

IsoRay, Inc.  
Form 10-Q  
February 17, 2015

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 December 31, 2014

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

Edgar Filing: IsoRay, Inc. - Form 10-Q

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 "

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 such shorter period that the registrant was required to submit and post such files).

Yes x 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 x

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

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 February 11, 2015</u>
Common stock, \$0.001 par value	54,883,445

**ISORAY, INC.**

**Table of Contents**

**PART I FINANCIAL INFORMATION**

Item 1	Consolidated Unaudited Financial Statements	1
	<u>Consolidated Balance Sheets</u>	1
	<u>Consolidated Statements of Operations (Unaudited)</u>	2
	<u>Consolidated Statements of Cash Flows (Unaudited)</u>	3
	<u>Notes to Consolidated Unaudited Financial Statements</u>	4
Item 2	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4	<u>Controls and Procedures</u>	22

**PART II OTHER INFORMATION**

Item 1A	<u>Risk Factors</u>	22
Item 6	<u>Exhibits</u>	22
	<u>Signatures</u>	23

**PART I – FINANCIAL INFORMATION****IsoRay, Inc. and Subsidiaries****Consolidated Balance Sheets**

	(Unaudited)	
	December 31, 2014	June 30, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,336,853	\$ 7,680,073
Certificates of deposit (Note 3)	10,047,298	10,002,912
Accounts receivable, net of allowance for doubtful accounts of \$30,000 and \$38,607, respectively	797,381	913,049
Inventory	411,420	359,737
Other receivables	10,978	53,082
Prepaid expenses and other current assets	221,167	206,047
<b>Total current assets</b>	<b>12,825,097</b>	<b>19,214,900</b>
Fixed assets, net of accumulated depreciation and amortization		
Certificates of deposit, non-current (Note 3)	761,425	1,017,915
Restricted cash	10,096,680	5,401,398
Inventory, non-current	181,235	181,208
Other assets, net of accumulated amortization	469,758	469,758
	250,903	264,076
<b>Total assets</b>	<b>\$ 24,585,098</b>	<b>\$ 26,549,255</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 488,321	\$ 574,855
Accrued protocol expense	90,380	80,433
Accrued radioactive waste disposal	108,068	141,592
Accrued payroll and related taxes	146,745	236,282
Accrued vacation	108,378	120,765
<b>Total current liabilities</b>	<b>941,892</b>	<b>1,153,927</b>
Warrant derivative liability	209,000	573,000
Asset retirement obligation	906,294	866,560

Edgar Filing: IsoRay, Inc. - Form 10-Q

Total liabilities	2,057,186	2,593,487
Commitments and contingencies (Note 7)		
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	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series D: 1,671 and 0 shares allocated; no shares issued and outstanding	-	-
Common stock, \$.001 par value; 192,998,329 & 193,000,000 shares authorized; 54,883,445 and 54,701,708 shares issued and outstanding	54,883	54,702
Treasury stock, at cost, 13,200 shares	(8,390 )	(8,390 )
Additional paid-in capital	82,224,632	81,959,853
Accumulated deficit	(59,743,272 )	(58,050,456)
Total shareholders' equity	22,527,912	23,955,768
Total liabilities and shareholders' equity	\$ 24,585,098	\$ 26,549,255

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

**IsoRay, Inc. and Subsidiaries****Consolidated Statements of Operations****(Unaudited)**

	Three months ended December 31,		Six months ended December 31,	
	2014	2013	2014	2013
Product sales, net	\$ 1,065,585	\$ 1,085,408	\$ 2,107,686	\$ 2,135,323
Cost of product sales	1,103,549	1,119,314	2,200,452	2,246,537
Gross loss	(37,964 )	(33,906 )	(92,766 )	(111,214 )
Operating expenses:				
Research and development expenses	140,627	170,030	317,237	317,020
Sales and marketing expenses	303,783	326,467	657,526	685,652
General and administrative expenses	537,940	513,964	1,113,891	1,165,000
Total operating expenses	982,350	1,010,461	2,088,654	2,167,672
Operating loss	(1,020,314 )	(1,044,367 )	(2,181,420 )	(2,278,886 )
Non-operating income (expense):				
Interest income	72,360	481	145,055	835
Change in fair value of warrant derivative liability	41,000	117,000	347,000	81,000
Financing and interest expense	-	(86 )	(3,451 )	(827 )
Non-operating income (expense), net	113,360	117,395	488,604	81,008
Net loss	(906,954 )	(926,972 )	(1,692,816 )	(2,197,878 )
Preferred stock dividends (Note 10)			-	(726,378 )
Preferred stock dividends	(2,658 )	(2,658 )	(5,316 )	(5,316 )
Net loss applicable to common shareholders	\$ (909,612 )	\$ (929,630 )	\$ (1,698,132 )	\$ (2,929,572 )
Basic and diluted loss per share	\$ (0.02 )	\$ (0.02 )	\$ (0.03 )	\$ (0.08 )
Weighted average shares used in computing net loss per share: Basic and diluted	54,883,445	38,419,502	54,875,749	37,133,875

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



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

	Six months ended December 31,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,692,816 )	\$ (2,197,878 )
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(8,607 )	(20,083 )
Depreciation and amortization of fixed assets	305,147	349,232
Amortization other assets	15,469	15,371
Change in fair value of warrant derivative liability	(347,000 )	(81,000 )
Accretion of asset retirement obligation	39,734	36,326
Share-based compensation	42,907	51,786
Changes in operating assets and liabilities:		
Accounts receivable, gross	124,275	26,641
Inventory	(51,683 )	(20,762 )
Other receivables	42,104	1,438
Prepaid expenses and other current assets	(15,120 )	46,515
Accounts payable and accrued expenses	(86,534 )	(2,273 )
Accrued protocol expense	9,947	21,668
Accrued radioactive waste disposal	(33,524 )	24,000
Accrued payroll and related taxes	(89,537 )	13,663
Accrued vacation	(12,387 )	(2,646 )
Net cash used by operating activities	(1,757,625 )	(1,738,002 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(48,657 )	(14,419 )
Additions to licenses and other assets	(2,296 )	(1,562 )
Proceeds from the maturity of certificates of deposit	5,013,694	-
Purchases of certificates of deposit	(5,058,080 )	-
Purchases of certificates of deposit - non-current	(4,695,282 )	-
Change in restricted cash	(27 )	(32 )
Net cash used by investing activities	(4,790,648 )	(16,013 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Preferred dividends paid	(10,632 )	(10,632 )
Proceeds from sales of preferred stock, pursuant to underwritten offering, net	-	1,478,712
Proceeds from sales of common stock, pursuant to underwritten offering, net	-	1,800,580
Proceeds from sales of common stock, pursuant to exercise of warrants, net	70,411	-



Edgar Filing: IsoRay, Inc. - Form 10-Q

Proceeds from sales of common stock, pursuant to exercise of options	145,274	-
Net cash provided by financing activities	205,053	3,268,660
Net increase (decrease) in cash and cash equivalents	(6,343,220 )	1,514,645
Cash and cash equivalents, beginning of period	7,680,073	2,899,927
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 1,336,853</b>	<b>\$ 4,414,572</b>
Non-cash investing and financing activities:		
Reclassification of derivative warrant liability to equity on exercise	\$ 17,000	\$ -
Total non-cash investing and financing activities	\$ 17,000	\$ -

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

**IsoRay, Inc.**

**Notes to the Consolidated Unaudited Financial Statements**

**For the three and six months ended December 31, 2014 and 2013**

**1. Basis of Presentation**

The accompanying 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 consolidation. Certain amounts in the prior-year financial statements have been reclassified to conform to the current year presentation.

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. 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, 2014, as it may be amended from time to time.

The results of operations for the periods presented may not be indicative of those which may be expected for a full year. 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.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, the reported amounts of revenues and expenses during the reporting period and the disclosures of contingent liabilities. Accordingly, ultimate results could differ materially from those estimates.

**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, 2016, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15—Presentation of Financial Statements—Going Concern. The guidance requires an entity's management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). If conditions or events exist that raise substantial doubt about an entity's ability to continue as a going concern, the guidance requires disclosure in the financial statements. The guidance will be effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

### 3. Certificates of Deposit

Remaining time to maturity	Under 90 days	91 days to six months	Six months to 1 year	1 to 3 years
Certificates of Deposit <sup>1</sup>	\$5,014,366	\$5,032,932	\$ -	\$10,096,680

<sup>1</sup> - Certificate of Deposit Account Registry Service (CDARS), which is a system method by which the Company may access multi-million-dollar Certificates of Deposit (CDs) deposits in principal and interest amounts that are fully insured by the Federal Deposit Insurance Corporation (FDIC) with original maturities that were greater than three months and up to three years at the time of purchase.

### 4. Loss per Share

Basic earnings per share is 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 potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At December 31, 2014 and 2013, the calculation of diluted weighted average shares did not include 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 are presented on an as converted to common stock basis which could be dilutive in the future as of December 31, 2014 and 2013, were as follows:

	December 31,	
	2014	2013
Series B preferred stock	59,065	59,065
Series D preferred stock	-	3,121,480
Common stock warrants	396,574	7,605,771
Common stock options	2,180,858	2,370,072
Total potential dilutive securities	2,636,497	13,156,388

### 5. Inventory

Inventory consisted of the following at December 31, 2014 and June 30, 2014:

Edgar Filing: IsoRay, Inc. - Form 10-Q

	December 31, 2014	June 30, 2014
Raw materials	\$ 191,581	\$173,417
Work in process	191,229	151,321
Finished goods	28,610	34,999
Total inventory	\$ 411,420	\$359,737

## 6.Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and six months ended December 31, 2014 and 2013:

	Three months ended December 31,		Six months ended December 31,	
	2014	2013	2014	2013
Cost of product sales	\$ 7,972	\$ 4,499	\$ 15,945	\$ 8,921
Research and development expenses	3,117	3,482	6,235	6,965
Sales and marketing expenses	2,158	879	4,317	1,757
General and administrative expenses	8,206	4,572	16,410	34,143
Total share-based compensation	\$ 21,453	\$ 13,432	\$ 42,907	\$ 51,786

As of December 31, 2014, total unrecognized compensation expense related to stock-based options was \$297,591 and the related weighted-average period over which it is expected to be recognized is approximately 2.05 years.

The Company currently provides stock-based compensation under four equity incentive plans approved by the Board of Directors. Options granted under each of the plans have a ten-year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

A summary of stock options within the Company's share-based compensation plans as of December 31, 2014 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2014	2,057,620	\$ 1.98	4.43	\$ 672,597
Vested and expected to vest at December 31, 2014	1,988,995	\$ 2.00	4.35	\$ 645,947
Vested and exercisable at December 31, 2014	1,821,504	\$ 1.96	3.83	\$ 644,927

Edgar Filing: IsoRay, Inc. - Form 10-Q

There were 133,564 options exercised during the six months ended December 31, 2014 and no options exercised during the six months ended December 31, 2013. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised during the six months ended December 31, 2014 was \$252,308.

There were no stock option awards granted and 65,000 stock option awards granted during the six months ended December 31, 2014 and 2013, respectively.

There were 84,236 stock option awards forfeited and no stock option awards forfeited by former employees during the six months ended December 31, 2014 and 2013, respectively.

There were 39,002 stock option awards which expired and no stock option awards which expired during the six months ended December 31, 2014 and 2013, respectively.

There were 50,000 director stock options issued to the Chief Executive Officer and Chairman on September 5, 2013 with an exercise price of \$0.58 per share which was the closing price of the Company common stock on the day of issuance. The fair value of the stock options issued on September 5, 2013 using a Black Scholes model was \$25,150 utilizing the closing price on the day of grant of \$0.58 per share as the grant and exercise price, a five- year term, volatility of 132.31% and a discount rate of 1.85%.

There were 15,000 employee stock options issued to three members of management on September 6, 2013 with an exercise price of \$0.59 per share which was the closing price of the Company common stock on the day of issuance. The fair value of the stock options issued on September 6, 2013 using a Black Scholes model was \$6,906 utilizing the closing price on the day of grant of \$0.59 per share as the grant and exercise price, a five year term, volatility of 132.31% and a discount rate of 1.77%.

## **7. Commitments and Contingencies**

### Patent and Know-How Royalty License Agreement

The Company is the holder of an exclusive license to use certain “know-how” developed by one of the founders of a predecessor to the Company and licensed to the Company by the Lawrence Family Trust, a Company shareholder. The terms of this license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor’s patent application was ultimately abandoned, only a 1% “know-how” royalty based on Net Factory Sales Price, as defined in the agreement, remains applicable. To date, management believes that there have been no product sales incorporating the “know-how” and therefore no royalty is due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this “know-how” in the future.

The licensor of the “know-how” has disputed management’s contention that it is not using this “know-how”. On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

## **8. Fair Value Measurements**



Edgar Filing: IsoRay, Inc. - Form 10-Q

The table below sets forth the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2014 and June 30, 2014, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Description	Balance at December 31, 2014	Balance at June 30, 2014	Input Hierarchy Level
Assets:			
Cash and cash equivalents	\$ 1,336,853	\$ 7,680,073	Level 1
Restricted cash	181,235	181,208	Level 1
Liabilities:			
Warrant derivative liability	\$ 209,000	\$ 573,000	Level 2

## 9. Preferred Dividends

On December 17, 2014, the Board of Directors declared a dividend on the Series B Preferred Stock of all currently payable and accrued outstanding and cumulative dividends through December 31, 2014 in the amount of \$10,632. Dividends on the Series B Preferred Stock were last declared by the Board of Directors on December 19, 2013 in the amount of \$10,632. The dividends outstanding and cumulative through December 31, 2014 of \$10,632 and through December 31, 2013 of \$10,632 were paid as of those dates.

## 10. Shareholders' Equity

### *Common and preferred stock transactions*

On August 29, 2013, the Company entered into an agreement to sell 3,800,985 common units, each consisting of 1 share of common stock and a warrant to purchase 0.816 shares of common stock (the Common Units), and 1,670 preferred units, each consisting of 1 share of Series D Convertible Preferred Stock and a warrant to purchase 1,525.23 shares of common stock (the Preferred Units) on a firm commitment underwritten basis. The Common Units were sold at an initial per unit purchase price of \$0.535 and the Preferred Units were sold at an initial per unit purchase price of \$1,000. The warrants were all exercisable at \$0.72 per share and had a twenty-four month term. Each share of the Series D Convertible Preferred Stock was convertible into 1,869.15 shares of common stock at any time at the option of the holder, subject to adjustment. The Series D Preferred Shares which were convertible into shares of common stock contain a beneficial conversion feature of \$726,378 which was recognized as a deemed dividend to the Series D preferred shareholders on the date of issuance. This public offering resulted in gross proceeds of \$3.7 million. The offering yielded approximately \$3,279,292 in cash after expenses.

Gross proceeds from public offering	\$3,703,527
Underwriting discount	(185,176 )
Legal and accounting expense	(184,514 )
Listing expense	(48,500 )
Other expense	(6,045 )
Net proceeds	\$3,279,292

### *Warrant liability and related offering cost deferral*

Based on the guidance contained in ASC 815 "Derivatives and Hedging", management has concluded that the warrants issued in the October 13, 2011 underwritten registered offering of 2,500,000 shares of common stock should be classified as a derivative liability and has recorded a liability at fair value. The Company determined the fair value of

Edgar Filing: IsoRay, Inc. - Form 10-Q

the warrants using the Black-Scholes fair value model. The Company determined the fair value of the warrants on the date of the offering to be as disclosed in the tables below. The Company has recognized a change in fair value as described in the table below:

Change in fair value of the derivative warrant liability for the three months ended December 31, 2014 and 2013, respectively.

	Three months ended December 31, 2014	Three months ended December 31, 2013
Change in fair value	\$ (41,000 )	\$ (117,000 )

Purchaser warrants and underwriter warrants issued in October 2011 and December 2011:

	Three months ended December 31, 2014		Three months ended December 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of period	229,861	\$250,000	713,601	\$140,000
Change in fair value		(41,000)		(117,000)
Balance, end of period	229,861	\$209,000	713,601	\$23,000

Change in fair value of the derivative warrant liability for the six months ended December 31, 2014 and 2013, respectively.

	Six months ended December 31, 2014	Six months ended December 31, 2013
Change in fair value	\$ (347,000 )	\$ (81,000 )

Purchaser warrants and underwriter warrants issued in October 2011 and December 2011:

	Six months ended December 31, 2014		Six months ended December 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of period	238,296	\$573,000	713,601	\$104,000
Change in fair value		(347,000)		(81,000)
Warrants exercised	(8,435 )	(17,000 )	-	-
Balance, end of period	229,861	\$209,000	713,601	\$23,000

<sup>1</sup> The quantity of warrants either exercised or outstanding as of the date of valuation.

### *Warrants*

The following table summarizes the warrants outstanding as of the beginning of the fiscal year, warrants exercised and warrants issued during the period and weighted average prices for each category.

Edgar Filing: IsoRay, Inc. - Form 10-Q

	Warrants	Weighted average exercise price
Outstanding as of June 30, 2014	444,747	\$ 1.43
Warrants exercised	(48,173 )	1.45
Outstanding as of December 31, 2014	396,574	\$ 1.22

*Warrants outstanding as of December 31, 2014*

Quantity	Expiration date	Exercise price <sup>1</sup>
6,000	June 8, 2015	\$ 1.18
25,000	July 27, 2015	2.00
130,713	November 21, 2015	1.56
204,211	October 19, 2016	0.94
25,650	December 7, 2016	0.94
5,000	June 27, 2017	0.98
396,574		\$ 1.22

<sup>1</sup> – Amounts are rounded to the nearest whole cent

## 11. Related Party Transaction

During the six months ended December 31, 2014 and 2013, the Company continued to engage the services of APEX Data Systems, Inc., owned by Dwight Babcock, the Company's Chairman and Chief Executive Officer, to modify and maintain the Company's web interfaced data collection application to aggregate patient data in a controlled environment. The Audit Committee and Board of Directors approved the use of the ongoing services of APEX Data Systems. Mr. Babcock recused himself from the Board vote due to his conflict of interest. The cost recorded during the six months ended December 31, 2014 and 2013 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection application was \$6,000 and \$9,720. An additional \$6,000 was spent on the implementation and maintenance of Customer Relationship Management software during the six months ended December 31, 2014 and 2013, respectively.

## 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 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" section of our Form 10-K for the fiscal year ended June 30, 2014 that may cause actual results to differ materially.*

*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, 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 29, 2014 are those that depend most heavily on these judgments and estimates. As of December 31, 2014, there had been no material changes to any of the critical accounting policies contained therein.

### **Cash Management**

Company management has determined the appropriate amount of cash that is to be maintained for operational use and has determined that the remainder should be invested in certificates of deposit with varying maturities up to three years in order to balance return and risk. At December 31, 2014, the Company had \$1.34 million of operating cash on hand, \$10.05 million of cash invested in certificates of deposit which mature within the current operating cycle and \$10.1 million of cash invested in certificates of deposit which mature beyond the current operating cycle. Cash and cash equivalents and the cash invested in certificates of deposit totaled approximately \$21.5 million at December 31, 2014.

### **Results of Operations**

#### **Three months ended December 31, 2014 compared to three months ended December 31, 2013.**

**Revenues.** During the three months ended December 31, 2014, total revenue decreased from the three months ended December 31, 2013.



Prostate revenue generated by the top five customers continues to make up a significant portion of the total revenue. These customers increased their overall contribution to 62% of total revenue during the three months ended December 31, 2014 compared to 52% of total revenue during the three months ended December 31, 2013. Revenue created by the top 15 customers remains materially unchanged in the three months ended December 31, 2014 when compared to the three months ended December 31, 2013. The application of seed brachytherapy to non-prostate body sites increased approximately 13% during the three months ended December 31, 2014 when compared to the three months ended December 31, 2013 but continues to represent the same proportion of total revenue in each three month period. Gliasite® Radiation Therapy System (Gliasite® RTS) revenue, which decreased by approximately 30%, was significantly impacted by the reduction in the purchasing volume of a distributor and partially offset by purchases made by new customers purchasing an inventory of catheters required for these new customers to be positioned to treat cases using the Gliasite® RTS.

Seed brachytherapy treatments classified as Product Sales (Other) when combined with the revenue generated by the GliaSite® RTS product line represent more developmental applications of our product which may not lead to either a long-term revenue source or a significant product line and therefore revenue fluctuation in this segment is expected to be subject to more significant variation from quarter to quarter. Company management is actively pursuing alternative uses for the Company's brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible. The products being implemented by the Company are very dependent on first adopters as a source of revenue to partially offset some of the developmental cost, and there is initially a significant change in revenue period over period that will reach a plateau due to treatment capacity and quantity of cases available to the first adopters until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. However, to date the Company has only experienced minimal sales to first adopters.

Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as intensity modulated radiation therapy (IMRT) and robotics but management believes that combining treatments incorporating brachytherapy with other modalities in the prostate, the addition of new treatment facilities, and treatment of other body sites with brachytherapy have the potential to continue to increase revenue.

During the three months ended December 31, 2014 and 2013, respectively, all product sales were generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of GliaSite® RTS which include the sale of the Cesisitex® solution, Iotrex® solution, catheter trays and access trays. The conversion of prospects to new GliaSite® RTS customers has been a longer process than originally anticipated by the Company. The Company has experienced lengthy timelines in the internal processes of the medical facilities in reviewing and approving the use of the product at the request of their physician(s). These longer than anticipated internal processes are compounded by uncertain timelines and delays in receiving the approval for the requested modification of each facility's nuclear materials license, which is required to begin using GliaSite® RTS and is dependent on external government regulators.

### **Key operating factors**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$ 916,694	\$ 936,806	\$ (20,112 )	(2 )%
Product Sales (Other)	148,891	148,602	289	0 %
Total product sales	\$ 1,065,585	\$ 1,085,408	\$ (19,823 )	(2 )%

### **Cost of product sales.**

Cost of product sales nominally decreased during the three months ended December 31, 2014 compared to the three months ended December 31, 2013.

Cost of product sales related to brachytherapy seed production increased by one percent during the three months ended December 31, 2014 when compared to the three months ended December 31, 2014. No summary line item within cost of product sales changed by greater than one percent as a percentage of total cost of product sales during the three months ended December 31, 2014 when compared to the three months ended December 31, 2013, except depreciation and amortization expense which decreased by four percent as fixed assets continue to reach the end of their depreciable lives. Cost of product sales related to GliaSite<sup>®</sup> RTS decreased by 72% during the three months ended December 31, 2014 when compared to the three months ended December 31, 2013 primarily as the result of recovering a portion of the minimum royalty payment due on a licensing agreement and the lack of an inventory impairment during the three months ended December 31, 2014 compared to the three months ended December 31, 2014.

**Key operating factors**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Depreciation and amortization	131,585	169,054	(37,469 )	(22 )%
Other cost of product sales (Seeds)	961,254	912,078	49,176	5 %
GliaSite® RTS	10,710	38,182	(27,472 )	(72 )%
Total cost of product sales	\$ 1,103,549	\$ 1,119,314	\$ (15,765 )	(1 )%

**Gross loss.** Gross loss for the three months ended December 31, 2014 increased compared to the three month period ended December 31, 2013 as a result of decreased revenue from product sales partially offset by decreased cost of product sales.

**Key operating factor**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Gross loss	\$ (37,964 )	\$ (33,906 )	\$ (4,058 )	12 %
Gross loss percentage	(4 )%	(3 )%		

**Research and development.** Research and development costs decreased during the three months ended December 31, 2014 compared to the three months ended December 31, 2013. The single category which changed significantly was protocol expense. The Company continues to invest in aggregating data regarding the performance of its products. During the three months ended December 31, 2014, the Company did not incur a one-time payment for initiating a protocol which it did incur during the three months ended December 31, 2013.

**Key operating factors**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Protocol expense	\$ 28,084	\$ 53,792	\$ (25,708 )	(48 )%
Other research-development expense	112,543	116,238	(3,695 )	(3 )%
Total research and development	\$ 140,627	\$ 170,030	\$ (29,403 )	(17 )%

**Sales and marketing expenses.** Sales and marketing expenses were reduced during the three months ended December 31, 2014 compared to the three months ended December 31, 2013. The single category which changed nominally was payroll, taxes, benefits and share-based compensation expense, primarily as a function of the Company having fewer sales personnel during the three months ended December 31, 2014 when compared to the three months ended December 31, 2013.

**Key operating factors**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Payroll, taxes, benefits and share-based compensation	\$ 198,430	\$ 215,079	\$ (16,649 )	(8 )%
Other sales and marketing expense	105,353	111,388	(6,035 )	(5 )%
Total sales and marketing	\$ 303,783	\$ 326,467	\$ (22,684 )	(7 )%

**General and administrative expenses.** General and administrative expenses increased in the three months ended December 31, 2014 compared to the three months ended December 31, 2013. The single operating factor that changed materially was public company expense, which was partially offset by a combination of nominal changes in other cost categories. This increase in estimate of allowance for doubtful accounts resulted in an unusually large expense being recognized in the statement of operations during the three months ended December 31, 2014. Public company expense was reduced during the three months ended December 31, 2014, as the Company had two independent directors compared to three independent directors during the three months ended December 31, 2013, and had reduced costs related to investor relations and SEC filing fees.

**Key operating factors**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Public company expense	46,380	69,273	(22,893 )	(33 )%
General and administrative (Other)	491,560	444,691	46,869	11 %
Total general and administrative	\$ 537,940	\$ 513,964	\$ 23,976	5 %

**Operating loss.** Operating loss for the three months ended December 31, 2014 increased compared to the three months ended December 31, 2013 primarily as the result of the decrease in product sales coupled with an increase in operating expenses which were partially reduced by a decrease in cost of product sales.

**Key operating factor**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Operating loss	\$ (1,069,874 )	\$ (1,044,367 )	\$ (25,507 )	2 %

**Interest income.** Interest income increased during the three months ended December 31, 2014 when compared to the three months ended December 31, 2013 as the result of the investment of excess cash in laddered certificates of deposit in amounts that are fully FDIC insured.

**Key operating factor**

Three months	Three months
--------------	--------------

Edgar Filing: IsoRay, Inc. - Form 10-Q

Description	ended 12-31-14	ended 12-31-13	Variance (\$)	Variance (%)
Interest income	\$ 72,360	\$ 481	\$ 71,879	14,944 %

**Change in fair value of warrant liability.** During the three months ended December 31, 2011, there was a warrant derivative liability established upon issuance of warrants during 2011 to purchasers in the Company's registered offering. The warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2014 and December 31, 2013, 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 as of December 31, 2014 and December 31, 2013.

**Key operating factor**

Description	Three months ended 12-31-14	Three months ended 12-31-13	Variance (\$)	Variance (%)
Change in fair value of warrant liability	\$ 41,000	\$ 117,000	\$ (76,000 )	(65 )%

**Six months ended December 31, 2014 compared to six months ended December 31, 2013.**

**Revenues.** Revenue decreased by a nominal amount during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013. The overall decrease in revenue was the direct result of the decrease in revenue from product sales – other during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013. Revenue generated by prostate brachytherapy experienced a nominal increase while the industry continued to experience a decrease as a whole. The revenue increase is primarily the result of increased purchases by the five highest volume users during the six months ended December 31, 2014 when compared with the six months ended December 31, 2013. This increase in the five highest volume users increased their percentage of the total revenue from 57% to 59% during the six months ended December 31, 2014 and 2013, respectively.

Product sales - other include the revenue generated from the sale of brachytherapy seeds for non-prostate applications including the treatment of brain, lung, head and neck and other cancers as well as the revenue from the sale of the GliaSite® RTS. Product sales - other decreased during the six months ended December 31, 2014 when compared with the six months ended December 31, 2013. The decrease in the revenue from product sales - other is due to decreased sales of the GliaSite® RTS. Revenues for the non-prostate applications of the Company's brachytherapy seeds decreased by an insignificant amount during the six months ended December 31, 2014 when compared with the six months ended December 31, 2013. The decrease in revenue from the sale of the GliaSite® RTS came from the decrease in revenue generated from sales to foreign distributors during the six months ended December 31, 2014 when compared with the six months ended December 31, 2013. Revenues from domestic sales remained unchanged. Company management is actively pursuing alternative uses for the Company's brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments as previously identified and management continues to due diligence new applications in coordination with physicians.

Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as IMRT and robotics but that combination treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have the potential to continue to increase.

**Key operating factors**



Edgar Filing: IsoRay, Inc. - Form 10-Q

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$ 1,832,321	\$ 1,789,559	\$ 42,762	2 %
Product Sales (Other)	275,365	345,764	(70,399 )	(20 )%
Total product sales	\$ 2,107,686	\$ 2,135,323	\$ (27,637 )	(1 )%

15

**Cost of product sales.** Cost of product sales related to brachytherapy seed sales decreased by a nominal amount during the six months ended December 31, 2014 compared to the six months ended December 31, 2013 as the result of a combination of individually nominal cost increases which are described as other cost of product sales (seeds) and an increase in pre-loading expense, which were partially offset by the decrease in depreciation and amortization expense. The increase in pre-loading expense was the result of being required to use a third-party loader for a specific customer until such time as it is cost effective to proceed through the 510(k) process to be able to load seeds with the C4 markers in our own facility, combined with the increase in the cost of certain materials such as needles and stranding materials, an increase in repairs and maintenance to equipment and an increased cost of product testing in the sterilization process. Depreciation and amortization expense decreased as equipment continues to reach the end of its depreciable lives without requiring replacement. Cost of product sales related to GliaSite® RTS decreased as a function of the decreased volume of revenue.

### **Key operating factors**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Depreciation and amortization expense	\$ 297,964	\$ 341,369	\$ (43,405 )	(13 )%
Pre-loading expense	173,312	138,316	34,996	25 %
GliaSite® RTS	22,614	81,071	(58,457 )	(72 )%
Other cost of product sales (Seeds)	1,706,562	1,685,781	20,781	1 %
Total cost of product sales	\$ 2,200,452	\$ 2,246,537	\$ (46,085 )	(2 )%

**Gross loss.** Gross loss for the six month period ended December 31, 2014 decreased compared to the six month period ended December 31, 2013 primarily as a result of the decreased product sales offset by a greater reduction in cost of product sales.

### **Key operating factor**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Gross loss	\$ (92,766 )	\$ (111,214 )	\$ 18,448	(17 )%
Gross loss percentage	(4 )%	(5 )%		

**Research and development.** Research and development costs increased by a nominal amount in the six months ended December 31, 2014 compared to the six months ended December 31, 2013. Two operating factors changed in research and development expense which net to an insignificant change overall. Protocol expense decreased during the six months ended December 31, 2014, as the Company did not incur a one-time payment initiating a protocol which it did

incur during the six months ended December 31, 2013. Legal expense related to intellectual property increased during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013.

**Key operating factors**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Protocol expense	\$ 58,888	\$ 87,613	\$ (28,725 )	(33 )%
Legal expense	33,057	1,032	32,025	3,103 %
Research and development (Other)	225,292	228,375	(3,083 )	(1 )%
Total research and development	\$ 317,237	\$ 317,020	\$ 217	0 %

**Sales and marketing expenses.** Sales and marketing expenses decreased during the six months ended December 31, 2014 compared to the six months ended December 31, 2013. Payroll, benefits and share-based compensation increased partially as a function of a decreased number of sales employees in the field and also as a function of decreased auto allowance expense as the Company transitioned to primarily a mileage reimbursement model. Travel expense increased as the result of the Company transitioning to a mileage reimbursement model from an auto allowance model of reimbursement which was approximately cost neutral without factoring in payroll tax savings. Tradeshows and convention expense increased primarily as the result of increased attendance at society meetings, conventions and tradeshows as the Company works to develop additional revenue sources.

### **Key operating factors**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)	
Travel expense	\$ 121,821	\$ 113,627	\$ 8,194	7	%
Payroll, benefits and share-based compensation	421,254	452,137	(30,883 )	(7	)%
Convention and tradeshow expense	58,638	46,492	12,146	26	%
Sales and marketing (Other)	55,813	73,396	(17,583 )	(24	)%
Total sales and marketing	\$ 657,526	\$ 685,652	\$ (28,126 )	(4	)%

**General and administrative expenses.** General and administrative expenses decreased nominally in the six months ended December 31, 2014 compared to the six months ended December 31, 2013 primarily as a result of three operating factors. As of December 31, 2014, there was a significant increase in the amounts classified by management for inclusion in the allowance for doubtful accounts when compared to the balance as of June 30, 2014. This increase in estimate of allowance for doubtful accounts resulted in an unusually large expense being recognized in the statement of operations during the six months ended December 31, 2014. Public company expense was reduced during the six months ended December 31, 2014, as the Company had two independent directors compared to three independent directors during the six months ended December 31, 2013, along with reduced costs related to investor relations which were partially offset by increased SEC filing fees related to the registration statement for the Employee Stock Option Plan approved by the shareholders at the fiscal year 2014 annual shareholder meeting. Payroll, benefits and share-based compensation expense decreased partially as the result of no option grants being made in the six months ended December 31, 2014 compared to the six months ended December 31, 2013 during which options were granted to purchase 65,000 shares of common stock, of which 50,000 were immediately vested and the full expense recognized in that period. The remaining 15,000 options were subject to a 3-year vesting schedule and the expense will be recognized proportionally throughout the vesting period. The additional savings were the result of a favorable renewal of the Company's medical insurance coverage which reduced both the employee and employer cost of coverage prior to the complete implementation of the Affordable Care Act in combination with certain employees retiring, and employees or their dependents gaining coverage elsewhere.

### **Key operating factors**

Edgar Filing: IsoRay, Inc. - Form 10-Q

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Payroll, taxes, benefits and share-based compensation	526,626	569,526	(42,900 )	(8 )%
Public company expense	107,181	140,854	(33,673 )	(24 )%
General and administrative (Other)	488,692	474,603	25,464	6 %
Total general and administrative	\$ 1,113,891	\$ 1,165,000	\$ (51,109 )	(4 )%

17

**Operating loss.** Operating loss for the six months ended December 31, 2014 decreased compared to the six months ended December 31, 2013 primarily as a result of a decrease in the cost of product sales which exceeded the decreased revenue and the overall decrease in operating expenses which was primarily from the decreases associated with sales and marketing.

**Key operating factor**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Operating loss	\$ (2,181,420 )	\$ (2,278,886 )	\$ 97,466	(4 )%

**Interest income.** Interest income increased during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013 as the result of the investment of excess cash in laddered certificates of deposit in amounts that are fully insured by the FDIC.

**Key operating factor**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Interest income	\$ 145,055	\$ 835	\$ 144,220	17,272 %

**Change in fair value of warrant liability.** During the three months ended December 31, 2011, there were warrant liabilities established upon issuance of warrants to the purchasers and underwriters in the Company's registered offering during 2011. Per ASC 820, the warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2014 and December 31, 2013, the Company evaluated the fair value of the warrant liability using the Black-Scholes option pricing model on which the original warrant liability was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of December 31, 2014 and December 31, 2013.

**Key operating factor**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Change in fair value of warrant liability	\$ 347,000	\$ 81,000	\$ 266,000	328 %

**Liquidity and capital resources.** The Company has historically financed its operations through cash investments from shareholders. During the six months ended December 31, 2014 and December 31, 2013, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

*Cash flows from operating activities*

The net loss was adjusted by a net decrease in the non-cash items and a net increase in non-cash changes in operating assets and liabilities, which resulted in an overall increase in net cash used by operating activities for the six months ended December 31, 2014 when compared to the six months ended December 31, 2013. The decreased net loss during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013 was primarily the result of the non-cash change in fair value of derivative warrant liabilities. The change in the fair value of the warrant liability is a model driven item contained in the statement of operations which is primarily impacted by the market price of the stock, the volatility of the market price and the remaining life of the warrant derivative liability. Cash used by operating activities adjusted for the change in the fair value of the derivative warrant liability increased during the six months ended December 31, 2014 compared to the six months ended December 31, 2013. The items that created the increased use of cash in operating activities were the changes in gross accounts receivable, accounts payable and accrued expenses and accrued payroll and related taxes during the six months ended December 31, 2014 compared to the six months ended December 31, 2013.

**Key operating factors**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Net loss	\$ (1,742,375 )	\$ (2,197,878 )	\$ 455,503	(21 )%
Non-cash items	97,209	351,632	(254,423 )	(72 )%
Non-cash changes in operating assets and liabilities	(112,459 )	108,244	(220,703 )	(204 )%
Net cash used by operating activities	\$ (1,757,625 )	\$ (1,738,002 )	\$ (19,623 )	1 %

*Cash flows from investing activities*

Cash used by investing activities during the six months ended December 31, 2014 was primarily related to the addition of capitalized equipment, purchases of certificates of deposit and purchases of certificates of deposit – non-current and was partially reduced by the proceeds from the maturity of certificates of deposit. During the six months ended December 31, 2013, cash used by investing activities was primarily related to the addition of capitalized equipment. The amounts recorded as change in restricted cash in both periods are the accrual of interest earned on certificates of deposit with two financial institutions that are a requirement of the Washington State Department of Health.

**Key operating factors**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Purchases of fixed assets	\$ (48,657 )	\$ (14,419 )	\$ (34,238 )	237 %
Additions to licenses and other assets	(2,296 )	(1,562 )	(734 )	47 %
Proceeds from the maturity of certificates of deposit	5,013,694	-	5,103,694	(100 )%
Purchases of certificates of deposit	(5,058,080 )	-	(5,058,080 )	100 %
Purchases of certificates of Deposit – non-current	(4,695,282 )	-	(4,695,282 )	100 %
Change in restricted cash	(27 )	(32 )	5	(16 )%
Net cash used by investing activities	\$ (4,790,648 )	\$ (16,013 )	\$ (4,774,635 )	29,817 %

*Cash flows from financing activities*



Edgar Filing: IsoRay, Inc. - Form 10-Q

Cash provided by financing activities in the six months ended December 31, 2014 was provided by proceeds from the exercise of warrants and the exercise of employee stock options. During the six months ended December 31, 2013, cash provided by financing activities was the result of the sales of common stock through registered direct and underwritten offerings. Cash used during the six months ended December 31, 2014 and 2013 was the result of dividend payments to the Series B preferred shareholders.

**Key operating factor**

Description	Six months ended 12-31-14	Six months ended 12-31-13	Variance (\$)	Variance (%)
Preferred dividend payments	\$ (10,632 )	\$ (10,632 )	\$-	- %
Proceeds from sale of preferred stock pursuant to underwritten offering, net	-	1,478,712	(1,478,712)	(100) %
Proceeds from sale of common stock pursuant to underwritten offering, net	-	1,800,580	(1,800,580)	(100) %
Proceeds from sale of common stock pursuant to exercise of warrants	70,411	-	70,411	100 %
Proceeds from sale of common stock pursuant to exercises of options	145,274	-	145,274	100 %
Net cash provided by financing activities	\$ 205,053	\$ 3,268,660	\$(3,063,607)	(94) %

*Projected Fiscal Year 2015 Liquidity and Capital Resources*

At December 31, 2014, the Company held cash and cash equivalents of \$1,336,852 as compared to \$7,680,073 of cash and cash equivalents at June 30, 2014.

The Company had approximately \$1.06 million of cash and cash equivalents as of January 23, 2015, and had certificates of deposit in the amount of \$5.02 million as of December 31, 2014 which will continue to earn interest from January 1, 2015 until maturity on March 19, 2015. There are additional certificates of deposit of \$5.03M as of December 31, 2014 which will continue to earn interest from January 1, 2015 to maturity on June 18, 2015. The Company had approximately \$10.1 million in certificates of deposit, non-current as of December 31, 2014. The investment of excess cash is classified on the balance sheet as certificates of deposit and certificates of deposit, non-current which are fully insured by the FDIC.

The Company's monthly required cash operating expenditures were approximately \$294,000 in the six months ended December 31, 2014, which represents a 1% increase or approximately \$4,000 from average monthly cash operating expenditures of \$290,000 in the six months ended December 31, 2013. Management believes that there will not be a significant requirement for capital equipment with the exception of the production of liquid Cesium-131 for use in the GliaSite® RTS which is expected to be less than \$50,000, however, there is no assurance that unanticipated needs for capital equipment may not arise for other needs.

Management intends to continue its existing protocol studies and to begin new protocol studies on lung and inter-cranial cancer treatments using Cesium-131 brachytherapy seeds and the GliaSite® RTS. The Company

continues to believe that approximately \$180,000 in expense will be incurred during fiscal year 2015 related to protocol expenses relating to lung cancer, intra-cranial cancer and both dual therapy and mono-therapy prostate cancer protocols but there is no assurance that unanticipated needs for additional protocols in support of the development of new applications of our existing products may not arise.

Based on the foregoing assumptions, management believes that the cash and cash equivalents of approximately \$1.06 million as of January 23, 2015, certificates of deposit in the amount of \$5.02 million that mature on March 19, 2015 and \$5.03 million that mature on June 18, 2015, and certificates of deposit, non-current of \$10.1 million at December 31, 2014 will be sufficient to meet our anticipated cash needs, assuming both revenue and expenses remain at current levels, for at least the next five years.

Management plans to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), increasing sales of the Company's GliaSite® RTS, expanding into other market applications which initially will include inter-cranial, head and neck, and lung implants, while maintaining the Company's focus on cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain increases in its revenue. Sales in the prostate market have not shown the increases necessary to breakeven during the past seven fiscal years.

For the six months ended December 31, 2014, revenue from other treatment modalities with brachytherapy seeds has decreased by 1% when compared to the six months ended December 31, 2013. When including the revenue from the sale of GliaSite® RTS, revenue from non-prostate treatments has decreased 20% in the six months ended December 31, 2014 compared to the six months ended December 31, 2013. These non-prostate brachytherapy treatments are in the early stages of application in the clinical setting and the purchasing patterns are subject to the influence of a few key physicians which can significantly influence revenue from quarter to quarter. Management is focused on increasing revenue from head and neck, colorectal, lung and brain applications of Cesium-131 brachytherapy seeds in addition to increasing the number of cases treated with the GliaSite® RTS. Management has not been successful in doing so during the six months ended December 31, 2014 when compared to the six months ended December 31, 2013. Management believes that the Company has sufficient cash and cash equivalents to sustain protocols, marketing staff, production staff and production equipment as it works to make these new applications successful.

There was no material change in the use of proceeds from our public offerings as described in our final prospectus supplements filed with the SEC pursuant to Rule 424(b) on August 29, 2013 and March 24, 2014. Through December 31, 2014, the Company had used the net proceeds raised through the August 2013 and March 2014 offerings as described in the table below and held the remaining net proceeds in cash and cash equivalents and certificates of deposit. 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.

Offering description	Period	Net proceeds	Remaining net proceeds
Underwritten offering	August 2013	\$3,279,292	\$ 1,155,989
Registered direct offering	March 2014	13,814,742	13,814,742
Total		17,094,034	14,970,731

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 is subject to various local; state; and federal environmental regulations and laws due to the isotopes used to produce the Company's products. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company's obligations at its current production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all leasehold improvements.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its products.

The Company also carries product liability insurance to help protect it from this risk. The Company has no off-balance sheet arrangements.

### **ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As a smaller reporting company, the Company is not required to provide Part I, Item 3 disclosure in this Quarterly Report.

### **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 December 31, 2014. 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 is 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 1A – RISK FACTORS**

There have been no material changes for the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2014.

**ITEM 6. EXHIBITS**

Exhibits:

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 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

\* 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: February 17, 2015

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock  
Dwight Babcock, Chief Executive Officer

(Principal Executive Officer)

By /s/ Brien Ragle  
Brien Ragle, Chief Financial Officer  
(Principal Financial and Accounting Officer)