IRADIMED CORP
Form 10-Q
November 07, 2018
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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 September 30, 2018

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 every Interactive Data File required to be submitted 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 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 o
Non-accelerated filer o	Smaller reporting company x
	Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with

any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Yes x No 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 10,934,315 shares of common stock, par value $0.0001 per share, outstanding as of October 31, 2018.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

IRADIMED CORPORATION

CONDENSED BALANCE SHEETS

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,699,164	$ 18,205,976
Accounts receivable, net of allowance for doubtful accounts of $52,756 as of September 30, 2018 and $37,225 as of December 31, 2017	5,219,259	3,778,929
Investments	7,487,283	8,135,123
Inventory, net	4,275,409	4,210,846
Prepaid expenses and other current assets	578,178	648,881
Prepaid income taxes	1,409,113	127,855
Total current assets	42,668,406	35,107,610
Property and equipment, net	1,879,619	1,868,851
Intangible assets, net	832,144	885,502
Deferred income taxes, net	1,227,043	950,375
Other assets	204,305	200,196
Total assets	$ 46,811,517	$ 39,012,534
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 970,972	$ 656,723
Accrued payroll and benefits	1,810,982	1,512,336
Other accrued taxes	86,281	109,502
Warranty reserve	39,951	60,538
Deferred revenue	1,776,953	1,617,571
Other current liability	108,421	108,571
Accrued income taxes		12,731
Total current liabilities	4,793,560	4,077,972
Deferred revenue	1,925,782	2,003,685
Total liabilities	6,719,342	6,081,657
Stockholders equity:		
Common stock; $0.0001 par value; 31,500,000 shares authorized; 10,933,989 shares issued and outstanding as of September 30, 2018 and 10,596,566 shares issued and outstanding as of December 31, 2017	1,093	1,060
Additional paid-in capital	15,203,263	12,623,181
Retained earnings	24,962,478	20,355,545
Accumulated other comprehensive loss	(74,659)	(48,909)
Total stockholders equity	40,092,175	32,930,877
Total liabilities and stockholders equity	$ 46,811,517	$ 39,012,534

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 7,614,655	$ 5,689,724	$ 22,099,591	$ 16,376,648
Cost of revenue	1,826,716	1,307,767	5,229,141	3,929,699
Gross profit	5,787,939	4,381,957	16,870,450	12,446,949
Operating expenses:				
General and administrative	2,181,839	2,551,290	6,563,727	6,848,472
Sales and marketing	1,784,418	1,251,901	4,946,398	3,940,216
Research and development	373,583	382,704	1,149,397	1,373,005
Total operating expenses	4,339,840	4,185,895	12,659,522	12,161,693
Income from operations	1,448,099	196,062	4,210,928	285,256
Other income, net	42,555	28,715	110,465	79,377
Income before provision for income taxes	1,490,654	224,777	4,321,393	364,633
Provision for income tax (benefit) expense	(909,619)	32,384	(275,044)	48,507
Net income	$ 2,400,273	$ 192,393	$ 4,596,437	$ 316,126
Net income per share:				
Basic	$ 0.22	$ 0.02	$ 0.43	$ 0.03
Diluted	$ 0.20	$ 0.02	$ 0.38	$ 0.03
Weighted average shares outstanding:				
Basic	10,824,421	10,565,598	10,695,601	10,664,132
Diluted	12,195,870	11,643,044	12,059,694	11,710,377

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 September 30,		For the Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Net income	$ 2,400,273	$ 192,393	$ 4,596,437	$ 316,126
Other comprehensive income (loss):				
Change in fair value of available-for-sale securities, net of tax expense (benefit) of $2,299 and $2,159 for the three months ended September 30, 2018 and 2017, respectively, and $(10,714) and $5,825 for the nine months ended September 30, 2018 and 2017, respectively	6,566	3,576	(32,180)	9,623
Realized loss on available-for-sale securities reclassified to net income, net of tax benefit of $5,601 and $119 for the three months ended September 30, 2018 and 2017, respectively, and $6,103 and $2,162 for the nine months ended September 30, 2018 and 2017, respectively	16,099	122	16,926	4,595
Other comprehensive income (loss)	22,665	3,698	(15,254)	14,218
Comprehensive income	$ 2,422,938	$ 196,091	$ 4,581,183	$ 330,344

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities:		
Net income	$ 4,596,437	$ 316,126
Adjustments to reconcile net income to net cash provided by operating activities:		
Change in allowance for doubtful accounts	26,146	(9,557)
Change in provision for excess and obsolete inventory	97,901	38,021
Depreciation and amortization	844,885	970,705
Write-off of non-trade accounts receivable		205,444
Stock-based compensation	1,361,964	1,735,078
Deferred income taxes, net	(272,056)	(769,615)
Loss on maturities of investments	22,486	6,757
Changes in operating assets and liabilities:		
Accounts receivable	(1,466,476)	71,380
Inventory	(257,884)	(273,121)
Prepaid expenses and other current assets	(430,889)	(576,504)
Other assets	(19,833)	(6,714)
Accounts payable	203,918	(334,051)
Accrued payroll and benefits	298,646	403,151
Other accrued taxes	(23,221)	(50,847)
Warranty reserve	(20,587)	7,608
Deferred revenue	166,344	632,341
Other current liability	(150)	
Accrued income taxes, net of prepaid income taxes	(1,293,989)	(351,403)
Net cash provided by operating activities	3,833,642	2,014,799
Investing activities:		
Purchases of investments	(1,124,512)	(1,321,257)
Proceeds from maturity of investments	1,730,000	2,495,004
Purchases of property and equipment	(150,609)	(653,171)
Capitalized intangible assets	(13,484)	(28,800)
Net cash provided by investing activities	441,395	491,776
Financing activities:		
Proceeds from exercises of stock options and underwriters warrants	1,234,565	49,460
Taxes paid related to the net share settlement of equity awards	(16,414)	(45,059)
Purchases of treasury stock		(1,818,542)
Net cash provided by (used in) financing activities	1,218,151	(1,814,141)
Net increase in cash and cash equivalents	5,493,188	692,434
Cash and cash equivalents, beginning of period	18,205,976	17,713,871
Cash and cash equivalents, end of period	$ 23,699,164	$ 18,406,305
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 1,291,160	$ 1,171,964

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 nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

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, 2017. The accounting policies followed in the preparation of these interim condensed financial statements, except as described in Note 2, are consistent in all material respects with those described in Note 1 of our Form 10-K.

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

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

FDA Warning Letter

The FDA conducted a routine inspection of our prior facility between April 7 and April 16, 2014. This was the first FDA inspection of our facility since the voluntary product recall in August 2012 of certain infusion sets and the voluntary recall in July 2013 of our DERS software. The FDA issued a Form 483 on April 16, 2014 that identified eight observations. Most 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 responses 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 states 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 states 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 had been made over time. We believed 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.

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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.

Between July 11 and July 18, 2016, the FDA conducted a routine inspection of our facility. This was the first FDA inspection of our facility since the receipt of the Warning Letter. During this inspection, the updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the FDA determined that no further actions were necessary.

On December 15, 2016, we received FDA 510(k) clearance for our MRidium 3860+ MRI IV infusion pump system, including the DERS software feature. As of September 30, 2018, the Warning Letter remains open.

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

Accounting Pronouncements Implemented in 2018

In May 2014, the FASB issued ASU 2014-09, Revenue from 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. We adopted the new guidance effective January 1, 2018 using the modified retrospective method to contracts that were not completed as of January 1, 2018.

We have evaluated each of the five steps in the new revenue recognition model, which are: 1) Identify the contract with the customer; 2) Identify the performance obligations in the contract; 3) Determine the transaction price; 4) Allocate the transaction price to the performance obligations; and 5) Recognize revenue when (or as) performance obligations are satisfied. We have concluded that the adoption of this guidance did not require any adjustment to the opening balance of retained earnings and did not have a material impact to our financial statements. Additionally, our method and timing for recognizing revenue after the implementation of this guidance does not vary significantly from our revenue recognition practices under the previous revenue recognition guidance.

Disclosure requirements under Topic 606 have been significantly expanded in comparison to the disclosure requirements under the previous guidance. See Note 2.

In February 2016, the FASB issued ASU 2018-02, Income Statement Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. We adopted the new guidance on January 1, 2018 and reclassified an immaterial amount from accumulated other comprehensive income to beginning retained earnings.

Recently Issued Accounting Pronouncements to be Implemented

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 have only one material lease contract outstanding, for our sole facility. We are in the process of determining the method of adoption and assessing the impact of the update on our financial condition and results of operations.

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2 Revenue Recognition

On January 1, 2018, we adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606) using the modified retrospective method applied to contracts which were incomplete as of January 1, 2018. Results from reporting periods beginning after January 1, 2018 are presented under this new guidance, while prior period amounts are unadjusted and continue to be reported under previous revenue recognition guidance.

We generate revenue from the one-time sale of MRI compatible medical devices and accessories, extended warranty agreements and the sale of disposable products used with our devices. The principal customers for our MRI compatible products include hospitals and acute care facilities, both in the U.S. and internationally. 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.

For most domestic sales, we enter into agreements with healthcare supply contracting companies, commonly referred to as Group Purchasing Organizations (GPOs), which enable us to sell and distribute our products to their member hospitals. Our agreements with GPOs typically include negotiated pricing for all group members established at time of GPO contract execution.

We do not sell to GPOs. Hospitals, group practices and other acute care facilities that are members of a GPO, purchase products directly from us under the terms of our GPO agreements.

We recognize revenue when all of the following criteria are met: we have a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount we expect to receive, is determinable and we have transferred control of the promised products or services to the customer. We consider transfer of control evidenced upon the passage of title and risks and rewards of ownership to the customer. We allocate the transaction price using the relative standalone selling price method. Customer sale prices for our MRI compatible IV infusion pump systems and related disposables and services are contractually fixed over the GPO contract term. We recognize a receivable at the point in time we have an unconditional right to payment. Payment terms are typically within 45 days after transferring control to U.S. customers. Most international distributors are required to pay a portion of the transaction price in advance and the remaining amount within 30 days of receiving the related products. Accordingly, we have elected to use the practical expedient that allows us to ignore the possible existence of a significant financing component within the contract.

We have elected to account for shipping and handling charges billed to customers as revenue and shipping and handling related expenses as cost of revenue.

In certain U.S. states we are required to collect sales taxes from our customers. We have elected to exclude the amounts collected for these taxes from revenue and record them as a liability until remitted to the taxing authority.

Disaggregation of Revenue

We disaggregate revenue from contracts with customers by geographic region and revenue type as we believe it best depicts the nature, amount, timing and uncertainty of our revenue and cash flow.

Revenue information by geographic region is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
United States	$ 6,099,767	$ 5,016,550	$ 17,808,918	$ 14,176,357
International	1,514,888	673,174	4,290,673	2,200,291
Total revenue	$ 7,614,655	$ 5,689,724	$ 22,099,591	$ 16,376,648

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Revenue information by type is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Devices:				
MRI Compatible IV Infusion Pump Systems	$ 3,532,670	$ 3,606,327	$ 10,748,830	$ 9,888,166
MRI Compatible Patient Vital Signs Monitoring Systems	1,817,361	118,598	4,526,735	907,622
Total Devices Revenue	5,350,031	3,724,925	15,275,565	10,795,788
Disposables and Services	1,874,439	1,673,254	5,722,573	4,893,990
Amortization of extended warranty agreements	390,185	291,545	1,101,453	686,870
Total revenue	$ 7,614,655	$ 5,689,724	$ 22,099,591	$ 16,376,648

Contract Liabilities

We record contract liabilities, or deferred revenue, when we have an obligation to provide a product or service to the customer and payment is received in advance of our performance. When we sell a product or service with a future performance obligation, we defer revenue allocated to the unfulfilled performance obligation and recognize this revenue when (or as) the performance obligation is satisfied.

Our deferred revenue consists of advance payments received from customers prior to the transfer of products or services, shipments that are in-transit at the end of a period and sales of extended warranty agreements. Advanced payments received from customers and shipments in-transit are recognized in revenue at the time control of the related products has been transferred to the customer or services have been delivered. Amounts related to extended warranty agreements are deferred and recognized in revenue ratably over the agreement period, which is typically one to four years after control of the related products is transferred to the customer, as we believe this recognition pattern best depicts the transfer of services being provided.

Deferred revenue is classified as current or long-term deferred revenue in our Balance Sheets, depending on the expected timing of satisfying the related performance obligations. Our contract liabilities consist of:

	September 30, 2018 (unaudited)	December 31, 2017
Advance payments from customers	$ 53,273	$ 251,087
Shipments in-transit	84,865	13,326
Extended warranty agreements	3,564,597	3,356,843
Total	$ 3,702,735	$ 3,621,256

Changes in the contract liabilities during the period are as follows:

		Deferred Revenue
Contract liabilities, December 31, 2017	$	3,621,256
Increases due to cash received from customers		1,764,735
Decreases due to recognition of revenue		(1,683,256)
Contract liabilities, September 30, 2018	$	3,702,735

Capitalized Contract Costs

We capitalize commissions paid to our sales managers related to contracts with customers when the associated revenue is expected to be earned over a period of time. Deferred commissions are primarily related to the sale of extended warranty agreements. Capitalized commissions are included in Prepaid Expenses and Other Current Assets in our Balance Sheets when the associated expense is expected to be recognized in one year or less, or Other Assets when the associated expense is expected to be recognized in greater than one year. The associated expense is included in Sales and Marketing expenses in our Statements of Operations.

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Our total capitalized contract costs as of September 30, 2018 and December 31, 2017 were $188,591 and $168,757, respectively. Expense for the three and nine months ended September 30, 2018 and 2017 related to the amortization of capitalized contract costs were immaterial to our financial statements.

Variable Consideration

Most of our sales are subject to 30 to 60-day customer-specified acceptance provisions primarily for purposes of ensuring products were not damaged during the shipping process. Historically, we have experienced immaterial product returns and, when experienced, we typically exchange the affected products with new products. Accordingly, variable consideration from contracts with customers is immaterial to our financial statements.

3 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 September 30,		Nine Months Ended September 30,	
		2018	2017	2018	2017
		(unaudited)		(unaudited)	
Net income		$ 2,400,273	$ 192,393	$ 4,596,437	$ 316,126
Weighted-average shares outstanding	Basic	10,824,421	10,565,598	10,695,601	10,664,132
Effect of dilutive securities:					
Underwriters warrants		107,820		86,469	
Stock Options		1,115,986	1,060,598	1,167,050	1,041,997
Restricted Stock Units		147,643	16,848	110,574	4,248
Weighted-average shares outstanding	Diluted	12,195,870	11,643,044	12,059,694	11,710,377
Basic net income per share		$ 0.22	$ 0.02	$ 0.43	$ 0.03
Diluted net income per share		$ 0.20	$ 0.02	$ 0.38	$ 0.03

Stock options and warrants to purchase shares of our commons 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	

Anti-dilutive stock options and restricted stock units	10,196	466,702	39,869	507,329

4 Inventory

Inventory consists of:

	September 30, 2018 (unaudited)	December 31, 2017
Raw materials	$ 3,535,042	$ 3,593,136
Work in process	314,632	280,443
Finished goods	645,917	537,466
Inventory before allowance for excess and obsolete	4,495,591	4,411,045
Allowance for excess and obsolete	(220,182)	(200,199)
Total	$ 4,275,409	$ 4,210,846

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5 Property and Equipment

Property and equipment consist of:

	September 30, 2018 (unaudited)	December 31, 2017
Computer software and hardware	$ 534,644	$ 490,272
Furniture and fixtures	864,376	655,518
Leasehold improvements	202,026	191,139
Machinery and equipment	2,137,665	2,046,808
Tooling in-process	47,943	46,970
	3,786,654	3,430,707
Accumulated depreciation	(1,907,035)	(1,561,856)
Total	$ 1,879,619	$ 1,868,851

Depreciation expense of property and equipment was $121,133 and $97,991 for the three months ended September 30, 2018 and 2017, respectively, and $345,592 and $255,814 for the nine months ended September 30, 2018 and 2017, respectively.

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

	September 30, 2018 (unaudited)	December 31, 2017
United States	$ 1,426,058	$ 1,349,897
International	453,561	518,954
Total property and equipment, net	$ 1,879,619	$ 1,868,851

Long-lived assets held outside of the United States consist principally of tooling and machinery and equipment, which are components of property and equipment, net.

6 Intangible Assets

The following table summarizes the components of intangible asset balances:

	September 30, 2018 (unaudited)	December 31, 2017
Patents in use	$ 304,270	$ 168,383

Patents	in process	61,376	116,260
Internally developed software	in use	867,569	867,569
Internally developed software	in process	2,645	
Trademarks		23,017	23,017
		1,258,877	1,175,229
Accumulated amortization		(426,733)	(289,727)
Total		$ 832,144	$ 885,502

Amortization expense of intangible assets was $22,491 and $20,600 for the three months ended September 30, 2018 and 2017, respectively, and $66,842 and $61,799 for the nine months ended September 30, 2018 and 2017, respectively.

Expected annual amortization expense for the remaining portion of 2018 and the next five years related to intangible assets is as follows (excludes in process intangible assets):

Three months ending December 31, 2018	$ 22,491
2019	89,963
2020	89,963
2021	89,963
2022	89,392
2023	88,740

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7 Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Cost of revenue	$ 70,000	$ 57,144	$ 207,498	$ 152,574
General and administrative	312,042	699,196	795,280	1,149,371
Sales and marketing	82,994	122,282	244,887	342,775
Research and development	38,519	34,653	114,299	90,358
Total	$ 503,555	$ 913,275	$ 1,361,964	$ 1,735,078

As of September 30, 2018, we had $148,976 of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 0.7 years. As of September 30, 2018, we had $2,251,204 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.4 years.

The following table presents a summary of our stock-based compensation activity for the nine months ended September 30, 2018 (shares):

	Stock Options	Restricted Stock Units
Outstanding beginning of period	1,430,962	252,733
Awards granted		10,204
Awards exercised/vested	(295,129)	(23,695)
Awards canceled	(5,875)	(2,374)
Outstanding end of period	1,129,958	236,868

8 Investments

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

	September 30, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,418,761	$	$ 100,558	$ 6,318,203
International corporations	1,167,850	1,230		1,169,080
Total	$ 7,586,611	$ 1,230	$ 100,558	$ 7,487,283

	December 31, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 7,244,771	$ 746	$ 63,575	$ 7,181,942
International corporations	971,087	707	18,613	953,181
Total	$ 8,215,858	$ 1,453	$ 82,188	$ 8,135,123

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 September 30, 2018.

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9 Fair Value Measurements

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

		Fair Value at September 30, 2018				
		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	$	6,318,203	$	$	6,318,203	$
International corporations		1,169,080			1,169,080	
Total	$	7,487,283	$	$	7,487,283	$

		Fair Value at December 31, 2017				
		Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Corporate bonds:						
U.S. corporations	$	7,181,942	$	$	7,181,942	$
International corporations		953,181			953,181	
Total	$	8,135,123	$	$	8,135,123	$

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

There were no transfers into or out of any Levels during the nine months ended September 30, 2018 or the year ended December 31, 2017.

10 Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss, net of tax, for the three months ended September 30, 2018 and 2017 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balance at June 30, 2018	$	(97,324)
Gains, net		6,566
Reclassification realized in net earnings		16,099
Balance at September 30, 2018	$	(74,659)

Balance at June 30, 2017	$	(26,329)
Gains, net		3,576
Reclassification realized in net earnings		122
Balance at September 30, 2017	$	(22,631)

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The components of accumulated other comprehensive loss, net of tax, for the nine months ended September 30, 2018 and 2017 are as follows:

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balance at December 31, 2017	$	(48,909)
Losses, net		(32,180)
Reclassification realized in net earnings		16,926
Cumulative effect from adoption of accounting standard update		(10,496)
Balance at September 30, 2018	$	(74,659)
Balance at December 31, 2016	$	(36,849)
Gains, net		9,623
Reclassification realized in net earnings		4,595
Balance at September 30, 2017	$	(22,631)

11 Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Act) was enacted. The 2017 Act includes a number of changes to U.S. tax laws that impact us, most notably a reduction of the U.S. corporate income tax from 34 percent to 21 percent effective January 1, 2018. The 2017 Act also provides for the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes beginning in 2018, including repeal of the domestic production activities deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures and additional limitations on executive compensation.

We recognized the income tax effects of the 2017 Act in our 2017 financial statements reported on Form 10-K in accordance with Staff Accounting Bulletin No. 118, which provides SEC staff guidance for the application of ASC Topic 740, *Income Taxes*, in the reporting period in which the 2017 Act was signed into law. As such, our 2017 financial results reported on Form 10-K reflected the income tax effects of the 2017 Act for which the accounting under ASC Topic 740 is complete and provisional amounts for those specific income tax effects of the 2017 Act for which the accounting under ASC Topic 740 is incomplete but a reasonable estimate could be determined. We did not identify items for which the income tax effects of the 2017 Act have not been completed and a reasonable estimate could not be determined as of December 31, 2017. No subsequent adjustments have been made to the amounts recorded as of December 31, 2017, which continue to represent a provisional estimate of the impact of the 2017 Act. The estimate of the impact of the 2017 Act is based on certain assumptions and our current interpretation, and may change, as we receive additional clarification and implementation guidance and as the interpretation of the 2017 Act evolves over time.

For the three and nine months ended September 30, 2018, we recorded a provision for income tax benefit of $(909,619) and $(275,044), respectively. Our effective tax rate was (61.0) percent and (6.4) percent and differed from the U.S. Federal statutory rate primarily due to discrete items related to tax benefits associated with the exercise and sale of employee options and underwriters warrants, partially offset by U.S. state tax expense.

For the three and nine months ended September 30, 2017, we recorded a provision for income tax expense of $32,384 and $48,507. Our effective tax rate was 14.4 percent and 13.3 percent and differed from the U.S. Federal statutory rate primarily due to favorable tax return adjustments, the domestic production activities deduction and a discrete item related to certain employee incentive stock options, partially offset by expense associated with employee incentive stock options and U.S. state tax expense.

As of September 30, 2018 and December 31, 2017, 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 believe that our tax positions comply in all material respects with applicable tax law. However, tax law is subject to interpretation, and interpretations by taxing authorities could be different from ours, which could result in the imposition of additional taxes and penalties.

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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 2013 and subsequent years. The Internal Revenue Service is currently examining the 2016 tax year and the examination is expected to be finalized within 12 months. This examination is in the early stages and no adjustments have been proposed. However, the completion of this examination, or additional examinations, could result in an adjustment to our liability for income taxes, assessments of additional taxes and penalties. Any such adjustments could be material to our financial condition, results of operations and cash flow.

12 Commitments and Contingencies

Leases. In January 2014, we entered into a non-cancelable operating lease, commencing July 1, 2014, for a new manufacturing and headquarters facility in Winter Springs, Florida owned by Susi, LLC, an entity controlled by our President and CEO, Roger Susi. Pursuant to the terms of our lease for this property, the monthly base rent is $33,171, 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 September 30, 2018 is as follows:

Three months ending December 31, 2018	$	102,399
2019		170,664
2020		
2021		
2022		
Total non-cancelable operating lease commitments	$	273,063

Rent expense under our operating leases was $106,662 and $103,197 for the three months ended September 30, 2018 and 2017, respectively, and $355,125 and $306,221 for the nine months ended September 30, 2018 and 2017, 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 $2,437,329 and $2,219,818 as of September 30, 2018 and December 31, 2017, respectively. No amounts related to these purchase orders have been recognized in our balance sheet.

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

13 Common Stock

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

Balance, December 31, 2017	10,596,566
Option and warrant exercises	314,698
Vesting of restricted stock units, net of shares withheld for taxes	22,725
Balance, September 30, 2018	10,933,989

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

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

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

Our Business

We develop, manufacture, market and distribute Magnetic Resonance Imaging (MRI) compatible medical devices and accessories, disposables and services relating to them.

We are a leader in the development of innovative magnetic resonance imaging (MRI) compatible medical devices. We are the only known provider of a non-magnetic intravenous (IV) infusion pump system that is 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 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 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 to remain immobile during an MRI scan.

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

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

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

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

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FDA Warning Letter

The FDA conducted a routine inspection of our prior facility between April 7 and April 16, 2014. This was the first FDA inspection of our facility since the voluntary product recall in August 2012 of certain infusion sets and the voluntary recall in July 2013 of our DERS software. The FDA issued a Form 483 on April 16, 2014 that identified eight observations. Most 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 responses 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 states 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 states 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 had been made over time. We believed 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.

Between July 11 and July 18, 2016, the FDA conducted a routine inspection of our facility. This was the first FDA inspection of our facility since the receipt of the Warning Letter. During this inspection, the updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the FDA determined that no further actions were necessary.

On December 15, 2016, we received FDA 510(k) clearance for our MRidium 3860+ MRI IV infusion pump system, including the DERS software feature. As of September 30, 2018, the Warning Letter remains open.

Financial Highlights and Outlook

Our revenue increased $1.9 million, or 33.8 percent, to $7.6 million for the third quarter ended September 30, 2018, compared to $5.7 million for the third quarter last year. Net income was $2.4 million, or $0.20 per diluted share in the third quarter ended September 30, 2018, compared to net income of $0.2 million, or $0.02 per diluted share in the third quarter last year. Our net income for the third quarter ended September 30, 2018 was favorably impacted by discrete tax items related to tax benefits associated with the exercise of employee options and underwriters warrants, which are not likely to be recurring.

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For the remainder of 2018, we expect our revenues to increase when compared to same period in 2017 as we continue to focus on expanding global sales of our new MRI compatible patient vital signs monitor and penetrating the MRI compatible IV pump market of first-time adopters more deeply. We intend to continue targeting hospitals and acute care facilities that have yet to adopt our MRI compatible IV pump and patient monitoring solutions and penetrating the Intensive Care Unit, Emergency Room and other critical care locations within hospitals where there is a high probability that interventional radiology procedures will need to be performed on patients.

We expect higher full year 2018 operating expenses compared to 2017 due primarily to higher sales and marketing expenses.

Application of Critical Accounting Policies

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

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

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

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

September 30, 2018.

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

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Results of Operations

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

	Percent of Revenue Three Months Ended September 30,		Percent of Revenue Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	24.0	23.0	23.7	24.0
Gross profit	76.0	77.0	76.3	76.0
Operating expenses:				
General and administrative	28.7	44.8	29.7	41.8
Sales and marketing	23.4	22.0	22.4	24.1
Research and development	4.9	6.7	5.2	8.4
Total operating expenses	57.0	73.6	57.3	74.3
Income from operations	19.0	3.4	19.1	1.7
Other income, net	0.6	0.5	0.5	0.5
Income before provision for income taxes	19.6	4.0	19.6	2.2
Provision for income tax (benefit) expense	(11.9)	0.6	(1.2)	0.3
Net income	31.5%	3.4%	20.8%	1.9%

Three and Nine Months Ended September 30, 2018 and 2017

Revenue by Geographic Region

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
United States	$ 6,099,767	$ 5,016,550	21.6%	$ 17,808,918	$ 14,176,357	25.6%
International	1,514,888	673,174	125.0%	4,290,673	2,200,291	95.0%
Total Revenue	$ 7,614,655	$ 5,689,724	33.8%	$ 22,099,591	$ 16,376,648	34.9%

Revenue by Type

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Devices:						
MRI Compatible IV Infusion Pump Systems	$ 3,532,670	$ 3,606,327	(2.0)%	$ 10,748,830	$ 9,888,166	8.7%
MRI Compatible Patient Vital Signs Monitoring Systems	1,817,361	118,598	1,432.4%	4,526,735	907,622	398.7%
Total Devices Revenue	5,350,031	3,724,925	43.6%	15,275,565	10,795,788	41.5%

Disposables and Services	1,874,439	1,673,254	12.0%	5,722,573	4,893,990	16.9%
Amortization of extended warranty agreements	390,185	291,545	33.8%	1,101,453	686,870	60.4%
Total revenue	$ 7,614,655	$ 5,689,724	33.8%	$ 22,099,591	$ 16,376,648	34.9%

For the three months ended September 30, 2018, revenue increased $1.9 million, or 33.8 percent, to $7.6 million from $5.7 million for the same period in 2017. This increase is due to higher sales of our MRI compatible devices, disposables and services and amortization of extended maintenance contracts.

The average selling price of our MRI compatible IV infusion pump system during the three months ended September 30, 2018 was approximately $31,800, compared to $35,000 for the same period in 2017. The decrease in ASP relates to higher international sales as a percent of revenue during the third quarter of 2018 and an unfavorable sales mix when compared to the same period in 2017.

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The average selling price of our MRI compatible patient vital signs monitoring system during the three months ended September 30, 2018 was approximately $37,900, compared to $26,100 for the same period in 2017. The increase in ASP primarily relates to sales of this device in the U.S. during the third quarter 2018. During the third quarter 2017, this device was only available internationally. These average selling prices reflect introductory promotions and are lower than what we expect in the future.

Revenue from sales in the U.S. increased $1.1 million, or 21.6 percent, to $6.1 million from $5.0 million for the same period in 2017. Revenue from sales internationally increased $0.8 million, or 125.0 percent, to $1.5 million for the three months ended September 30, 2018, from $0.7 million for the same period in 2017. Domestic sales accounted for 80.1 percent of revenue in the third quarter 2018, compared to 88.2 percent in the third quarter 2017.

Revenue from sales of devices increased $1.7 million, or 43.6 percent, to $5.4 million from $3.7 million for the same period in 2017. Revenue from sales of our disposables and services increased $0.2 million, or 12.0 percent, to $1.9 million from $1.7 million for the same period in 2017. Revenue from the amortization of extended maintenance contracts increased $0.1 million, or 33.8%, to $0.4 million from $0.3 million for the same period in 2017.

For the nine months ended September 30, 2018, revenue increased $5.7 million, or 34.9 percent, to $22.1 million from $16.4 million for the same period in 2017. This increase is due to higher sales of our MRI compatible devices, disposables and services and amortization of extended maintenance contracts.

The average selling price of our MRI compatible IV infusion pump system during the nine months ended September 30, 2018 was approximately $31,400, compared to $35,100 for the same period in 2017. The decrease in ASP relates to higher international sales as a percent of revenue during the nine months ended September 30, 2018 and an unfavorable sales mix when compared to the same period in 2017.

The average selling price of our MRI compatible patient vital signs monitoring system during the nine months ended September 30, 2018 was approximately $35,400, compared to $21,600 for the same period in 2017. The increase in ASP primarily relates to sales of this device in the U.S. during the 2018 period. During the 2017 period, this device was only available internationally. These average selling prices reflect introductory promotions and are lower than what we expect in the future.

Revenue from sales in the U.S. increased $3.6 million, or 25.6 percent, to $17.8 million from $14.2 million for the same period in 2017. Revenue from sales internationally increased $2.1 million, or 95.0 percent, to $4.3 million for the nine months ended September 30, 2018, from $2.2 million for the same period in 2017. Domestic sales accounted for 80.6 percent of revenue in the nine months ended September 30, 2018, compared to 86.6 percent for the same period in 2017.

Revenue from sales of devices increased $4.5 million, or 41.5 percent, to $15.3 million from $10.8 million for the same period in 2017. Revenue from sales of our disposables and services increased $0.8 million, or 16.9 percent, to $5.7 million from $4.9 million for the same period in 2017. Revenue from the amortization of extended maintenance contracts increased $0.4 million, or 60.4%, to $1.1 million from $0.7 million for the same period in 2017.

Cost of Revenue and Gross Profit

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 7,614,655	$ 5,689,724	$ 22,099,591	$ 16,376,648
Cost of revenue	1,826,716	1,307,767	5,229,141	3,929,699
Gross profit	$ 5,787,939	$ 4,381,957	$ 16,870,450	$ 12,446,949
Gross profit percentage	76.0%	77.0%	76.3%	76.0%

For the three months ended September 30, 2018, cost of revenue increased $0.5 million, or 39.7 percent, to $1.8 million from $1.3 million for the same period in 2017. Gross profit increased $1.4 million, or 32.1 percent, to $5.8 million for the third quarter 2018 from $4.4 million for the same period in 2017. The increase in cost of revenue and gross profit is primarily attributable to higher sales.

Gross profit margin was 76.0 percent for third quarter 2018, compared to 77.0 percent for the third quarter 2017. This is primarily due to a lower average selling price for our MRI compatible IV pump system resulting from higher international sales as a percent of revenue and unfavorable inventory materials cost and overhead adjustments, partially offset by favorable labor variances and a higher average selling price for our MRI compatible patient vital signs monitoring system when compared to the same period last year.

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For the nine months ended September 30, 2018, cost of revenue increased $1.3 million, or 33.1 percent, to $5.2 million from $3.9 million for the same period in 2017. Gross profit increased $4.5 million, or 35.5 percent, to $16.9 million for the nine months ended September 30, 2018 from $12.4 million for the same period in 2017. The increase in cost of revenue and gross profit is primarily attributable to higher sales.

Gross profit margin was 76.3 percent for the nine months ended September 30, 2018, compared to 76.0 percent for the same period in 2017. This is primarily the result of a higher average selling price for our MRI compatible patient vital signs monitoring system and favorable labor variances, partially offset by unfavorable inventory materials cost and overhead adjustments.

Operating Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
General and administrative	$ 2,181,839	$ 2,551,290	$ 6,563,727	$ 6,848,472
Percentage of revenue	28.7%	44.8%	29.7%	41.8%
Sales and marketing	$ 1,784,418	$ 1,251,901	$ 4,946,398	$ 3,940,216
Percentage of revenue	23.4%	22.0%	22.4%	24.1%
Research and development	$ 373,583	$ 382,704	$ 1,149,397	$ 1,373,005
Percentage of revenue	4.9%	6.7%	5.2%	8.4%

General and Administrative

For the three months ended September 30, 2018, general and administrative expense decreased $(0.4) million, or 14.5 percent, to $2.2 million from $2.6 million for the same period last year. This decrease is primarily due to lower stock compensation resulting from a one-time charge for the modification of the underwriters warrants during the third quarter 2017 and lower regulatory expenses, partially offset by higher expenses for computer supplies, software and employee payroll and benefits during the 2018 period.

For the nine months ended September 30, 2018, general and administrative expense decreased $(0.2) million, or 4.2 percent, to $6.6 million from $6.8 million for the same period last year. This decrease is primarily due to lower stock compensation expense resulting from a one-time charge for the modification of the underwriters warrants during the third quarter 2017 and the write-off of non-trade accounts receivable also during the 2017 period, and lower expenses for consulting and regulatory costs, partially offset by higher expenses for payroll and employee benefits, computer supplies and software during the 2018 period.

Sales and Marketing

For the three months ended September 30, 2018, sales and marketing expense increased $0.5 million, or 42.5 percent, to $1.8 million from $1.3 million for the same period last year. This is primarily the result of higher sales commissions, payroll and sales activities expenses due to higher headcount, partially offset by lower stock compensation expense.

For the nine months ended September 30, 2018, sales and marketing expense increased $1.0 million, or 25.5 percent, to $4.9 million from $3.9 million for the same period last year. This is primarily the result of higher sales activities, commissions and payroll expenses, partially offset by lower stock compensation expense.

Research and Development

For the three months ended September 30, 2018, research and development expense was consistent at $0.4 million. This is primarily the result of lower expenses for outside engineering services, offset by higher payroll expenses.

For the nine months ended September 30, 2018, research and development expense decreased $(0.3) million, or 16.3 percent, to $1.1 million from $1.4 million for the same period last year. This is primarily the result of lower expenses for consulting, project development supplies and outside engineering services.

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Other Income, Net

Other income, net consists of interest income, foreign currency gains and losses, and other miscellaneous income. For the three months ended September 30, 2018 and 2017, we reported other income of approximately $43,000 and $29,000, respectively. This increase is primarily due to higher interest income, partially offset by losses on maturities of investments.

For the nine months ended September 30, 2018 and 2017, we reported other income of approximately $110,000 and $79,000, respectively. This increase is primarily due to higher interest income, partially offset by losses on maturities of investments.

Income Taxes

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Act) was enacted. The 2017 Act includes a number of changes to U.S. tax laws that impact us, most notably a reduction of the U.S. corporate income tax from 34 percent to 21 percent effective January 1, 2018. The 2017 Act also provides for the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes beginning in 2018, including repeal of the domestic production activities deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures and additional limitations on executive compensation.

We recognized the income tax effects of the 2017 Act in our 2017 financial statements reported on Form 10-K in accordance with Staff Accounting Bulletin No. 118, which provides SEC staff guidance for the application of ASC Topic 740, *Income Taxes*, in the reporting period in which the 2017 Act was signed into law. As such, our 2017 financial results reported on Form 10-K reflected the income tax effects of the 2017 Act for which the accounting under ASC Topic 740 is complete and provisional amounts for those specific income tax effects of the 2017 Act for which the accounting under ASC Topic 740 is incomplete but a reasonable estimate could be determined. We did not identify items for which the income tax effects of the 2017 Act have not been completed and a reasonable estimate could not be determined as of December 31, 2017. No subsequent adjustments have been made to the amounts recorded as of December 31, 2017, which continue to represent a provisional estimate of the impact of the 2017 Act. The estimate of the impact of the 2017 Act is based on certain assumptions and our current interpretation, and may change, as we receive additional clarification and implementation guidance and as the interpretation of the 2017 Act evolves over time.

For the three and nine months ended September 30, 2018, we recorded a provision for income tax benefit of $(909,619) and $(275,044), respectively. Our effective tax rate was (61.0) percent and (6.4) percent and differed from the U.S. Federal statutory rate primarily due to discrete items related to tax benefits associated with the exercise and sale of employee options and underwriters warrants, partially offset by U.S. state tax expense.

For the three and nine months ended September 30, 2017, we recorded a provision for income tax expense of $32,384 and $48,507. Our effective tax rate was 14.4 percent and 13.3 percent and differed from the U.S. Federal statutory rate primarily due to favorable tax return adjustments, the domestic production activities deduction and a discrete item related to certain employee incentive stock options, partially offset by expense associated with employee incentive stock options and U.S. state tax expense.

As of September 30, 2018 and December 31, 2017, 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 believe that our tax positions comply in all material respects with applicable tax law. However, tax law is subject to interpretation, and interpretations by taxing authorities could be different from ours, which could result in the imposition of additional taxes and penalties.

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 2013 and subsequent years. The Internal Revenue Service is currently examining the 2016 tax year and the examination is expected to be finalized within 12 months. This examination is in the early stages and no adjustments have been proposed. However, the completion of this examination, or additional examinations, could result in an adjustment to our liability for income taxes, assessments of additional taxes and penalties. Any such adjustments could be material to our financial condition, results of operations and cash flow.

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Liquidity and Capital Resources

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

As of September 30, 2018, we had cash and cash equivalents and investments of $31.2 million, stockholders equity of $40.1 million, and working capital of $37.9 million. As of December 31, 2017, we had cash and cash equivalents and investments of $26.3 million, stockholders equity of $32.9 million, and working capital of $31.0 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.

	Nine Months Ended September 30,	
	2018	2017
Net cash provided by operating activities	$ 3,833,642	$ 2,014,799
Net cash provided by investing activities	441,395	491,776
Net cash provided by (used in) financing activities	1,218,151	(1,814,141)

For the nine months ended September 30, 2018, cash provided by operating activities increased $1.8 million to $3.8 million, compared to $2.0 million for the same period in 2017. This increase was primarily the result of higher net income and lower cash outflows related to accounts payable, prepaid expenses and other current assets, partially offset by lower cash inflows of accounts receivable and deferred revenue.

Cash provided by investing activities decreased $(0.1) million to $0.4 million for the nine months ended September 30, 2018, compared to $0.5 million for the same period in 2017. This decrease primarily relates to lower maturities of investments, net of purchases, partially offset by lower cash outflows related to capital expenditures.

Cash provided by financing activities increased $3.0 million to $1.2 million for the nine months ended September 30, 2018, compared to cash used in financing activities of $(1.8) million for the same period in 2017. This increase primarily relates to purchases of treasury stock during the 2017 period and higher cash inflows related to exercises of stock options and warrants during the 2018 period.

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

Our manufacturing and headquarters facility has been leased from Susi, LLC, an entity controlled by our President and CEO, Roger Susi. Pursuant to the terms of our lease, the monthly base rent is $33,171, 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 September 30, 2018. We had no other off-balance sheet arrangements during the nine months ended September 30, 2018 or for the year ended December 31, 2017 that had, or are reasonably likely to have, a material effect on our financial condition, results of operations, or liquidity.

Contractual Obligations

There have been no material changes outside the ordinary course of business to our contractual obligations and commercial commitments since December 31, 2017.

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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 because 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 nine months ended September 30, 2018 and 2017.

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 September 30, 2018, we had $7.5 million in corporate bonds, with $3.5 million that matures in less than 1 year, $3.1 million that matures between 1 and 3 years and $0.9 million that matures between 3 and 5 years. These corporate bonds have fixed interest rates and semi-annual interest payment dates. If market interest rates were to change by 100 basis points from levels at September 30, 2018, we expect the corresponding change in fair value of our investments would be approximately $100,000. This is based on sensitivity analyses performed on our financial position as of September 30, 2018. 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

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

Item 1A. Risk Factors

Risks Relating to Our Business and Financial Condition

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

Our current revenue and profitability is significantly dependent on the sale of the MRidium 3860+ MRI compatible IV infusion pump system (a Class II medical device) and the ongoing sale of disposable tubing sets and related services. Sales of the MRidium 3860+ MRI compatible IV infusion pump system have historically comprised a substantial majority of our net revenue. Although we have recently launched our marketing efforts for our new 3880 MRI compatible patient vital signs monitor in the U.S., our near-term revenue and profitability will be dependent upon our ability to successfully market and sell the MRidium 3860+ MRI compatible IV infusion pump system.

In the past, the FDA has issued us a Warning Letter that impacted our ability to commercially distribute our MRidium 3860+ MRI compatible IV infusion pump system. Although we have resumed commercial distribution of the MRidium 3860+ MRI compatible IV infusion pump system, the Warning Letter remains open and there can be no guarantee that the FDA will not take similar action in the future. The FDA could require us to cease shipment of our products, notify health professionals and others that the devices present unreasonable risk or substantial harm to public health, order a recall, repair, replacement, or refund of the devices, detain or seize adulterated or misbranded medical devices, or ban the medical devices. The FDA may also issue further warning letters or untitled letters, refuse future requests 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.

Our products could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to:

- entrance of new competitors into our markets;

- technological advancements of MRI scanners;

- 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 products or services would cause our revenues to decline and have a material adverse impact on our business, financial condition and our common stock.

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

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

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

We must have sufficient sources of liquidity to fund our working capital requirements, our capital improvement plans, and execute on our strategic initiatives. Our decline in operating results during 2017 limited our generation of capital resources and that situation could return if we are unable to continue to increase revenues or adjust our costs appropriately. Further, our 3880 Monitor launch is demanding increased working capital before any long-term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, which cannot at all times be assured. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plan, pursuing additional financing to the extent available, reducing capital expenditures, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

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

Many of the component parts of our products are obtained through supply agreements with third parties. Some of these parts require our partners to engage in complex manufacturing processes and involve long lead times or delivery periods. Considering 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 or deliver 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 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, or manufacture or deliver such materials later than anticipated, we could experience protracted delays or interruptions in the supply of materials which would ultimately delay our manufacture of products for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition.

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

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

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

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

- a supplier s inability or unwillingness to continue supplying raw materials and/or components;
- regulatory requirements or action by regulatory agencies or others, including changes in international trade treaties and/or tariffs;
- adverse financial or other strategic developments at or affecting the supplier, including bankruptcy;
- unexpected demand for or shortage of raw materials or components;
- failure to comply with quality standards which results in quality and product failures, product contamination and/or recall;
- discovery of previously unknown or undetected imperfections in raw materials or components;
- labor disputes or shortages, including from the effects of health emergencies and natural disasters; and
- political instability and actual or anticipated military or political conflicts.

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

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

The manufacture of our 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, the affected products 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.

Our markets are very competitive and we sell certain of our products in a mature market.

The market for our 3880 MRI compatible patient vital signs monitoring system is well-developed and sales growth for our monitor could be slow. Our vital signs monitoring system could face difficult competition, including competitors offering lower prices, which could have an adverse effect on our revenue and margins. Our competitors may have certain advantages, which include the ability to devote greater resources to the development, promotion, and sale of their products. Consequently, we may need to increase our efforts, and related expenses for research and development, marketing, and selling to maintain or improve our position. We may not realize the per unit revenue we have planned for and expect. Continued sales to our existing customers is expected to be significant to our revenue in the future, and if our existing customers do not continue to purchase from us, our revenue may decline.

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

We manufacture and store our products at a single facility in Winter Springs, Florida. If by reason of fire, hurricane or other natural disaster, or for any other reason, the facility is destroyed or seriously damaged or our access to it is limited, our ability to provide products to our customers would be seriously interrupted or impaired and our operating results and financial condition would be materially and 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, and may in the future have, accounts receivables from one or two customers that accounted for 10 percent or more of our gross accounts receivable. As a result, we may be exposed to a certain level of concentration of credit risk. If a major customer experiences financial difficulties, the effect on us could be material and have an adverse effect on our business, financial condition and results of operations.

If we fail to maintain relationships with Group Purchasing Organizations, sales of our products could decline.

Our ability to sell our products to U.S. hospitals, acute care facilities and outpatient imaging centers depends in part on our relationships with Group Purchasing Organizations (GPOs). Many existing and potential customers for our products are members of GPOs. GPOs negotiate pricing arrangements and contracts, which are sometimes exclusive, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO s affiliated hospitals and other members. We pay the GPOs an administrative fee in the form of a percentage of the volume of products sold to their affiliated hospitals and other members. If we are not an approved provider selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products. Should a GPO negotiate a sole source or bundling contract covering a future or current competitor s products, we may be precluded from making sales of our competing products to members of that GPO for the duration of the contractual arrangement. For example, even if we have an existing contract with a GPO for sales of our MRidium 3860+ MRI compatible IV infusion pump, we may encounter difficulties in selling, or be unable to sell, our 3880 MRI compatible patient vital signs monitoring system to that GPO s affiliated hospitals and other members, which may result in a longer sales cycle or an inability to sell. 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 medical devices are considered capital equipment by many potential customers, and hence changes in the budgets of healthcare organizations and the timing of spending under these budgets and conflicting spending priorities can have a significant effect on the demand for our products and related services. Any decrease in expenditures by these healthcare facilities could decrease demand for our products and related services and reduce our revenue. Additionally, changes to reimbursement policies by third-party payors could also decrease demand for our products and related services and reduce our revenue.

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

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

The lengthy sales cycle for medical devices 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 typically three to six months and expect the same for our 3880 MRI compatible patient vital signs monitor. Sales cycles can also be delayed because 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 our products before other medical professionals routinely use them for other procedures and in other departments of the hospital. Such time would delay potential sales of additional units and disposable products or additional optional accessories to that medical facility or hospital. These delays could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

We believe that Mr. Susi 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, including in the MRI compatible medical device segment. If our current employees with experience in the MRI compatible device industry leave our company, we may have difficulty finding replacements with an equivalent amount of experience and skill, which could harm our operations. Our future success will also depend in part on our ability to identify, hire and retain additional personnel, including skilled engineers to develop new products, and executives to oversee our marketing, sales, customer support and production staff. We may not be successful in attracting, integrating or retaining qualified personnel to meet our current growth plans or future needs. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively.

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

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

We may be unable to scale our operations successfully.

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

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

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

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

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

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

Significant changes and volatility in most aspects of the current business environment, including financial markets, consumer behavior, speed of technological, regulatory and competitive changes, 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. These factors are also influenced by regular changes to GAAP, some of which are material to most companies, such as recent changes to revenue recognition. These changes introduce risk to our financial reporting processes due to implementation and internal control implications.

We base the aforementioned 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.

Our adoption and implementation of the new revenue accounting standard on January 1, 2018 included management s judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle based and interpretation of those principles may vary from company to company based on their unique circumstances. If our initial judgments and assumptions require change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

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Changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results.

On December 22, 2017, President Trump signed into law new legislation that significantly revised the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law, including potential U.S. state and foreign tax jurisdiction responses, is uncertain and our business and financial condition could be adversely affected.

In addition, we are subject to the continuous examination of our income tax returns by the Internal Revenue Service, or IRS, and other tax authorities. It is possible that tax authorities may disagree with certain positions we have taken, and any adverse outcome of such a review or audit could have a negative effect on our financial position and operating results. We regularly assess the likelihood of adverse outcomes resulting from these examinations to determine the adequacy of our provision for income taxes, but the determination of our provision for income taxes and other tax liabilities requires significant judgment by management, and there are transactions where the ultimate tax determination is uncertain. Although we believe that our estimates are reasonable, the ultimate tax outcome may differ from the amounts recorded in our financial statements and may materially affect our financial results in the period or periods for which such determination is made. There can be no assurance that the outcomes from continuous examinations will not have an adverse effect on our business, financial condition, and results of operations.

We are subject to various privacy and consumer protection laws.

Our privacy policy is posted on our website, and any failure by us or our vendor or other business partners to comply with it or with federal, state or international privacy, data protection or security laws or regulations could result in regulatory or litigation-related actions against us, legal liability, fines, damages and other costs. Substantial expenses and operational changes may be required in connection with maintaining compliance with such laws, and in particular certain emerging privacy laws are still subject to a high degree of uncertainty as to their interpretation and application. For example, in May 2018, the General Data Protection Regulation (the GDPR) began to fully apply to the processing of personal information collected from individuals located in the European Union. The GDPR has created new compliance obligations and has significantly increased fines for noncompliance. Although we take steps to protect the security of our customers personal information, we may be required to expend significant resources to comply with data breach requirements if third parties improperly obtain and use the personal information of our customers or we otherwise experience a data loss with respect to customers personal information. A breach of our network security and systems could have negative consequences for our business and future prospects, including possible fines, penalties and damages, reduced customer demand for our products, and harm to our reputation and brand.

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 or current clearances or approvals and criminal prosecution.

In addition, our products are subject to pre-clearance 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.

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

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

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

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

Sales to customers outside of the U.S. have historically comprised of approximately one-tenth to one-third of our net revenues and we expect that non-U.S. sales will contribute to future growth. 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 U.S. 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, which might increase with increasing nationalism;

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

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

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

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

- potentially negative consequences from changes in or interpretations of tax laws, including U.S. state and foreign tax jurisdiction responses to recent changes in U.S. federal 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.

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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 $5,000,000; 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 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. We updated the software in all product subject to the recall. In July 2015, the FDA notified us that it had concluded its audit and confirmed that the recall was terminated. To avoid future product recalls we have made and continue to invest in our quality systems, processes and procedures. We will continue to make improvements to our products and systems to further reduce issues related to patient safety.

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

Our products or product types, or MR imaging 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.

Our products are designed for use around MRI scanners. MRI has been an important imaging diagnostic for some time now, however should MRI technology change materially or decline in usage due to new technologies or concerns about costs or efficacy of MR imaging, our products would suffer as MRI usage and installations declined. Such a matter may also have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the PPACA), enacted in 2010, implemented changes that are expected to significantly impact the medical device industry. Beginning on January 1, 2013, the Affordable Care Act imposed a 2.3 percent excise tax on sales of products defined as medical devices by the regulations of the FDA. We believe that all our medical products are medical devices within the meaning of the FDA regulations. On December 18, 2015, under the Consolidated Appropriations Act of 2015, the medical device excise tax was suspended for two years beginning on January 1, 2016. New legislation passed in January 2018 further suspended the medical device excise tax through December 31, 2019. While this tax was suspended by legislation for 2018 and 2019, its return beginning on January 1, 2020 and potential increases from the 2.3 percent level in future years would negatively impact our operating results. We cannot currently foresee that the suspension will be reinstated.

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

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

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

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

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

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

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

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

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

We submitted responses to the Form 483 in August 2016 and October 2016 in which we described our proposed corrective and preventative actions to address each of the observations. As part of our response, on October 13, 2016 we initiated a customer follow up to our August 2012 Safety Alert, and made available an updated instruction card for customers. As of September 30, 2018, the Safety Alert remains open.

During the July 2016 inspection, updated documents and actions implemented in response to the Warning Letter findings were reviewed, and the FDA determined that no further actions were necessary in response to the Warning Letter. As of September 30, 2018, the Warning Letter remains open.

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

procedure or to our or our suppliers manufacturing facility could materially harm our reputation in the marketplace.

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

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

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Risks Relating to our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Furthermore, the costs of resolving any patent litigation or other intellectual property proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a

material adverse effect on our ability to compete in the marketplace. Patent litigation and other intellectual property proceedings may also consume significant management time.

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- a lack of liquidity in the public trading of our common stock;
- the commercial success or failure of our key products;
- delayed or reduced orders from our customers;
- manufacturing or supply interruptions;

- changes or developments in laws or regulations applicable to our products and product candidates;
- introduction of competitive products or technologies;
- poorly executed acquisitions or acquisitions whose projected potential is not realized;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed our own estimates and projections or the estimates and projections of securities analysts or investors;
- new or revised earnings estimates or guidance by us or securities analysts or investors;
- varying economic and market conditions in the U.S.;
- negative developments impacting the medical device industry in general and changes in the market valuations of companies deemed similar to us;
- negative developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents, trademarks or other proprietary rights;
- litigation or investigations involving us, our industry, or both;

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- issuances of debt, equity or convertible securities at terms deemed unfavorable by the market;
- major catastrophic events;
- sales of large blocks of our stock;
- exercise of the underwriters warrant that may lead to sales that put downward pressure on our stock price;
- changes in our Board of Directors, management or key personnel; or
- the other factors described in this Risk Factors section.

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

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

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

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

On September 26, 2014, we filed a registration statement under Form S-8 to register all of the shares issuable upon exercise of options outstanding or reserved for future issuance under our equity compensation plans. In addition, on December 3, 2015 we filed a registration

statement on Form S-3/A to register $40 million of shares of common stock that may be offered or sold by us. If any of the foregoing shares are sold by the Company, or if it is perceived that they will be sold, the trading price of our common stock could decline.

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

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

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

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

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

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

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

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

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

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

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

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are investing additional resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative

expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. These compliance requirements and costs will increase once we are no longer an emerging growth company as defined in the JOBS Act, which we anticipate will occur on December 31, 2019.

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.

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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.

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. We anticipate that starting December 31, 2019, we will no longer be an emerging growth company and after that date we will no longer be able to avail ourselves of these exemptions.

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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: November 7, 2018

/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)