

IsoRay, Inc.
Form 10-Q
November 09, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended September 30, 2016

or

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. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota 41-1458152
(State or other jurisdiction of incorporation or (I.R.S. Employer
organization) Identification No.)

350 Hills St., Suite 106, Richland, Washington 99354
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (509) 375-1202

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 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

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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 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 the definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" 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

Number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date:

<u>Class</u>	<u>Outstanding as of November 4, 2016</u>
Common stock, \$0.001 par value	55,017,419

ISORAY, INC.

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PART I – FINANCIAL INFORMATION**ITEM 1 – FINANCIAL STATEMENTS****IsoRay, Inc. and Subsidiaries****Consolidated Balance Sheets****(In thousands, except shares)**

	September 30, 2016 (unaudited)	June 30, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,459	\$10,139
Certificates of deposit (Note 3)	5,249	2,247
Accounts receivable, net of allowance for doubtful accounts of \$30 and \$30, respectively	574	605
Inventory	380	334
Prepaid expenses and other current assets	263	304
 Total current assets	 14,925	 13,629
 Property and equipment, net	 703	 577
Certificates of deposit, non-current (Note 3)	-	2,973
Restricted cash	181	181
Inventory, non-current	584	591
Other assets, net of accumulated amortization	292	151
 Total assets	 \$ 16,685	 \$18,102
 LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 493	\$612
Accrued protocol expense	150	122
Accrued radioactive waste disposal	189	177
Accrued payroll and related taxes	170	72
Accrued vacation	122	111
 Total current liabilities	 1,124	 1,094
Long-term liabilities:		
Warrant derivative liability	-	27

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Asset retirement obligation	588	580
Total liabilities	1,712	1,701
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, \$.001 par value; 7,001,671 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	-	-
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series D: 1,671 shares allocated; no shares issued and outstanding	-	-
Common stock, \$.001 par value; 192,998,329 shares authorized; 55,010,619 and 55,010,619 shares issued and outstanding	55	55
Additional paid-in capital	82,858	82,788
Accumulated deficit	(67,940)	(66,442)
Total shareholders' equity	14,973	16,401
Total liabilities and shareholders' equity	\$ 16,685	\$ 18,102

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc. and Subsidiaries**Consolidated Statements of Operations (Unaudited)****(Dollars and shares in thousands, except for per-share amounts)**

	Quarter ended September 30,	
	2016	2015
Product sales, net	\$ 1,081	\$ 1,261
Cost of product sales	1,033	1,178
Gross profit	48	83
Operating expenses:		
Research and development	172	144
Sales and marketing	524	278
General and administrative	927	752
Total operating expenses	1,623	1,174
Operating loss	(1,575)	(1,091)
Non-operating income:		
Interest income, net	30	56
Change in fair value of warrant derivative liability	27	15
Other income	20	-
Non-operating income, net	77	71
Net loss	(1,498)	(1,020)
Preferred stock dividends	(3)	(3)
Net loss applicable to common shareholders	(1,501)	(1,023)
Basic and diluted loss per share	\$ (0.03)	\$ (0.02)
Weighted average shares used in computing net loss per share:		
Basic and diluted	55,011	55,013

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc. and Subsidiaries**Consolidated Statements of Cash Flows (Unaudited)****(In thousands)**

	Quarter ended September 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,498) \$ (1,020
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	16	137
Loss on equipment disposals	5	-
Amortization of other assets	10	21
Change in fair value of warrant derivative liability	(27) (15
Accretion of asset retirement obligation	7	21
Share-based compensation	70	32
Changes in operating assets and liabilities:		
Accounts receivable, gross	31	(81
Inventory	(39) (57
Prepaid expenses and other current assets	41	14
Accounts payable and accrued expenses	(118) (87
Accrued protocol expense	28	28
Accrued radioactive waste disposal	12	12
Accrued payroll and related taxes	98	(83
Accrued vacation	11	(31
Net cash used by operating activities	(1,353) (1,109
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(147) (4
Additions to other assets	(151) (16
Proceeds from maturity of certificates of deposit	-	3,527
Purchases of and interest from certificates of deposit	(29) (6,084
Net cash used by investing activities	(327) (2,577
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sales of common stock, pursuant to exercise of options	-	47
Net cash provided by financing activities	-	47
Net decrease in cash and cash equivalents	(1,680) (3,639
Cash and cash equivalents, beginning of quarter	10,139	5,227
CASH AND CASH EQUIVALENTS, END OF QUARTER	\$ 8,459	\$ 1,588

Supplemental disclosures of cash flow information:

Cash paid for interest

The accompanying notes are an integral part of these consolidated financial statements.

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three months ended September 30, 2016 and 2015

1. Basis of Presentation

The accompanying unaudited interim consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries ("IsoRay" or the "Company"). All significant intercompany accounts and transactions have been eliminated in the consolidation. In the opinion of management, all adjustments necessary for the fair presentation of the consolidated financial statements have been included. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2016.

The unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP) have been condensed or omitted pursuant to those rules and regulations, although we believe that the disclosures are adequate for the information not to be misleading.

Certain prior period amounts have been reclassified to conform to the current period's presentation. The results of operations for the periods presented may not be indicative of those which may be expected for a full year. The Company anticipates that as the result of continuing operating losses and the significant net operating losses available from prior fiscal years, its effective income tax rate for fiscal year 2017 will be 0%.

2. New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09), which supersedes the revenue recognition requirements in FASB Accounting Standards Codification (ASC) Topic 605, "Revenue Recognition". The guidance requires that an entity recognize revenue in a way that depicts the transfer of promised goods or services to customers in the amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods and services. The guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2019. This update is not expected to

have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11: Inventory. The guidance requires an entity's management to measure inventory within the scope of this ASU 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 guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The Company continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2018.

In November 2015, the FASB issued an ASU 2015-17 to simplify the balance sheet classification of deferred taxes. This update requires all deferred tax assets and liabilities to be reported as non-current in the consolidated balance sheets. This update will be effective as of the beginning of fiscal 2018. This update is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 Leases (Subtopic 842), which will require lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by most leases. The update is effective for annual and interim reporting periods beginning after December 15, 2018. The Company continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2019.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. Except to indicate an evaluation of a recent pronouncement is in process, the Company does not discuss recent pronouncements that are not anticipated to have potential impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

3. Certificates of deposit

Certificate of Deposit Account Registry Service (CDARS) is a system that allows the Company to invest in certificates of deposit through a single financial institution that exceed the \$250,000 limit to be fully insured by the Federal Deposit Insurance Corporation (FDIC). That institution utilizes the CDARS system to purchase certificates of deposit at other financial Institutions while keeping the investment at each institution fully insured by the Federal Deposit Insurance Corporation (FDIC). CDARS held by the Company as of September 30, 2016 and June 30, 2016 are as follows (in thousands):

As of September 30, 2016			
	Under 90 Days	91 days to Six months	to Greater than 1 year
CDARS	\$ -	\$ -	\$ 5,249
			\$ -

As of June 30, 2016			
	Under 90 Days	91 days to Six months	to Greater than 1 year
CDARS	\$ -	\$ -	\$ 2,247
			\$ 2,973

4. Loss per Share

Basic and diluted earnings (loss) per share are calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any

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potentially dilutive common stock equivalents. At September 30, 2016 and 2015, the calculation of diluted weighted average shares did not include convertible preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2016 and 2015, were as follows (in thousands):

	September 30,	
	2016	2015
Series B preferred stock	59	59
Common stock warrants	230	361
Common stock options	2,609	2,364
Total potential dilutive securities	2,898	2,784

5. Inventory

Inventory consisted of the following at September 30, 2016 and June 30, 2016 (in thousands):

	September 30, 2016	June 30, 2016
Raw materials	\$ 194	\$ 155
Work in process	164	161
Finished goods	22	18
Total inventory, current	\$ 380	\$ 334

	September 30, 2016	June 30, 2016
Enriched barium, non-current	\$ 470	\$ 470
Raw materials, non-current	114	121
Total inventory, non-current	\$ 584	\$ 591

Inventory, non-current is raw materials that were ordered in quantities to obtain volume cost discounts which based on current and anticipated sales volumes will not be consumed within an operating cycle and the enriched barium which will only be utilized if required to obtain volumes of isotope not able to be purchased from an existing source in the short or long-term. Management does not anticipate the need to utilize the enriched barium within the current operating cycle.

6. Property and Equipment

Property and equipment consisted of the following at September 30, 2016 and June 30, 2016 (in thousands):

	September 30, 2016	June 30, 2016
Land	\$ 168	\$ 168
Equipment	3,614	3,606
Leasehold improvements	4,130	4,130
Other ¹	331	214
Property and equipment	8,243	8,118
Less accumulated depreciation	(7,540)	(7,541)
Property and equipment, net	\$ 703	\$ 577

¹ – Plant & equipment, not placed in service are items that meet the capitalization threshold or which management believes will meet the threshold at the time of completion and which have yet to be placed into service as of the date of the balance sheet. Also included at September 30, 2016 and June 30, 2016 are costs associated with automation of production processes and advance planning and design work on the Company's new production facility.

7.Share-Based Compensation

The following table presents the share-based compensation expense recognized during the quarter ended September 30, 2016 and 2015 (in thousands):

	Quarter ended September 30,	
	2016	2015
Cost of product sales	\$ 27	\$ 18
Research and development expenses	8	3
Sales and marketing expenses	15	3
General and administrative expenses	20	8
Total share-based compensation	\$ 70	\$ 32

As of September 30, 2016, total unrecognized compensation expense related to stock-based options was approximately \$732,000 and the related weighted-average period over which it is expected to be recognized is approximately 1.84 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2016 was as follows:

	Number of	Weighted	Weighted	Intrinsic
As of September 30, 2016	Options	Exercise	Contractual	Value
		Price	Term (Years)	
Outstanding	2,609,189	\$ 1.07	7.12	\$ 141,677
Vested and expected to vest	2,530,789	\$ 1.06	7.06	\$ 141,677
Vested and exercisable	1,629,996	\$ 1.09	5.74	\$ 139,802

There were no and 45,994 stock options exercised and no and \$21,654 of intrinsic value associated with these exercises during the quarters ended September 30, 2016 and 2015, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were no stock option awards granted during the quarters ended September 30, 2016 and 2015, respectively.

There were 280,534 and 1,608 stock option awards which expired during quarters ended September 30, 2016 and 2015, respectively.

There were 35,336 and 6,334 stock option awards forfeited during quarters ended September 30, 2016 and 2015, respectively.

8. Commitments and Contingencies

Class Action Lawsuit Related to Press Release

On May 22, 2015, the first of three lawsuits was filed against IsoRay, Inc. and two of its officers – Dwight Babcock (the Company’s retired CEO) and Brien Ragle, CFO – related to a press release on May 20, 2015 regarding a May 19 online publication of the peer-reviewed article in the journal Brachytherapy titled “Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-Stage Lung Cancer” by Dr. Bhupesh Parashar, et al. The lawsuits are class actions alleging violations of the federal securities laws. By Order dated August 17, 2015, all of the pending lawsuits were consolidated into one case – In re IsoRay, Inc. Securities Litigation; Case No. 4:15-cv-05046-LRS, in the US District Court for the Eastern District of Washington. On October 16, 2015, an amended complaint was filed with more detailed allegations relating to alleged violations of federal securities laws. On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. On June 1, 2016, the court entered an order denying IsoRay's motion to dismiss, holding that the complaint's allegations, if accepted as true, state a plausible claim to relief. The order did not adjudicate the merits of the lawsuit. No other issues were decided in the ruling.

On June 15, 2016, IsoRay filed their answer to the amended complaint. As IsoRay previously disclosed, on September 23, 2016, the parties entered into a stipulation of settlement which, if it becomes final, will provide for a payment to the plaintiff class of \$3,537,500, which will be paid by our insurers. On October 4, 2016, the stipulation of settlement was filed with the court, along with plaintiffs' unopposed motion for preliminary approval of the settlement. On October 20, 2016, the court granted preliminary approval of the settlement. Following notice to class members, the class action is subject to final approval by the court. A final approval hearing is scheduled for March 7, 2017. If the proposed settlement is not approved by the court or if IsoRay is otherwise unable to obtain a favorable resolution of the claims set forth in the complaint, the lawsuit could have a material adverse effect on our business, results of operations and financial condition.

Derivative Complaint related to shareholder value

On September 29, 2016, a purported shareholder derivative complaint captioned *Kitley v. Babcock, et al.*, No. 0:16-cv-03297, was filed on behalf of the Company in the United States District Court for the District of Minnesota against certain of the Company's current and former officers and directors. The complaint alleges that the defendants breached their fiduciary duties by causing the Company to issue allegedly false and misleading statements in a May 20, 2015 press release – the same press release at issue in the pending securities class action – concerning the results from a peer reviewed study of its Cesium-131 isotope seeds and mesh product for the treatment of non-small cell lung cancers. The complaint brings claims of breach of fiduciary duty, gross mismanagement, and unjust enrichment, and seeks unspecified compensatory damages, changes in corporate governance, and attorney's fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. The Company may be obligated pursuant to indemnification obligations to advance fees and costs incurred by the individuals defending against the action. The Company has applicable directors and officers insurance policies. Defendants' response to the complaint is due November 17, 2016.

9. Fair Value Measurements

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement (in thousands):

	Fair value at September 30, 2016			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$8,459	\$8,459	\$ -	\$ -
Warrant derivative liability	-	-	-	-

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Fair value at June 30, 2016

	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$10,139	\$10,139	\$ -	\$ -
Warrant derivative liability	27	-	27	-

The Company's cash and cash equivalent instruments are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices.

The Company's warrant derivative liability is valued using the Black-Scholes option pricing model which requires a variety of inputs. Such instruments are typically included in Level 2.

10. Preferred Dividends

As of September 30, 2016, there were accrued but undeclared dividends on Series B Preferred Stock outstanding in the amount of approximately \$8,000.

11. Shareholders' Equity

Warrants

The following table summarizes all warrants outstanding as of the beginning of the fiscal year, all activity related to warrants issued, cancelled, exercised or expired during the period and weighted average prices by category.

	Warrants	Weighted average exercise price
Outstanding as of June 30, 2016	230,087	\$ 0.94
Warrants expired	-	-
Outstanding as of September 30, 2016	230,087	\$ 0.94

The following table summarizes additional information about the Company's common warrants outstanding as of September 30, 2016:

Number of Warrants	Range of <u>Exercise Prices</u> ¹	Expiration Date
199,437	\$ 0.94	October 2016
25,650	\$ 0.94	December 2016
5,000	\$ 0.98	June 2017
230,087		

¹ – Exercise prices have been rounded to the nearest whole cent.

12. Related Party Transaction

In previous fiscal years the Company engaged the services of APEX Data Systems, Inc. (APEX), owned by Dwight Babcock, former Chairman and Chief Executive Officer, to build and maintain a web interfaced data collection application to aggregate patient data in a controlled environment. An alternative vendor began providing these services beginning January 2016.

The cost recorded during the quarter ended September 30, 2015 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection applications in combination with the updating of the Company website was approximately \$3,000. An additional approximately \$3,000 was spent on the maintenance of Customer Relationship Management (CRM) software in the quarter ended September 30, 2015.

During the quarter ended June 30, 2016, the Company engaged GO Intellectual Capital, LLC (GO) for marketing services in support of the Company's rebranding effort. Michael McCormick, a member of the Company Board of Directors, is a 1/3 owner of GO. A statement of work was developed defining the scope of the effort and the deliverables to the Company including a new logo with brand messaging and communication tools including a website, sales presentation tools and a public relations strategy. For the quarter ended September 30, 2016, the Company paid approximately \$15,000 to GO for its performance of work related to the agreed upon statement of work. No such services were provided in the quarter ended September 30, 2015.

13. Concentrations of Credit and Other Risks

One group of customers, facilities or physician practices have revenues that aggregate to greater than 10% of total Company product sales:

Facility	Quarter ended	
	September 30, 2016	June 30, 2016
El Camino Hospital of Los Gatos, Fremont Surgery Center & other facilities ¹	22.33%	23.39%

¹ – This group of facilities individually do not aggregate to more than 10% of total Company product sales. They are serviced by the same physician group, one of whom is our Medical Director.

The Company routinely assesses the financial strength of its customers and provides an allowance for doubtful accounts as necessary.

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-Q contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (“PSLRA”). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words “believe,” “expect,” “anticipate,” “intends,” “estimate,” “forecast,” “project,” and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the

foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under “Risk Factors” under Part II, Item 1A below and in the “Risk Factors” sections of our Form 10-K for the fiscal year ended June 30, 2016 .

Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, derivative liabilities and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 9, 2016 are those that depend most heavily on these judgments and estimates. As of September 30, 2016, there had been no material changes to any of the critical accounting policies contained therein.

Overview

IsoRay, Inc. is a brachytherapy device manufacturer with FDA clearance and CE marking for a single medical device that can be delivered to the physician in multiple configurations as prescribed for the treatment of cancers in multiple body sites. The Company manufactures and sells this product as the Cesium-131 brachytherapy seed.

The brachytherapy seed utilizes Cesium-131, with a 9.7 day half-life, as its radiation source. The Company believes that it is the unique combination of the short half-life and the energy of the Cesium-131 isotope that are yielding the beneficial treatment results that have been published in peer reviewed journal articles and presented in various forms at conferences and tradeshow.

The Company has distribution agreements outside of the United States through its subsidiary IsoRay International LLC. These distributors are responsible for obtaining regulatory clearance to sell the Company's products in their territories, with the support of the Company. As of the date of this Report, the Company had distributors in Italy and the Russian Federation, with no reported revenues in the quarter ended September 30, 2016.

Results of Operations

Quarter ended September 30, 2016 and 2015 (in thousands)

	Quarter ended September 30,				2016 - 2015 %
	2016		2015		
	Amount	% (a)	Amount	% (a)	Change
Product sales, net	\$1,081	100	\$1,261	100	(14)
Cost of product sales	1,033	96	1,178	93	(12)
Gross profit	48	4	83	7	(42)
Research and development expenses	172	16	144	11	19
Sales and marketing expenses	524	48	278	22	88
General and administrative expenses	927	86	752	60	23
Non-operating income	77	7	71	6	8
Net loss	\$(1,498)	(139)	\$(1,020)	(81)	(47)

(a) Expressed as a percentage of product sales, net

Product Sales.

Focus on a new marketing approach and sales training coupled with a summer vacation by some key accounts resulted in lower sales when compared to the prior year's first quarter (in thousands):

	Quarter ended September 30,				
	2016		2015		2016 - 2015
	Amount	% (a)	Amount	% (a)	% Change
Prostate brachytherapy	\$966	89	\$1,116	88	(13)
Other brachytherapy	115	11	145	12	(21)
Product sales, net	1,081	100	1,261	100	(14)

(a) Expressed as a percentage of product sales, net

Prostate Brachytherapy.

Prostate brachytherapy sales decreases were impacted by physician's reduced summer schedules and the timing of ASTRO, which is typically held during the second quarter of the Company's fiscal year but was held in the first quarter of this fiscal year. Relationship development was emphasized following a transitional period where the Company added a Vice-President of Sales and Marketing and a Senior Marketing Consultant as well as two Senior Account Managers bringing approximately 45 years of combined experience in the prostate cancer treatment and related markets. Management believes growth in prostate brachytherapy revenues will be the result of physicians, payors, and patients increasingly considering overall treatment advantages including costs, better treatment outcomes and improvement in the quality of life for patients, when compared with non-brachytherapy treatments.

Management believes increased pressure to deliver effective healthcare in both terms of outcome and cost drove treatment options in the quarter ended September 30, 2015, with prostate brachytherapy receiving more consideration than in previous years and believes this trend is continuing in the quarter ended September 30, 2016.

Other Brachytherapy.

Other brachytherapy includes, but is not limited to, brain, lung, head/neck, and gynecological treatments. Initial applications for these other brachytherapy treatments are primarily used in recurrent cancer treatments or salvage cases that are generally difficult to treat aggressive cancers where other treatment options are either ineffective or unavailable.

These other brachytherapy treatments continue to be subject to the influence of a small pool of innovative physicians who are the early adopters of the technology who also tend to be faculty at teaching hospitals training the next generation of physicians. This causes the revenue created by these types of treatment applications to be more volatile and vary significantly from quarter to quarter.

Cost of product sales.

Cost of product sales consists primarily of the costs of manufacturing and distributing the Company's products. Contributing to the quarter ended September 30, 2016 and 2015 comparison were decreases attributed to a change in the asset retirement obligation and reduced depreciation expense as several production related assets became fully depreciated.

The Company purchases an excess supply of isotope to meet not only known customer orders but also enough to fill anticipated orders which may or may not materialize. Excess isotope is utilized in the production of upcoming orders where possible considering the decay rates of Cesium-137. Loss of isotope to decay is also included as a cost of production.

Research and development.

Research and development consists primarily of the costs related to employee and third party research and development activities. Contributing to the quarter ended September 30, 2016 and 2015 comparison were increased legal expenses related to maintenance of intellectual property.

Sales and marketing expenses.

Sales and marketing expenses consist primarily of the costs related to the internal and external activities of the Company's sales, marketing and customer service. Contributing to the quarter ended September 30, 2016 and 2015 comparison increase were rebranding efforts and a website redesign that launched during the quarter and increased costs attributed to filled sales positions, including the position of Vice President of Sales and Marketing, some of which were unfilled in the previous quarter ended September 30, 2015 and others that were added including a Product Manager and a Senior Marketing Consultant. These increases were partially offset by decreased costs associated with attending trade shows.

General and administrative expenses.

General and administrative expenses consist primarily of the costs related to the executive, quality assurance/regulatory affairs departments, finance, and information technology of the Company. Contributing to the quarter ended September 30, 2016 and 2015 comparison were increased salary, benefits, and share-based compensation related to the hiring of the Director of Quality Assurance and Regulatory Affairs and the Senior Accountant in June 2016, and the Vice President of Human Resources and Training in July 2016. There were also increased public company expenses related to the executive compensation review by an independent consultant and the attendance of the Company's Chief Executive, Financial and Operating/Scientific Officers to the Rodman & Renshaw investor conference.

Non-operating income (expense).

Interest income consists primarily of interest earned on certificates of deposit in the CDARS system which are FDIC insured.

The warrant derivative liability requires periodic evaluation for changes in fair value. For the quarter ended September 30, 2016 and 2015, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model and applied updated inputs as of those dates. The resulting change in fair value was recorded during the quarters ended September 30, 2016 and 2015.

Other income consists primarily of gains on asset disposals and other revenues not attributed to the Company's core business products. In the quarter ended September 30, 2016 the Company recorded a gain of approximately \$5,000 on asset disposals and approximately \$16,000 of refunds resulting from an audit performed on one of our vendors.

Liquidity and capital resources.

The Company assesses its liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company has historically financed its operations through selling equity to investors. During the quarter ended September 30, 2016 and 2015, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio).

	Quarter ended September 30,	
	2016	2015
Net cash used by operating activities	\$ (1,353)	\$ (1,109)
Net cash used by investing activities	(327)	(2,577)
Net cash provided by financing activities	-	47
Net decreases in cash and cash equivalents	\$ (1,680)	\$ (3,639)
Working capital	\$ 13,801	\$ 14,409
Current ratio	13.28	16.47

Cash flows from operating activities

Net cash used by operating activities in the quarter ended September 30, 2016 was primarily due to a net loss of approximately \$1.5 million net of approximately \$81,000 in adjustments for non-cash activity such as depreciation and amortization expense, the change in fair value of the warrant derivative liability and share-based compensation. Changes in operating assets and liabilities contributed approximately \$64,000 to the cash provided by operating activities, such as improved effectiveness from accounts receivable collection efforts which was offset by the timing of accounts payable and accrued expenses.

Cash flows from investing activities

Investing activities consisted of transactions related to the purchase of fixed assets, including automation of production processes and advance planning and design work on the Company's new production facility, as well as the purchase and subsequent maturity of certificates of deposit. Management will continue to invest in technology and machinery that improves and streamlines production processes and to invest and reinvest maturing certificates of deposit in low-risk investment opportunities that safeguard assets and provide greater assurance those resources will be liquid and available for business needs as they arise.

Cash flows from financing activities

Financing activities in the quarter ended September 30, 2015 were due to sales of common stock through option exercises.

Projected 2017 Liquidity and Capital Resources

Operating activities

Management forecasts that fiscal 2017 cash requirements will be similar to previous years and that current cash and cash equivalents along with certificates of deposit (current and non-current) will be sufficient to meet projected operating cash needs for the coming year. Assuming no extraordinary expenses occur (whether operating or capital), if management is successful at implementing its strategy to focus on renewed emphasis to drive the consumer to the prostate market and meets or exceeds its annual growth targets of twenty percent increase in revenue in fiscal 2017 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. There is no assurance that the targeted sales growth will materialize but management is encouraged by the depth and experience of its restructured sales team.

Capital expenditures

Management is in the design process of a future production and administration facility. If financing is obtained and the facility constructed, it is believed that the new facility will have non-cash depreciation cost equal to or greater than the monthly rental cost of the current facility. Management is reviewing all aspects of production operations (including process automation), research and development, sales and marketing, and general and administrative functions to evaluate the most efficient deployment of capital to ensure that the appropriate materials, systems, and personnel are available to support and drive product sales. Through the quarter ended September 30, 2016, the Company has invested approximately \$110,000 towards the automation of thirteen production processes, three of which have been received, are being tested and evaluated, and are expected to be placed in service in the coming quarter. Management is expecting to invest approximately \$390,000 more during fiscal 2017 on the remaining production process automation projects. This investment is designed to allow the Company to significantly increase the output of Cs-131 brachytherapy seeds while allowing the Company to control the highest cost inputs to seed production while also improving the overall safety of our operations.

Financing activities

There was no material change in the use of proceeds from our public offering as described in our final prospectus supplement filed with the SEC pursuant to Rule 424(b) on March 24, 2014. Through June 30, 2016, the Company had used the net proceeds raised through the March 2014 offering as described in the public offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

On August 25, 2015, the Company filed a registration statement on Form S-3 to register securities up to \$20 million in value for future issuance in our capital raising activities. The registration statement became effective on November 19, 2015, and the SEC file number assigned to the registration statement is 333-206559.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders, Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders.

Other Commitments and Contingencies

The Company presented its other commitments and contingencies in our Annual Report on Form 10-K for the fiscal year ended June 30, 2016. There have been no material changes outside of the ordinary course of business in those obligations during the quarter ended September 30, 2016 other than those previously disclosed in Note 8 to the interim financial statements contained in this Form 10-Q.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. The Company evaluates its estimates and judgments on an ongoing basis. The Company bases its estimates on historical experience and on various other factors the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Actual results could therefore differ materially from those estimates if actual conditions differ from our assumptions.

During the quarter ended September 30, 2016, there have been no changes to the critical accounting policies and estimates, as discussed in Part II, Item 7 of our Form 10-K for the year ended June 30, 2016.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes to the disclosure in the “Quantitative and Qualitative Disclosures about Market Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2016.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of September 30, 2016. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures are designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

The Company may, in the ordinary course of business, be subject to various legal proceedings. Legal proceedings are discussed in Note 8 of Notes to Condensed Consolidated Financial Statements (Unaudited). We refer you to that discussion for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought. We provide the following additional information concerning those legal proceedings, including the name of the lawsuit, the court in which the lawsuit is pending, and the date on which the petition commencing the lawsuit was filed.

Class Action Lawsuit Related to Press Release

On May 22, 2015, the first of three lawsuits was filed against IsoRay, Inc. and two of its officers – Dwight Babcock (the Company’s retired CEO) and Brien Ragle, CFO – related to a press release on May 20, 2015 regarding a May 19 online publication of the peer-reviewed article in the journal Brachytherapy titled “Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-Stage Lung Cancer” by Dr. Bhupesh Parashar, et al. The lawsuits are class actions alleging violations of the federal securities laws. By Order dated August 17, 2015, all of the pending lawsuits were consolidated into one case – In re IsoRay, Inc. Securities Litigation; Case No. 4:15-cv-05046-LRS, in the US District Court for the Eastern District of Washington. On October 16, 2015, an amended complaint was filed with more detailed allegations relating to alleged violations of federal securities laws. On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. On June 1, 2016, the court entered an order denying IsoRay's motion to dismiss, holding that the complaint's allegations, if accepted as true, state a plausible claim to relief. The order did not adjudicate the merits of the lawsuit. No other issues were decided in the ruling.

On June 15, 2016, IsoRay filed their answer to the amended complaint. As IsoRay previously disclosed, on September 23, 2016, the parties entered into a stipulation of settlement which, if it becomes final, will provide for a payment to the plaintiff class of \$3,537,500, which will be paid by our insurers. On October 4, 2016, the stipulation of settlement was filed with the court, along with plaintiffs' unopposed motion for preliminary approval of the settlement. On October 20, 2016, the court granted preliminary approval of the settlement. Following notice to class members, the class action is subject to final approval by the court. A final approval hearing is scheduled for March 7, 2017. If the proposed settlement is not approved by the court or if IsoRay is otherwise unable to obtain a favorable resolution of the claims set forth in the complaint, the lawsuit could have a material adverse effect on our business, results of operations and financial condition.

Derivative Complaint related to shareholder value

On September 29, 2016, a purported shareholder derivative complaint captioned *Kitley v. Babcock, et al.*, No. 0:16-cv-03297, was filed on behalf of the Company in the United States District Court for the District of Minnesota against certain of the Company's current and former officers and directors. The complaint alleges that the defendants breached their fiduciary duties by causing the Company to issue allegedly false and misleading statements in a May 20, 2015 press release – the same press release at issue in the pending securities class action – concerning the results from a peer reviewed study of its Cesium-131 isotope seeds and mesh product for the treatment of non-small cell lung cancers. The complaint brings claims of breach of fiduciary duty, gross mismanagement, and unjust enrichment, and seeks unspecified compensatory damages, changes in corporate governance, and attorney's fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. The Company may be obligated pursuant to indemnification obligations to advance fees and costs incurred by the individuals defending against the action. The Company has applicable directors and officers insurance policies. Defendants' response to the complaint is due November 17, 2016.

ITEM 1A – RISK FACTORS

A description of the risk factors associated with our business is included under "Risk Factors" contained in Part I, Item 1A of our Form 10-K for the year ended June 30, 2016, and is incorporated herein by reference. There have been no material changes in our risk factors since such filing, except for the following:

We Rely Heavily On Five Customers

For the quarter ended September 30, 2016 approximately 48% of the Company's revenues were dependent on five customers with nearly 22% being generated by one customer. The loss of any of these customers would have a

material adverse effect on the Company's revenues which may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments.

ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 - MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 – OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibits:

- 10.1* Stipulation of settlement dated September 23, 2016, by and between IsoRay, Inc., Dwight Babcock, and the settlement class
- 31.1* Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer
- 31.2* Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer
- 32** Section 1350 Certifications
- 101.INS* XBRL Instance Document
- 101.SCH* XBRL Taxonomy Extension Schema Document
- 101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF* XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB* XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 9, 2016

ISORAY, INC., a Minnesota corporation

By/s/ Thomas C. LaVoy

Thomas C. LaVoy, Chief Executive Officer

(Principal Executive Officer)

By /s/ Brien L. Ragle

Brien L. Ragle, Chief Financial Officer

(Principal Financial and Accounting Officer)