

IsoRay, Inc.  
Form 10-Q  
May 15, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**x** **QUARTERLY Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2013

or

Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-33407

**ISORAY, INC.**

(Exact name of registrant as specified in its charter)

Minnesota

41-1458152

(State or other jurisdiction of incorporation or (I.R.S. Employer

organization) Identification No.)

350 Hills St., Suite 106, Richland, Washington

99354

(Address of principal executive offices)

(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

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

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 1, 2013</u>
Common stock, \$0.001 par value	34,611,517

**ISORAY, INC.**

**Table of Contents**

PART I FINANCIAL INFORMATION		
Item 1	Consolidated Unaudited Financial Statements	1
	Consolidated Balance Sheets	1
	Consolidated Statements of Operations (Unaudited)	2
	Consolidated Statements of Cash Flows (Unaudited)	3
	Notes to Unaudited Consolidated Financial Statements	4
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3	Quantitative and Qualitative Disclosures About Market Risk	18
Item 4	Controls and Procedures	19
PART II OTHER INFORMATION		
Item 1A	Risk Factors	20
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	20
Item 6	Exhibits	21
	Signatures	22

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

	(Unaudited)	
	March 31, 2013	June 30, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$3,684,214	\$2,672,711
Accounts receivable, net of allowance for doubtful accounts of \$25,430 and \$57,604, respectively	830,035	865,056
Inventory	356,977	444,345
Other receivables	7,721	9,925
Prepaid expenses and other current assets	213,543	144,116
Total current assets	5,092,490	4,136,153
Fixed assets, net of accumulated depreciation and amortization		
Restricted cash	1,853,003	2,416,853
Inventory, non-current	181,131	181,027
Other assets, net of accumulated amortization	469,758	469,758
	293,581	301,691
Total assets	\$7,889,963	\$7,505,482
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$367,580	\$389,105
Accrued protocol expense	27,500	-
Accrued radioactive waste disposal	88,000	52,000
Accrued payroll and related taxes	65,227	119,881
Accrued vacation	100,967	88,006
Total current liabilities	649,274	648,992
Warrant derivative liability	131,000	314,000
Asset retirement obligation	774,681	724,298
Total liabilities	1,554,955	1,687,290

## Commitments and contingencies (Note 6)

## Shareholders' equity:

Preferred stock, \$.001 par value; 7,000,000 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	-	-
Common stock, \$.001 par value; 193,000,000 shares authorized; 34,611,517 and 30,950,108 shares issued and outstanding	34,612	30,950
Treasury stock, at cost, 13,200 shares	(8,390 )	(8,390 )
Additional paid-in capital	57,406,497	54,030,311
Accumulated deficit	(51,097,770)	(48,234,738)
 Total shareholders' equity	 6,335,008	 5,818,192
 Total liabilities and shareholders' equity	 \$7,889,963	 \$7,505,482

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

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

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

	Three months ended March 31,		Nine months ended March 31,	
	2013	2012	2013	2012
Product sales	\$ 1,251,478	\$ 1,317,371	\$ 3,283,167	\$ 3,759,443
Cost of product sales	1,065,574	1,113,151	3,276,314	3,289,982
Gross profit	185,904	204,220	6,853	469,461
Operating expenses:				
Research and development expenses	155,137	132,237	445,785	573,212
Research and development reimbursement	-	-	-	(50,000 )
Sales and marketing expenses	290,812	259,010	928,962	877,549
General and administrative expenses	564,075	575,832	1,678,487	1,726,017
Total operating expenses	1,010,024	967,079	3,053,234	3,126,778
Operating loss	(824,120 )	(762,859 )	(3,046,381 )	(2,657,317 )
Non-operating income (expense):				
Interest income	83	144	355	599
Change in fair value of warrant derivative liability	109,000	213,095	183,000	379,095
Financing and interest expense	-	(3,266 )	(6 )	(6,323 )
Non-operating income / (expense), net	109,083	209,973	183,349	373,371
Net loss	(715,037 )	(552,886 )	(2,863,032 )	(2,283,946 )
Preferred stock dividends	(2,658 )	(2,658 )	(7,974 )	(7,974 )
Net loss applicable to common shareholders	\$(717,695 )	\$(555,544 )	\$(2,871,006 )	\$(2,291,920 )
Basic and diluted loss per share	\$(0.02 )	\$(0.02 )	\$(0.08 )	\$(0.08 )
Weighted average shares used in computing net loss per share:				
Basic and diluted	34,611,517	29,316,306	34,359,567	28,128,125

The accompanying notes are an

integral part of  
these  
consolidated  
financial  
statements.

2

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

	Nine months ended March 31,	
	2013	2012
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(2,863,032)	\$(2,283,946)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(32,174 )	(10,256 )
Depreciation and amortization of fixed assets	563,850	643,262
Amortization of deferred financing costs and other assets	21,036	26,577
Change in fair value of warrant derivative liability	(183,000 )	(379,095 )
Accretion of asset retirement obligation	50,383	46,062
Share-based compensation	85,369	99,568
Changes in operating assets and liabilities:		
Accounts receivable	67,195	(50,006 )
Inventory	87,368	(161,103 )
Other receivables	2,204	406,426
Prepaid expenses and other current assets	(69,427 )	(13,617 )
Accounts payable and accrued expenses	(21,525 )	(26,441 )
Accrued protocol expense	27,500	(11,493 )
Accrued radioactive waste disposal	36,000	(68,060 )
Accrued payroll and related taxes	(54,654 )	(54,303 )
Accrued vacation	12,961	12,206
Net cash used by operating activities	(2,269,946)	(1,824,219)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	-	(26,000 )
Additions to licenses and other assets	(12,926 )	(42,900 )
Change in restricted cash	(104 )	(187 )
Net cash used by investing activities	(13,030 )	(69,087 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Preferred dividends paid	(10,632 )	(10,632 )
Proceeds from sales of common stock, pursuant to registered direct offering, net	3,291,977	2,274,485
Proceeds from sales of common stock, pursuant to exercise of warrants, net	1,825	40,244
Proceeds from sales of common stock, pursuant to exercise of options	11,309	1,352
Net cash provided by financing activities	3,294,479	2,305,449
Net increase in cash and cash equivalents	1,011,503	412,143
Cash and cash equivalents, beginning of period	2,672,711	2,112,254



CASH AND CASH EQUIVALENTS, END OF PERIOD	\$3,684,214	\$2,524,397
Non-cash investing and financing activities:		
Initial deferral of financing expense	\$-	\$61,511
Initial fair value of warrant liabilities	-	484,000
	\$-	\$545,511

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, 2013 and 2012**

**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, 2012.

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. The Company anticipates that as the result of continuing operating losses and the significant net operating losses available from prior fiscal years, its effective income tax rate for fiscal year 2013 will be 0%.

**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 diluted earnings per share calculations when their effect is antidilutive. At March 31, 2013 and 2012, 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, 2013 and 2012, were as follows:

	March 31,	
	2013	2012
Preferred stock	59,065	59,065
Common stock warrants	1,957,033	2,390,062
Common stock options	2,312,072	2,280,706
Total potential dilutive securities	4,328,170	4,729,833

#### 4. Inventory

Inventory consisted of the following at March 31, 2013 and June 30, 2012:

	March 31, 2013	June 30, 2012
Raw materials	\$ 103,076	\$ 261,835
Work in process	208,518	114,124
Finished goods	45,383	68,386
	\$ 356,977	\$ 444,345

During the three months ended March 31, 2012, the Company reclassified its stock of enriched barium from inventory classified as a current asset to other inventory classified as a non-current asset. During the nine months ended March 31, 2013, the Company continued to classify its stock of enriched barium as a non-current asset and does not expect to consume the enriched barium during the current operating cycle, however, in the future the Company will classify the portion of the inventory that is forecast to be consumed during an operating cycle as raw material within inventory.

#### 5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and nine months ended March 31, 2013 and 2012:

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

	Three months		Nine months	
	ended March 31,		ended March 31,	
	2013	2012	2013	2012
Cost of product sales	\$10,164	\$12,090	\$30,492	\$36,270
Research and development expenses	7,607	7,630	25,042	22,890
Sales and marketing expenses	1,386	2,606	4,568	7,818
General and administrative expenses	8,423	10,864	25,267	32,590
Total share-based compensation	\$27,580	\$33,190	\$85,369	\$99,568

As of March 31, 2013, total unrecognized compensation expense related to stock-based options was \$82,399 and the related weighted-average period over which it is expected to be recognized is approximately 0.74 years.

A summary of stock options within the Company's share-based compensation plans as of March 31, 2013 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at March 31, 2013	2,312,072	\$ 1.82	4.88	\$ 149,208
Vested and expected to vest at March 31, 2013	2,221,210	\$ 1.87	4.83	\$ 135,927
Vested and exercisable at March 31, 2013	2,037,064	\$ 1.93	4.59	\$ 148,708

There were 31,700 options exercised during the nine months ended March 31, 2013 and 5,200 options exercised during the nine months ended March 31, 2012. 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, 2013 and 2012, was \$13,866 and \$ 2,964, respectively.

No stock option awards were granted during the nine months ended March 31, 2013 and 2012.

## 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, 2013 and June 30, 2012, 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, 2013	Balance at June 30, 2012	Input Hierarchy Level
Assets:			
Cash and cash equivalents	\$3,684,214	\$2,672,711	Level 1
Restricted cash	181,131	181,027	Level 1
Liabilities:			
Warrant derivative liability	\$131,000	\$314,000	Level 2

Cash and cash equivalents and restricted cash are valued at Level 1 inputs which utilize quoted prices in active markets for identical instruments. Warrant derivative liability is valued using inputs other than Level 1 inputs that are observable by utilizing the inputs to the Black-Scholes Option Pricing Model.

## 8. Preferred Dividends

On December 21, 2012, 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, 2012 in the amount of \$10,632. Dividends on the Series B Preferred Stock were last paid on December 28, 2011 as declared by the Board of Directors on December 16, 2011 in the amount of \$10,632. The dividends outstanding and cumulative through December 31, 2012 of \$10,632 and through December 31, 2011 of \$10,632 were paid as of those dates.

As of March 31, 2013, there were accrued dividends on Series B Preferred Stock outstanding in the amount of \$2,658.

## 9. Shareholders' Equity

### *Common stock transactions*



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

On July 13, 2012, the Company entered into an agreement with Ladenburg Thalmann & Co. Inc. as placement agent for a registered direct offering to sell 3,626,943 shares of the Company's common stock, par value \$0.001 per share, with an aggregate purchase price of \$3.5 million at a price per share of \$0.965. The offering yielded \$3,291,977 in cash after expenses.

	July 13, 2012 Registered offering
Gross cash proceeds	\$3,500,000
Commission expense	(87,500 )
Legal and accounting expense	(67,306 )
Listing expense	(47,000 )
Other expense	(6,217 )
Net cash proceeds	\$3,291,977

*Warrant derivative 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 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 the change in fair value as described in the table below:

	Three months ended March 31, 2013	Nine months ended March 31, 2013
Change in fair value of warrant		
Derivative liability:	\$ 109,000	\$ 183,000

The change in fair value of the warrant derivative liability:

Purchaser and underwriter warrants issued in October 2011:

	Three months ended March 31, 2013		Nine months ended March 31, 2013	
Balance, beginning of period	650,003	\$ 218,000	650,003	\$ 286,000
Change in fair value	650,003	(99,000 )	650,003	(167,000)
Warrants exercised	-	-	-	-
Balance, end of period	650,003	\$ 119,000	650,003	\$ 119,000

Purchaser warrants issued in December 2011:

	Three months ended March 31, 2013		Nine months ended March 31, 2013	
Balance, beginning of period	63,598	\$ 22,000	63,598	\$ 28,000

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

Change in fair value	63,598	(10,000)	63,598	(16,000)
Warrants exercised	-	-	-	-
Balance, end of period	63,598	\$12,000	63,598	\$12,000

Total fair value of warrant derivative liability at March 31, 2013: \$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, 2012	1,959,799	\$ 1.3800
Warrants exercised	(2,766 )	0.6472
Outstanding as of March 31, 2013	1,957,033	\$ 1.3800

On September 12, 2012, the holder of the remaining Series C warrants exercised warrants for 2,666 shares of common stock at an exercise price of \$0.6715 for a total of \$1,791.

On November 26, 2012, the holder of the final Series C warrants exercised the remaining warrants for 100 shares of common stock at an exercise price of \$0.3497 for a total of \$34.92.

## **10. Related Party Transaction**

During the nine months ended March 31, 2013 and 2012, 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 Board of Directors approved the use of the ongoing services of APEX Data Systems. Mr. Babcock recused himself due to his conflict of interest. The cost recorded during the nine months ended March 31, 2013 and 2012 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection application was \$10,960 and \$15,000. During the nine months ended March 31, 2012, APEX Data Systems, Inc was also paid \$14,070 to build a web interfaced data collection application.

## **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, 2012 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 28, 2012 are those that depend most heavily on these judgments and estimates. As of March 31, 2013, there had been no material changes to any of the critical accounting policies contained therein.

### **Results of Operations**

**Three months ended March 31, 2013 compared to three months ended March 31, 2012.**

#### **Revenues.**

##### *Prostate Brachytherapy.*

The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole. 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 robotic-assisted surgery 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.

##### *Other Brachytherapy including Brain and Lung Treated with Seed Therapy and GliaSite RTS.*

The strategy implemented by management in the prior year in diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed and GliaSite RTS has continued to partially mitigate the lost revenue from the prostate seed brachytherapy business.

The Company made the first sales of the Iotrex liquid isotope in Europe for its FDA cleared and CE marked Gliasite Radiation Therapy System (Gliasite RTS) to its German distributor for use in clinical treatment during February 2013 and sold an additional inventory of catheters to the same customer for use in future cases during January 2013.

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.

The timeline of developing and bringing new products from concept to revenue production in the pharmaceutical/medical device segment is lengthy, typically measured in years, with a very low probability of any new cancer treatment product reaching the stage at which it produces revenue.

Company management has been investing in the development of alternative uses for the Company's brachytherapy seed that management believes have the ability to generate revenue in the near-term to offset the development costs. 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, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters.

Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$1,005,544	\$1,119,662	\$(114,118)	(10 %)
Product Sales (Other <sup>1</sup> )	245,934	197,709	48,225	24 %
Total product sales	\$1,251,478	\$1,317,371	\$(65,893)	(5 %)

<sup>1</sup> Other sales include brachytherapy seed treatment of brain cancer, lung cancer, head and neck cancer, colorectal cancer, gynecological cancer, ocular cancer and other body site cancers that have been treated previously with the Company's Cs-131 brachytherapy seeds. In addition, other sales includes the sale of GliaSite RTS and its related components for use.

#### Cost of product sales.

Cost of product sales decreased by an immaterial amount during the three months ended March 31, 2013 when compared to the three months ended March 31, 2012. The immaterial decrease in the cost of product sales was primarily the result of reduced amortization and depreciation expense as assets reached the end of their depreciable lives, combined with immaterial changes in other cost segments including an immaterial increase in the cost of product sales related to the production of the GliaSite RTS and its related components.

Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)
Total cost of product sales	\$1,065,574	\$1,113,151	\$(47,577)	(4 %)

**Gross profit.** Gross profit for the three month period ended March 31, 2013 had an immaterial decrease compared to the three month period ended March 31, 2012 primarily as a result of the decreased brachytherapy seed revenue from prostate cancer treatment which was partially offset by a decrease in cost of product sales.



Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)
Total gross profit	\$ 185,904	\$ 204,220	\$(18,316)	(9 %)
Total gross profit percentage	15 %	16 %		

**Research and development.** Research and development costs were increased by an immaterial amount for the three months ended March 31, 2013 compared to the three months ended March 31, 2012. The immaterial change was created by an increase in legal expense along with payroll and benefits as the result of an increase in research and development projects as the Company continues to investigate different applications for using its products in treating various cancers during the three months ended March 31, 2013 when compared to the three months ended March 31, 2012. The increase in legal expense in the three months ended March 31, 2013 was the result of a patent granted in India for which the costs had not been capitalized thereby reducing legal expenses as a result of capitalizing the patent during the three months ended March 31, 2012.

Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)	
Total research and development	\$155,137	\$132,237	\$22,900	17	%

**Sales and marketing expenses.** Sales and marketing expenses did not change by a material amount during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. The single expense that increased significantly was travel expense as the Company added to the number of sales people in the field and added costs related to working to establish a market for GliaSite RTS with new physicians during the three months ended March 31, 2013 as compared to the three months ended March 31, 2012.

Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)	
Total sales and marketing	\$290,812	\$259,010	\$31,802	12	%

**General and administrative expenses.** General and administrative expenses were substantially unchanged during the three months ended March 31, 2013 when compared to the three months ended March 31, 2012.

Description	Three months ended 03-31-13	Three months ended 03-31-12	Variance (\$)	Variance (%)	
Total general and administrative	\$564,075	\$575,832	\$(11,757)	(2)	%

**Operating loss.** Operating loss for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 decreased as a result of decreased revenue generated from the sales of brachytherapy seeds for the treatment of prostate cancer. The changes in product sales from other seed brachytherapy; sales of GliaSite RTS; cost of product sales; research and development expense; research and development reimbursement; sales and marketing expense and general and administrative expense were immaterial to the change in operating loss.

Description	Three months	Three months
-------------	-----------------	-----------------

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

	ended	ended	Variance	Variance	
	03-31-13	03-31-12	(\$)	(%)	
Operating loss	\$(824,120)	\$(762,859)	\$(61,261)	8	%

**Change in fair value of warrant derivative liability.**

During the three months ended March 31, 2013 and March 31, 2012, there were changes in the fair value of the warrant derivative liabilities established upon issuance of the warrants during October 2011 and December 2011 to the purchasers and underwriters in the Company's registered public offering. Per ASC 820, the warrant derivative liability requires periodic evaluation for changes in fair value. As required at March 31, 2013 and March 31, 2012, 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, 2013 and March 31, 2012, respectively.

**Key operating factor**

Description	Three months ended	Three months ended	Variance (\$)	Variance (%)	
	03-31-13	03-31-12			
Change in fair value of warrant derivative liabilities	\$ 109,000	\$ 213,095	\$(104,095)	(49	%)

**Nine months ended March 31, 2013 compared to nine months ended March 31, 2012**

**Revenues.**

*Prostate Brachytherapy.*

The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole, as described above in the “Revenues” section above for the three month period.

*Other Brachytherapy including Brain and Lung.*

During the nine months ended March 31, 2013, the strategy implemented by management in the prior year of diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to partially mitigate the lost revenue from the prostate brachytherapy segment which in total remains unchanged from the nine months ended March 31, 2012.

The products being implemented by the Company are very dependent on first adopters as a source of revenue, and there is initially a steep growth in revenue that will reach a plateau due to capacity until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. Management strategy includes soliciting the use of other applications for the Company's brachytherapy seeds at major medical institutions that are more likely to publish their outcomes and that are training the next generation of decision makers. Company management intends to actively pursue 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.

*GliaSite Radiation Therapy System.*

The Company made the first sales of its FDA cleared and CE marked GliaSite Radiation Therapy System (GliaSite RTS) for use in clinical treatment and sold an additional inventory of catheters to the same customer for use in future cases during the three months ended December 31, 2011. The Company sold additional catheters and an initial delivery of the Iotrex liquid isotope to the distributor in Germany during the nine months ended March 31, 2013. All product sales are generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of GliaSite RTS which come from sale of the liquid isotope, catheter trays and access trays.

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

During the nine months ended March 31, 2013, revenue from the GliaSite RTS increased by approximately 32% or \$27,000 compared to the nine months ended March 31, 2012. The GliaSite RTS is in the early stages of adoption and the Company is actively soliciting medical institutions to serve as the first adopters to facilitate the wider adoption of the product.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Product sales (Prostate)	\$2,728,219	\$3,239,227	\$(511,008)	(16 %)
Product sales (Other)	554,948	520,216	34,732	7 %
Total product sales	\$3,283,167	\$3,759,443	\$(476,276)	(13 %)

**Cost of product sales.** Cost of product sales overall have remained substantially unchanged during the nine months ended March 31, 2013 compared to the nine months ended March 31, 2012. There were no costs segments in cost of product sales that changed by a material amount during the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Total cost of product sales	\$3,276,314	\$3,289,982	\$(13,668)	-%

**Gross profit.** Gross profit for the nine months ended March 31, 2013 decreased substantially when compared to the nine months ended March 31, 2012. The change in gross profit was primarily as a result of the previously discussed reduction in sales in the prostate market as the cost of product sales was substantially unchanged during the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Total gross profit	\$ 6,853	\$469,461	\$(462,608)	(99 %)
Total gross profit percentage	0	% 12	%	

**Research and development.** Research and development costs were decreased by three key operating factors for the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012. The first key operating factor was other organ research expense which decreased as development related to isotope development projects and brain application development projects was complete which was partially offset by the initiation of additional research surrounding our GliaSite RTS product. The second key operating factor that decreased was payroll, benefits and share-based compensation as there was a decreased need for personnel as projects came to an end thereby decreasing the wage, benefit and overhead expenses related to those personnel. The third key operating factor was protocol expense which decreased as the result of the Company having a temporary no cost period on one of the protocol agreements. The Company continued to invest in protocols in support of products that have been developed and sales have begun in support of gaining general acceptance in the market. During the nine months ended March 31, 2013 and March 31, 2012, the Company accrued protocol costs in accordance with its agreements with participating facilities.

#### Key operating factors

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Other organs research	\$23,204	\$55,911	\$(32,707)	(58 %)

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

Payroll, benefits and share compensation	195,250	282,565	(87,315 )	(31 %)
Protocol expense	67,025	92,781	(25,756 )	(28 %)
Other research and development	160,306	141,955	18,351	13 %
Total research and development	\$445,785	\$573,212	\$(127,427)	(22 %)

**Research and development reimbursement.** Research and development reimbursement costs were reduced for the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012. This reduction was the result of a reimbursement that was recorded in the amount of \$50,000 during the nine months ended March 31, 2012 that did not recur during the nine months ended March 31, 2013. This reimbursement amount represented the amount of cost sharing that was negotiated with the future distributor of the GliaSite RTS in support of the development of the product.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Total research and development reimbursement	\$ -	\$(50,000 )	\$50,000	(100 %)

**Sales and marketing expenses.** Sales and marketing expenses increased during the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012 primarily as a result of changes in three key operating factors which were not individually significant. The first key operating factor of conventions and tradeshow increased as the result of attending an increased number of events with an emphasis on both seed and GliaSite RTS based treatment of brain cancer as well as expanding general product acceptance through the dissemination of the latest findings from the protocols being conducted. The second key operating factor of marketing and advertising increased primarily as the result of the reversal of an accrued expense that management determined a claim for no longer existed. The third key operating factor is travel expense which increased as the result of the addition of a sales team member in the field, the additional travel associated with establishing new facilities as customers and the addition of the new GliaSite RTS products which required additional travel expense during its introduction to the market.

### Key operating factors

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)	
Conventions and tradeshow	\$37,264	\$22,848	\$14,416	63	%
Marketing and advertising	26,946	14,121	12,825	91	%
Travel	201,010	180,825	20,185	11	%
Sales and marketing (Other)	663,742	659,755	3,987	1	%
Total sales and marketing	\$928,962	\$877,549	\$51,413	6	%

**General and administrative expenses.** General and administrative expenses were substantially unchanged during the nine months ended March 31, 2013 compared to the nine months ended March 31, 2012. There were no costs segments in general and administrative expense that changed by an individually significant amount during the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)	
Total general and administrative	\$1,678,487	\$1,726,017	\$(47,530)	(3)	%

**Operating loss.** Operating loss for the nine months ended March 31, 2013 was increased when compared to the nine months ended March 31, 2012 as a result of reduced product sales which was partially offset by the net effect of individually insignificant changes in cost of product sales, research and development expense, research and



development reimbursement, sales and marketing expense and general and administrative expense.

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Operating loss	\$(3,046,381)	\$(2,657,317)	\$(389,064)	15 %

**Change in fair value of warrant derivative liability.** During the nine months ended March 31, 2013 and March 31, 2012, there were warrant derivative liabilities established upon issuance of warrants to the purchasers and underwriters in the Company's registered public offering during October 2011 and December 2011. Per ASC 820, the warrant derivative liability requires a periodic evaluation for changes in fair value. As required at March 31, 2013 and March 31, 2012, 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 that was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of March 31, 2013 and March 31, 2012.

**Key operating factor**

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Change in fair value of warrant derivative liability	\$ 183,000	\$ 379,095	\$(196,095)	(52 %)

**Liquidity and capital resources.** The Company has historically financed its operations through cash investments from shareholders. During the nine months ended March 31, 2013 and March 31, 2012, 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. The increase in net cash used in operating activities for the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012 is primarily the result of the increased net loss that is primarily the result of decreased revenues. Management has continued to maintain prior reductions of expenses that consumed cash in operating activities through a combination of cost reductions and operational efficiencies that were previously identified and implemented in operations. The remaining increase in cash used by operating activities is the net of an increase from the changes in operating assets and liabilities partially reduced by the decrease in non-cash operating expenses.

**Key operating factor**

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)
Net loss	\$(2,863,032)	\$(2,283,946)	\$(579,086)	25 %
Non-cash items	505,464	426,118	79,346	19 %
Non-cash changes in operating assets and liabilities	87,622	33,609	54,013	161 %
Net cash used by operating activities	\$(2,269,946)	\$(1,824,219)	\$(445,727)	24 %

*Cash flows from investing activities*

Cash used by investing activities during the nine months ended March 31, 2013 was primarily related to the capitalization of costs related to other assets and in the nine months ended March 31, 2012 was primarily that required to bring the GliaSite RTS to market.

**Key operating factor**

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)	
Purchases of fixed assets	\$-	\$ (26,000 )	\$ 26,000	(100	%)
Additions to licenses and other assets	(12,926 )	(42,900 )	29,974	(70	%)
Change in restricted cash	(104 )	(187 )	83	(44	%)
Net cash used by investing activities	\$(13,030 )	\$(69,087 )	\$ 56,057	(81	%)

*Cash flows from financing activities*

Cash provided by financing activities in the nine months ended March 31, 2013 and March 31, 2012 was the result of sales of common stock in a registered direct offering through warrant exercises and option exercises. Cash used during the nine months ended March 31, 2013 and March 31, 2012 was the result of dividend payments to the preferred shareholders.

**Key operating factor**

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)	
Preferred dividend payments	\$(10,632 )	\$(10,632 )	\$-	0	%
Proceeds from sale of common stock	3,305,111	2,316,081	989,030	43	%
Net cash provided by financing activities	\$3,294,479	\$2,305,449	\$989,030	43	%

*Projected Fiscal Year 2013 Liquidity and Capital Resources*

At March 31, 2013, the Company held cash and cash equivalents of \$3,684,214 as compared to \$2,672,711 at June 30, 2012. The Company had approximately \$3.54 million of cash and cash equivalents and no short-term investments as of May 1, 2013.

The Company's monthly required cash operating expenditures increased during the nine months ended March 31, 2013 when compared to the nine months ended March 31, 2012. Net cash used by operating activities increased by the net effect of the increased net loss when adjusted for the increase in cash used by non-cash expenses and for the increase in cash used by operating assets and liabilities. Management believes that less than \$100,000 will be spent on capital expenditures during the final three months of fiscal year 2013, but there is no assurance that unanticipated needs for capital equipment may not arise.

**Key operating factor**

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

Description	Nine months ended 03-31-13	Nine months ended 03-31-12	Variance (\$)	Variance (%)	
Net loss	\$(2,863,032)	\$(2,283,946)	\$(579,086)	25	%
Increase in non-cash expenses	505,464	426,118	79,346	19	%
Increase in operating assets and liabilities	87,622	33,609	54,013	161	%
Net cash used by operating activities	\$(2,269,946)	\$(1,824,219)	\$(445,727)	24	%
Number of months to calculate	9	9			
Average monthly cash required for operating expense	\$(252,000 )	\$(203,000 )	\$(49,000 )	24	%

The Company 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 Radiation Therapy System. The Company continues to believe that approximately \$100,000 in expense will be incurred during fiscal year 2013 related to protocol expenses relating to lung cancer, inter-cranial cancer and both dual therapy and mono therapy prostate cancer protocols.

Based on the foregoing assumptions, management believes cash and cash equivalents of approximately \$3.54 million on hand at May 1, 2013 will be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements through at least the next twelve months 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 GliSite RTS, expanding into other market applications which initially will include head and neck, colorectal 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 five fiscal years and continued to decrease during the nine months ended March 31, 2013.

As management is focused on increasing revenue from inter-cranial, head and neck, and lung applications of Cesium-131 brachytherapy seeds in addition to increasing the number of cases treated with of the GliSite RTS, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it works to gain market share.

Offering description	Period	Net proceeds	Remaining net proceeds
Registered direct offering	November 2010	\$2,219,306	\$-
Registered direct offering	October / December 2011	2,274,486	-
Registered direct offering	July 2012	3,291,977	3,291,977
Total remaining proceeds		\$7,785,769	\$3,291,977

The Company expects to finance its future cash or requirements to meet NYSE MKT listing standards needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders. Management anticipates that when it raises any 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. If the Company is unable to raise additional funds, it may be unable to expand into new applications and may need to curtail operations.

#### *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 March 31, 2013. 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 developing and implementing the remediation plan to address the material weakness and significant deficiency identified in its Form 10-K for the fiscal year ended June 30, 2012.

Progress made on this plan in the nine months ended March 31, 2013 is as follows:

The Company has hired an accounting professional who is a certified public accountant to fill the previously open position which allows the Company to continue the process of remediating the issues previously identified.

With the addition of the second accounting professional as discussed above, the Company presently has two qualified accounting professionals who are certified public accountants in the State of Washington and that are knowledgeable as to the operations of the Company and with the filing requirements of the US Securities and Exchange Commission, which provides an improved controls environment and reduced risk related to the reporting of the Company.



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

The Company added an accounting professional with a BA in Accounting in the position of staff accountant which was created as part of the Company plan of remediating the issues previously identified. The creation of the staff accountant position did not expand the overall number of accounting staff members as a position was eliminated during the remediation process.

- The Company plans to continue to enhance staff knowledge through continued training and periodic reviews.

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, 2013 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 for the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2012, except as follows:

*Failure to Comply with NYSE MKT Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock.* Our common stock is presently listed on the NYSE MKT. The NYSE MKT will consider delisting a company's securities if, among other things, the company fails to maintain minimum stockholders equity or the company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE MKT, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. There can be no assurance that we will be able to maintain our listing on the NYSE MKT indefinitely. If we do not raise additional capital, we expect to fall below the minimum stockholders equity requirement for the quarter ending June 30, 2013. In the event that our common stock is delisted from the NYSE MKT, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock.

### **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.

There was no material change in the use of proceeds from our October 2011 public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) on October 13, 2011. Through March 31, 2013, we had used all of the net proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) and as further described in the table below.

There was no material change in the use of proceeds from the December 7, 2011 over-allotment closing for the October 2011 registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) on October 13, 2011. Through March 31, 2013, we had used all of the net proceeds from this registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) and as further described in the table below.

There was no material change in the use of proceeds from the July 17, 2012 registered public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 17, 2012. Through March 31, 2013, we had not 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 net proceeds in cash and cash equivalents.

On September 12, 2012, the holder of the Series C warrants issued in the November 2010 offering exercised Series C warrants in the exercise amount of \$1,791 in exchange for 2,666 shares of common stock with an exercise price of \$0.6715. As of March 31, 2013, none of the proceeds from the warrant exercise had been used.

On November 26, 2012, the holder of the Series C warrants issued in the November 2010 offering exercised Series C warrants in the exercise amount of \$34 in exchange for 100 shares of common stock with an exercise price of \$0.3497. As of March 31, 2013, none of the proceeds from the warrant exercise had been used.

Proceeds used in the nine months ended March 31, 2013:	
Indirect payments to directors and officers for database maintenance and development	\$ 10,960
Direct payments of compensation to directors	102,000
Direct payments of salaries to officers	542,510
Working capital	1,626,829
Total proceeds used in the nine months ended March 31, 2013:	\$2,282,299

## 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 Schema Document

101.CAL\*\*\* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF\*\*\* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB\*\*\* XBRL Taxonomy Extension Label Linkbase Document

101.PRE\*\*\* XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith.

\*\*\* 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 14, 2013

ISORAY, INC., a Minnesota corporation

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

(Principal Executive Officer)

By /s/ Brien Ragle  
Brien Ragle, Controller

(Principal Financial and Accounting Officer)