IRADIMED CORP
Form 10-Q
November 06, 2017
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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, 2017

OR

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

For the transition period from to

Commission File No.: 001-36534

IRADIMED CORPORATION

(Exact name of Registrant as specified in its charter)

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

(407) 677-8022

(Registrant s telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o
	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 10,555,233 shares of common stock, par value $0.0001 per share, outstanding as of October 31, 2017.

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IRADIMED CORPORATION

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

IRADIMED CORPORATION

CONDENSED BALANCE SHEETS

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,406,305	$ 17,713,871
Accounts receivable, net of allowance for doubtful accounts of $34,751 as of September 30, 2017 and $44,308 as of December 31, 2016	3,508,432	3,775,699
Investments	6,804,783	7,965,521
Inventory, net	4,129,357	3,886,590
Prepaid expenses and other current assets	287,061	362,900
Prepaid income taxes	311,217	151,820
Total current assets	33,447,155	33,856,401
Property and equipment, net	1,853,506	1,456,149
Intangible assets, net	885,713	918,712
Deferred income taxes	1,553,469	789,402
Other assets	179,785	173,820
Total assets	$ 37,919,628	$ 37,194,484
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 794,446	$ 1,120,830
Accrued payroll and benefits	1,438,417	1,035,266
Other accrued taxes	68,247	119,094
Warranty reserve	48,513	40,905
Deferred revenue	1,380,618	1,033,146
Other current liability	120,634	120,634
Accrued income taxes		192,006
Total current liabilities	3,850,875	3,661,881
Deferred revenue	1,928,347	1,643,478
Total liabilities	5,779,222	5,305,359
Stockholders equity:		
Common stock; $0.0001 par value; 31,500,000 shares authorized; 10,554,753 shares issued and outstanding as of September 30, 2017 and 10,722,675 shares issued and outstanding as of December 31, 2016	1,076	1,072
Additional paid-in capital	13,808,596	12,055,188
Retained earnings	20,171,907	19,869,714
Treasury stock	(1,818,542)	
Accumulated other comprehensive loss	(22,631)	(36,849)
Total stockholders equity	32,140,406	31,889,125
Total liabilities and stockholders equity	$ 37,919,628	$ 37,194,484

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,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 5,689,724	$ 7,673,217	$ 16,376,648	$ 26,506,275
Cost of revenue	1,307,767	1,405,884	3,929,699	4,850,748
Gross profit	4,381,957	6,267,333	12,446,949	21,655,527
Operating expenses:				
General and administrative	2,551,290	1,869,927	6,848,472	7,217,854
Sales and marketing	1,251,901	1,346,742	3,940,216	4,039,550
Research and development	382,704	457,134	1,373,005	983,291
Total operating expenses	4,185,895	3,673,803	12,161,693	12,240,695
Income from operations	196,062	2,593,530	285,256	9,414,832
Other income (expense), net	28,715	(4,017)	79,377	23,092
Income before provision for income taxes	224,777	2,589,513	364,633	9,437,924
Provision for income tax expense	32,384	1,029,029	48,507	3,364,179
Net income	$ 192,393	$ 1,560,484	$ 316,126	$ 6,073,745
Net income per share:				
Basic	$ 0.02	$ 0.15	$ 0.03	$ 0.56
Diluted	$ 0.02	$ 0.13	$ 0.03	$ 0.50
Weighted average shares outstanding:				
Basic	10,565,598	10,684,650	10,664,132	10,852,476
Diluted	11,643,044	11,867,997	11,710,377	12,055,467

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,	
	2017	**2016**	**2017**	**2016**
Net income	$ 192,393	$ 1,560,484	$ 316,126	$ 6,073,745
Other comprehensive income:				
Change in fair value of available-for-sale securities, net of tax expense (benefit) of $2,159 and $(7,211) for the three months ended September 30, 2017 and 2016, respectively, and $5,825 and $(1,220) for the nine months ended September 30, 2017 and 2016, respectively	3,576	(13,049)	9,623	(1,156)
Realized loss on available-for-sale securities reclassified to net income, net of tax benefit of $119 and $12,778 for the three months ended September 30, 2017 and 2016, respectively, and $2,162 and $29,495 for the nine months ended September 30, 2017 and 2016, respectively	122	22,091	4,595	51,047
Other comprehensive income	3,698	9,042	14,218	49,891
Comprehensive income	$ 196,091	$ 1,569,526	$ 330,344	$ 6,123,636

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,	
	2017	**2016**
Operating activities:		
Net income	$ 316,126	$ 6,073,745
Adjustments to reconcile net income to net cash provided by operating activities:		
Change in allowance for doubtful accounts	(9,557)	19,100
Change in provision for excess and obsolete inventory	38,021	86,543
Depreciation and amortization	970,705	709,871
Write-off of non-trade accounts receivable	205,444	
Excess tax benefit on the exercise of stock options		(550,431)
Stock-based compensation	1,735,078	1,788,045
Loss on maturities of investments	6,757	80,542
Changes in operating assets and liabilities:		
Accounts receivable	71,380	(648,730)
Inventory	(273,121)	(1,170,928)
Prepaid expenses and other current assets	(576,504)	(622,454)
Other assets	(6,714)	(87,001)
Deferred income taxes	(769,615)	(638,467)
Accounts payable	(334,051)	(13,542)
Accrued payroll and benefits	403,151	7,667
Other accrued taxes	(50,847)	160,594
Warranty reserve	7,608	4,061
Deferred revenue	632,341	1,259,997
Other current liabilities		115,489
Accrued income taxes, net of prepaid income taxes	(351,403)	608,526
Net cash provided by operating activities	2,014,799	7,182,627
Investing activities:		
Purchases of investments	(1,321,257)	(4,284,445)
Proceeds from maturity of investments	2,495,004	4,075,103
Purchases of property and equipment	(653,171)	(547,087)
Capitalized intangible assets	(28,800)	(588,228)
Net cash provided by (used in) investing activities	491,776	(1,344,657)
Financing activities:		
Proceeds from stock option exercises	49,460	217,015
Taxes paid related to the net share settlement of equity awards	(45,059)	
Income tax benefit credited to equity		550,431
Purchases of treasury stock	(1,818,542)	(9,969,468)
Net cash used in financing activities	(1,814,141)	(9,202,022)
Net increase (decrease) in cash and cash equivalents	692,434	(3,364,052)
Cash and cash equivalents, beginning of period	17,713,871	19,368,114
Cash and cash equivalents, end of period	$ 18,406,305	$ 16,004,062
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 1,171,964	$ 3,392,722

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, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

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, 2016. The accounting policies followed in the preparation of these interim condensed financial statements are consistent in all material respects with those described in Note 1 of our Form 10-K.

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

FDA Warning Letter

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

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

device design primarily related to software quality assurance.

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

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

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

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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.

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

In July 2015, the FASB issued Accounting Standard Update (ASU) 2015-11, Simplifying the Measurement of Inventory (Topic 330). The amendments in this update require that inventory within the scope of this ASU be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The amendments in this ASU do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured at first-in, first-out (FIFO) or average cost. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period. We adopted this guidance effective January 1, 2017 on a prospective basis. The adoption of this guidance did not impact our financial condition, results of operations or cash flows.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes (Topic 740). The amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The amendments in the update apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this update. The update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period. We adopted this guidance effective January 1, 2017 on a retrospective basis. As a result of the adoption, $311,871 of deferred taxes was reclassified from current to noncurrent assets, as of December 31, 2016.

In March 2016, the FASB issued ASU 2016-09, Compensation Stock Compensation (Topic 718). This update identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the recognition of excess tax benefits and deficiencies, the classification of excess tax benefits on the statement of cash flows, classification of awards as either equity or liabilities and an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur. This update is effective for annual and interim periods beginning after December 15, 2016. We adopted this guidance effective January 1, 2017.

Beginning January 1, 2017, excess tax benefits and deficiencies are reflected in the Statement of Operations as a component of the provision for income tax expense, whereas they were previously recognized as additional paid-in capital on the Balance Sheet. Adoption of this guidance resulted in the recognition of net tax deficiencies of $580 and $63,157 in our provision for income tax expense, with the effect of increasing our income tax expense for the three and nine months ended September 30, 2017.

Additionally, beginning on January 1, 2017, and on a prospective basis, the guidance now requires excess tax benefits and deficiencies be presented in the Statement of Cash Flows as an operating activity rather than as a financing activity, while the payment of withholding taxes on the net share settlement of equity awards be presented as a financing activity. The implementation of this guidance did not have a material impact on the Statement of Cash Flows for the nine months ended September 30, 2017. Prior period amounts were not retrospectively adjusted.

Effective January 1, 2017, we elected to recognize forfeitures as they occur rather than continue to estimate forfeitures expected to occur. This change in accounting policy resulted in an immaterial cumulative-effect adjustment to retained earnings for the nine months ended September 30, 2017.

The remaining updates required by this standard did not have a material impact to our interim unaudited condensed financial statements.

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Recently Issued Accounting Pronouncements to be Implemented

In May 2014, the FASB issued ASU 2014-09, Revenue Contracts with Customers (Topic 606). This update provides guidance on the recognition of revenue based upon the entity s contracts with customers to transfer goods or services at an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. This update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. This update is effective for annual periods beginning after December 15, 2017, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2018. Early adoption is now permitted. Our preliminary assessment indicates implementation of this standard will not have a material impact on the financial statements. Our evaluation has included determining whether the unit of account (i.e., performance obligations) will change as compared to current GAAP, as well as determing the standalone selling price for each performance obligation. Standalone selling prices under ASU 2014-09 may not be substantially different from the Company s current methodologies of establishing fair value on multiple element arrangements. We continue to evaluate the impact of this guidance and its subsequent amendments on the financial position and results of operations, and any preliminary assessments are subject to change.

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 and date of adoption and assessing the impact of the update on our financial condition and results of operations.

2 Basic and Diluted Net Income per Share

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

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2017	2016	2017	2016
		(unaudited)		(unaudited)	
Net income		$ 192,393	$ 1,560,484	$ 316,126	$ 6,073,745
Weighted-average shares outstanding	Basic	10,565,598	10,684,650	10,664,132	10,852,476
Effect of dilutive securities:					
Underwriters warrants			103,268		104,069
Stock options		1,060,598	1,077,209	1,041,997	1,097,957
Restricted stock units		16,848	2,870	4,248	965
Weighted-average shares outstanding	Diluted	11,643,044	11,867,997	11,710,377	12,055,467

Basic net income per share	$ 0.02	$ 0.15	$ 0.03	$ 0.56
Diluted net income per share	$ 0.02	$ 0.13	$ 0.03	$ 0.50

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Anti-dilutive stock options and restricted stock units	466,702	83,913	507,329	89,347

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3 Inventory

Inventory consists of:

	September 30, 2017 (unaudited)	December 31, 2016
Raw materials	$ 3,594,517	$ 3,241,642
Work in process	272,163	135,626
Finished goods	446,219	716,666
Inventory before allowance for excess and obsolete	4,312,899	4,093,934
Allowance for excess and obsolete	(183,542)	(207,344)
Total	$ 4,129,357	$ 3,886,590

4 Property and Equipment

Property and equipment consist of:

	September 30, 2017 (unaudited)	December 31, 2016
Computer software and hardware	$ 487,136	$ 462,352
Furniture and fixtures	416,526	358,587
Leasehold improvements	191,139	191,139
Machinery and equipment	1,998,411	1,064,957
Tooling in-process	215,092	578,098
	3,308,304	2,655,133
Accumulated depreciation	(1,454,798)	(1,198,984)
Total	$ 1,853,506	$ 1,456,149

Depreciation and amortization expense of property and equipment was $97,991 and $58,903 for the three months ended September 30, 2017 and 2016, respectively, and $255,814 and $168,900 for the nine months ended September 30, 2017 and 2016, respectively.

5 Intangible Assets

The following table summarizes the components of intangible asset balances:

		September 30, 2017 (unaudited)	December 31, 2016
Patents	in use	$ 168,383	$ 168,383
Patents	in process	95,871	67,071
Internally developed software	in use	867,569	148,967
Internally developed software	in process		718,602
Trademarks		23,017	23,017
		1,154,840	1,126,040
Accumulated amortization		(269,127)	(207,328)
Total		$ 885,713	$ 918,712

Amortization expense of intangible assets was $20,600 and $2,634 for the three months ended September 30, 2017 and 2016, respectively, and $61,799 and $15,382 for the nine months ended September 30, 2017 and 2016, respectively.

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Expected annual amortization expense for the remaining portion of 2017 and the next five years related to intangible assets is as follows:

Three months ending December 31, 2017	$ 20,600
2018	82,398
2019	82,398
2020	82,398
2021	82,398
2022	82,398

6 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,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Cost of revenue	$ 57,144	$ 36,023	$ 152,574	$ 106,723
General and administrative	699,196	15,964	1,149,371	1,241,856
Sales and marketing	122,282	126,527	342,775	398,131
Research and development	34,653	13,942	90,358	41,335
Total	$ 913,275	$ 192,456	$ 1,735,078	$ 1,788,045

On July 17, 2017 (Modification Date), our Board of Directors approved a modification to the underwriters warrants originally issued pursuant to our initial public offering (IPO Warrants). This modification extends the expiration date of the IPO Warrants from the Modification Date to July 17, 2019 and revises the strike price from $8.125 to $10.05. The fair value of the amended IPO Warrants is $2.42 per share as measured using the Black-Scholes options pricing model. Related to this modification, we recognized $380,452 of expense during the three and nine months ended September 30, 2017, which is included in General and administrative expenses in our Condensed Statements of Operations. As of September 30, 2017, IPO Warrants to purchase 181,600 shares of our common stock remained outstanding.

As of September 30, 2017 we had $762,023 of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.3 years. As of September 30, 2017, we had $2,125,894 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.7 years.

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

	Stock Options	Restricted Stock Units
Outstanding beginning of period	1,482,204	159,646
Awards granted	3,000	70,984

Awards exercised/vested	(25,511)	(20,224)
Awards canceled	(16,000)	(4,318)
Outstanding end of period	1,443,693	206,088

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7 Investments

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

	September 30, 2017			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 5,872,289	$ 3,569	$ 28,824	$ 5,847,034
International corporations	971,087	1,645	14,983	957,749
Total	$ 6,843,376	$ 5,214	$ 43,807	$ 6,804,783

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

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

8 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, 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	$ 5,847,034	$	$ 5,847,034	$
International corporations	957,749		957,749	
Total	$ 6,804,783	$	$ 6,804,783	$

	Fair Value at December 31, 2016

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

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

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

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9 Accumulated Other Comprehensive Loss

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

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balances at June 30, 2017	$	(26,329)
Gains, net		3,576
Reclassification realized in net earnings		122
Balances at September 30, 2017	$	(22,631)
Balances at June 30, 2016	$	(14,436)
Losses, net		(13,049)
Reclassification realized in net earnings		22,091
Balances at September 30, 2016	$	(5,394)

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

		Unrealized (Losses) Gains on Available-For-Sale Securities
Balances at December 31, 2016	$	(36,849)
Gains, net		9,623
Reclassification realized in net earnings		4,595
Balances at September 30, 2017	$	(22,631)
Balances at December 31, 2015	$	(55,285)
Losses, net		(1,156)
Reclassification realized in net earnings		51,047
Balances at September 30, 2016	$	(5,394)

10 Income Taxes

We recorded provisions for income tax expense of $32,384 and $48,507 for the three and nine months ended September 30, 2017, respectively. Our effective tax rate was 14.4% and 13.3% for the three and nine months ended September 30, 2017, respectively. Our effective tax rates for the three and nine months ended September 30, 2017 differed from the U.S. Federal statutory rate primarily due to favorable tax return adjustments, domestic production activities deductions 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.

We recorded provisions for income tax expense of $1,029,029 and $3,364,179 for the three and nine months ended September 30, 2016, respectively. Our effective tax rate was 39.7% and 35.6% for the three and nine months ended September 30, 2016, respectively. Our effective tax rates for the three and nine months ended September 30, 2016 differed from the U.S. Federal statutory rate primarily due to U.S. state tax expense, partially offset by the domestic production activities deduction and research and development credits.

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

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

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11 Segment, Customer and Geographic Information

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

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

Revenue information by geographic region is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
United States	$ 5,016,550	$ 6,914,921	$ 14,176,357	$ 23,784,112
International	673,174	758,296	2,200,291	2,722,163
Total revenue	$ 5,689,724	$ 7,673,217	$ 16,376,648	$ 26,506,275

Revenue information by type is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Devices:				
IV infusion pump system	$ 3,606,327	$ 5,890,612	$ 9,888,166	$ 21,323,224
Patient monitoring systems	118,598	122,074	907,622	181,802
Total Devices revenue	3,724,925	6,012,686	10,795,788	21,505,026
Disposable IV sets and services	1,964,799	1,660,531	5,580,860	5,001,249
Total revenue	$ 5,689,724	$ 7,673,217	$ 16,376,648	$ 26,506,275

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

	September 30, 2017	December 31, 2016
	(unaudited)	
United States	$ 1,316,365	$ 1,112,382
International	537,141	343,767
Total property and equipment, net	$ 1,853,506	$ 1,456,149

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

12 Commitments and Contingencies

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

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

Three months ending December 31, 2017	$	99,513
2018		398,051
2019		165,855
2020		
2021		
Total non-cancelable operating lease commitments	$	663,419

Rent expense under our operating leases was $103,197 and $101,372 for the three months ended September 30, 2017 and 2016, respectively, and $306,221 and $303,811 for the nine months ended September 30, 2017 and 2016, respectively.

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

Purchase commitments. We had various purchase orders for goods or services totaling approximately $2,400,000 at September 30, 2017 and $3,700,000 at December 31, 2016. No amounts related to these purchase orders have been recognized in our balance sheet.

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

13 Common Stock

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

Balance, December 31, 2016	10,722,675
Option exercises	25,511
Vesting of restricted stock units, net of shares withheld for taxes	16,489
Treasury stock	(209,922)
Balance, September 30, 2017	10,554,753

14 Subsequent Event

On October 26, 2017, we issued a press release announcing that our 3880 MRI compatible patient vital signs monitoring system had been 510(k) cleared by the U.S. Food and Drug Administration.

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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) compabtible medical devices and accessories and services relating to them.

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

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

Our 3880 MRI compatible patient vital signs monitoring system has been designed with non-magnetic components and other special features in order to safely and accurately monitor a patient s vital signs during various MRI procedures. The IRADIMED 3880 monitor is rated for operation 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, facilitating the transportation of patients 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; 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, small form factor and unique wireless tablet remote control that allows for the effective communication of patient vital signs information to clinicians located in the MRI control room. Our 3880 MRI compatible patient vital signs monitoring system is currently available to domestic and international customers.

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

We sell our MRI compatible products through our direct sales force in the U.S. and independent distributors internationally. We have distribution agreements for our products with 49 independent distributors selling our products internationally. We also enter into agreements with healthcare supply contracting companies in the U.S., which enable us to sell and distribute our MRidium MRI compatible IV infusion pump systems to their member hospitals. Under these agreements, we are required to pay these group purchasing organizations (GPOs) a fee of three percent of the sales of our products to their member hospitals. Our current GPO contracts effectively give us the ability to sell to more than approximately 95% of all U.S. hospitals and acute care facilities.

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

FDA Warning Letter

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

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

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

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

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

On November 25, 2014, we announced that we filed the 510(k) submission related to our MRidium 3860+ MRI IV infusion pumps and on December 12, 2014 we were notified that our 510(k) submission had been formally accepted for review by the FDA. On December 22, 2014, under FDA enforcement discretion, we announced that we resumed domestic distribution of our MRI compatible MRidium 3860+ MRI IV

infusion pump systems, without the DERS option. On January 28, 2015, under FDA enforcement discretion, we announced that we resumed domestic distribution of our DERS option. On December 9, 2015, we met with the FDA to review responses to the agency s additional information letter.

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

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Financial Highlights and Outlook

Our revenue decreased $(2.0) million, or (25.8)%, to $5.7 million for the third quarter ended September 30, 2017, compared to $7.7 million for the third quarter of last year. Net income was $0.2 million, or $0.02 per diluted share, in the third quarter ended September 30, 2017, compared to $1.6 million, or $0.13 per diluted share, in the third quarter last year. During the third quarter of 2017, we recognized revenue on 103 pump systems, compared to 184 pump systems during the same period in 2016.

For the remainder of 2017, we expect our revenues to increase, when compared to same period in 2016, as we continue to focus on 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 technology and penetrating the Intensive Care Unit, Emergency Room and other critical care locations within hospitals where there is a high probability that interventional radiology procedures will need to be performed on patients. Additionally, we expect to expand international sales of our new MRI compatible patient vital signs monitor and plan to commence shipments of this device in the U.S. during the fourth quarter of 2017, if FDA clearance is received by that time. We expect higher full year 2017 operating expenses compared to 2016 due to higher sales and marketing, regulatory, research and development expenses and a one-time charge related to the modification of the underwriters warrants.

Application of Critical Accounting Policies

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

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

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

- Stock-based compensation

- Income taxes

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

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

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Results of Operations

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

	Percent of Revenue Three Months Ended September 30,		Percent of Revenue Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	100.0%	100.0%	100.0%	100.0%
Cost of revenue	23.0	18.3	24.0	18.3
Gross profit	77.0	81.7	76.0	81.7
Operating expenses:				
General and administrative	44.8	24.4	41.8	27.2
Sales and marketing	22.0	17.6	24.1	15.2
Research and development	6.7	6.0	8.4	3.7
Total operating expenses	73.6	47.9	74.3	46.2
Income from operations	3.4	33.8	1.7	35.5
Other income (expense), net	0.5	(0.1)	0.5	0.1
Income before provision for income taxes	4.0	33.7	2.2	35.6
Provision for income tax expense	0.6	13.4	0.3	12.7
Net income	3.4%	20.3%	1.9%	