IRADIMED CORP
Form 10-Q
May 11, 2015
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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 March 31, 2015

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 o
Non-accelerated filer o	Smaller reporting company x

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 10,973,463 shares of common stock, par value $0.0001 per share, outstanding as of April 30, 2015.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

IRADIMED CORPORATION

CONDENSED BALANCE SHEETS

	March 31, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,773,513	$ 9,454,150
Accounts receivable, net of allowance for doubtful accounts of $71,921 as of March 31, 2015 and $28,119 as of December 31, 2014	3,517,255	1,960,214
Investments	7,928,974	7,913,793
Inventory, net	2,229,071	2,125,838
Prepaid expenses and other current assets	205,004	276,540
Prepaid income taxes	11,447	320,941
Deferred income taxes	148,415	116,339
Total current assets	24,813,679	22,167,815
Property and equipment, net	793,339	794,835
Intangible assets, net	186,684	250,836
Deferred income taxes	197,206	76,557
Other assets	20,720	19,676
Total assets	$ 26,011,628	$ 23,309,719
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 781,585	$ 629,167
Accrued payroll and benefits	676,529	1,244,898
Other accrued taxes	16,822	65,790
Warranty reserve	59,180	27,925
Deferred revenue	691,351	308,341
Accrued income taxes	653,414	
Total current liabilities	2,878,881	2,276,121
Deferred revenue	165,859	142,902
Total liabilities	3,044,740	2,419,023
Stockholders equity:		
Common stock; $0.0001 par value; 90,000,000 shares authorized; 10,973,463 shares issued and outstanding as of March 31, 2015 and 10,814,650 shares issued and outstanding as of December 31, 2014	1,098	1,082
Additional paid-in capital	16,365,123	15,785,838
Retained earnings	6,612,744	5,125,249
Accumulated other comprehensive loss	(12,077)	(21,473)
Total stockholders equity	22,966,888	20,890,696
Total liabilities and stockholders equity	$ 26,011,628	$ 23,309,719

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(Unaudited)

	For the Three Months Ended March 31,	
	2015	**2014**
Revenue	$ 6,991,705	$ 3,557,237
Cost of revenue	1,328,180	656,366
Gross profit	5,663,525	2,900,871
Operating expenses:		
General and administrative	1,968,017	1,092,695
Sales and marketing	1,088,696	759,789
Research and development	342,301	224,304
Total operating expenses	3,399,014	2,076,788
Income from operations	2,264,511	824,083
Other income, net	46,815	3,452
Income before provision for income taxes	2,311,326	827,535
Provision for income taxes	823,831	304,168
Net income	$ 1,487,495	$ 523,367
Other comprehensive income:		
Change in fair value of available-for-sale securities, net of tax expense of $5,785 and $1,171 for the three months ended March 31, 2015 and 2014, respectively	9,396	2,176
Comprehensive income	$ 1,496,891	$ 525,543
Net income per share:		
Basic	$ 0.14	$ 0.07
Diluted	$ 0.12	$ 0.06
Weighted average shares outstanding:		
Basic	10,906,224	7,000,000
Diluted	11,977,959	8,859,015

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2015	**2014**
Operating activities:		
Net income	$ 1,487,495	$ 523,367
Adjustments to reconcile net income to net cash provided by operating activities:		
Bad debt expense	43,802	136,971
Provision for excess and obsolete inventory	8,442	
Depreciation and amortization	51,309	20,768
Stock-based compensation	275,031	162,809
Impairment of intangible assets	55,433	
Changes in operating assets and liabilities:		
Accounts receivable	(1,600,843)	(174,563)
Inventory	(111,675)	(85,826)
Prepaid expenses and other current assets	72,488	40,844
Other assets	(1,996)	(1,688)
Deferred income taxes	(158,510)	(62,248)
Accounts payable	152,418	125,479
Accrued payroll and benefits	(568,369)	(219,097)
Other accrued taxes	(48,968)	(47,196)
Warranty reserve	31,255	
Deferred revenue	405,967	(16,927)
Accrued income taxes, net of prepaid income taxes	962,908	59,416
Net cash provided by operating activities	1,056,187	462,109
Investing activities:		
Purchases of investments		(1,237)
Purchases of property and equipment	(40,294)	(4,292)
Capitalized intangible assets	(800)	(3,165)
Net cash used in investing activities	(41,094)	(8,694)
Financing activities:		
Proceeds from stock option exercises	191,837	
Income tax benefits credited to equity	112,433	
Repayment of officer note payable		(6,333)
Net cash provided by (used in) financing activities	304,270	(6,333)
Net increase in cash and cash equivalents	1,319,363	447,082
Cash and cash equivalents, beginning of period	9,454,150	2,461,559
Cash and cash equivalents, end of period	$ 10,773,513	$ 2,908,641
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 5,000	$ 307,000

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION

Notes to Unaudited Condensed Financial Statements

1 Basis of Presentation

The accompanying interim condensed financial statements of IRADIMED CORPORATION (IRADIMED , the Company , we , our) have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally presented in annual financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. The interim financial information is unaudited, but reflects all normal adjustments that are, in the opinion of management, necessary for the fair presentation of our financial position, results of operations and cash flows for the interim periods presented. Operating results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

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, 2014. The accounting policies followed in the preparation of these interim condensed financial statements are consistent in all material respects with those described in Note 1 of our 10-K.

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

FDA Warning Letter

On September 2, 2014 we announced we received a Warning Letter from the U.S. Food and Drug Administration (FDA) relating to an inspection of our facility that took place in April 2014. At the conclusion of the April inspection, FDA issued a Form 483 that identified eight observations. The majority of the observations related to procedures and documentation associated with the design, development and validation testing 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 procedures and processing 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 concerns.

FDA s 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 Food, Drug and Cosmetic Act (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 Dose Error Reduction System (DERS) option. On January 28, 2015, under FDA enforcement discretion, we announced that we resumed domestic distribution of our DERS option.

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

Certain Significant Risks and Uncertainties

We market our products to end users in the United States and to distributors internationally. Sales to end users in the United States are generally made on open credit terms. Management maintains an allowance for potential credit losses. As of December 31, 2014, two international customers accounted for approximately 35% of gross accounts receivable.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (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 contracts with customers. This update is effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, which will require us to adopt this update in the first quarter of 2017. Early adoption is not permitted. We are evaluating this guidance and have not yet determined the effect it will have on our financial statements and related disclosures, if any.

2 Basic and Diluted Net Income per Share

Basic net income per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. As discussed further in Note 13, the effect of our 1.75:1 stock split and recapitalization is reflected in the number of outstanding shares and per share information in the table below. The underwriters warrants, preferred stock and stock options 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 March 31,	
	2015	**2014**
	(unaudited)	
Net income	$ 1,487,495	$ 523,367
Weighted-average shares outstanding Basic	10,906,224	7,000,000
Effect of dilutive securities:		
Underwriters warrants	90,612	
Preferred stock		1,400,000

Stock options			981,123		459,015
Weighted-average shares outstanding	Diluted		11,977,959		8,859,015
Basic net income per share		$	0.14	$	0.07
Diluted net income per share		$	0.12	$	0.06

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

	Three Months Ended March 31,	
	2015	2014
	(unaudited)	
Anti-dilutive stock options	215,000	586,509

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3 Inventory

Inventory consists of:

	March 31, 2015 (unaudited)	December 31, 2014
Raw materials	$ 1,649,720	$ 1,541,688
Work in process	181,583	126,188
Finished goods	397,768	457,962
Total	$ 2,229,071	$ 2,125,838

The Company reviews its inventory on a periodic basis for excess, obsolete or impaired inventory and records a reserve for items identified. As of March 31, 2015 and December 31, 2014, the Company maintained an allowance for excess and obsolete inventory of $70,511 and $62,069, respectively.

4 Property and Equipment

Property and equipment consist of:

	March 31, 2015 (unaudited)	December 31, 2014
Computer software and hardware	$ 315,272	$ 303,076
Furniture and fixtures	198,253	198,253
Leasehold improvements	185,440	182,105
Machinery and equipment	909,490	849,852
Tooling in-process	7,440	42,315
	1,615,895	1,575,601
Accumulated depreciation	(822,556)	(780,766)
Total	$ 793,339	$ 794,835

Depreciation and amortization expense of property and equipment was $41,790 and $11,214 for the three months ended March 31, 2015 and 2014, respectively.

5 Intangible Assets

The following table summarizes the components of intangible asset balances:

	March 31, 2015 (unaudited)	December 31, 2014
Patents in use	$ 168,383	$ 238,548
Patents in process	32,158	31,358
Internally developed software	148,967	148,967
	349,508	418,873
Accumulated amortization	(162,824)	(168,037)
Total	$ 186,684	$ 250,836

Amortization expense of intangible assets was $9,519 and $9,554 for the three months ended March 31, 2015 and 2014, respectively. During the three months ended March 31, 2015, we recorded an impairment charge of $55,433 on patents related to certain of our IV sets. This charge is included as general and administrative expense in our Condensed Statements of Operations and Comprehensive Income.

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Expected annual amortization expense for the next five years related to intangible assets is as follows:

Nine months ending December 31, 2015	$	26,489
2016		18,016
2017		10,538
2018		10,538
2019		10,538
2020		10,538

6 Stock-Based Compensation

Stock-based compensation was recognized as follows in the statement of operations:

		Three Months Ended March 31,		
		2015		2014
		(unaudited)		
Cost of revenue	$	15,721	$	959
General and administrative		116,929		56,935
Sales and marketing		127,346		95,536
Research and development		15,035		9,379
Total	$	275,031	$	162,809

As of March 31, 2015 we had $3,078,102 of total unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 3.1 years.

The following table presents a summary of our stock option activity as of and for the three months ended March 31, 2015:

	Options
Outstanding beginning of period	1,945,192
Options granted	24,000
Options exercised	(158,813)
Options canceled	
Outstanding end of period	1,810,379

7 Investments

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

	March 31, 2015			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,433,286	$ 5,328	$ 19,138	$ 6,419,476
International corporations	1,515,200	2,650	8,352	1,509,498
Total	$ 7,948,486	$ 7,978	$ 27,490	$ 7,928,974

	December 31, 2014			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds:				
U.S. corporations	$ 6,433,286	$	$ 27,067	$ 6,406,219
International corporations	1,515,200		7,626	1,507,574
Total	$ 7,948,486	$	$ 34,693	$ 7,913,793

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8 Fair Value Measurements

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

	Fair Value at March 31, 2015			
	Fair Value	Quoted Prices in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Corporate bonds:				
U.S. corporations	$ 6,419,476	$	$ 6,419,476	$
International corporations	1,509,498		1,509,498	
Total	$ 7,928,974	$	$ 7,928,974	$

	Fair Value at December 31, 2014			
	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:				