in the MRI scanner room, including in very close proximity to the MRI scanner bore. Our 3880 Monitor has a compact, lightweight design allowing it to travel with the patient from their critical care unit, to the MRI and back, resulting in increased patient safety through uninterrupted vital signs monitoring and decreasing the amount of time critically ill patients are away from critical care units. Other MRI compatible patient vital signs monitors are large and heavy, creating workflow issues for users. The features of the IRADIMED 3880 Monitor include: wireless ECG with dynamic gradient filtering; wireless SpO2 using Masimo® algorithms; non-magnetic respiratory CO2; non-invasive blood pressure; patient temperature, and; optional advanced multi-gas anesthetic agent unit featuring continuous Minimum Alveolar Concentration measurements. The 3880 Monitor has an easy-to-use design and allows for the effective communication of patient vital signs information to clinicians.

We generate revenue from the one-time sale of MRI compatible medical devices and accessories, ongoing service contracts and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the United States and internationally.

We sell our MRI compatible products through our direct sales force in the U.S. and independent distributors internationally. We have distribution agreements for our products with 44 independent distributors selling our products internationally. We also enter into agreements with healthcare supply contracting companies in the U.S., which enable us to sell and distribute our MRidium MRI compatible IV infusion pump systems to their member hospitals. Under these agreements, we are required to pay these group purchasing organizations (GPOs) a fee of three percent of the sales of our products to their member hospitals. Our current GPO contracts effectively give us the ability to sell to more than approximately 95% of all U.S. hospitals and acute care facilities.

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During 2015, we began experiencing extended selling cycles for our medical devices; however, historical selling cycles for our devices varied widely and were typically three to six months in duration.

FDA Warning Letter

The FDA conducted a routine inspection of our prior facility between April 7 and April 16, 2014. This was the first FDA inspection of our facility since the voluntary product recall in August 2012 of certain infusion sets and the voluntary recall in July 2013 of our DERS software. The FDA issued a Form 483 on April 16, 2014 that identified eight observations. The majority of the observations related to procedural and documentation issues associated with the design, development, validation testing and documentation of software used in certain of our products. Other observations were related to the design validation of pump labeling, design analysis of tube stretching, procedures for post-market design review, and control and procedures related to handling certain reported complaints. We submitted a response to the Form 483 in May 2014 and June 2014 in which we described our proposed corrective and preventative actions to address each of the FDA s observations.

On September 2, 2014, we received a warning letter from the FDA related to this inspection (the Warning Letter). The Warning Letter stated that the FDA accepted as adequate several of our responses to Form 483 observations, identified two responses whose accuracy will be determined in the next scheduled inspection of our facility and identified issues for which our response was determined to be inadequate. The issues identified as inadequate concern our procedures for validating device design primarily related to software quality assurance.

Also, the Warning Letter raised a new issue. The Warning Letter stated that modifications made to software on our previously cleared infusion pumps, the MRidium 3860 and MRidium 3850, were significant and required submission of new premarket notifications under Section 510(k) (a 510(k) submission) of the FDC Act. These modifications were made over time. We believe they were insignificant and did not require premarket notification submissions. However, the FDA indicated that the modifications of the software for the MRidium 3860 and the software for the MRidium 3850 were significant modifications because they could significantly affect the safety or effectiveness of these devices. As a result, the Warning Letter states that the products being sold by us are adulterated and misbranded under the FDC Act. The Warning Letter also indicates that the MRidium 3860+ infusion pump requires separate FDA clearance from the MRidium 3860 and MRidium 3850.

The Warning Letter requested that we immediately cease activities that result in the misbranding or adulteration of the MRidium 3860 MRI infusion pump, MRidium 3850 MRI infusion pump, and the MRidium 3860+ MRI infusion pump, including the commercial distribution of the devices. We immediately complied with the Warning Letter and ceased sale and distribution of the identified products in the United States.

On September 4, 2014, we submitted to the FDA our initial response to the Warning Letter and on September 17, 2014 we sent an additional response that included supplemental information related to the Form 483 inspection observations for which the FDA considered our initial responses inadequate.

On November 25, 2014, we announced that we filed the 510(k) submission related to our MRidium 3860+ MRI IV infusion pumps and on December 12, 2014 we were notified that our 510(k) submission had been formally accepted for review by the FDA. On December 22, 2014, under FDA enforcement discretion, we announced that we resumed domestic distribution of our MRI compatible MRidium 3860+ MRI IV infusion pump systems, without the DERS option. On January 28, 2015, under FDA enforcement discretion, we announced that we resumed domestic distribution of our DERS option. On December 9, 2015, we met with the FDA to review responses to the agency s additional information letter.

On December 15, 2016, we received FDA 510(k) clearance for our MRidium 3860+ MRI IV infusion pump system, including the DERS software feature. We continue to pursue closure of the Warning Letter, however, as of June 30, 2017, the Warning Letter remains open.

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Financial Highlights and Outlook

Our revenue decreased $(4.4) million, or (44.0)%, to $5.5 million for the second quarter ended June 30, 2017, compared to $9.9 million for the second quarter of last year. Net income was $0.4 million, or $0.03 per diluted share, in the second quarter ended June 30, 2017, compared to $2.2 million, or $0.19 per diluted share, in the second quarter last year. During the second quarter of 2017, we recognized revenue on 92 pump systems, compared to 262 pump systems during the same period in 2016.

For the remainder of 2017, we expect our revenues to decrease, when compared to 2016, as we move beyond the benefits of the past three years of converting customers from our former competitor s IV pump to our MRI compatible IV infusion pump system and re-focus on penetrating the market of first-time adopters more deeply. We intend to continue targeting hospitals and acute care facilities that have yet to adopt our technology and penetrating the Intensive Care Unit, Emergency Room and other critical care locations within hospitals where there is a high probability that interventional radiology procedures will need to be performed on patients. Additionally, we expect to expand international sales of our new MRI compatible patient vital signs monitor throughout 2017 and plan to commence shipments of this device in the U.S. during the fourth quarter of 2017, if FDA clearance is received by that time. We expect higher full year 2017 operating expenses compared to 2016 due to higher sales and marketing, regulatory, research and development expenses and a one-time charge related to the modification of the underwriters warrants.

Application of Critical Accounting Policies

We prepare our financial statements in conformity with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and use assumptions that affect the reported amounts of assets, liabilities and related disclosures at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

We believe that the following critical accounting policies require the use of significant estimates, assumptions, and judgments.

- Revenue recognition
- Accounts receivable and allowance for doubtful accounts
- Inventory carried at the lower of cost or net realizable value
- Stock-based compensation
- Income taxes

These critical accounting policies are described in more detail in our Annual Report filed on Form 10-K, under *Management s Discussion and Analysis and Results of Operations.* Except as disclosed in Note 1 to the unaudited condensed financial statements contained herein related to the adoption of recent accounting pronouncements, there have been no changes to these policies during the three and six months ended June 30, 2017.

The use of different estimates, assumptions, and judgments could have a material effect on the reported amounts of assets, liabilities and related disclosures as of the date of the financial statements and revenue and expenses during the reporting period.

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Results of Operations

The following table sets forth selected statements of operations data as a percentage of total revenue for the periods indicated. Our historical operating results are not necessarily indicative of the results for any future period.

	Percent of Revenue Three Months Ended June 30,		Percent of Revenue Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	22.3	17.6	24.5	18.3
Gross profit	77.7	82.4	75.5	81.7
Operating expenses:				
General and administrative	39.6	31.3	40.2	28.4
Sales and marketing	24.0	14.3	25.2	14.3
Research and development	8.1	3.0	9.3	2.8
Total operating expenses	71.7	48.5	74.6	45.5
Income from operations	5.9	33.8	0.8	36.2
Other income (expense), net	0.4	(0.0)	0.5	0.1
Income before provision for income taxes	6.3	33.8	1.3	36.4
Provision for income tax (benefit) expense	(0.2)	11.2	0.2	12.4
Net income	6.5%	22.6%	1.2%	24.0%

Three and Six Months Ended June 30, 2017 and 2016

Revenue by Geographic Region

	Three Months Ended June 30,			Six Months Ended June 30,		
	2017	**2016**	**Change**	**2017**	**2016**	**Change**
United States	$ 4,842,913	$ 8,994,675	(46.2)%	$ 9,159,807	$ 16,869,191	(45.7)%
International	681,451	874,230	(22.1)%	1,527,117	1,963,867	(22.2)%
Total Revenue	$ 5,524,364	$ 9,868,905	(44.0)%	$ 10,686,924	$ 18,833,058	(43.3)%

Revenue by Type

Three Months Ended June 30,			Six Months Ended June 30,		
2017	**2016**	**Change**	**2017**	**2016**	**Change**

Devices:						
IV Infusion Pump Systems	$ 3,279,228	$ 8,196,898	(60.0)%	$ 6,281,839	$ 15,492,340	(59.5)%
Patient Vital Signs Monitoring Systems	399,322		NM	789,024		NM
Total Devices Revenue	3,678,550	8,196,898	(55.1)%	7,070,863	15,492,340	(54.4)%
Disposable IV Sets and Services	1,845,814	1,672,007	10.4%	3,616,061	3,340,718	8.2%
Total Revenue	$ 5,524,364	$ 9,868,905	(44.0)%	$ 10,686,924	$ 18,833,058	(43.3)%

For the three months ended June 30, 2017, revenue decreased $(4.4) million, or (44.0)%, to $5.5 million from $9.9 million for the same period in 2016. This decrease is primarily due to a decrease in the number of MRI compatible IV infusion pump systems that we recognized in revenue, partially offset by international sales of our MRI compatible patient vital signs monitors and a higher average selling price for our infusion pump systems resulting from a favorable product sales mix as we sold more higher priced optional pump features per pump sale on average in the second quarter 2017 compared to the second quarter 2016. During the three months ended June 30, 2017, we recognized revenue on 92 MRI compatible IV infusion pumps compared to 262 pumps for the same period in 2016. The average selling price of our MRI compatible IV infusion pump systems during the three months ended June 30, 2017 was approximately $35,600, compared to $31,100 for the same period in 2016.

For the three months ended June 30, 2017, revenue from sales in the U.S. decreased $(4.2) million, or (46.2)%, to $4.8 million from $9.0 million for the same period in 2016. Revenue from sales internationally decreased $(0.2) million, or (22.1)%, to $0.7 million for the three months ended June 30, 2017, from $0.9 million for the same period in 2016. International revenue for the three months ended June 30, 2017 included $0.4 million in sales of our MRI compatible patient vital signs monitoring systems. Domestic sales accounted for 87.7% of total revenue in the second quarter 2017, compared to 91.1% in the second quarter 2016.

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For the three months ended June 30, 2017, revenue from sales of devices decreased $(4.5) million, or (55.1)%, to $3.7 million from $8.2 million for the same period in 2016. Revenue from the devices for the three months ended June 30, 2017 included $0.4 million in sales of our MRI compatible patient vital signs monitoring systems.

For the three months ended June 30, 2017, revenue from sales of our disposable IV sets and services increased $0.1 million, or 10.4%, to $1.8 million from $1.7 million for the same period in 2016. We expect revenue from sales of disposables and services to increase relative to the sales of devices as the installed base of our MRI compatible IV infusion pumps systems increases.

For the six months ended June 30, 2017, revenue decreased $(8.1) million, or (43.3)%, to $10.7 million from $18.8 million for the same period in 2016. This decrease is primarily due to a decrease in the number of MRI compatible IV infusion pump systems that we recognized in revenue, partially offset by international sales of our MRI compatible patient vital signs monitors and a higher average selling price for our infusion pump systems resulting from a favorable product sales mix as we sold more higher priced optional pump features per pump sale on average in the first six months of 2017 compared to the same period in 2016. During the six months ended June 30, 2017, we recognized revenue on 179 MRI compatible IV infusion pumps compared to 437 pumps for the same period in 2016. The average selling price of our MRI compatible IV infusion pump systems during the six months ended June 30, 2017 was approximately $35,000, compared to $29,000 for the same period in 2016.

For the six months ended June 30, 2017, revenue from sales in the U.S. decreased $(7.7) million, or (45.7)%, to $9.2 million from $16.9 million for the same period in 2016. Revenue from sales internationally decreased $(0.5) million, or (22.2)%, to $1.5 million for the six months ended June 30, 2017, from $2.0 million for the same period in 2016. International revenue for the six months ended June 30, 2017 included $0.8 million in sales of our MRI compatible patient vital signs monitoring systems. Domestic sales accounted for 85.7% of total revenue in six months ended June 30, 2017, compared to 89.6% for the same period in 2016.

For the six months ended June 30, 2017, revenue from sales of devices decreased $(8.4) million, or (54.4)%, to $7.1 million from $15.5 million for the same period in 2016. Revenue from devices for the six months ended June 30, 2017 included $0.8 million in sales of our MRI compatible patient vital signs monitoring systems.

For the six months ended June 30, 2017, revenue from sales of our disposable IV sets and services increased $0.3 million, or 8.2%, to $3.6 million from $3.3 million for the same period in 2016. We expect revenue from sales of disposables and services to increase relative to the sales of devices as the installed base of our MRI compatible IV infusion pumps systems increases.

Cost of Revenue and Gross Profit

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Revenue	$ 5,524,364	$ 9,868,905	$ 10,686,924	$ 18,833,058
Cost of revenue	1,234,314	1,739,067	2,621,932	3,444,864
Gross profit	$ 4,290,050	$ 8,129,838	$ 8,064,992	$ 15,388,194
Gross profit percentage	77.7%	82.4%	75.5%	81.7%

For the three months ended June 30, 2017, cost of revenue decreased $(0.5) million, or (29.0)%, to $1.2 million from $1.7 million for the same period in 2016. Gross profit decreased $(3.8) million, or (47.2)%, to $4.3 million for the second quarter 2017 from $8.1 million for the same period in 2016. The decrease in cost of revenue and gross profit is primarily attributable to lower sales of our MRI compatible IV infusion pump systems. Gross profit margin was 77.7% for second quarter 2017, compared to 82.4% for the second quarter 2016. This is the result of unfavorable overhead absorption rates due to lower production output during the second quarter 2017 when compared to the second quarter 2016, unfavorable inventory cost adjustments, higher depreciation and amortization expense and higher international sales as a percent of total revenue when compared to the same period last year.

For the six months ended June 30, 2017, cost of revenue decreased $(0.8) million, or (23.9)%, to $2.6 million from $3.4 million for the same period in 2016. Gross profit decreased $(7.3) million, or (47.6)%, to $8.1 million for the six months ended June 30, 2017 from $15.4 million for the same period in 2016. The decrease in cost of revenue and gross profit is primarily attributable to lower sales of our MRI compatible IV infusion pump systems. Gross profit margin was 75.5% for the six months ended June 30, 2017, compared to 81.7% for the same period in 2016. This is the result of unfavorable overhead absorption rates due to lower production output during the six months ended June 30, 2017 when compared to the same period in 2016, higher depreciation and amortization expense and higher international sales as a percent of total revenue when compared to the same period last year.

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Operating Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
General and administrative	$ 2,189,925	$ 3,088,205	$ 4,297,182	$ 5,347,927
Percentage of revenue	39.6%	31.3%	40.2%	28.4%
Sales and marketing	$ 1,323,539	$ 1,409,758	$ 2,688,315	$ 2,692,807
Percentage of revenue	24.0%	14.3%	25.2%	14.3%
Research and development	$ 449,011	$ 291,822	$ 990,301	$ 526,157
Percentage of revenue	8.1%	3.0%	9.3%	2.8%

General and Administrative

For the three months ended June 30, 2017, general and administrative expense decreased $(0.9) million, or (29.1)%, to $2.2 million from $3.1 million for the same period last year. This decrease is primarily due to higher stock compensation expense during the second quarter 2016 resulting from the modification of awards granted to our previous chairman, lower GPO administration fees due to lower sales and lower legal and professional fees, partially offset by the write-off of non-trade accounts receivable.

For the six months ended June 30, 2017, general and administrative expense decreased $(1.0) million, or (19.6)%, to $4.3 million from $5.3 million for the same period last year. This decrease is primarily due to higher stock compensation expense during the six months ended June 30, 2016 resulting from the modification of awards granted to our previous chairman, lower GPO administrative fees due to lower sales and lower legal and professional fees, partially offset by the write-off of non-trade accounts receivable and higher payroll and employee benefits expense.

Sales and Marketing

For the three months ended June 30, 2017, sales and marketing expense decreased $(0.1) million, or (6.1)%, to $1.3 million from $1.4 million for the same period in 2016. This is primarily the result of lower sales commissions due to lower sales and lower employee recruiting expenses, partially offset by higher payroll expense due to higher headcount.

For the six months ended June 30, 2017 and 2016, sales and marketing expense was $2.7 million. This is primarily the result of lower sales commissions due to lower sales, lower stock compensation expense and lower employee recruiting expenses, offset by higher payroll expense.

Research and Development

For the three months ended June 30, 2017, research and development expense increased $0.2 million, or 53.9%, to $0.5 million from $0.3 million for the same period in 2016. This is primarily due to the capitalization of certain internally developed software costs during the three months ended June 30, 2016 associated with the development of our patient vital signs monitor, which had the effect of reducing expense in that period. There was no such capitalization of similar costs during the three months ended June 30, 2017. Additionally, the increase was also partially the result of higher payroll expense, which was partially offset by lower costs for outside engineering services.

For the six months ended June 30, 2017, research and development expense increased $0.5 million, or 88.2%, to $1.0 million from $0.5 million for the same period in 2016. This is primarily due to the capitalization of certain internally developed software costs during the six months ended June 30, 2016 associated with the development of our patient vital signs monitor, which had the effect of reducing expense in that period. There was no such capitalization of similar costs during the six months ended June 30, 2017. Additionally, the increase was also partially the result of higher payroll expense, which was partially offset by lower costs for outside engineering services.

Other Income, Net

Other income, net consists of interest income, foreign currency gains and losses, and other miscellaneous income. For the three months ended June 30, 2017, we reported other income of approximately $21,000 compared to other expense of approximately $4,700 for the same period in 2016. This increase is primarily due lower losses on the maturity of securities during the second quarter 2017 compared to the second quarter 2016.

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For the six months ended June 30, 2017 and 2016, we reported other income of approximately $51,000 and $27,000, respectively. This increase is primarily due to lower losses on the maturity of securities during the six months ended June 30, 2017 compared to the same period in 2016.

Income Taxes

We recorded provisions for income tax (benefit) expense of $(8,360) and $16,123 for the three and six months ended June 30, 2017, respectively. Our effective tax rate was (2.4)% and 11.5% for the three and six months ended June 30, 2017, respectively. Our effective tax rates for the three and six months ended June 30, 2017 differed from the U.S. Federal statutory rate primarily due to research and development tax credits, domestic production activities deductions and a discrete items related certain employee incentive stock options, partially offset by expense associated with employee incentive stock options, U.S. state tax expense and other permanent items.

We recorded provisions for income tax expense of $1.1 million and $2.3 million for the three and six months ended June 30, 2016, respectively. Our effective tax rate was 33.1% and 34.1% for the three and six months ended June 30, 2016, respectively. Our effective tax rates for the three and six months ended June 30, 2016 differed from the U.S. Federal statutory rate primarily due to discrete items recorded during the three months ended June 30, 2016, the domestic production activities deduction and research and development credits, partially offset by U.S. state tax expense.

As of June 30, 2017 and December 31, 2016, we have not identified or accrued for any uncertain tax positions. We are currently unaware of any uncertain tax positions that could result in significant payments, accruals or other material deviations in this estimate over the next 12 months.

We file tax returns in the United States Federal jurisdiction and many state jurisdictions. Our returns are not currently under examination by the Internal Revenue Service or other taxing authorities. The Company is subject to income tax examinations for our United States Federal and State income taxes for 2013 and subsequent years.

Liquidity and Capital Resources

Our principal sources of liquidity have historically been our cash and cash equivalents balances, our investments, cash flow from operations and access to the financial markets. Our principal uses of cash are operating expenses, working capital requirements, capital expenditures and share repurchases.

As of June 30, 2017, we had cash and cash equivalents and investments of $23.8 million, stockholders equity of $31.3 million, and working capital of $29.4 million. As of December 31, 2016, we had cash and cash equivalents and investments of $25.7 million, stockholders equity of $31.9 million, and working capital of $30.2 million.

We believe that our current cash and cash equivalents and any cash generated from operations will be sufficient to meet our ongoing operating requirements for at least the next 12 months. We do not anticipate requiring additional capital; however, if required or desirable, we may seek to obtain a credit facility, raise debt or issue additional equity in the private or public markets.

	Six Months Ended June 30,	
	2017	**2016**
Net cash provided by operating activities	$ 106,889	$ 3,761,870
Net cash provided by (used in) investing activities	528,333	(1,451,009)
Net cash used in financing activities	(1,548,476)	(9,613,117)

For the six months ended June 30, 2017, cash from operations decreased $(3.7) million to $0.1 million, compared to $3.8 million for the same period in 2016. This decrease was primarily the result of lower net income; higher net cash outflows related to accrued income taxes and accounts payable; partially offset by higher net cash inflows from accounts receivable, inventory and deferred revenue. The sum of our net income and certain non-cash expense items, such as stock compensation, the write-off of non-trade accounts receivable, depreciation and amortization was $1.4 million for the six months ended June 30, 2017 compared to $6.2 million for the same period last year.

Cash provided by investing activities was $0.5 million for the six months ended June 30, 2017, compared to cash used in investing activities of $1.5 million for the same period in 2016. During the six months ended June 30, 2017, we had cash inflows of $2.3 million related to the maturities of certain investments, which were partially offset by $1.3 million of cash used to purchase additional investments and $0.4 million of cash used to purchase property and equipment.

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Cash used in financing activities was $1.5 million for the six months ended June 30, 2017, compared to $9.6 million during the same period in 2016 and primarily relates to purchases of treasury stock. During the six months ended June 30, 2017, we purchased $1.6 million of treasury stock, compared to $10.0 million during the same period in 2016.

We market our products to end users in the United States and to distributors internationally. Sales to end users in the United States are generally made on open credit terms. Management maintains an allowance for potential credit losses.

Our manufacturing and headquarters facility has been leased from Susi, LLC, an entity controlled by our President and CEO, Roger Susi. Pursuant to the terms of our lease, the monthly base rent is $32,649, adjusted annually for changes in the consumer price index.

Off-Balance Sheet Arrangements

Under our amended and restated bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences arising as a result of the officer or director serving in such capacity. We have a director and officer liability insurance policy that limits our exposure under these indemnifications and enables us to recover a portion of any future loss arising out of them. In addition, in the normal course of business, we enter into contracts that contain indemnification clauses whereby the Company indemnifies our customers against damages associated with product failures. We have obtained liability insurance providing coverage that limits our exposure for these indemnified matters. Based on our historical experience and the estimated probability of future loss, we have determined that the estimated fair value of these indemnities is not material to our financial position or results of operations and have not recorded a liability for these agreements as of June 30, 2017. We had no other off-balance sheet arrangements during the six months ended June 30, 2017 or for the year ended December 31, 2016 that had, or are reasonably likely to have, a material effect on our financial condition, results of operations, or liquidity.

Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations and commercial commitments since December 31, 2016.

Recent Accounting Pronouncements

See Note 1 to the unaudited condensed financial statements contained herein for a full description of recent accounting pronouncements including the respective expected dates of adoption and status of evaluation of expected effects on results of our operations and financial condition.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange Risk

We have foreign currency risks related to our revenue and operating expenses denominated in currencies other than the U.S. dollar, principally the Japanese yen (Yen). The volatility of the Yen depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income as a result of transaction gains (losses) related to revaluing Yen denominated accounts payable balances. In the event our Yen denominated accounts payable or expenses increase, our operating results may be affected by fluctuations in the Yen exchange rate. If the U.S. Dollar uniformly increased or decreased in strength by 10% relative to the Yen, our net income would have correspondingly increased or decreased by an immaterial amount for the three and six months ended June 30, 2017 and 2016.

Interest Rate Risk

When able, we invest excess cash in bank money-market funds, corporate debt securities or discrete short-term investments. The fair value of our cash equivalents and short-term investments is sensitive to changes in the general level of interest rates in the U.S., and the fair value of these investments will decline if market interest rates increase. As of June 30, 2017, we had $7.0 million in corporate bonds, with $1.0 million that matures in less than 1 year, $5.1 million that matures between 1 and 3 years and $0.9 million that matures between 3 and 5 years. These corporate bonds have fixed interest rates and semi-annual interest payment dates. If market interest rates were to change by 100 basis points from levels at June 30, 2017, we expect the corresponding change in fair value of our investments would be approximately $124,000. This is based on sensitivity analyses performed on our financial position as of June 30, 2017. Actual results may differ as our analysis of the effects of changes in interest rates does not account for, among other things, sales of securities prior to maturity and repurchase of replacement securities, the change in mix or quality of the investments in the portfolio, and changes in the relationship between short-term and long-term interest rates.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. 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 such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We may from time to time become party to various legal proceedings or claims that arise in the ordinary course of business. Our management reviews these matters if and when they arise and believes that the resolution of any such matters currently known will not have a material effect on our results of operations or financial position.

Item 1A. Risk Factors

Risks Relating to Our Business and Financial Condition

Our financial performance is significantly dependent on a single product, and disruptions in our ability to sell this product may have a material adverse effect on our business.

Our current revenue and profitability is significantly dependent on the sale of the MRidium 3860+ MRI compatible IV infusion pump system and the ongoing sale of disposable tubing sets. Sales of the MRidium 3860+ MRI compatible IV infusion pump system have historically comprised a substantial majority of our net revenue. Our near-term revenue and profitability will, accordingly, be dependent upon our ability to successfully market and sell this Class II medical device.

In the past, the FDA has issued us a Warning Letter that impacted our ability to commercially distribute our products. Although we have resumed commercial distribution of our product, the Warning Letter remains open and there can be no guarantee that the FDA will not take similar action in the future. The FDA could require us to cease shipment of our products, notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue further warning letters or untitled letters, refuse our request for 510(k) submission or premarket approval, revoke existing 510(k) clearances or premarket approvals previously granted, impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us.

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The MRidium 3860+ MRI compatible IV infusion pump could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including:

- entrance of new competitors into our markets;
- technological developments such as new imaging modalities which render MRI procedures obsolete or reduce the instances where MRI imaging is utilized;
- loss of key relationships with suppliers, group purchasing organizations, or end-user customers;
- manufacturing or supply interruptions;
- product liability claims;
- our reputation and product market acceptance; and
- product recalls or safety alerts.

Any major factor adversely affecting the sale of our MRidium 3860+ MRI compatible IV infusion pump would cause our revenues to decline and have a material adverse impact on our business, financial condition and our common stock.

We have been subject to securities class action litigation and derivative litigation and we may be subject to similar or other litigation in the future.

In the past, following adverse action by the FDA or volatility in our stock price, securities class action litigation has been brought against us. There can be no assurance that we will not face other securities litigation in the future. With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuits. A decision adverse to our interests on these actions or resulting from these matters could result in the payment of substantial damages and could have a material adverse effect on our business, financial condition and our common stock. Regardless of the outcome, these claims may result in injury to our reputation, significant costs, diversion of management s attention and resources, and loss of revenue.

There is no assurance that our internal and external sources of liquidity will at all times be sufficient for our cash requirements.

We must have sufficient sources of liquidity to fund our working capital requirements, our capital improvement plans, and execute on our strategic initiatives. Our recent operating losses have limited our capital resources, and could worsen if we are unable to increase revenues or adjust our costs appropriately. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plan, pursuing additional financing to the extent available, reducing capital expenditures, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

Our continued success depends on the integrity of our supply chain, including multiple single-source suppliers, the disruption of which could negatively impact our business.

Many of the component parts of our products are obtained through supply agreements with third parties. Some of these parts require our partners to engage in complex manufacturing processes. In light of our dependence on third-party suppliers, several of which are single-source suppliers, we are subject to inherent uncertainties and risks related to their ability to produce parts on a timely basis, to comply with product safety and other regulatory requirements and to provide quality parts to us at a reasonable price.

For example, we are dependent upon a single vendor for the ultrasonic motor at the core of our MRidium MRI compatible IV infusion pump. If this vendor fails to meet our volume requirements, which we anticipate will increase over time, or if the vendor becomes unable or unwilling to continue supplying motors to us, this would impact our ability to supply our pumps to customers until a replacement source is secured. Our executed agreement with this vendor provides that the price at which we purchase products from the vendor is determined by mutual agreement from time to time or should material costs change. Although we have had a long history of stable pricing with this supplier, this provision may make it difficult for us to continue to receive motors from this vendor on favorable terms or at all if we do not agree on pricing in the future. In such event, it could materially and adversely affect our commercial activities, operating results and financial condition.

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In the near term, we do not anticipate finding alternative sources for our primary suppliers, including single source suppliers. Therefore, if our primary suppliers become unable or unwilling to manufacture or deliver materials, we could experience protracted delays or interruptions in the supply of materials which would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

Additionally, any failure by us to forecast demand for, or to maintain an adequate supply of raw materials or finished products, could result in an interruption in the supply of certain products and a decline in our sales.

We rely on third-party suppliers for certain of our raw materials and components.

We rely on unaffiliated third-party suppliers for certain raw materials and components necessary for the manufacturing and operation of our products. Certain of those raw materials and components are proprietary products of those unaffiliated third-party suppliers and are specifically cited in our applications with regulatory agencies so that they must be obtained from that specific sole source or sources and could not be obtained from another supplier unless and until an appropriate application amendment is approved by the regulatory agency. For example, the non-magnetic ultra-sonic motor which drives our MRI compatible IV infusion pump is sole-sourced from a major multinational Japanese manufacturing company.

Among the reasons we may be unable to obtain these raw materials and components include:

- a supplier s inability or unwillingness to continue supplying raw materials and/or components;

- regulatory requirements or action by regulatory agencies or others, including changes in international trade treaties and/or tariffs;

- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;

- unexpected demand for or shortage of raw materials or components;

- failure to comply with quality standards which results in quality and product failures, product contamination and/or recall;

- discovery of previously unknown or undetected imperfections in raw materials or components;

- labor disputes or shortages, including from the effects of health emergencies and natural disasters; and

- political instability and actual or anticipated military or political conflicts.

These events could negatively impact our ability to satisfy demand for our products, which could have a material adverse effect on our product use and sales and our business and results of operations. We may experience these or other shortages in the future resulting in delayed shipments, supply constraints, contract disputes and/or stock-outs of our products.

The manufacture of our products requires strict adherence to regulatory requirements governing medical devices and if we or our suppliers encounter problems our business could suffer.

The manufacture of our pumps and products must comply with strict regulatory requirements governing Class II medical devices in the U.S. and other regulatory requirements in foreign locations. Problems may arise during manufacturing, quality control, storage or distribution of our products for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, manufacturing quality concerns, or problems with raw materials, electromechanical, software and other components, supplier issues, and natural disasters. If problems arise during production of our pump, the batch may have to be discarded. Manufacturing problems or delays could also lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, voluntary recalls, corrective actions or product liability related costs may also be incurred. Should we encounter difficulties in the manufacture of our products or be subject to a product recall, our business could suffer materially.

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We manufacture and store our products at a single facility in Florida.

We manufacture and store our products at a single facility in Winter Springs, Florida. If by reason of fire, hurricane or other natural disaster, or for any other reason, the facility is destroyed or seriously damaged or our access to it is limited, our ability to provide products to our customers would be seriously interrupted or impaired and our operating results and financial condition would be negatively affected.

Our inability to collect on our accounts receivables held by significant customers may have an adverse effect on our business operations and financial condition.

We market our products to end users in the United States and to distributors internationally. Sales to end users in the United States are generally made on open credit terms. Management maintains an allowance for potential credit losses. From time to time, we have had accounts receivables from one or two customers that accounted for 10% or more of our gross accounts receivable. As a result, we may be exposed to a certain level of concentration of credit risk. If a major customer experiences financial difficulties, the effect on us could be material and have an adverse effect on our business, financial condition and results of operations.

If we fail to maintain relationships with GPOs, sales of our products could decline.

Our ability to sell our products to U.S. hospitals, acute care facilities and outpatient imaging centers depends in part on our relationships with group purchasing organizations (GPOs). Many existing and potential customers for our products are members of GPOs. GPOs negotiate pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. We pay the GPOs an administrative fee in the form of a percentage of the volume of products sold to their affiliated hospitals and other members. If we are not an approved provider selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products. Should a GPO negotiate a sole source or bundling contract covering a future competitor s products, we may be precluded from making sales to members of that GPO for the duration of the contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. In the future, if another competitive supplier emerges, and we fail to keep our relationships and develop new relationships with GPOs, our competitive position would likely suffer.

Cost-containment efforts of our customers and purchasing groups could adversely affect our sales and profitability.

Our MRI compatible IV infusion pumps are considered capital equipment by many potential customers, and hence changes in the budgets of healthcare organizations and the timing of spending under these budgets and conflicting spending priorities can have a significant effect on the demand for our products and related services. Any decrease in expenditures by these healthcare facilities could decrease demand for our products and related services and reduce our revenue. Additionally, changes to reimbursement policies by third-party payors could also decrease demand for our products and related services and reduce our revenue.

Any failure in our efforts to educate clinicians, anesthesiologists, radiologists, and hospital administrators regarding the advantages of our products could significantly limit our product sales.

Our future success will require us to educate a sufficient number of clinicians, anesthesiologists, radiologists, hospital administrators and other purchasing decision-makers about our products and the costs and benefits of MRI compatible IV infusion pump systems. If we fail to demonstrate the safety, reliability and economic benefits of our products to hospitals and acute medical facilities, our products may not be adopted and our expected and actual sales would suffer.

The lengthy sales cycle for the MRidium 3860+ MRI compatible IV infusion pump could delay our sales.

The decision-making process of customers is often complex and time-consuming. Based on our experience, we believe the period between initial discussions concerning the MRidium 3860+ MRI compatible IV infusion pump and a purchase of a unit was three to six months. We are currently experiencing sales cycles beyond historical patterns resulting from the implementation of a sales strategy that targets more departments within the hospitals we focus our sales efforts. Sales cycles can also be delayed as a result of capital budgeting procedures. Moreover, even if one or two units are sold to a hospital, we believe that it will take additional time and experience with the MRidium 3860+ MRI compatible IV infusion pump before other medical professionals routinely use the MRidium 3860+ MRI compatible IV infusion pump for other procedures and in other departments of the hospital. Such time would delay potential sales of additional units and disposable tubing or additional optional accessories to that medical facility or hospital. These delays could have an adverse effect on our business, financial condition and results of operations.

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Because we rely on distributors to sell our products outside of the U.S., our revenues could decline if our existing distributors do not continue to purchase products from us or if our relationship with any of these distributors is terminated.

We rely on distributors for all of our sales outside the U.S. and hence do not have direct control over foreign sales activities. These distributors also assist us with regulatory approvals and the education of physicians and government agencies. Our revenues outside the U.S. have historically represented approximately one-tenth to one-third of our net revenues. If our existing international distributors fail to sell our products or sell at lower levels than we anticipate, we could experience a decline in revenues or fail to meet our forecasts. We cannot be certain that we will be able to attract new international distributors nor retain existing ones that market our products effectively or provide timely and cost-effective customer support and service. None of our existing distributors are obligated to continue selling our products.

If we do not successfully develop and commercialize enhanced products or new products that remain competitive, we could lose revenue opportunities and customers, and our ability to achieve growth would be impaired.

The medical device industry is characterized by rapid product development and technological advances, which places our products at risk of obsolescence. Our long-term success depends upon the development and successful commercialization of new products, new or improved technologies and additional applications for non-magnetic infusion technology. The research and development process is time-consuming and costly and may not result in products or applications that we can successfully commercialize. If we do not successfully adapt our technology, products and applications, we could lose revenue opportunities and customers. In addition, we may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our markets and continue to grow our business.

We are highly dependent on our founder, CEO, President, Chairman and controlling shareholder, Roger Susi.

Roger Susi developed our MRidium MRI compatible IV infusion pump system, and we believe that he will play a significant role in our continued success and in the development of new products. Our current and future operations could be adversely impacted if we were to lose his services. Accordingly, our success will be dependent on appropriately managing the risks related to executing a succession plan for Mr. Susi on a timely basis.

If we fail to attract and retain the talent required for our business, our business could be materially harmed.

Competition for highly skilled personnel is often intense in the medical device industry, and more specifically in the MRI compatible medical device industry. A number of our executives and employees are former employees of Invivo Corporation, where Mr. Susi developed the first MRI compatible patient monitoring system. If our current employees with experience in the MRI compatible device industry leave our company, we may have difficulty finding replacements with an equivalent amount of experience and skill, which could harm our operations. Our future success will also depend in part on our ability to identify, hire and retain additional personnel, including skilled engineers to develop new products, and executives to oversee our marketing, sales, customer support and production staff. We may not be successful in attracting, integrating or retaining qualified personnel to meet our current growth plans or future needs. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively.

We may also have difficulty finding and retaining qualified Board members. Any failure to do so could be perceived negatively and could adversely affect our business.

Also, to the extent we hire personnel from competitors, we may be subject to allegations that we have improperly solicited, or that they have divulged proprietary or other confidential information, or that their former employers own their inventions or work product.

We may be unable to scale our operations successfully.

We are working to expand our size and scale via more penetration of existing markets and the launch of new complementary products. This growth, if it occurs as planned, will place significant demands on our management and manufacturing capacity, as well as our financial, administrative and other resources. We cannot guarantee that any of the systems, procedures and controls we put in place will be adequate to support the manufacture and distribution of our products. Our operating results will depend substantially on the ability of our officers and key employees to manage changing business conditions and to implement and improve our financial and administrative systems and manage other resources. If we are unable to respond to and manage changing business conditions, or the scale of our products, services and operations, then the quality of our services, our ability to retain key personnel and our business could be harmed.

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We engage in related party transactions, which result in a conflict of interest involving our management.

We have engaged in the past, and continue to engage, in related party transactions, particularly between our company and Roger Susi and his affiliates. The only significant ongoing related party transaction is the lease agreement between our company and Susi, LLC, an affiliate of Roger Susi, with respect to our sole production and headquarters facility in Winter Springs, Florida. Related party transactions present difficult conflicts of interest, could result in disadvantages to our company and may impair investor confidence, which could materially and adversely affect us. Related party transactions could also cause us to become materially dependent on related parties in the ongoing conduct of our business, and related parties may be motivated by personal interests to pursue courses of action that are not necessarily in the best interests of our company and our stockholders.

Any acquisitions of technologies, products and businesses, may be difficult to integrate, could adversely affect our relationships with key customers, and/or could result in significant charges to earnings.

We plan to periodically review potential acquisitions of technologies, products and businesses that are complementary to our products and that could accelerate our growth. However, our company has never completed an acquisition and there can be no assurance that we will be successful in finding any acquisitions in the future. The process of identifying, executing and realizing attractive returns on acquisitions involves a high degree of uncertainty. Acquisitions typically entail many risks and could result in difficulties in integrating operations, personnel, technologies and products. If we are not able to successfully integrate our acquisitions, we may not obtain the advantages and synergies that the acquisitions were intended to create, which may have a material adverse effect on our business, results of operations, financial condition and cash flows, our ability to develop and introduce new products and the market price of our stock.

The environment in which we operate makes it increasingly difficult to accurately forecast our business performance.

Significant changes and volatility in global financial markets, in consumer and business environments, and our general competitive landscape may make it increasingly difficult for us to predict our revenues and earnings into the future. Our quarterly sales and profits depend substantially on the volume and timing of orders fulfilled during the quarter, and such orders are difficult to forecast. Product demand is dependent upon the capital spending budgets of our customers and prospects as well as government funding policies, and matters of public policy as well as product and economic cycles that can affect the spending decisions of these entities. As a result, any revenue, earnings or financial guidance or outlook which we have given or might give may turn out to be inaccurate. Though we will endeavor to give reasonable estimates of future revenues, earnings and financial information at the time we give such guidance, based on then-current conditions, there is a significant risk that such guidance or outlook will turn out to be incorrect. Historically, companies that have overstated their operating guidance have suffered significant declines in their stock price when such results are announced to the public.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with United States GAAP. Furthermore, portions of GAAP require the use of fair value models which are variable in application and methodology from appraiser to appraiser. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and operating results.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such assumptions and estimates include those related to revenue recognition, accruals for product returns, valuation of inventory, impairment of intangibles and long-lived assets, accounting for income taxes and stock-based compensation and allowances for uncertainties.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as discussed in greater detail in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations. Our actual operating results may differ and fall below our assumptions and the financial forecasts of securities analysts and investors, resulting in a significant decline in our stock price.

Risks Related to Our Industry

We are subject to substantial government regulation that is subject to change and could force us to make modifications to how we develop, manufacture, market and price our products.

The medical device industry is regulated extensively by governmental authorities, principally the FDA in the U.S. and corresponding state and foreign regulatory agencies. The majority of our manufacturing processes are required to comply with quality systems regulations, including current good manufacturing practice requirements that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. Failure to comply with

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applicable medical device regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspensions of production, refusal of the FDA or other regulatory agencies to grant pre-market clearances or approvals for our products, withdrawals or suspensions of future current clearances or approvals and criminal prosecution.

In addition, our products are subject to pre-approval requirements by the FDA and similar international agencies that govern a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations may be time consuming, burdensome and expensive for us. The failure to obtain, or the loss or suspension of any such pre-approval, would negatively affect our ability to sell our products, and harm our anticipated revenues.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we sell our products in foreign countries, we may be subject to rigorous regulation in the future. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated revenue.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or other necessary approvals to commercially distribute new products, our ability to maintain profitability or grow will suffer.

Our current products are Class II medical devices and hence require regulatory pre-market approval by the FDA and other federal and state authorities prior to their sale in the U.S. Similar approvals are required by foreign governmental authorities for sale of our products outside of the U.S. We are responsible for obtaining the applicable regulatory approval for the commercial distribution of our products. As part of our strategy, we plan to seek approvals for new MRI compatible products. The process of obtaining approvals, particularly from the FDA, is costly and time consuming, and there can be no assurance that we will obtain the required approvals on a timely basis, or at all. Failure to receive approvals for new products will hurt our ability to grow.

We are subject to risks associated with doing business outside of the U.S.

Sales to customers outside of the U.S. have historically comprised of approximately one-tenth to one-third of our net revenues and we expect that non-U.S. sales will contribute to future growth. However, our expectation of revenue from outside the U.S. over the next twelve months is on the low end of our historical averages. A majority of our international sales originate from Europe and Japan, and we also make sales in Canada, Hong Kong, Australia, Mexico and certain parts of the Middle East. The risks associated with operations outside the United States include:

- foreign regulatory and governmental requirements that could change and restrict our ability to manufacture and sell our products;

- possible failure to comply with anti-bribery laws such as the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions;

- foreign currency fluctuations that can impact our financial statements when foreign denominations are translated into U.S. dollars;

- different local product preferences and product requirements;

- trade protection and restriction measures under international trade treaties and via tariffs, and import or export licensing requirements;

- difficulty in establishing, staffing and managing non-U.S. operations;

- failure to maintain relationships with distributors, especially those who have assisted with foreign regulatory or government clearances;

- changes in labor, environmental, health and safety laws;

- potentially negative consequences from changes in or interpretations of tax laws;

- political instability and actual or anticipated military or political conflicts;

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- economic instability, inflation, deflation, recession or interest rate fluctuations;

- uncertainties regarding judicial systems and procedures; and

- minimal or diminished protection of intellectual property.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition.

We may incur product liability losses, or become subject to other lawsuits related to our products, business, and insurance coverage could be inadequate or unavailable to cover these losses.

Our business is subject to potential product liability risks that are inherent in the design, development, manufacture and marketing of our medical devices and consumable products. We carry third party product liability insurance coverage to protect against such risks, but there can be no assurance that our policy is adequate. In the ordinary course of business, we may become the subject of product liability claims and lawsuits alleging that our products have resulted or could result in an unsafe condition or injury to patients. Any product liability claim brought against us, with or without merit, could be costly to defend and could result in settlement payments and adjustments not covered by or in excess of our product liability insurance. We currently have third-party product liability insurance with maximum coverage of $3,000,000; however, such coverage requires a substantial deductible that we must pay before becoming eligible to receive any insurance proceeds. The deductible amount is currently equal to $25,000 per occurrence and $125,000 in the aggregate. We will have to pay for defending product liability or other claims that are not covered by our insurance. These payments could have a material adverse effect on our profitability and financial condition. Product liability claims and lawsuits, safety alerts, recalls or corrective actions, regardless of their ultimate outcome, could have a material adverse effect on our business, financial condition, reputation and on our ability to attract and retain customers. In addition, we may not be able to obtain insurance in the future on terms acceptable to us or at all.

Defects or failures associated with our products and/or our quality control systems could lead to the filing of adverse event reports, recalls or safety alerts

and negative publicity and could subject us to regulatory actions.

Safety problems associated with our products could lead to a product recall or the issuance of a safety alert relating to such products and result in significant costs and negative publicity. An adverse event involving one of our products could require us to file an adverse event report with the FDA. Such disclosure could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals or clearances.

We may also voluntarily undertake a recall of our products or temporarily shut down production lines based on internal safety, quality monitoring and testing data. For example, in August 2012, we initiated a voluntary recall of a particular lot of MRidium Series 1000 MR Infusion Sets, Type 1058 MR IV, an extension set used with our MRidium MRI compatible IV infusion pumps, due to an out-of-specification dimension of one section of the IV set. We retrieved and destroyed all unused infusion sets subject to the recall. In July 2013, the FDA notified us that it had concluded its audit and confirmed that the recall was considered terminated. In July 2013, we issued a voluntary recall of our MRI compatible IV infusion pump systems equipped with MRidium 1145 DERS Drug Library due to their potential risk in providing an incorrect recommended value for the infusion rate during the pump s initial infusion setup. To avoid future product recalls we have made and continue to invest in our quality systems, processes and procedures. We will continue to make improvements to our products and systems to further reduce issues related to patient safety.

However, there can be no assurance our systems will be sufficient. Future quality concerns, whether real or perceived, could adversely affect our operating results.

Our products or product types could be subject to negative publicity, which could have a material adverse effect on our financial position and results of operations and could cause the market value of our common stock to decline.

The market s perception of our products could be harmed if any of our products or similar products offered by others in our industry become the subject of negative publicity due to a product safety issue, withdrawal, recall, or are proven or are claimed to be harmful to patients. The FDA Warning Letter may harm the market perception of our company and products. The harm to market perception may have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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Recent U.S. healthcare policy changes, including the Affordable Care Act and PPACA, may have a material adverse effect on our financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), enacted in 2010, implemented changes that are expected to significantly impact the medical device industry. Beginning on January 1, 2013, the Affordable Care Act imposed a 2.3% excise tax on sales of products defined as medical devices by the regulations of the FDA. We believe that all of our medical products are medical devices within the meaning of the FDA regulations. While this tax has been suspended by legislation for 2016 and 2017, it s return thereafter (or earlier) and potential increases from the 2.3% level in future years would negatively impact our operating results.

Other significant measures contained in the PPACA include research on the comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial payments to and arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA established an Independent Payment Advisory Board (IPAB), to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including treatments and procedures which incorporate use of our products. The IPAB proposals may impact payments for treatments and procedures that use our technology beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our products.

In addition, it is possible that changes in administration policy, including the potential repeal of all or parts of the PPACA, resulting from recent U.S. presidential actions and congressional legislative efforts could result in additional proposals and continued developments with respect to healthcare reform. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We are subject to healthcare fraud and abuse regulations that could result in significant liability, require us to change our business practices and restrict our operations in the future.

We and our customers are subject to various U.S. federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in healthcare programs such as Medicare and Medicaid, and Veterans Administration health programs and health programs outside the U.S. These laws and regulations are broad in scope and are subject to evolving interpretations, which could require us to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our sales, profitability and financial condition. Furthermore, since many of our customers rely on reimbursement from Medicare, Medicaid and other governmental programs to cover a substantial portion of their expenditures, if we or our customers are excluded from such programs as a result of a violation of these laws, it could have an adverse effect on our results of operations and financial condition. We have developed and implemented business practices and processes to train our personnel to perform their duties in compliance with healthcare fraud and abuse laws and conduct informal oversight to detect and prevent these types of fraud and abuse. However, we lack formal written policies and procedures at this time. If we are unable to formally document and implement the controls and procedures required in a timely manner or we are otherwise found to be in violation of such laws, we might suffer adverse regulatory consequences or face criminal sanctions, which could harm our operations, financial reporting or financial results.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We intend to adopt policies for compliance with these anti-bribery laws, which often carry substantial penalties.

We cannot assure you that our internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by our affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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We and our suppliers and customers are required to obtain regulatory approvals to comply with FDA regulations applicable to medical devices and infusion pumps, and these approvals could result in delays or increased costs in developing new products.

In December 2014, the FDA issued guidance entitled Infusion Pumps Total Product Life Cycle. This guidance established substantial additional pre-market requirements for new and modified infusion pumps. Through this guidance, the FDA indicated more data demonstrating product safety will be required for future 510(k) submissions for infusion pumps, including the potential for more clinical and human factors data. The process for obtaining regulatory approvals to market infusion pumps and related accessories have become more costly and time consuming. The impact of this guidance is likely to result in a more time consuming and costly process to obtain regulatory clearance to market infusion pumps. In addition, new requirements could result in longer delays for the clearance of new products, modification of existing infusion pump products or remediation of existing products in the market. Future delays in the receipt of, or failure to obtain, approvals could result in delayed or no realization of product revenues.

We and our suppliers and customers are required to maintain compliance with FDA regulations applicable to medical devices and infusion pumps, and it could be costly to comply with these regulations and to develop compliant products and processes. Failure to comply with these regulations could subject us to sanctions and could adversely affect our business.

Even if we are able to obtain approval for introducing new products to the market, we and our suppliers may not be able to remain in compliance with applicable FDA and other material regulatory requirements once clearance or approval has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, off-label marketing, advertising and post-marketing reporting, adverse event reports and field alerts. Compliance with these FDA requirements is subject to continual review and is monitored through periodic inspections by the FDA. For example, the FDA conducted routine inspections of our facility in Winter Springs, Florida in July 2016. The FDA issued a Form 483 on July 18, 2016 resulting from an inspection of our facility between July 11 and July 18, 2016 that identified three observations. This was the first FDA inspection of our facility since the receipt of the Warning Letter. During this inspection, updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the

FDA determined that no further actions were necessary in response to the Warning Letter.

As a result of the July 2016 inspection, the FDA issued a Form 483 on July 18, 2016 that identified three observations. These observations were related to procedural and documentation issues associated with the CAPA system, vendor requirements and complaint investigation.

We submitted responses to the Form 483 in August 2016 and October 2016 in which we described our proposed corrective and preventative actions to address each of the observations. As part of our response, on October 13, 2016 we initiated a customer follow up to our August 2012 Safety Alert, and made available an updated instruction card for customers. This action is ongoing until the majority of customers have confirmed receipt of this instruction card.

As of June 30, 2017, the Warning Letter remains open.

In addition, manufacturing flaws, component failures, design defects, off-label uses or inadequate disclosure of product related information could result in an unsafe condition or the injury or death of a patient. All of these events could harm our sales, margins and profitability in the affected periods and may have a material adverse effect on our business. Any adverse regulatory action or action taken by us to maintain appropriate regulatory compliance, with respect to these laws and regulations could disrupt our business and have a material adverse effect on our sales, profitability and financial condition. Furthermore, an adverse regulatory action with respect to any of our products or operating procedure or to our or our suppliers manufacturing facility could materially harm our reputation in the marketplace.

Our operations are subject to environmental laws and regulations, with which compliance is costly and which exposes us to penalties for non-compliance.

Our business, products, and product candidates are subject to federal, state, and local laws and regulations relating to the protection of the environment, worker health and safety and the use, management, storage, and disposal of hazardous substances, waste, and other regulated materials. These environmental laws and regulations could require us to pay for environmental remediation and response costs at third-party locations where we dispose of or recycle hazardous substances. The costs of complying with these various environmental requirements, as they now exist or as may be altered in the future, could adversely affect our financial condition and results of operations.

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Risks Relating to our Intellectual Property

Our success depends on our ability to protect our intellectual property.

We intend to rely on a combination of patents, trademarks, trade secrets, know-how, license agreements and contractual provisions to establish and protect our proprietary rights to our technologies and products. We cannot guarantee that the steps we have taken or will take to protect our intellectual property rights will be adequate or that they will deter infringement, misappropriation or violation of our intellectual property. We may fail to secure patents that are important to our business, and we cannot guarantee that any pending U.S. trademark or patent application, if ultimately issued, will provide us some relative competitive advantage. Litigation may be necessary to enforce our intellectual property rights and to determine the validity and scope of our proprietary rights.

Any litigation could result in substantial expenses and may not adequately protect our intellectual property rights. In addition, the laws of some of the countries in which our products may in the future be sold may not protect our products and intellectual property to the same extent as U.S. laws, or at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. If our trade secrets become known, we may lose our competitive advantages.

Even if we are able to secure necessary patents in the U.S., we may not be able to secure necessary patents and trademarks in foreign countries in which we sell our products or plan to sell our products. In March 2013, the U.S. transitioned to a first inventor to file system for patents in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to a patent. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, inter parties review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

Our unpatented trade secrets, know-how, confidential and proprietary information, and technology may be inadequately protected.

We rely on unpatented trade secrets, know-how and technology. This intellectual property is difficult to protect, especially in the medical device industry, where much of the information about a product must be submitted to regulatory authorities during the regulatory approval process. We seek to protect trade secrets, confidential information and proprietary information, in part, by entering into confidentiality and invention assignment agreements with employees, consultants, and others. These parties may breach or terminate these agreements, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other confidential or proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets and our other confidential and proprietary information, we or our collaboration partners, board members, employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

There is a risk that our trade secrets and other confidential and proprietary information could have been, or could, in the future, be shared by any of our former employees with, and be used to the benefit of, any company that competes with us.

If we fail to maintain trade secret protection or fail to protect the confidentiality of our other confidential and proprietary information, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secret protections against them, which could have a material adverse effect on our business.

There can be no assurance of timely patent review and approval to minimize competition and generate sufficient revenues.

There can be no assurance that the Patent and Trademark Office will have sufficient resources to review our patent applications in a timely manner. Consequently, even if our patent applications are ultimately successful, our patent applications may be delayed, which would prevent intellectual property protection for our products. If we fail to successfully commercialize our products due to the lack of intellectual property protection, we may be unable to generate sufficient revenues to meet or grow our business according to our expected goals and this may have a materially adverse effect on our profitability, financial condition, and operations.

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We may become involved in patent litigation or other intellectual property proceedings relating to our future product approvals, which could result in liability for damages or delay or stop our development and commercialization efforts.

The medical device industry has been characterized by significant litigation and other proceedings regarding patents, patent applications, and other intellectual property rights. The situations in which we may become parties to such litigation or proceedings may include any third parties (which may have substantially greater resources than we have) initiating litigation claiming that our products infringe their patent or other intellectual property rights; in such case, we will need to defend against such proceedings.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, or using products that use the disputed intellectual property;

- obtain a license from the intellectual property owner to continue selling, making, licensing, or using products, which license may require substantial royalty payments and may not be available on reasonable terms, or at all;

- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; or

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible.

If any of the foregoing events occur, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition. As the number of participants in our industry grows, the possibility of intellectual property infringement claims against us increases.

Furthermore, the costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

In the event that a competitor infringes upon our patent or other intellectual property rights, enforcing those rights may be costly, difficult, and time-consuming. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time-consuming and could divert our management s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patent or other intellectual property rights against a challenge. If we are unsuccessful in enforcing and protecting our intellectual property rights and protecting our products, it could materially harm our business.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an at-risk launch). The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. An adverse decision could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

In addition, we may indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

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We may be subject to claims that we, our board members, employees or consultants have used or disclosed alleged trade secrets or other proprietary information belonging to third parties and any such individuals who are currently affiliated with one of our competitors may disclose our proprietary technology or information.

As is commonplace in the medical device industry, some of our board members, employees and consultants are or have been associated with other medical device companies that compete with us. For example, Mr. Susi and a number of our other employees are former employees of Invivo Corporation. While associated with such other medical device companies, these individuals may have been exposed to research and technology similar to the areas of research and technology in which we are engaged. We may become subject to future claims that we, our employees, board members, or consultants have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of those companies. Litigation may be necessary to defend against such claims.

We have entered into confidentiality agreements with our executives and key consultants. However, we do not have, and are not planning to enter into, any confidentiality agreements with our non-executive directors because they have a fiduciary duty of confidentiality as directors.

There is the possibility that any of our former board members, employees, or consultants who are currently or who may be employed at, or associated with, one of our competitors may unintentionally or willfully disclose our proprietary technology or information.

Risks Related to Ownership of Our Common Stock

Our common stock price has been and will likely continue to be subject to significant fluctuations and volatility, and you may be unable to sell your shares at a fair price, or at all.

Our stock could be subject to wide fluctuations in price in response to various factors, including the following:

- a lack of liquidity in the public trading of our common stock;

- the commercial success or failure of our key products;
- delayed or reduced orders from our customers;
- manufacturing or supply interruptions;
- changes or developments in laws or regulations applicable to our products and product candidates;
- introduction of competitive products or technologies;
- poorly executed acquisitions or acquisitions whose projected potential is not realized;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed our own estimates and projections or the estimates and projections of securities analysts or investors;
- new or revised earnings estimates or guidance by us or securities analysts or investors;
- varying economic and market conditions in the U.S.;
- negative developments impacting the medical device industry in general and changes in the market valuations of

companies deemed similar to us;

- negative developments concerning our sources of manufacturing supply;

- disputes or other developments relating to patents, trademarks or other proprietary rights;

- litigation or investigations involving us, our industry, or both;

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- issuances of debt, equity or convertible securities at terms deemed unfavorable by the market;

- major catastrophic events;

- sales of large blocks of our stock;

- exercise of the underwriters warrant that may lead to sales that put downward pressure on our stock price;

- changes in our Board of Directors, management or key personnel; or

- the other factors described in this Risk Factors section.

Any one of the factors above, or the cumulative effect of some of the factors referred to above, may result in significant fluctuations in our quarterly or annual operating results, fluctuations in our share price and investors perception of our business. If we fail to meet or exceed such expectations, our business and stock price could be materially adversely affected.

Our use of capital to repurchase shares of our common stock could have a material adverse effect on our stock price and our business.

Since we announced a stock repurchase programs in 2016 and 2017, we have used a significant amount of cash to repurchase shares of common stock of our company. As part of our strategy, we intend to opportunistically repurchase additional shares of common stock from time to time at prices that we believe are attractive. There can be no assurance that we will be able to repurchase shares on favorable terms or that, if we do repurchase shares, that such repurchases will increase shareholder value. Additionally, if we use a significant portion of our capital to repurchase shares, our financial flexibility will be reduced and we may be not be able to execute on other strategic initiatives or tolerate periods of operating losses. If we repurchase shares on unfavorable terms or if our use of capital to repurchase shares inhibits our ability to pursue other strategic initiatives or tolerate periods of operating losses, it could have a material adverse effect on our stock price and our business.

Future sales of our common stock may cause our stock price to decline.

On September 26, 2014, we filed a registration statement under Form S-8 to register all of the shares issuable upon exercise of options outstanding or reserved for future issuance under our equity compensation plans. In addition, on December 3, 2015 we filed a registration statement on Form S-3/A to register $40 million of shares of common stock that may be offered or sold by us. On December 18, 2015, Roger Susi sold 1,200,000 shares of our Common stock for his own account in a secondary offering pursuant to the registration statement on Form S-3/A. If any of the foregoing shares are sold by the Company or by selling stockholders, or if it is perceived that they will be sold, the trading price of our common stock could decline.

We may need or choose to raise additional capital in the future, which could result in dilution to our stockholders and adversely affect stock price.

While we believe that our cash and investment balances and prospective cash flow from our operations will provide us with adequate capital to fund operations for at least the next 12 months, we may need or choose to raise additional funds prior to that time. We may seek to sell additional equity or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If additional funds are raised through the issuance of debt securities or preferred stock, these securities could have rights that are senior to holders of common stock and any debt securities could contain covenants that would restrict our operations. The sale of such securities could hurt demand for our common stock and lead our share price to decline.

Roger Susi, who serves as our Chairman of the Board of Directors and an executive officer, owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Roger Susi, our founder, who serves as our Chairman of the Board of Directors, President and Chief Executive Officer, and his affiliates beneficially owns a majority of our outstanding common stock. Mr. Susi is able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. He may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

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Mr. Susi s majority ownership also qualifies our company as a controlled company and allows us to opt out of compliance with numerous corporate governance listing requirements.

In addition, we qualify for the controlled company exemption under the corporate governance rules of the NASDAQ Stock Market until such a time as Mr. Susi does not control a majority of our outstanding common stock. As a controlled company, we would be permitted to opt out of compliance with the requirements that a majority of our board of directors consist of independent directors, that our Board of Directors compensation committee be comprised solely of independent directors, and that director nominees be selected or recommended to the Board of Directors for selection by independent directors. Notwithstanding the availability of these exemptions, we have elected not to rely upon any of the exemptions afforded to a controlled company under NASDAQ rules. A majority of our Board of Directors is comprised of independent directors, our compensation committee is comprised solely of independent directors, and our director nominees are recommended for selection to our Board of Directors by a majority of our independent directors in a vote in which only independent directors may participate. Our compliance is voluntary, however, and there can be no assurance that we will continue to comply with these standards in the future. We no longer require as a matter of policy that our Chairman of the Board be an independent director.

We do not intend to pay dividends for the foreseeable future.

We do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Investors seeking cash dividends should not purchase our common stock.

Accordingly, if you purchase shares, realization of a gain on your investment will depend solely on the appreciation of the price of our common stock, which may never occur.

The requirements of being a public company may strain our resources, divert management s attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. As a result, management s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may need to hire more employees in the future or engage outside consultants to monitor and advise us regarding compliance, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are investing additional resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected.

We believe that being a public company and compliant with these new rules and regulations has made it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of being a public company, we are obligated to establish and maintain adequate internal controls. Failure to develop and maintain adequate internal controls or to implement new or improved controls could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal controls over financial reporting are

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designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. We are developing the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act of 2002. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls are effective.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until the date we are no longer an emerging growth company as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future.

Our business practices have become more visible as a public company, and this could impact our competitive environment and our risk of potential litigation.

As a result of disclosure of information in filings required of a public company, our business and financial condition have become more visible potentially exposing us to new competition and threatened or actual litigation, including by competitors and other third parties. New competition could result in reduced sales of our products and adversely impact our profitability. If lawsuits prevail against us, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

We may and have become involved in securities class action litigation that could divert management s attention from our business and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices of small capitalization medical device companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this Risk Factors section, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. We have become, and may in the future, become involved in this type of litigation. Litigation is expensive and could divert management s attention and resources from our primary business, which could adversely affect our operating results. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require us to make significant payments. Such payment could have a material impact on how investors view our company and result in a decline in our stock price.

We are an emerging growth company, and we are not certain if the reduced reporting requirements applicable to emerging growth companies has made our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and intend to take advantage of certain exemptions from various reporting requirements. We cannot predict if investors will respond negatively to our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

As an emerging growth company we have also chosen to take advantage of certain provisions of the JOBS Act that allow us to provide you with less information in our public filings than would otherwise be required. As a result it may be more difficult for you to evaluate an investment in our company.

If securities or industry analysts fail to initiate research coverage of our stock, downgrade our stock, or discontinue coverage, our trading volume might be reduced and our stock price could decline.

The trading market for our common stock depends, in part, on the research reports that securities or industry analysts publish about our business. If securities or industry analysts do not commence or continue coverage of our company, trading market for our stock may not be robust and the price of our stock could likely be negatively impacted. In the event securities or industry analysts initiate coverage, and later downgrade our stock or discontinue such coverage, our stock price could decline.

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Our charter documents and Delaware law have provisions that may discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our charter documents, as well as provisions of the Delaware General Corporation Law (DGCL), could depress the trading price of our common stock by making it more difficult for a third party to acquire us at a price favorable to our shareholders. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval to defend against a takeover attempt; and

- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. We are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our common stock.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

Not Applicable.

Item 3. Default Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information

Not Applicable.

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Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description of Document
10.1+	Employment Agreement Between the Registrant and John McCreery dated March 28, 2017 (incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K (File No. 001-36534), filed on March 30, 2017).
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 I.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* This exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

+ Indicates a management contract or compensatory plan or arrangement.

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IRADIMED CORPORATION

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.

IRADIMED CORPORATION

Dated: August 4, 2017

/s/ Roger Susi
By: Roger Susi
Its: Chief Executive Officer and President (Principal Executive Officer and Authorized Officer)

/s/ Chris Scott
By: Chris Scott
Its: Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)