IRADIMED CORP
Form 10-Q
August 05, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended June 30, 2016

OR

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

For the transition period from to

Commission File No.: 001-36534

IRADIMED CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**73-1408526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number
1025 Willa Springs Drive **Winter Springs, Florida**	**32708**
(Address of principal executive offices)	(Zip Code)

(407) 677-8022

(Registrant s telephone number, including area code)

N/A

(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 o

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

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

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

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

The registrant had 10,672,600 shares of common stock, par value $0.0001 per share, outstanding as of July 31, 2016.

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IRADIMED CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

IRADIMED CORPORATION

CONDENSED BALANCE SHEETS

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,065,858	$ 19,368,114
Accounts receivable, net of allowance for doubtful accounts of $65,220 as of June 30, 2016 and $31,672 as of December 31, 2015	5,789,495	3,863,632
Investments	8,081,274	7,602,204
Inventory, net	2,946,314	2,383,158
Prepaid expenses and other current assets	247,663	320,529
Prepaid income taxes	292,793	273,968
Deferred income taxes	320,587	141,446
Total current assets	29,743,984	33,953,051
Property and equipment, net	1,219,672	905,622
Intangible assets, net	747,633	193,243
Deferred income taxes	498,403	88,398
Other assets	138,970	103,893
Total assets	$ 32,348,662	$ 35,244,207
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,180,810	$ 1,005,460
Accrued payroll and benefits	1,056,037	1,288,248
Other accrued taxes	20,493	30,687
Warranty reserve	36,082	34,081
Deferred revenue	462,264	529,867
Other current liability	108,317	
Accrued income taxes	36,782	
Total current liabilities	2,900,785	2,888,343
Deferred revenue	978,269	422,839
Total liabilities	3,879,054	3,311,182
Stockholders equity:		
Common stock; $0.0001 par value; 31,500,000 shares authorized; 10,667,475 shares issued and outstanding as of June 30, 2016 and 11,175,125 shares issued and outstanding as of December 31, 2015	1,124	1,118
Additional paid-in capital	21,283,957	19,332,023
Retained earnings	17,168,431	12,655,169
Treasury stock	(9,969,468)	
Accumulated other comprehensive loss	(14,436)	(55,285)
Total stockholders equity	28,469,608	31,933,025
Total liabilities and stockholders equity	$ 32,348,662	$ 35,244,207

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 9,868,905	$ 7,609,143	$ 18,833,058	$ 14,600,848
Cost of revenue	1,739,067	1,422,027	3,444,864	2,750,207
Gross profit	8,129,838	6,187,116	15,388,194	11,850,641
Operating expenses:				
General and administrative	3,088,205	1,985,269	5,347,927	3,953,287
Sales and marketing	1,409,758	1,104,682	2,692,807	2,193,378
Research and development	291,822	403,447	526,157	745,748
Total operating expenses	4,789,785	3,493,398	8,566,891	6,892,413
Income from operations	3,340,053	2,693,718	6,821,303	4,958,228
Other (expense) income, net	(4,669)	46,135	27,109	92,951
Income before provision for income taxes	3,335,384	2,739,853	6,848,412	5,051,179
Provision for income taxes	1,104,133	969,282	2,335,150	1,793,113
Net income	$ 2,231,251	$ 1,770,571	$ 4,513,262	$ 3,258,066
Net income per share:				
Basic	$ 0.21	$ 0.16	$ 0.41	$ 0.30
Diluted	$ 0.19	$ 0.15	$ 0.37	$ 0.27
Weighted average shares outstanding:				
Basic	10,778,673	10,974,448	10,937,311	10,940,525
Diluted	11,966,289	12,107,707	12,138,856	12,068,122

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Net income	$ 2,231,251	$ 1,770,571	$ 4,513,262	$ 3,258,066
Other comprehensive income (loss):				
Change in fair value of available-for-sale securities, net of tax expense (benefit) of $2,373 and $(8,249) for the three months ended June 30, 2016 and 2015, respectively, and $8,431 and $(2,464) for the six months ended June 30, 2016 and 2015, respectively	2,054	(13,398)	11,892	(4,002)
Realized loss on available-for-sale securities reclassified to net income, net of tax benefit of $14,097 and $0 for the three months ended June 30, 2016 and 2015, respectively, and $16,718 and $0 for the six months ended June 30, 2016 and 2015, respectively	24,701		28,957	
Other comprehensive income (loss)	26,755	(13,398)	40,849	(4,002)
Comprehensive income	$ 2,258,006	$ 1,757,173	$ 4,554,111	$ 3,254,064

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30,	
	2016	**2015**
Operating activities:		
Net income	$ 4,513,262	$ 3,258,066
Adjustments to reconcile net income to net cash provided by operating activities:		
Bad debt expense	33,548	58,666
Provision for excess and obsolete inventory	86,610	42,156
Depreciation and amortization	122,744	106,264
Excess tax benefit on the exercise of stock options	(266,094)	(162,240)
Stock-based compensation	1,595,589	582,085
Impairment of intangible assets		55,433
Loss on maturity of investments	46,753	
Changes in operating assets and liabilities:		
Accounts receivable	(1,959,411)	(2,359,135)
Inventory	(649,766)	(124,866)
Prepaid expenses and other current assets	68,582	133,004
Other assets	(30,793)	(17,332)
Deferred income taxes	(614,295)	(330,989)
Accounts payable	175,350	306,116
Accrued payroll and benefits	(232,211)	(199,949)
Other accrued taxes	(10,194)	(52,785)
Warranty reserve	2,001	31,255
Deferred revenue	487,827	993,558
Other current liabilities	108,317	
Accrued income taxes, net of prepaid income taxes	284,051	420,090
Net cash provided by operating activities	3,761,870	2,739,397
Investing activities:		
Purchases of investments	(2,762,917)	
Proceeds from maturity of investments	2,303,092	
Purchases of property and equipment	(424,047)	(121,415)
Capitalized intangible assets	(567,137)	(5,904)
Net cash used in investing activities	(1,451,009)	(127,319)
Financing activities:		
Proceeds from stock option exercises	90,257	199,060
Income tax benefits credited to equity	266,094	162,240
Purchases of treasury stock	(9,969,468)	
Net cash (used in) provided by financing activities	(9,613,117)	361,300
Net (decrease) increase in cash and cash equivalents	(7,302,256)	2,973,378
Cash and cash equivalents, beginning of period	19,368,114	9,454,150
Cash and cash equivalents, end of period	$ 12,065,858	$ 12,427,528
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 2,665,393	$ 1,802,000

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

Notes to Unaudited Condensed Financial Statements

1 Basis of Presentation

The accompanying interim condensed financial statements of IRADIMED CORPORATION (IRADIMED , the Company , we , our) have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally presented in annual financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The interim financial information is unaudited, but reflects all normal adjustments that are, in the opinion of management, necessary for the fair presentation of our financial position, results of operations and cash flows for the interim periods presented. Operating results for the three and six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

These accompanying interim condensed financial statements should be read with the financial statements and related footnotes to financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015. The accounting policies followed in the preparation of these interim condensed financial statements are consistent in all material respects with those described in Note 1 of our 10-K.

Certain prior year amounts have been reclassified to conform to current year presentation.

FDA Matters

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 Dose Error Reduction System (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 relating 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.

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On March 24, 2016, we received a letter dated March 23, 2016 that our 510(k) submission was denied with a finding of non-substantial equivalence. This finding was due to a lack of human factors data demonstrating that our DERS was adequately validated and that we may resubmit a new 510(k) application with data showing our infusion pump to be substantially equivalent to similar devices in the market. Specifically, the agency stated that two of fifty-six test subjects in our human factors tests unintentionally bypassed the DERS feature, thus avoiding the DERS hard dose limits that healthcare institutions can program into our MRI compatible MRidium 3860+ infusion pumps. On April 7, 2016, we submitted an appeal to this determination to a higher level within the FDA. On May 2, 2016, we met with the FDA to review our appeal. On June 2, 2016, we received FDA s written response to our appeal. In this response, FDA reinstated the subject 510(k) and we have been granted another 180 days to make certain specified changes to several messages displayed by the infusion pump. Specifically, changes to messages the infusion pump displays to clarify whether the DERS is active or inactive and to better describe the over and under range indications. Further, the FDA s response also stated that no additional human factors usability testing is required.

We continue to work with the FDA to fully resolve the Warning Letter and complete the review of the 510(k) submission. See the *Legal matters* portion of Note 12.

Certain Significant Risks and Uncertainties

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.

Recent Accounting Pronouncements

In June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, Financial Instruments Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. This update replaces the current impairment methodology by requiring entities to use a forward-looking approach based on expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates on certain types of financial instruments, including trade receivables. This update is effective for annual periods beginning after December 15, 2019, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2020. Early adoption is permitted. We are evaluating this guidance and have not yet determined the effect it will have on our financial statements and related disclosures, if any.

In March 2016, the FASB issued ASU 2016-09, Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the recognition of excess tax benefits and deficiencies, the classification of excess tax benefits on the statement of cash flows, classification of awards as either equity or liabilities and an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur. This update is effective for annual and interim periods beginning after December 15, 2016, which will require us to adopt these provisions in the first quarter of 2017. Early adoption is permitted. We are in the process of determining the method and date of adoption and assessing the impact of the update on our financial statements and footnote disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This update requires lessees to recognize, on the balance sheet, assets and liabilities for the rights and obligations created by all leases not considered short-term leases. For short-term leases, lessees may elect an

accounting policy by class of underlying assets under which right-of-use assets and lease liabilities are not recognized and lease payments are generally recognized as expense over the lease term on a straight-line basis. The accounting by lessors will remain largely unchanged from current U.S. GAAP. This update is effective for annual periods beginning after December 15, 2018, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2019. Early adoption is permitted. We are in the process of determining the method and date of adoption and assessing the impact of the update on our financial condition and results of operations.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in the update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2017. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The amendments in this update may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. We do not expect the adoption of this guidance will have a material impact upon our statement of financial position.

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In July 2015, the FASB issued ASU 2015-11, Simplifying the Measurement of Inventory (Topic 330). The amendments in this update require that inventory within the scope of this ASU be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predicable costs of completion, disposal and transportation. The amendments in this ASU do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured at first-in, first-out (FIFO) or average cost. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2017. The amendments in this update should be applied prospectively and early adoption is permitted. We do not expect the adoption of this guidance will have a material impact upon our financial condition or results of operations.

In May 2014, the FASB issued ASU 2014-09, Revenue Contracts with Customers (Topic 606). This update provides guidance on the recognition of revenue based upon the entity s contracts with customers to transfer goods or services at an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. This update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. This update is effective for annual periods beginning after December 15, 2017, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2018. Early adoption is now permitted. We are evaluating this guidance and have not yet determined the effect it will have on our financial statements and related disclosures, if any.

2 Basic and Diluted Net Income per Share

Basic net income per share is based upon the weighted-average number of common shares outstanding during the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The underwriters warrants, stock options and restricted stock units granted by us represent the only dilutive effect reflected in diluted weighted-average shares outstanding.

The following table presents the computation of basic and diluted net income per share:

		Three Months Ended June 30,		Six Months Ended June 30,	
		2016	2015	2016	2015
		(unaudited)		(unaudited)	
Net income		$ 2,231,251	$ 1,770,571	$ 4,513,262	$ 3,258,066
Weighted-average shares outstanding	Basic	10,778,673	10,974,448	10,937,311	10,940,525
Effect of dilutive securities:					
Underwriters warrants		102,277	111,878	104,822	102,541
Stock Options		1,085,029	1,021,381	1,096,592	1,025,056
Restricted Stock Units		310		131	
Weighted-average shares outstanding	Diluted	11,966,289	12,107,707	12,138,856	12,068,122
Basic net income per share		$ 0.21	$ 0.16	$ 0.41	$ 0.30
Diluted net income per share		$ 0.19	$ 0.15	$ 0.37	$ 0.27

Stock options to purchase shares of our common stock and restricted stock units excluded from the calculation of diluted net income per share because the effect would have been anti-dilutive are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Anti-dilutive stock options and restricted stock units	91,795	24,000	96,000	183,072

3 Inventory

Inventory consists of:

	June 30, 2016 (unaudited)	December 31, 2015
Raw materials	$ 2,522,818	$ 2,025,674
Work in process	203,808	184,478
Finished goods	419,456	286,164
Inventory before allowance for excess and obsolete	3,146,082	2,496,316
Allowance for excess and obsolete	(199,768)	(113,158)
Total	$ 2,946,314	$ 2,383,158

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4 Property and Equipment

Property and equipment consist of:

	June 30, 2016 (unaudited)	December 31, 2015
Computer software and hardware	$ 436,152	$ 404,950
Furniture and fixtures	331,882	267,643
Leasehold improvements	191,139	191,139
Machinery and equipment	1,001,756	963,897
Tooling in-process	337,442	46,695
	2,298,371	1,874,324
Accumulated depreciation	(1,078,699)	(968,702)
Total	$ 1,219,672	$ 905,622

Depreciation and amortization expense of property and equipment was $56,536 and $46,127 for the three months ended June 30, 2016 and 2015, respectively, and $109,997 and $87,917 for the six months ended June 30, 2016 and 2015.

5 Intangible Assets

The following table summarizes the components of intangible asset balances:

	June 30, 2016 (unaudited)	December 31, 2015
Patents in use	$ 168,383	$ 168,383
Patents in process	54,917	47,474
Internally developed software in use	148,967	148,967
Internally developed software in process	554,407	
Trademarks	23,017	17,730
	949,691	382,554
Accumulated amortization	(202,058)	(189,311)
Total	$ 747,633	$ 193,243

Amortization expense of intangible assets was $5,400 and $8,830 for the three months ended June 30, 2016 and 2015, respectively, and $12,747 and $18,347 for the six months ended June 30, 2016 and 2015. During the six months ended June 30, 2015, we recorded an impairment charge of $55,433 on patents related to certain of our IV sets. This charge is included as general and administrative expense in our Condensed Statements of Operations.

Expected annual amortization expense for the remaining portion of 2016 and the next five years related to intangible assets is as follows (excludes in process intangible assets):

Six months ending December 31, 2016	$	5,269
2017		10,538
2018		10,538
2019		10,538
2020		10,538
2021		10,538

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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,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Cost of revenue	$ 35,632	$ 19,079	$ 70,700	$ 34,800
General and administrative	1,023,645	132,955	1,225,892	249,884
Sales and marketing	131,339	141,303	271,604	268,649
Research and development	13,790	13,717	27,393	28,752
Total	$ 1,204,406	$ 307,054	$ 1,595,589	$ 582,085

During the three months ended June 30, 2016, the Board of Directors allowed for the continued vesting of all options and restricted stock units previously granted to our former chairman in recognition of his continuing advice to the Board of Directors. These unvested options and restricted stock units would have otherwise been forfeited upon separation from the Company and will now continue to vest under their original vesting schedules. This was accounted for as a modification of the awards and resulted in approximately $867,000 of additional expense.

As of June 30, 2016 we had $2,643,537 of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.1 years. As of June 30, 2016, we had $1,453,771 of unrecognized compensation cost related to unvested Restricted Stock Units (RSUs), which is expected to be recognized over a weighted-average period of 3.2 years.

The following table presents a summary of our stock-based compensation activity for the six months ended June 30, 2016:

	Stock Options	Restricted Stock Units
Outstanding beginning of period	1,629,342	
Awards granted	24,000	71,976
Awards exercised	(61,563)	
Awards canceled	(40,000)	(4,138)
Outstanding end of period	1,551,779	67,838

RSUs are granted at a value equal to the market price of our common stock on the date of grant. RSUs are settled in shares at the end of their vesting period, which is generally four years for employees and two years for directors.

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, 2016			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,089,327	$ 13,976	$ 27,665	$ 6,075,638
International corporations	2,016,125	5,774	16,263	2,005,636
Total	$ 8,105,452	$ 19,750	$ 43,928	$ 8,081,274

	December 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,176,341	$	$ 68,381	$ 6,107,960
International corporations	1,515,200		20,956	1,494,244
Total	$ 7,691,541	$	$ 89,337	$ 7,602,204

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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, 2016.

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, 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	$ 6,075,638	$	$ 6,075,638	$
International corporations	2,005,636		2,005,636	
Total	$ 8,081,274	$	$ 8,081,274	$

		Fair Value at December 31, 2015			
	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	$ 6,107,960	$	$ 6,107,960	$
International corporations	1,494,244		1,494,244	
Total	$ 7,602,204	$	$ 7,602,204	$

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, 2016 or the year ended December 31, 2015.

9 Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss, net of tax, for the three months ended June 30, 2016 and 2015 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
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)
Balances at March 31, 2015	$	(12,077)
Losses, net		(13,398)
Balances at June 30, 2015	$	(25,475)

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The components of accumulated other comprehensive loss, net of tax, for the six months ended June 30, 2016 and 2015 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
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)
Balances at December 31, 2014	$	(21,473)
Losses, net		(4,002)
Balances at June 30, 2015	$	(25,475)

10 Income Taxes

We recorded provisions for income taxes 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 primarly 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.

We recorded provisions for income taxes of $969,282 and $1,793,113 for the three and six months ended June 30, 2015, respectively. Our effective tax rate was 35.4% and 35.5% for the three and six months ended June 30, 2015, respectively. Our effective tax rates for the three and six months ended June 30, 2015 differed from the U.S. Federal statutory rate primarily due to U.S. state tax expense, partially offset by the domestic production activities deduction.

As of June 30, 2016 and December 31, 2015, 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. The Company is subject to income tax examinations for our United States Federal and State income taxes for 2009 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 IV infusion pump systems and products 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,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
United States	$ 8,994,675	$ 7,199,343	$ 16,869,191	$ 13,497,549
International	874,230	409,800	1,963,867	1,103,299
	$ 9,868,905	$ 7,609,143	$ 18,833,058	$ 14,600,848

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Revenue information by type is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Devices	$ 8,196,898	$ 6,367,010	$ 15,492,340	$ 12,254,263
Disposable IV Sets and Services	1,672,007	1,242,133	3,340,718	2,346,585
	$ 9,868,905	$ 7,609,143	$ 18,833,058	$ 14,600,848

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

	June 30, 2016 (unaudited)	December 31, 2015
United States	$ 1,035,221	$ 837,728
International	184,451	67,894
Total	$ 1,219,672	$ 905,622

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 Chairman, President, CEO and controlling stockholder, Roger Susi. Pursuant to the terms of our lease for this property, the monthly base rent is $32,616, 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 as of June 30, 2016 is as follows:

Six months ending December 31, 2016	$ 196,641
2017	392,617
2018	392,617

2019		163,080
2020		
Total non-cancelable operating lease commitments	$	1,144,955

Rent expense under our operating leases was $101,180 and $100,361 for the three months ended June 30, 2016 and 2015, respectively, and $202,439 and 200,536 for the six months ended June 30, 2016 and 2015, 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 $3,130,103 at June 30, 2016 and $3,564,088 at December 31, 2015. No amounts related to these purchase orders have been recognized in our balance sheet.

Legal matters. On September 10, 2014, a Civil Action was filed in the U.S. District Court for the Southern District of Florida (Lam Civil Action). The Lam Civil Action was a putative class action lawsuit brought against the Company and certain individuals who are officers and / or directors of the Company. The plaintiff was an alleged shareholder of the Company, and in the operative complaint sought relief on behalf of a class of persons who purchased the Company s common stock during the period from July 15, 2014 through September 17, 2014. The complaint alleged that the defendants failed to disclose material information concerning the Company s compliance with FDA regulations in violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder, and that the putative class members suffered damages as a result. The complaint additionally alleged control person liability against the individual defendants under Section 20(a) of the Securities Exchange Act of 1934. The Company disputed the plaintiff s allegations and theories of liability. On May 26, 2015, the court granted the defendants motions to dismiss the complaint in its entirety. On June 22, 2015, the plaintiff filed a notice of appeal in the U.S. Court of Appeals for the Eleventh Circuit. The appeal was dismissed with prejudice by the Court of Appeals on October 28, 2015 on joint motion of the parties.

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In addition to the foregoing, we may from time to time become party to various legal proceedings or claims that arise in the ordinary course of business.

13 Common Stock

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

Balance, December 31, 2015	11,175,125
Option exercises	61,563
Purchases of treasury stock	(569,213)
Balance, June 30, 2016	10,667,475

On January 28, 2016 (the Authorization Date), the Board of Directors approved a stock repurchase program, authorizing the repurchase of up to $10.0 million of our common stock through January 28, 2017. Since the Authorization Date and through June 30, 2016, we used $9,969,468 to acquire 569,213 shares of our common stock. Our treasury stock is currently available for general corporate purposes.

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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 are the only known provider of non-magnetic intravenous (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. MRidium is a trademark of IRADIMED CORPORATION.

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. We generate revenue from the one-time sale of pumps and accessories, ongoing service contracts and the sale of proprietary disposable IV tubing sets used during each patient infusion. The principal customers for our MRI compatible products include hospitals, acute care facilities and outpatient imaging centers.

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 35 independent distributors selling our products internationally. Selling cycles for medical devices vary widely but are typically three to six months in duration. 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 percentage

fee based on sales of our products to their member hospitals. We currently have contracts with four major GPOs that effectively give us the ability to sell to more than 95% of all U.S. acute care facilities.

FDA Matters

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 Dose Error Reduction System (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.

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On September 2, 2014, we received a warning letter from the FDA relating 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 March 24, 2016, we received a letter dated March 23, 2016 that our 510(k) submission was denied with a finding of non-substantial equivalence. This finding was due to a lack of human factors data demonstrating that our DERS was adequately validated and that we may resubmit a new 510(k) application with data showing our infusion pump to be substantially equivalent to similar devices in the market. Specifically, the agency stated that two of fifty-six test subjects in our human factors tests unintentionally bypassed the DERS feature, thus avoiding the DERS hard dose limits that healthcare institutions can program into our MRI compatible MRidium 3860+ infusion pumps. On April 7, 2016, we submitted an appeal to this determination to a higher level within the FDA. On May 2, 2016, we met with the FDA to review our appeal. On May 2, 2016, we met with the FDA to review our appeal. On June 2, 2016, we received FDA s written response to our appeal. In this response, FDA reinstated the subject 510(k) and we have been granted another 180 days to make certain specified changes to several messages displayed by the infusion pump. Specifically, changes to messages the infusion pump displays to clarify whether the DERS is active or inactive and to better describe the over and under range indications. Further, the FDA s response also stated that no additional human factors usability testing is required.

We continue to work with the FDA to fully resolve the Warning Letter and complete the review of the 510(k) submission.

Financial Highlights and Outlook

Our revenue increased $2.3 million, or 29.7%, to $9.9 million for the second quarter ended June 30, 2016, compared to $7.6 million for the second quarter of last year. Net income was $2.2 million, or $0.19 per diluted share, in the second quarter ended June 30, 2016, compared with net income of $1.8 million, or $0.15 per diluted share, in the second quarter last year. During the second quarter of 2016, we recognized revenue on 262 pump systems, compared to 220 pump systems during the same period in 2015, a 19.1% increase.

For the remainder of 2016, we expect continued revenue growth as our U.S. direct sales force continues to expand market awareness of the advantages of patient safety and operating efficiencies provided by our MRI compatible IV infusion pump system and the introduction of our patient vital signs monitor that we expect to launch during the second half of 2016. We intend to continue targeting hospitals and acute care facilities that have yet to adopt our technology. We also recently implemented a sales strategy to penetrate the Intensive Care Unit, Emergency Room and other locations within hospitals where there is a high probability that interventional radiology procedures will need to be performed on patients. We expect operating expenses to increase in 2016 due to increased headcount, higher stock-based compensation expense, costs incurred in bringing the patient vital signs monitor to market and higher depreciation expense from additional capital expenditures.

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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 market
- 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.* There have been no changes to these policies during the three and six months ended June 30, 2016.

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.

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,	
	2016	2015	2016	2015
Revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	17.6	18.7	18.3	18.8
Gross profit	82.4	81.3	81.7	81.2
Operating expenses:				
General and administrative	31.3	26.1	28.4	27.1
Sales and marketing	14.3	14.5	14.3	15.0
Research and development	3.0	5.3	2.8	5.1
Total operating expenses	48.5	45.9	45.5	47.2
Income from operations	33.8	35.4	36.2	34.0
Other (expense) income, net	(0.0)	0.6	0.1	0.6
Income before provision for income taxes	33.8	36.0	36.4	34.6
Provision for income taxes	11.2	12.7	12.4	12.3
Net income	22.6%	23.3%	24.0%	22.3%

Three Months Ended June 30, 2016 and 2015

Revenue

Revenue increased approximately $2.3 million, or 29.7%, to $9.9 million for the three months ended June 30, 2016, compared to $7.6 million for the same period in 2015.

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Revenue from sales in the U.S. increased approximately $1.8 million, or 24.9%, to $9.0 million for the three months ended June 30, 2016, from $7.2 million for the same period in 2015. Revenue from sales internationally increased approximately $0.5 million, or 113.3%, to $0.9 million for the three months ended June 30, 2016, from $0.4 million for the same period in 2015.

Revenue from sales of devices increased approximately $1.8 million, or 28.7%, to $8.2 million for the three months ended June 30, 2016, from $6.4 million for the same period in 2015. During the three months ended June 30, 2016, we recognized revenue on 262 MRI compatible IV infusion pumps compared to 220 pumps for the same period in 2015. The average selling price of our MRI compatible IV infusion pump systems during the three months ended June 30, 2016 and 2015 was approximately $31,000 and $29,000, respectively.

Revenue from sales of our disposable IV sets and services increased approximately $0.5 million, or 34.6%, to $1.7 million for the three months ended June 30, 2016, from $1.2 million for the same period in 2015.

Cost of Revenue

Cost of revenue increased approximately $0.3 million, or 22.3%, to $1.7 million for the three months ended June 30, 2016, from $1.4 million for the same period in 2015. Gross profit increased approximately $1.9 million, or 31.4%, to $8.1 million for the three months ended June 30, 2016 from $6.2 million for the same period in 2015. The increase in cost of revenue and gross profit is due to higher sales during the three months ended June 30, 2016, compared to the second quarter 2015. Gross profit margin was 82.4% and 81.3% for the three months ended June 30, 2016 and 2015, respectively. This is the result of favorable sales mix and higher sales leverage, partially offset by higher international sales as a percent of total sales when compared to the same period last year.

General and Administrative

General and administrative expense increased approximately $1.1 million, or 55.6%, to $3.1 million for the three months ended June 30, 2016 from $2.0 million for the same period last year. This increase is primarily due to higher stock compensation expense associated with the modification of awards granted to our previous chairman, higher payroll and employee benefits resulting from higher headcount and GPO administration fee expense resulting from higher sales, partially offset by lower medical device excise tax expense.

Sales and Marketing

Sales and marketing expense increased approximately $0.3 million, or 27.6%, to $1.4 million for the three months ended June 30, 2016, from $1.1 million for the same period in 2015. This is primarily the result of higher salary and travel expenses resulting from the increased size of our sales organization and higher commissions expense from higher sales.

Research and Development

Research and development expense decreased approximately $0.1 million, or (27.7%), to $0.3 million for the three months ended June 30, 2016, from $0.4 million for the same period in 2015. This is primarily due to the capitalization of certain internally developed software costs associated with the development of our patient vital signs monitor, which has the effect of reducing expense. This was partially offset by higher prototype expenses.

Other (Expense) Income, Net

Other (expense) income, net consists of interest income, foreign currency gains and losses, and other miscellaneous income. We reported other expense of approximately $4,700 for the three months ended June 30, 2016, compared to other income of approximately $46,000 for the same period in 2015. This decrease is primarily the result of losses on the maturities of investments and lower foreign currency gains on international transactions.

Income Taxes

We recorded income tax expense of approximately $1.1 million and $1.0 million for the three months ended June 30, 2016 and 2015, respectively. The higher income tax expense for the second quarter of 2016 is due to higher income before provision for income taxes, partially offset by a lower effective tax rate when compared to the same period in 2015. Our effective tax rate for the second quarter of 2016 was 33.1% compared to 35.4% for the same quarter in 2015. The decrease in our effective tax rate is primarily the result of discrete items and research and development tax credits, partially offset by higher U.S. state tax expense.

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Six Months Ended June 30, 2016 and 2015

Revenue

Revenue increased approximately $4.2 million, or 29.0%, to $18.8 million for the six months ended June 30, 2016, compared to $14.6 million for the same period in 2015.

Revenue from sales in the U.S. increased approximately $3.4 million, or 25.0%, to $16.9 million for the six months ended June 30, 2016, from $13.5 million for the same period in 2015. Revenue from sales internationally increased approximately $0.8 million, or 78.0%, to $1.9 million for the six months ended June 30, 2016, from $1.1 million for the same period in 2015.

Revenue from sales of devices increased approximately $3.2 million, or 26.4%, to $15.5 million for the six months ended June 30, 2016, from $12.3 million for the same period in 2015. During the six months ended June 30, 2016, we recognized revenue on 525 MRI compatible IV infusion pumps compared to 437 pumps for the same period in 2015. The average selling price of our MRI compatible IV infusion pump systems during the six months ended June 30, 2016 and 2015 was approximately $29,000 and $28,000, respectively.

Revenue from sales of our disposable IV sets and services increased approximately $1.0 million, or 42.4%, to $3.3 million for the six months ended June 30, 2016, from $2.3 million for the same period in 2015.

Cost of Revenue

Cost of revenue increased approximately $0.6 million, or 25.3%, to $3.4 million for the six months ended June 30, 2016, from $2.8 million for the same period in 2015. Gross profit increased approximately $3.5 million, or 29.9%, to $15.4 million for the six months ended June 30, 2016 from $11.9 million for the same period in 2015. The increase in cost of revenue and gross profit is due to higher sales during the six months ended June 30, 2016, compared to the same period in 2015. Gross profit margin was 81.7% and 81.2% for the six months ended June 30, 2016 and 2015, respectively. This is the result of favorable sales mix and higher sales leverage, partially offset by higher international sales as a percent of total sales when compared to the same period last year.

General and Administrative

General and administrative expense increased approximately $1.3 million, or 35.3%, to $5.3 million for the six months ended June 30, 2016, from $4.0 million for the same period last year. This increase is primarily due to higher stock compensation expense associated with the modification of awards granted to our previous chairman, payroll and employee benefits resulting from higher headcount, corporate franchise taxes, GPO administration fee expense resulting from higher sales and higher consulting services, partially offset by lower medical device excise

tax expense legal and professional expenses.

Sales and Marketing

Sales and marketing expense increased approximately $0.5 million, or 22.8%, to $2.7 million for the six months ended June 30, 2016, from $2.2 million for the same period in 2015. This is primarily the result of higher salary and travel expenses resulting from the increased size of our sales organization and higher commissions expense from higher sales.

Research and Development

Research and development expense decreased approximately $0.2 million, or (29.4%), to $0.5 million for the six months ended June 30, 2016, from $0.7 million for the same period in 2015. This is primarily due to the capitalization of certain internally developed software costs associated with the development of our patient vital signs monitor, which has the effect of reducing expense. This was partially offset by higher prototype expenses.

Other (Expense) Income, Net

Other (expense) income, net consists of interest income, foreign currency gains and losses, and other miscellaneous income. We reported other income of approximately $27,000 and $93,000 for the six months ended June 30, 2016 and 2015, respectively. This decrease is primarily the result of losses on the maturities of investments and lower foreign currency gains on international transactions.

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Income Taxes

We recorded income tax expense of approximately $2.3 million and $1.8 million for the six months ended June 30, 2016 and 2015, respectively. The higher income tax expense for the six months ended June 30, 2016 is due to higher income before provision for income taxes, partially offset by a lower effective tax rate when compared to the same period in 2015. Our effective tax rate for the six months ended June 30, 2016 was 34.1% compared to 35.5% for the same period in 2015. The decrease in our effective tax rate is primarily the result of discrete items and research and development tax credits, partially offset by higher U.S. state tax expense.

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 and capital expenditures.

As of June 30, 2016, we had cash and cash equivalents and investments of approximately $20.1 million, stockholders equity of $28.5 million, and working capital of $26.8 million. As of December 31, 2015, we had cash and cash equivalents and investments of approximately $27.0 million, stockholders equity of $31.9 million, and working capital of $31.1 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.

For the six months ended June 30, 2016, cash provided by operations increased approximately $1.1 million to $3.8 million, compared to cash provided by operations of $2.7 million for the same period in 2015. This increase was primarily the result of higher net income; higher net cash inflows related to accounts receivable and other current liabilities; and the add back of non-cash items such as stock compensation, impairment of intangible assets, depreciation and amortization, partially offset by higher net cash outflows related to inventory, deferred revenue and accrued income taxes. The sum of our net income and certain non-cash expense items, such as stock compensation, impairment of intangible assets, depreciation and amortization was approximately $6.2 million for the six months ended June 30, 2016 compared to $4.0 million for the same period last year.

Cash used in investing activities was approximately $1.5 million for the six months ended June 30, 2016 compared to approximately $0.1 million for the same period last year. During the six months ended June 30, 2016, we used approximately $2.8 million of cash to purchase investments, capitalized approximately $0.6 million of intangible assets and purchased approximately $0.4 million of property and equipment. These cash outflows were partially offset by the maturity of approximately $2.3 million of investments.

Cash used in financing activities was approximately $9.6 million for the six months ended June 30, 2016 and related to the purchase of approximately $10.0 million of treasury stock, partially offset by cash received from the exercise of stock options by employees and related tax benefits. For the six months ended June 30, 2015, cash provided by financing activities was approximately $0.4 million and related to the

exercise of stock options by employees and the tax benefits.

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 Chairman, President and CEO, Roger Susi. Pursuant to the terms of our lease, the monthly base rent is $32,616, 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, 2016. We had no other off-balance sheet arrangements during the six months ended June 30, 2016 or for the year ended December 31, 2015 that had, or are reasonably likely to have, a material effect on our financial condition, results of operations, or liquidity.

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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, 2016 and 2015.

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, 2016, we had approximately $8.1 million in corporate bonds, with approximately $4.1 million that matures in less than 1 year, $3.8 million that matures between 1 and 3 years and $0.2 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, 2016, we expect the corresponding change in fair value of our investments would be approximately $107,000. This is based on sensitivity analyses performed on our financial position as of June 30, 2016. 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.

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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On September 10, 2014, a Civil Action was filed in the U.S. District Court for the Southern District of Florida (Lam Civil Action). The Lam Civil Action was a putative class action lawsuit brought against the Company and certain individuals who are officers and / or directors of the Company. The plaintiff was an alleged shareholder of the Company, and in the operative complaint sought relief on behalf of a class of persons who purchased the Company s common stock during the period from July 15, 2014 through September 17, 2014. The complaint alleged that the defendants failed to disclose material information concerning the Company s compliance with FDA regulations in violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder, and that the putative class members suffered damages as a result. The complaint additionally alleged control person liability against the individual defendants under Section 20(a) of the Securities Exchange Act of 1934. The Company disputed the plaintiff s allegations and theories of liability. On May 26, 2015, the court granted the defendants motions to dismiss the complaint in its entirety. On June 22, 2015, the plaintiff filed a notice of appeal in the U.S. Court of Appeals for the Eleventh Circuit. The appeal was dismissed with predjudice by the Court of Appeals on October 28, 2015 on joint motion of the parties.

Item 1A. Risk Factors

Risks Relating to Our Business and Financial Condition

Our financial performance is currently 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 dependent on the sale of the MRidium 3860+ and 3850/R MRI compatible IV infusion pump system and the ongoing sale of disposable tubing sets related to them. Sales of the MRidium 3860+ and 3850/R MRI compatible IV infusion pump systems 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.

On September 2, 2014 we announced we received a Warning Letter from the FDA. The FDA stated in the Warning Letter 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 Food, Drug and Cosmetic Act (the FDCA). Such updates occurred periodically over time. As stated in the warning letter, the FDA indicated that the modifications of the software related to the MRidium 3860 from version 2.0 to current version 3.5.1 and the modifications of the software related to the MRidium 3850 from version 1.0 to version 585.11.1 as significant modifications because they could significantly affect the safety or effectiveness of the devices. As a result, the Warning Letter alleges that the products being sold by us are adulterated and misbranded under the FDCA. 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, such as 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. 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 Dose Error Reduction System (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.

The disruption in the shipment of our products had a significant adverse effect on our business and our financial condition. We are working with the FDA to resolve the Warning Letter and complete the review of the 510(k) submission. Although we have resumed commercial distribution of our product, there can be no guarantee that our efforts will be successful in obtaining clearance of our 510(k) submission. The FDA could require us to, again, cease shipment of our products, or 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+ or 3850/R MRI compatible IV infusion pumps 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.

We and certain of our officers and/or directors were defendants in a lawsuit filed in the United States District Court for the Southern District of Florida, brought on behalf of our stockholders that alleged that the defendants failed to disclose material information concerning our compliance with FDA regulations. On May 26, 2015, the District Court granted the defendants motions to dismiss the complaint in its entirety. On June 22, 2015, the plaintiff filed a notice of appeal in the U.S. Court of Appeals for the Eleventh Circuit. On October 28, 2015, the U.S. Court of Appeals for the Eleventh Circuit, on joint motion of the parties, dismissed with prejudice the plaintiff s appeal.

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.

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 MRidium MRI compatible IV infusion pumps 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.

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.

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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.

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.

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 10.0% or more of our gross accounts receivable. As a result, we are 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. 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.

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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 sales will 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 is three to six months. The process can 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.

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. Our expectation of revenue from outside the U.S. over the next twelve months is on the low end of our historical averages as we focus on fulfilling orders from our significant U.S. backlog. 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, Director 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.

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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.

Our plan is to grow rapidly. Our 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.

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. One 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.

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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 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 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 growth strategy, we plan to seek approvals for new MRI compatible products. The process of obtaining approvals, particularly from the FDA, can be 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;

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- trade protection and restriction measures 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;
- 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.

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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.

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.

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 that identified three observations.

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.

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.

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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.

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;

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- 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.

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.

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Risks Related to Ownership of Our Common Stock

Our common stock price may 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;

- 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;

- 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.

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

In July 2014, we sold approximately 2.3 million shares of common stock in our initial public offering, and such shares are registered and freely tradable. If these stockholders sell, or indicate an intention to sell, our common stock in the public market, the trading price of our common stock could decline. In addition, our directors, officers and stockholders who beneficially own approximately 8.4 million shares of common stock, which were subject to lock-up agreements that expired in January 2015. As a result, up to approximately 1.0 million shares became eligible for sale in the public market and approximately 7.4 million shares held by affiliates became eligible for sale subject to volume limitations under Rule 144 under the Securities Act. Moreover, 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, we filed a registration statement on Form S-3 to register shares of common stock that may be offered or sold by us or by selling stockholders. On December 18, 2015, Roger Susi sold 1,043,479 shares of our Common stock in a secondary offering pursuant to the registration statement on Form S-3. If additional Company shares are sold, or if it is perceived that they will be sold, the trading price of our common stock could decline.

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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 the proceeds from our recent initial public offering and our current positive cash flow 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 an additional 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 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 one of 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.

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.

The continued expansion of our business will require funding. Accordingly, 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.

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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 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.

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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.

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
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.

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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 5, 2016

/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)