

IRADIMED CORP
Form 10-Q
November 13, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2014

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
(State or other jurisdiction of
incorporation or organization)

73-1408526
(I.R.S. Employer

Identification Number

1025 Willa Springs Drive

Winter Springs, Florida
(Address of principal executive offices)

32708
(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 No

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 No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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The registrant had 10,814,650 shares of common stock, par value \$0.0001 per share, outstanding as of October 31, 2014.

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IRADIMED CORPORATION

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IRADIMED CORPORATION
CONDENSED BALANCE SHEETS

	September 30, 2014 (unaudited)	December 31, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,113,859	\$ 2,461,559
Accounts receivable, net of allowance for doubtful accounts of \$37,368 as of September 30, 2014 and \$136,971 as of December 31, 2013	1,174,103	1,982,083
Investments		246,203
Inventory, net	1,639,977	1,340,331
Prepaid expenses and other current assets	247,937	119,974
Prepaid income taxes		170,496
Deferred income taxes	67,916	65,961
Total current assets	21,243,792	6,386,607
Property and equipment, net	755,267	327,343
Intangible assets, net	259,473	267,024
Deferred income taxes	131,130	
Other assets	21,866	5,897
Total assets	\$ 22,411,528	\$ 6,986,871
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 640,235	\$ 427,474
Accrued payroll and benefits	919,044	655,362
Other accrued taxes	40,384	80,787
Warranty reserve	15,671	12,002
Deferred revenue	343,051	207,395
Officer note payable		6,333
Accrued income taxes	141,818	62,971
Total current liabilities	2,100,203	1,452,324
Deferred revenue	160,387	57,676
Deferred income taxes		54,087
Total liabilities	2,260,590	1,564,087
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; none issued and outstanding as of September 30, 2014 and 1,400,000 shares issued and outstanding as of December 31, 2013		140
Common stock; \$0.0001 par value; 90,000,000 shares authorized; 10,718,400 shares issued and outstanding as of September 30, 2014 and 7,000,000 shares issued and outstanding as of December 31, 2013	1,072	700
Additional paid-in capital	15,295,438	2,346,137
Retained earnings	4,854,428	3,074,883

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Accumulated other comprehensive income				924
Total stockholders' equity		20,150,938		5,422,784
Total liabilities and stockholders' equity	\$	22,411,528	\$	6,986,871

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 September 30,		For the Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	\$ 3,811,947	\$ 2,479,749	\$ 12,069,553	\$ 7,883,071
Cost of revenue	959,593	669,765	2,485,704	1,904,597
Gross profit	2,852,354	1,809,984	9,583,849	5,978,474
Operating expenses:				
General and administrative	1,261,872	640,987	3,485,051	1,671,726
Sales and marketing	880,711	513,734	2,505,019	1,578,119
Research and development	303,463	299,422	753,267	664,257
Total operating expenses	2,446,046	1,454,143	6,743,337	3,914,102
Income from operations	406,308	355,841	2,840,512	2,064,372
Other income, net	(8,808)	18,817	6,275	38,216
Income before provision for income taxes	397,500	374,658	2,846,787	2,102,588
Provision for income taxes	160,143	113,983	1,067,242	639,678
Net income	\$ 237,357	\$ 260,675	\$ 1,779,545	\$ 1,462,910
Other comprehensive income (loss):				
Change in fair value of available-for-sale securities, net of tax expense (benefit) of \$70 and \$(432) for the three months ended September 30, 2014 and 2013, respectively, and \$2,063 and \$(2,681) for the nine months ended September 30, 2014 and 2013, respectively	130	(803)	3,832	(4,979)
Realized gain on available-for-sale securities reclassified to net income, net of tax of \$70 and \$2,560 for the three and nine months ended September 30, 2014, respectively	(130)		(4,756)	
Comprehensive income	\$ 237,357	\$ 259,872	\$ 1,778,621	\$ 1,457,931
Net income per share:				
Basic	\$ 0.02	\$ 0.04	\$ 0.22	\$ 0.21
Diluted	\$ 0.02	\$ 0.03	\$ 0.18	\$ 0.17
Weighted average shares outstanding:				
Basic	10,112,139	7,000,000	8,048,779	7,000,000
Diluted	11,269,358	8,665,599	9,688,602	8,562,704

See accompanying notes to unaudited condensed financial statements.

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IRADIMED CORPORATION
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income	Stockholders Equity
Balances, December 31, 2013	\$ 140	\$ 700	\$ 2,346,137	\$ 3,074,883	\$ 924	\$ 5,422,784
Net income				1,779,545		1,779,545
Other comprehensive loss					(924)	(924)
Stock-based compensation			503,881			503,881
Issuance of common stock pursuant to initial public offering		232	14,489,768			14,490,000
Common stock issuance costs and underwriter fees			(2,044,348)			(2,044,348)
Conversion of preferred stock	(140)	140				
Balances, September 30, 2014	\$	\$ 1,072	\$ 15,295,438	\$ 4,854,428	\$	\$ 20,150,938

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,	
	2014	2013
Operating activities:		
Net income	\$ 1,779,545	\$ 1,462,910
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for excess and obsolete inventory	36,709	
Depreciation and amortization	99,638	97,945
Stock-based compensation	503,881	203,939
Changes in operating assets and liabilities:		
Accounts receivable	807,980	(129,914)
Inventory	(336,355)	(279,055)
Prepaid expenses and other current assets	(126,434)	(61,276)
Other assets	(17,498)	(4,504)
Deferred income taxes	(189,235)	(44,940)
Accounts payable	212,761	34,349
Accrued payroll and benefits	263,682	(92,257)
Other accrued taxes	(40,403)	34,881
Warranty reserve	3,669	(134)
Deferred revenue	238,367	96,298
Accrued income taxes, net of prepaid income taxes	249,343	(611,450)
Other	1,461	
Net cash provided by operating activities	3,487,111	706,792
Investing activities:		
Purchases of investments	(3,011)	(2,958)
Proceeds from sale of investments	255,109	
Purchases of property and equipment	(504,502)	(121,173)
Capitalized intangible assets	(21,726)	(22,711)
Net cash used in investing activities	(274,130)	(146,842)
Financing activities:		
Repayment of officer note payable	(6,333)	(214,267)
Proceeds from the issuance of common stock pursuant to initial public offering	14,490,000	
Payment of initial public offering costs	(2,044,348)	
Net cash provided by (used in) financing activities	12,439,319	(214,267)
Net increase in cash and equivalents	15,652,300	345,683
Cash and cash equivalents, beginning of period	2,461,559	1,697,306
Cash and cash equivalents, end of period	\$ 18,113,859	\$ 2,042,989
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 1,004,574	\$ 1,301,500

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 in accordance with accounting principles generally accepted in the United States of America (GAAP). The accounting policies followed in the preparation of these interim condensed financial statements are consistent in all material respects with those presented in Note 1 of the Company s financial statements for the year ended December 31, 2013 included in the Company s Registration Statement on Form S-1, as amended (File No. 333-196875) (Registration Statement), which was declared effective by the Securities and Exchange Commission (SEC) on July 15, 2014.

Interim financial reports are prepared in accordance with the rules and regulations of the SEC; accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. 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. These accompanying condensed financial statements should be read in conjunction with the Company s Registration Statement.

Our significant accounting policies are disclosed in the Registration Statement and no significant accounting policies were changed. Certain prior year amounts have been reclassified to conform to current year presentation. Operating results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

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. We intend to respond to this Warning Letter finding.

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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 FDCA). 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 FDCA. The Warning Letter also indicates that the MRidium 3860+ infusion pump requires separate FDA clearance from the MRidium 3860 and MRidium 3850.

The Warning Letter requested that we immediately cease activities that result in the misbranding or adulteration of the MRidium 3860 MRI infusion pump, MRidium 3850 MRI infusion pump, and the MRidium 3860+ MRI infusion pump, 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.

We are working with the FDA to resolve this issue and resume commercial distribution of our products. 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. See Note 12.

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Initial Public Offering

On July 21, 2014, the Company completed an initial public offering (IPO) of its common stock and sold 2,318,400 shares of common stock (including 302,400 shares sold upon the underwriters' exercise of their over-allotment option to purchase additional shares) at a price of \$6.25 per share. The IPO generated net proceeds of approximately \$12.4 million, after deducting underwriting discounts and expenses of approximately \$2.0 million. These expenses were recorded against the proceeds received from the IPO. Concurrent with the closing of the IPO, all outstanding preferred stock was automatically converted into common stock on a 1:1 basis.

Associated with our IPO, we issued the underwriters warrants to purchase up to a total of 201,600 shares of our common stock. The grant date aggregate fair value of the warrants was \$611,000. The warrants are exercisable, in whole or in part, commencing July 21, 2015 through July 21, 2017. The warrants are exercisable at a per share price equal to \$8.13 per share, or 130% of the public offering price per share of our common stock in the IPO. The exercise price and number of warrant shares may be adjusted upon (1) voluntarily at our discretion, or (2) if we undertake a stock split, stock dividend, recapitalization or reorganization of our common stock into a lesser / greater number of shares, the warrant exercise price will be proportionately reduced / increased and the number of warrant shares will be proportionately increased / decreased. The warrants may only be settled through the issuance of our common stock in exchange for cash. We have classified the warrants as equity and incremental direct costs associated with our IPO. Accordingly, the warrants do not impact our financial statements.

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, 2013, one customer accounted for 10.8% of gross accounts receivable.

Revenue for the three months ended September 30, 2013 included sales to two international customers that represented 20.9% of total revenue for the three months ended September 30, 2013.

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

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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 6, 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Net income	\$ 237,357	\$ 260,675	\$ 1,779,545	\$ 1,462,910
Weighted-average shares outstanding Basic	10,112,139	7,000,000	8,048,779	7,000,000
Effect of dilutive securities:				
Underwriters' warrants	847			
Preferred stock	228,261	1,400,000	1,005,128	1,400,000
Stock options	928,111	265,599	634,695	162,704
Weighted-average shares outstanding Diluted	11,269,358	8,665,599	9,688,602	8,562,704
Basic net income per share	\$ 0.02	\$ 0.04	\$ 0.22	\$ 0.21
Diluted net income per share	\$ 0.02	\$ 0.03	\$ 0.18	\$ 0.17

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Warrants and 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(unaudited)		(unaudited)	
Anti-dilutive stock options	17,625	357,158	660,159	789,933

3 Inventory

Inventory consists of:

	September 30, 2014	December 31, 2013
	(unaudited)	
Raw materials	\$ 1,427,014	\$ 1,143,495
Work in process	91,448	14,337
Finished goods	121,515	182,499
Total	\$ 1,639,977	\$ 1,340,331

The Company reviews its inventory on a periodic basis for excess, obsolete or impaired inventory and records a reserve for items identified. The Company recorded an allowance for excess and obsolete inventory of \$36,709 as of September 30, 2014.

4 Property and Equipment

Property and equipment consist of:

	September 30, 2014	December 31, 2013
	(unaudited)	
Computer software and hardware	\$ 242,086	\$ 154,709
Furniture and fixtures	184,912	87,611
Leasehold improvements	168,844	47,623
Machinery and equipment	831,107	721,270
Tooling in-process	69,086	46,562
	1,496,035	1,057,775
Accumulated depreciation	(740,768)	(730,432)
Total	\$ 755,267	\$ 327,343

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Depreciation and amortization expense of property and equipment was \$35,316 and \$23,274 for the three months ended September 30, 2014 and 2013, respectively, and \$70,361 and \$69,908 for the nine months ended September 30, 2014 and 2013, respectively.

5 Intangible Assets

The following table summarizes the components of intangible asset balances:

	September 30, 2014 (unaudited)	December 31, 2013
Patents in use	\$ 238,548	\$ 228,430
Patents in process	30,773	19,165
Internally developed software	148,967	148,967
	418,288	396,562
Accumulated amortization	(158,815)	