

IsoRay, Inc.  
Form 10-Q  
May 15, 2014

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 March 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)

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

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

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

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  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  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 May 7, 2014</u>
Common stock, \$0.001 par value	54,392,781

**ISORAY, INC.**

**Table of Contents**

PART I	<u>FINANCIAL INFORMATION</u>	
Item 1	Consolidated Unaudited Financial Statements	1
	<u>Consolidated Balance Sheets</u>	3
	<u>Consolidated Statements of Operations (Unaudited)</u>	4
	<u>Consolidated Statements of Cash Flows (Unaudited)</u>	5
	<u>Notes to Unaudited Consolidated Financial Statements</u>	6
Item 2	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4	<u>Controls and Procedures</u>	23
PART II	<u>OTHER INFORMATION</u>	24
Item 1A	<u>Risk Factors</u>	24
Item 2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	24
Item 5	<u>Other Information</u>	24
Item 6	<u>Exhibits</u>	25
	<u>Signatures</u>	26

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

	(Unaudited)	
	March 31, 2014	June 30, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$23,702,901	\$2,899,927
Accounts receivable, net of allowance for doubtful accounts of \$71,377 and \$52,598, respectively	805,326	923,780
Inventory	387,020	405,571
Prepaid expenses and other current assets	212,079	214,382
Total current assets	25,107,326	4,443,660
Fixed assets, net of accumulated depreciation and amortization	1,183,067	1,684,282
Restricted cash	181,194	181,149
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	258,619	276,507
Total assets	\$27,199,964	\$7,055,356
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$609,761	\$432,566
Accrued protocol expense	75,057	25,305
Accrued radioactive waste disposal	130,301	100,000
Accrued payroll and related taxes	87,660	127,419
Accrued vacation	117,971	107,578
Total current liabilities	1,020,750	792,868
Warrant derivative liability	678,000	104,000
Asset retirement obligation	847,351	792,242
Total liabilities	2,546,101	1,689,110

## Commitments and contingencies (Note 6)

## 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 &amp; 193,000,000 shares authorized;

54,181,444 and 34,618,517 shares issued and outstanding

54,181

34,618

Treasury stock, at cost, 13,200 shares

(8,390 )

(8,390 )

Additional paid-in capital

80,980,664

57,431,293

Accumulated deficit

(56,372,651)

(52,091,334)

Total shareholders' equity

24,653,863

5,366,246

Total liabilities and shareholders' equity

\$27,199,964

\$7,055,356

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

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

	Three months ended March 31,		Nine months ended March 31,	
	2014	2013	2014	2013
Product sales	\$ 1,134,319	\$ 1,251,478	\$ 3,269,642	\$ 3,283,167
Cost of product sales	1,083,413	1,065,574	3,329,950	3,276,314
Gross profit / (loss)	50,906	185,904	(60,308 )	6,853
Operating expenses:				
Research and development expenses	153,611	155,137	470,631	445,785
Sales and marketing expenses	245,558	290,812	931,210	928,962
General and administrative expenses	640,732	564,075	1,805,732	1,678,487
Total operating expenses	1,039,901	1,010,024	3,207,573	3,053,234
Operating loss	(988,995 )	(824,120 )	(3,267,881 )	(3,046,381 )
Non-operating income (expense):				
Interest income	556	83	1,391	355
Change in fair value of warrant derivative liability	(1,095,000 )	109,000	(1,014,000 )	183,000
Financing and interest expense	-	-	(827 )	(6 )
Non-operating income / (expense), net	(1,094,444 )	109,083	(1,013,436 )	183,349
Net loss	(2,083,439 )	(715,037 )	(4,281,317 )	(2,863,032 )
Preferred stock deemed dividends (Note 9)	-	-	(726,378 )	-
Preferred stock dividends	(2,658 )	(2,658 )	(7,974 )	(7,974 )
Net loss applicable to common shareholders	\$ (2,086,097 )	\$ (717,695 )	\$ (5,015,669 )	\$ (2,871,006 )
Basic and diluted loss per share	\$ (0.05 )	\$ (0.02 )	\$ (0.13 )	\$ (0.08 )
Weighted average shares used in computing net loss per share:				
Basic and diluted	42,506,077	34,611,517	38,852,980	34,359,567

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



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

	Nine months ended March 31,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(4,281,317 )	\$(2,863,032 )
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	18,779	(32,174 )
Depreciation and amortization of fixed assets	517,548	563,850
Amortization of deferred financing costs and other assets	23,056	21,036
Change in fair value of warrant derivative liability	1,014,000	(183,000 )
Accretion of asset retirement obligation	55,109	50,383
Share-based compensation	65,217	85,369
Changes in operating assets and liabilities:		
Accounts receivable, gross	99,675	67,195
Inventory	18,551	87,368
Other receivables	4,516	2,204
Prepaid expenses and other current assets	(2,213 )	(69,427 )
Accounts payable and accrued expenses	177,195	(21,525 )
Accrued protocol expense	49,752	27,500
Accrued radioactive waste disposal	30,301	36,000
Accrued payroll and related taxes	(39,759 )	(54,654 )
Accrued vacation	10,393	12,961
Net cash used by operating activities	(2,239,197 )	(2,269,946 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(16,333 )	-
Additions to licenses and other assets	(5,168 )	(12,926 )
Change in restricted cash	(45 )	(104 )
Net cash used by investing activities	(21,546 )	(13,030 )
<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	1,478,703	-
Proceeds from sales of common stock, pursuant to underwritten offering, net	1,800,589	-
Proceeds from sales of common stock, pursuant to registered direct offering, net	13,818,927	3,291,977
Proceeds from sales of common stock, pursuant to exercise of warrants, net	5,961,001	1,825
Proceeds from sales of common stock, pursuant to exercise of options	15,129	11,309

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

Net cash provided by financing activities	23,063,717	3,294,479
Net increase in cash and cash equivalents	20,802,974	1,011,503
Cash and cash equivalents, beginning of period	2,899,927	2,672,711
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 23,702,901</b>	<b>\$ 3,684,214</b>
Non-cash investing and financing activities:		
Reclassification of derivative warrant liability to equity upon exercise	\$ (440,000	) \$ -
Reclassification of convertible preferred stock to common stock upon conversion	(1,478,703	)

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

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the three and nine months ended March 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, 2013, 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**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standards setting bodies that are adopted by us as of the specified effective dates. Unless otherwise

discussed, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position, results of operations and cash flows upon adoption.

### **3. 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 March 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, but that could be dilutive in the future as of March 31, 2014 and 2013, were as follows:

	March 31,	
	2014	2013
Series B preferred stock	59,065	59,065
Common stock warrants	646,811	1,957,033
Common stock options	2,324,072	2,312,072
Total potential dilutive securities	3,029,948	4,328,170

#### 4. Inventory

Inventory consisted of the following at March 31, 2014 and June 30, 2013:

	March 31,	June 30,
	2014	2013
Raw materials	\$ 165,657	\$ 167,671
Work in process	181,457	195,323
Finished goods	39,906	42,577
	\$ 387,020	\$ 405,571

#### 5. Share-Based Compensation

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

	Three months ended March 31,		Nine months ended March 31,	
	2014	2013	2014	2013
Cost of product sales	\$4,500	\$10,164	\$13,421	\$30,492
Research and development expenses	3,482	7,607	10,447	25,042
Sales and marketing expenses	879	1,386	2,636	4,568
General and administrative expenses	4,572	8,423	38,713	25,267
Total share-based compensation	\$13,433	\$27,580	\$65,217	\$85,369

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

As of March 31, 2014, total unrecognized compensation expense related to stock-based options was \$29,192 and the related weighted-average period over which it is expected to be recognized is approximately 0.87 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 March 31, 2014 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at March 31, 2014	2,324,072	\$ 1.82	4.3	\$2,050,334
Vested and expected to vest at March 31, 2014	2,238,840	\$ 1.86	4.23	\$1,923,611
Vested and exercisable at March 31, 2014	2,040,732	\$ 1.93	3.85	\$1,714,527

There were 26,333 options exercised during the nine months ended March 31, 2014 and 31,700 options exercised during the nine months ended March 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 nine months ended March 31, 2014 was \$15,130 and the nine months ended March 31, 2013 was \$13,866.

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

Of the 65,000 options, 50,000 were 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 is \$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%.

The remaining 15,000 were 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 is \$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%.

## 6. 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.

## 7. Fair Value Measurements

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 March 31, 2014 and June 30, 2013, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Description	Balance at March 31, 2014	Balance at June 30, 2013	Input Hierarchy Level
Assets:			
Cash and cash equivalents	\$ 23,702,901	\$ 2,899,927	Level 1
Restricted cash	181,194	181,149	Level 1
Liabilities:			
Warrant liability	\$ 678,000	\$ 104,000	Level 2

## 8. Preferred Dividends

On December 19, 2013, 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, 2013 in the amount of \$10,632. Dividends on the Series B Preferred Stock were last paid on December 31, 2012 as declared by the Board of Directors on December 21, 2012 in the amount of \$10,632. The dividends outstanding and cumulative through December 31, 2013 of \$10,632 and through December 31, 2012 of \$10,632 were paid as of those dates.

## 9. Shareholders’ Equity

*Common and preferred stock transactions*

### Series D

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 and certain ownership percentage restrictions. The preferred shares which were convertible into shares of common stock contained 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

During January 2014, the holder of the 1,670 shares of Series D convertible preferred stock fully exercised its right to convert the 1,670 shares of Series D convertible preferred stock into 3,121,480 shares of common stock which at the time of conversion resulted in an increase in shares of common stock outstanding from 38,419,502 to 41,540,982. Subsequent to the conversion, no shares of Series D convertible preferred stock remain outstanding.

### Common Stock

On March 21, 2014, the Company entered into a Securities Purchase Agreement with certain investors providing for the sale of a total of 5,644,300 shares of common stock for an aggregate purchase price of \$14,675,180 at a price per share of \$2.60 (the "Registered Direct Offering"). The Company received net proceeds from the offering of approximately \$13,818,927 from the Registered Direct Offering which will be used to meet the Company's working capital needs and general corporate purposes.

Gross proceeds from registered direct offering	\$14,675,180
Placement agent fees	(733,759 )
Legal and accounting expense	(72,494 )
Listing expense	(45,000 )
Other expense	(5,000 )
Net proceeds	13,818,927

### *Warrant exercises*

During the month of March 2014, the holder of the Series D warrants issued in November 2010 exercised its right to purchase 1,050,000 shares of common stock. Each warrant had an exercise price of \$1.56 per share of Company common stock and the exercise contributed \$1,638,000 in total additional cash and equity.

During the month of March 2014, certain holders of the warrants to purchase Company common stock issued in the October and December 2011 equity transaction exercised their right to purchase 37,574 shares of common stock. Each warrant had an original exercise price of \$1.053 that was reduced in accordance with the terms of the warrant for

dilution as the result of subsequent offerings to a revised exercise price of \$0.944 per share of Company common stock. This created a liability of \$35,470 as the stock had not been issued by the transfer agent as of the end of March, however, shares of common stock were issued during April in compliance with the contractual terms of the warrant.

During the month of March 2014, certain holders of the warrants to purchase Company common stock issued in the October and December 2011 equity transaction exercised their right to purchase 271,091 shares of common stock. Each warrant had an original exercise price of \$1.053 that was reduced in accordance with the terms of the warrant for dilution as the result of subsequent offerings to a current exercise price of \$0.944 per share of Company common stock and the exercise contributed \$255,910 in total additional cash and equity.

During the month of March 2014, the holders of the warrants to purchase Company common stock issued in the August 2013 equity transaction exercised their right to purchase 5,648,738 shares of common stock. Each warrant had an exercise price of \$0.72 per share of Company common stock and the exercise contributed \$4,067,091 in total additional cash and equity.

The gross proceeds from the exercise of the common stock warrants exercised were \$5,961,001 during the nine months ended March 31, 2014, net of the \$35,470 liability for the shares of common stock which were not issued until April 2014.

*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 and December 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 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 tables below:

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

	Three months ended March 31, 2014	Three months ended March 31, 2013
Change in fair value of the derivative warrant liability	\$ 1,095,000	\$ (109,000 )

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on October 19, 2011.

	Three months ended March 31, 2014		Three months ended March 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of the period	650,003	\$20,000	650,003	\$218,000
Change in fair value	650,003	1,004,000		(99,000 )
Warrants corrected	10,869	-	-	-
Warrants exercised	(258,943)	(423,000 )	-	-
Balance, end of the period	401,929	\$601,000	650,003	\$119,000

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on December 7, 2011.

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

	Three months ended March 31, 2014		Three months ended March 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of the period	63,598	\$3,000	63,598	\$22,000
Change in fair value	63,598	91,000	63,598	(10,000 )
Warrants corrected	(400 )	-	-	-
Warrants exercised	(12,148 )	(17,000 )	-	-
Balance, end of the period	51,050	\$77,000	63,598	\$12,000
Total fair value of warrant derivative liability at March 31, 2014 and 2013		\$678,000		\$131,000

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

	Nine months ended March 31, 2014	Nine months ended March 31, 2013
Change in fair value	\$ 1,014,000	\$ (183,000 )

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on October 19, 2011.

	Nine months ended March 31, 2014		Nine months ended March 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of the period	650,003	\$94,000	650,003	\$286,000
Change in fair value	650,003	914,000	650,003	(167,000)
Warrants corrected	10,869	16,000		
Warrants exercised	(258,943)	(423,000)	-	-
Balance, end of the period	401,929	\$601,000	650,003	\$119,000

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on December 7, 2011.

	Nine months ended March 31, 2014		Nine months ended March 31, 2013	
	Quantity <sup>1</sup>	Amount	Quantity <sup>1</sup>	Amount
Balance, beginning of the period	63,598	\$10,000	63,598	\$28,000
Change in fair value	63,598	85,000	63,598	(16,000 )
Warrants corrected	(400 )	(1,000 )		
Warrants exercised	(12,148)	(17,000 )	-	-
Balance, end of the period	51,050	\$77,000	63,598	\$12,000
Total fair value of warrant derivative liability at March 31, 2014 and 2013		\$678,000		\$131,000

<sup>1</sup> Quantity of warrants either issued 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 year and weighted average prices for each category.

	Warrants	Weighted average exercise price
Outstanding as of June 30, 2013	1,957,033	\$ 1.38
Warrants issued	5,648,738	0.72
Warrants corrected	10,869	0.94
Warrants exercised	(6,969,829)	0.86
Outstanding as of March 31, 2014	646,811	\$ 1.14

*Warrants outstanding as of March 31, 2014*

Quantity	Expiration date	Exercise price
6,000	June 8, 2015	\$ 1.18
25,000	July 27, 2015	2.00
157,832	November 21, 2015	1.56
401,929	October 19, 2016	0.944
51,050	December 7, 2016	0.944
5,000	June 27, 2017	0.98
646,811		\$ 1.14

## **10. Related Party Transaction**

During the nine months ended March 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 nine months ended March 31, 2014 and 2013 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection application was \$12,720 and \$10,960. An additional \$9,000 was spent on the implementation of Customer Relationship Management software in the nine months ended March 31, 2014.

## **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, 2013 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 30, 2013 are those that depend most heavily on these judgments and estimates. As of March 31, 2014, there had been no material changes to any of the critical accounting policies contained therein.

### **Results of Operations**

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

**Revenues.** During the three months ended March 31, 2014, total revenue decreased approximately nine (9%) percent when compared to the three months ended March 31, 2013. Revenue produced by prostate brachytherapy decreased in the three months ended March 31, 2014 by approximately 6%. Prostate seed brachytherapy contributed 82% of the overall product sales during the three months ended March 31, 2014 compared to 79% of overall product sales during the three months ended March 31, 2013. Management continues work with physicians to utilize the Company's FDA cleared products, sometimes in tandem with other FDA cleared devices or application methods, to develop innovative methods to provide alternative treatments for cancers in various other body sites, which contributed the balance of product sales, which were 18% of product sales during the three months ended March 31, 2014 compared to 21% of product sales during the three months ended March 31, 2014. During the three months ended March 31, 2014, the Company primarily treated five body sites including brain, gynecological, head and neck, lung and prostate cancers. 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, however, management believes that the treatment strategy of combining treatments which incorporate brachytherapy with other modalities in the prostate, the addition of new treatment facilities and treatment of additional other body sites with brachytherapy has the potential to increase revenue.

**Key operating factors**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Product Sales	\$ 1,134,319	\$ 1,251,478	\$ (117,159 )	(9 )%

**Cost of product sales.** Cost of product sales nominally increased during the three months ended March 31, 2014 compared to the three months ended March 31, 2013. The two key operating factors that changed significantly in the three months ended March 31, 2014 as compared to the three months ended March 31, 2013 were the increase in materials expense related to seed production which was primarily created by the price increase in isotope received from Russia in combination with one additional shipment of isotope during the three months ended March 31, 2014 when compared to the three months ended March 31, 2013 and a decrease in production costs of the GliSite® Radiation Therapy System (the “GliSite RTS”) which was primarily the result of improved timing of cases which allowed for a greater volume of Iotrex solution produced to be utilized in treating patients during the three months ended March 31, 2014 and the non-recurrence of an expense related to expired catheters which occurred during the three months ended March 31, 2013. Nominal cost changes which occurred in other categories of seed production expenses are summarized as Other cost of product sales (Seeds) which as a group were insignificant.

### Key operating factors

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)	
Materials expense	\$ 421,122	\$ 356,126	\$ 64,996	18	%
Other cost of product sales (Seeds)	637,150	663,723	(26,573 )	(4	)%
GliSite RTS	25,141	45,725	(20,584 )	(45	)%
Total cost of product sales	\$ 1,083,413	\$ 1,065,574	\$ 17,839	2	%

**Gross profit.** Gross profit for the three months ended March 31, 2014 decreased compared to the three month period ended March 31, 2013 as a result of decreased revenue from product sales which was further reduced by a nominal increase in total cost of product sales. Management continued to seek to control variable costs, however, at this time most remaining production costs are of a fixed nature and related to minimum personnel costs required to satisfy peak demand orders, however, during the three months ended March 31, 2014, there was an additional increase in the cost of some materials that could not be controlled as the result of limited sources for these materials.

### Key operating factor

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)	
Gross profit	\$ 50,906	\$ 185,904	\$ (134,998 )	(73	)%
Gross profit percentage	4	%	15	%	

**Research and development.** Research and development costs decreased by a nominal amount for the three months ended March 31, 2014 compared to the three months ended March 31, 2013. No single cost factor changed

significantly during the three months ended March 31, 2014 when compared to the three months ended March 31, 2013.

**Key operating factors**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Total research and development	\$ 153,611	\$ 155,137	\$ (1,526 )	(1 )%

**Sales and marketing expenses.** Sales and marketing expenses were decreased in the three months ended March 31, 2014 compared to the three months ended March 31, 2013. The single category which changed significantly was travel expense as the Company continues to manage its travel costs as actively as possible.

**Key operating factors**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Travel expense	\$ 46,430	\$ 69,470	\$ (23,040 )	(33 )%
Other sales-marketing expense	199,128	221,342	(22,214 )	(10 )%
Total sales and marketing	\$ 245,558	\$ 290,812	\$ (45,254 )	(16 )%

**General and administrative expenses.** General and administrative expenses increased in the three months ended March 31, 2014 compared to the three months ended March 31, 2013. A single expense category, bad debt expense (recovery), which is an estimate made based on established criteria by management of the unpaid invoices in accounts receivable which may not be paid by the customer, increased materially. This management estimate fluctuates significantly based on timeliness of payments received from our customers. The balance of the increased cost was from a combination of nominal changes in other cost categories which are summarized as general and administrative (Other).

**Key operating factors**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Bad debt expense (recovery)	\$ 38,861	\$ (18,697 )	57,558	308 %
General and administrative (Other)	601,871	582,772	19,099	3 %
Total general and administrative	\$ 640,732	\$ 564,075	\$ 76,657	14 %

**Operating loss.** Operating loss for the three months ended March 31, 2014 increased compared to the three months ended March 31, 2013 primarily as the result of the decrease in product sales coupled with the marginal increase in cost of product sales and the nominal increase in operating expenses.

**Key operating factor**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Operating loss	\$ (988,995 )	\$ (824,120 )	\$ 164,875	20 %

**Change in fair value of warrant derivative liability.** During the three months ended December 31, 2011, there was a warrant derivative liability established upon issuance of warrants during October 2011 to December 2011 to the purchasers and underwriters in the Company's registered offering. The warrant derivative liability requires periodic evaluation for changes in fair value. As required at March 31, 2014 and March 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 March 31, 2014 and March 31, 2013. The change in valuation of the warrant derivative liability as calculated using the Black-Scholes option pricing model is not reflective of Company operations which is why these changes are included in the consolidated statement of operations in the non-operating income/(expense) section and an adjusting item to reconcile net loss to net cash used by operating activities in the consolidated statement of cash flows.

The increase in the warrant derivative liability resulted from the significant increase in the value of the Company's common stock in March 2014. The Black-Scholes option pricing model utilizes multiple inputs over which management exerts little control. The model uses stock price (market driven), exercise price (contractual), expected life of the contractual life (estimate made by management when the warrant derivative liability is established and reduced by the life expended), volatility of the Company stock (market driven) and a risk-free rate.

#### **Key operating factor**

Description	Three months ended 3-31-14	Three months ended 3-31-13	Variance (\$)	Variance (%)
Change in fair value of warrant derivative liability	\$ (1,095,000 )	\$ 109,000	\$ (1,204,000 )	(1,105 )%

#### **Nine months ended March 31, 2014 compared to nine months ended March 31, 2013.**

**Revenues.** During the nine months ended March 31, 2014, total revenue, and revenue produced by prostate brachytherapy and brachytherapy utilized to provide brachytherapy treatment alternatives for other non-prostate applications, were unchanged when compared to the nine months ended March 31, 2013. Revenue produced by prostate brachytherapy was unchanged in the nine months ended March 31, 2014 when compared to the nine months ended March 31, 2013. Prostate seed brachytherapy contributed 83% of the overall product sales during the nine months ended March 31, 2013 and 2014, respectively. Management continues to work with physicians to utilize the Company's FDA cleared products, sometimes in tandem with other FDA cleared devices or application methods to develop innovative methods, to provide treatment alternatives for cancers in various other body sites, which contributed the balance of product sales of 17% during the nine months ended March 31, 2014 and 2013, respectively. During the nine months ended March 31, 2014, the Company primarily treated five body sites including brain, gynecological, head and neck, lung and prostate cancers. 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, however, management believes that the treatment strategy of combining treatments which incorporate brachytherapy with other modalities in the prostate, the

addition of new treatment facilities and treatment of additional other body sites with brachytherapy has the potential to increase revenue.

**Key operating factors**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Product Sales	\$ 3,269,642	\$ 3,283,167	\$ (13,525 )	0 %

**Cost of product sales.** Cost of product sales related to brachytherapy seed sales increased by a nominal amount during the nine months ended March 31, 2014 compared to the nine months ended March 31, 2013 as the result of a combination of factors including increases in materials expense and the addition of the medical device tax incurred as part of the Affordable Care Act beginning in the calendar year 2013 which only impacted three of the nine months ended March 31, 2013 compared to all nine of the months for the nine months ended March 31, 2014. These increases were partially reduced by decreases in depreciation and amortization expense as assets continue to reach the end of their depreciable lives without being replaced and a net reduction in preload expense as the result of a reduced utilization of third party loaders which was partially offset by increased internal costs to accommodate the increased volume of work. Cost of product sales related to GliaSite RTS increased as the result of increased Iotrex production required to support the increased sales of the product all of which was not able to be fully utilized due to the timing of cases along with the additional medical device tax incurred as part of the Affordable Care Act. The net impact of the changes resulted in a nominal increase in cost of product sales.

### **Key operating factors**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)	
Medical device tax	\$ 71,378	\$ 27,553	\$ 43,825	159	%
Materials expense	1,316,564	1,247,592	68,972	6	%
Depreciation and amortization expense	505,829	548,241	(42,412 )	(8	)%
Pre-loading expense	219,277	236,616	(17,339 )	(7	)%
GliaSite RTS	106,212	83,991	22,221	26	%
Other cost of product sales (Seeds)	1,110,690	1,132,321	(21,631 )	(2	)%
Total cost of product sales	\$ 3,329,950	\$ 3,276,314	\$ 53,636	2	%

**Gross profit / (loss).** Gross profit / (loss) for the nine month period ended March 31, 2014 decreased compared to the nine month period ended March 31, 2013 primarily as a result of the decreased product sales combined with a nominal increase in cost of product sales.

### **Key operating factor**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)	
Gross profit / (loss)	\$ (60,308 )	\$ 6,853	\$ (67,161 )	(980	)%
Gross profit / (loss) percentage	(2	)%	0	%	

**Research and development.** Research and development costs increased during the nine months ended March 31, 2014 compared to the nine months ended March 31, 2013 primarily as a result of a change in the single operating factor that increased in research and development expense which was the continued investment in protocol expenses.

**Key operating factors**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)	
Protocol expense	\$ 130,322	\$ 67,025	\$ 63,297	94	%
Research and development (Other)	340,309	378,760	(38,451 )	(10	)%
Total research and development	\$ 470,631	\$ 445,785	\$ 24,846	6	%

**Sales and marketing expenses.** Sales and marketing expenses were virtually unchanged during the nine months ended March 31, 2014 compared to the nine months ended March 31, 2013. Travel expense was reduced as the result of a decrease in meal expenses and automobile expense incurred during the nine months ended March 31, 2014 when compared to the nine months ended March 31, 2013. The overall decrease in travel expense and in particular meals expense is the result of a revision of the travel policy governing reimbursement for these expenses combined with the reduction in automobile travel expense is impacted by both the number of sales managers in the field and the method by which they are reimbursed for the use of their vehicles.

### **Key operating factors**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)	
Travel expense	\$ 160,057	\$ 201,010	\$ (40,953 )	(20	)%
Sales and marketing (Other)	771,153	727,952	43,201	6	%
Total sales and marketing	\$ 931,210	\$ 928,962	\$ 2,248	0	%

**General and administrative expenses.** General and administrative expenses increased in the nine months ended March 31, 2014 compared to the nine months ended March 31, 2013 primarily as a result of three operating factors. The three key operating factors that increased were bad debt expense/(recovery), legal expense and public company expense. Bad debt expense/(recovery) increased as the result of the aging of specific customer accounts that in the judgment of management required creating an allowance for their potential collectability, legal expenses increased as the result of increased SEC filings, compliance review, contract revisions and general corporate legal services while public company expense increased due to increased SEC filing expenses.

### **Key operating factors**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)	
Bad debt expense/(recovery)	\$ 18,879	\$ (32,174 )	\$ 51,053	159	%
Legal expense	150,475	102,381	48,094	47	%
Public company expense	230,495	206,565	23,930	12	%
General and administrative (Other)	1,405,883	1,401,715	4,168	0	%
Total general and administrative	\$ 1,805,732	\$ 1,678,487	\$ 127,245	8	%

**Operating loss.** Operating loss for the nine months ended March 31, 2014 increased compared to the nine months ended March 31, 2013 primarily as a result of a decrease in revenue from product sales and an increase in both cost of product sales and operating expenses.

**Key operating factor**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Operating loss	\$ (3,267,881 )	\$ (3,046,381 )	\$ 221,500	7 %

**Change in fair value of warrant derivative liability.** During the three months ended December 31, 2011, there were warrant derivative liabilities established upon issuance of warrants to the purchasers and underwriters in the Company's registered offering during October 2011 to December 2011. Per ASC 820, the warrant derivative liability requires periodic evaluation for changes in fair value. As required at March 31, 2014 and March 31, 2013, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model on which the original warrant derivative liability was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of March 31, 2014 and March 31, 2013. The change in valuation of the warrant derivative liability is calculated using the Black-Scholes option pricing model and not reflective of Company an operations which is why these changes are included in the consolidated statement of operations in the non-operating income/(expense) section and as an adjusting item to reconcile net loss to net cash used by operating activities in the consolidated statement of cash flows.

The increase in the warrant derivative liability resulted from the significant increase in the value of the Company's common stock in March 2014. The Black-Scholes option pricing model utilizes multiple inputs over which management exerts little control. The model uses stock price (market driven), exercise price (contractual), expected life of the contractual life (estimate made by management when the warrant derivative liability is established and reduced by the life expended), volatility of the Company stock (market driven) and a risk-free rate.

### **Key operating factor**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Change in fair value of warrant derivative liability	\$ (1,014,000 )	\$ 183,000	\$ (1,197,000 )	(654 )%

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

### *Cash flows from operating activities*

Cash used by operating activities is the net loss adjusted for non-cash items and changes in operating assets and liabilities. Management has continued to control cash used in operations which has increased by a nominal amount during the nine months ended March 31, 2014 when compared to the nine months ended March 31, 2013.

### **Key operating factor**

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

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Net loss	\$ (4,281,317 )	\$ (2,863,032 )	\$ (1,418,285 )	(50 )%
Non-cash items	1,693,709	505,464	1,188,245	235 %
Non-cash changes in operating assets and liabilities	348,411	87,622	260,789	298 %
Net cash used by operating activities	\$ (2,239,197 )	\$ (2,269,946 )	\$ 30,749	1 %

20

*Cash flows from investing activities*

Cash used by investing activities during the nine months ended March 31, 2014 was primarily related to the deployment of new equipment to improve the efficiency of operations and in the nine months ended March 31, 2013 was primarily related to the capitalization of costs related to other assets. The amounts recorded to 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 factor**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Purchases of fixed assets	\$ (16,333 )	\$ -	\$ (16,333 )	100 %
Additions to licenses and other assets	(5,168 )	(12,926 )	7,758	(60 )%
Change in restricted cash	(45 )	(104 )	59	(57 )%
Net cash used by investing activities	\$ (21,546 )	\$ (13,030 )	\$ (8,516 )	65 %

*Cash flows from financing activities*

Cash provided by financing activities in the nine months ended March 31, 2014 and March 31, 2013 was the result of the sales of common stock and Series D Convertible Preferred Stock through registered direct and underwritten offerings, common stock warrant exercises and non-qualified stock option exercises by former employees. Cash used during the nine months ended March 31, 2014 and 2013 was the result of dividend payments to the Series B preferred shareholders.

**Key operating factor**

Description	Nine months ended 3-31-14	Nine months ended 3-31-13	Variance (\$)	Variance (%)
Preferred dividend payments	\$ (10,632 )	\$ (10,632 )	\$-	0 %
Proceeds from exercise of employee stock options	15,129	11,309	3,820	34 %
Proceeds from exercise of common stock warrants	5,961,001	1,825	5,959,176	326,530 %
Proceeds from sale of preferred stock, pursuant to underwritten offering, net	1,478,703	-	1,478,703	100 %
	1,800,589	-	1,800,589	100 %

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

Proceeds from sale of common stock, pursuant to  
underwritten offering, net

Proceeds from sale of common stock, net	13,818,927	3,291,977	10,526,950	320	%
Net cash provided by financing activities	\$ 23,063,717	\$ 3,294,479	\$ 19,769,238	600	%

*Projected Fiscal Year 2014 Liquidity and Capital Resources*

At March 31, 2014, the Company held cash and cash equivalents of \$23,702,901 as compared to \$2,899,927 of cash and cash equivalents at June 30, 2013.

The Company had approximately \$23.62 million of cash and cash equivalents, which are fully insured by the Federal Depository Insurance Company (FDIC), and no short-term investments as of April 30, 2014. The Company's monthly required cash operating expenditures were approximately \$249,000 in the nine months ended March 31, 2014, which represents a 1% decrease or approximately \$3,000 from average monthly cash operating expenditures of \$252,000 in the nine months ended March 31, 2013. The increased use of cash in operating activities of approximately \$31,000 is primarily the result of the increased net loss of approximately \$1,418,285 which was driven primarily by the non-cash increased change in change in fair value of warrant derivative liability of \$1,197,000 and an increase of approximately \$261,000 in non-cash changes in operating assets and liabilities. 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 2014 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 cash, cash equivalents, and short-term investments of approximately \$23.62 million on hand at April 30, 2014 will be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements for several years assuming both revenue and expenses remain at current levels.

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, and 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 nine fiscal years and showed no change during the nine months ended March 31, 2014.

For the nine months ended March 31, 2014, revenue from other treatment modalities with brachytherapy seeds has decreased by 20% when compared to the nine months ended March 31, 2013. When including the revenue from the sale of GliaSite RTS, revenue from non-prostate treatments has decreased 4% in the nine months ended March 31, 2014 compared to the nine months ended March 31, 2013. As 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 of the GliaSite RTS, management believes the Company has sufficient cash and cash equivalents to sustain protocols, marketing staff, production staff and production equipment as it works to gain market share.

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 and year to year.

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 July 17, 2012, August 29, 2013 and March 24, 2014. Through March 31, 2014, the Company had used the net proceeds raised through the July 2012, August 2013 and March 2014 offerings as described in the table below and held the remaining net proceeds in cash and cash equivalents. No offering expenses were paid directly or indirectly to any of our directors or officers (or their

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

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
Registered direct offering	July 2012	\$ 3,291,977	\$ 643,681
Underwritten offering	August 2013	3,279,292	3,279,292
Registered direct offering	March 2014	13,818,927	13,818,927
Total		\$ 20,390,196	\$ 17,741,900

While management does not believe it needs to raise additional capital to meet its goals and objectives for the foreseeable future, if it does need to raise additional capital as the result of presently unanticipated opportunities or strategic acquisitions, the Company expects to finance its future cash needs through the conversion of outstanding warrants to purchase common stock, other 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. Of course, funding may not be available to it on acceptable terms, or at all.

#### *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 product. 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 product. 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 March 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.

The Company is continuing the process of remediating the single deficiency which constituted a material weakness identified in its Form 10-K for the fiscal year ended June 30, 2013.

Progress made on remediating the single deficiency which constituted a material weakness in the nine months ended March 31, 2014 consisted of the following:

The Company promoted its Controller, Principal Financial and Accounting Officer, to the position of Chief Financial Officer effective October 1, 2013.

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the consolidated financial statements for the three and nine months ended March 31, 2014 fairly present in all material respects the financial condition and results of operations for the Company in conformity with U.S generally accepted accounting principles.

## **PART II - OTHER INFORMATION**

### **ITEM 1A – RISK FACTORS**

There have been no material changes to the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2013.

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

#### *Use of Proceeds from Registered Securities*

On October 27, 2009, we filed a registration statement on Form S-3 to register securities up to \$15 million in value for future issuance in our capital raising activities. The registration statement became effective on November 13, 2009, and the Commission file number assigned to the registration statement is 333-162694. An additional \$585,559 was added to this registration statement through a Form S-3 MEF filed on July 16, 2012. The registration statement expired on November 12, 2012.

There was no material change in the use of proceeds from the July 17, 2012 registered direct offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 17, 2012. Through March 31, 2014, we had

begun to use the net proceeds from this registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) and had invested all remaining net proceeds in cash and cash equivalents.

The proceeds used during the nine months ended March 31, 2014 from the July 17, 2012 registered direct offering.

Proceeds used in the nine months ended March 31, 2014:

Indirect payments to directors and officers for database maintenance and development	\$21,720
Direct payments of compensation to directors	106,000
Direct payments of salaries to officers	475,757
Working capital	1,650,944
Total proceeds used in the nine months ended March 31, 2014	\$2,254,421

## ITEM 5. OTHER INFORMATION

### **Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers**

On May 12, 2014, the Board of Directors of IsoRay, Inc. (the “Registrant” or “IsoRay”), on the recommendation of the Compensation Committee, approved a 2.5% increase to the base salary of all employees of IsoRay and its subsidiaries, effective July 1, 2014. This increase applies to all of IsoRay’s executive officers, other than the Company’s CEO whose compensation will be considered separately at a future meeting.

On May 14, 2014, the Board of Directors of IsoRay, on the recommendation of the Compensation Committee, approved a form of option agreement under IsoRay’s 2014 Employee Stock Option Plan (the “Plan”), which was adopted by the Board on January 16, 2014 and approved by the IsoRay shareholders on March 5, 2014. The Plan authorizes the grant of options to employees, officers, consultants and advisors who provide services to the Registrant or its subsidiaries and who the Plan administrator determines are eligible persons. The Plan is administered by a committee of independent directors or the full Board. The Plan will expire on the ten-year anniversary of its adoption, and 2 million shares of IsoRay common stock are reserved and available for issuance under the Plan. IsoRay’s executive officers are eligible to receive grants of options under the Plan, in accordance with the terms and conditions of the Plan. The form of option agreement provides for a ten year option term and equal annual vesting over a three-year period.

The foregoing summaries of the Plan and the form of option agreement do not purport to be complete or describe all of their terms, and are qualified in their entirety by reference to the full text thereof, copies of which are filed herewith as Exhibits 4.32 and 4.33 and are incorporated by reference herein.



**ITEM 6. EXHIBITS**

Exhibits:

- 4.32\* 2014 Employee Stock Option Plan
- 4.33\* Form of Stock Option Agreement under the 2014 Employee Stock Option Plan
- 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

\* Filed herewith.

\*\* Furnished herewith.

\*\*\* Furnished herewith. In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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: May 15, 2014

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)