IsoRay, Inc.
Form 10-Q
November 14, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

þ**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2014

or

¨ 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 organization)	(I.R.S. Employer 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 website if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨

Smaller reporting company x

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

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

Class	Outstanding as of November 12, 2014
Common stock, $0.001 par value	54,883,445

ISORAY, INC.

Table of Contents

PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

IsoRay, Inc. and Subsidiaries

Consolidated Balance Sheets

	(Unaudited) September 30, 2014	June 30, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,075,317	$ 7,680,073
Short-term investments	10,025,267	10,002,912
Accounts receivable, net of allowance for doubtful accounts of $27,286 and $38,607, respectively	962,259	913,049
Inventory	407,479	359,737
Other receivables	5,258	53,082
Prepaid expenses and other current assets	252,183	206,047
Total current assets	13,727,763	19,214,900
Fixed assets, net of accumulated depreciation and amortization	855,398	1,017,915
Investments - other	10,046,537	5,401,398
Restricted cash	181,221	181,208
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	258,638	264,076
Total assets	$ 25,539,315	$ 26,549,255
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 509,688	$ 574,855
Accrued protocol expense	94,462	80,433
Accrued radioactive waste disposal	153,592	141,592
Accrued payroll and related taxes	105,503	236,282
Accrued vacation	115,821	120,765

Total current liabilities	979,066	1,153,927
Warrant derivative liability	250,000	573,000
Asset retirement obligation	886,204	866,560
Total liabilities	2,115,270	2,593,487
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,001,671 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series D: 1,671 and 0 shares allocated; no shares issued and outstanding	-	-
Common stock, $.001 par value; 192,998,329 & 193,000,000 shares authorized; 54,883,445 and 54,701,708 shares issued and outstanding	54,883	54,702
Treasury stock, at cost, 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	82,213,811	81,959,853
Accumulated deficit	(58,836,318)	(58,050,456)
Total shareholders' equity	23,424,045	23,955,768
Total liabilities and shareholders' equity	$ 25,539,315	$ 26,549,255

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

3

IsoRay, Inc. and Subsidiaries

Consolidated Statements of Operations

(Unaudited)

	For the quarter ended September 30, 2014	2013
Product sales, net	$1,042,101	$1,049,915
Cost of product sales	1,096,903	1,127,223
Gross loss	(54,802)	(77,308)
Operating expenses:		
Research and development expenses	176,610	146,990
Sales and marketing expenses	353,743	359,185
General and administrative expenses	575,951	651,036
Total operating expenses	1,106,304	1,157,211
Operating loss	(1,161,106)	(1,234,519)
Non-operating income (expense):		
Interest income	72,695	354
Change in fair value of warrant derivative liability	306,000	(36,000)
Financing and interest expense	(3,451)	(741)
Non-operating income (expense) , net	375,244	(36,387)
Net loss	(785,862)	(1,270,906)
Preferred stock deemed dividends (Note 10)	-	(726,378)
Preferred stock dividends	(2,658)	(2,658)
Net loss applicable to common shareholders	$(788,520)	$(1,999,942)
Basic and diluted loss per share	$(0.01)	$(0.06)
Weighted average shares used in computing net loss per share:		
Basic and diluted	54,868,053	35,921,712

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

4

IsoRay, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(Unaudited)

	Three months ended September 30, 2014		Three months ended September 30, 2013	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	(785,862	)	(1,270,906	)
Adjustments to reconcile net loss to net cash used by operating activities:				
Allowance for doubtful accounts	(11,321	)	(5,001	)
Depreciation and amortization of fixed assets	169,970		176,314	
Amortization of deferred financing costs and other assets	7,734		7,685	
Change in fair value of derivative warrant liabilities	(306,000	)	36,000	
Accretion of asset retirement obligation	19,644		17,960	
Share-based compensation	21,453		38,353	
Changes in operating assets and liabilities:				
Accounts receivable, gross	(37,889	)	(33,475	)
Inventory	(47,742	)	(30,673	)
Other receivables	47,824		2,209	
Prepaid expenses and other current assets	(46,136	)	(7,524	)
Accounts payable and accrued expenses	(65,167	)	220,824	
Accrued protocol expense	14,029		(16,999	)
Accrued radioactive waste disposal	12,000		12,000	
Accrued payroll and related taxes	(130,779	)	(42,486	)
Accrued vacation	(4,944	)	3,698	
Net cash used by operating activities	(1,143,186	)	(892,021	)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of fixed assets	(7,453	)	(2,041	)
Additions to licenses and other assets	(2,296	)	(2,572	)
Purchases of short term investments	(22,355	)	-	
Purchases of investments - other	(4,645,139	)	-	
Change in restricted cash	(13	)	(18	)
Net cash used by investing activities	(4,677,256	)	(4,631	)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from sales of preferred stock, pursuant to underwritten offering, net	-		1,479,431	
Proceeds from sales of common stock, pursuant to underwritten offering, net	-		1,801,457	
Proceeds from sales of common stock, pursuant to exercise of warrants	70,411		-	
Proceeds from sales of common stock, pursuant to exercise of options	145,275		-	

Net cash provided by financing activities	215,686	3,280,888
Net increase (decrease) in cash and cash equivalents	(5,604,756)	2,384,236
Cash and cash equivalents, beginning of year	7,680,073	2,899,927
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 2,075,317	$ 5,284,163
Non-cash investing and financing activities:		
Preferred stock deemed dividends (Note 10)	$ -	$ (726,378)
Reclassification of derivative warrant liability to equity upon exercise	(17,000)	-
Total non-cash investing and financing activities	$ (17,000)	$ (726,378)

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

5

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three months ended September 30, 2014 and 2013

1. Basis of Presentation

The accompanying unaudited interim consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries (IsoRay or the Company). All significant intercompany accounts and transactions have been eliminated in consolidation. Certain amounts in the prior-period financial statements have been reclassified to conform to the current-period presentation.

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2014.

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 2015 will be 0%.

2. New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09), which supersedes the revenue recognition requirements in FASB Accounting Standards Codification (ASC) Topic 605, "Revenue Recognition". The guidance requires that an entity recognize revenue in a way that depicts the transfer of promised goods or services to customers in the amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods and services. The guidance will be effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

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

3. Investments

Remaining time to maturity	Under 90 days	91 days to six months	Six months to 1 year	1 to 3 years
CDARS[1]	$5,007,821	$ -	$ 5,017,446	$10,046,537

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

6

4. Loss per Share

Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. At September 30, 2014 and 2013, the calculation of diluted weighted average shares did not include convertible preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2014 and 2013, were as follows:

	September 30, 2014	2013
Series B preferred stock	59,065	59,065
Series D preferred stock	-	3,121,481
Common stock warrants	396,574	7,605,771
Common stock options	2,180,858	2,370,072
Total potential dilutive securities	2,636,497	13,156,389

5. Inventory

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

	September 30, 2014	June 30, 2014
Raw materials	$ 189,768	$173,417
Work in process	173,996	151,321
Finished goods	43,715	34,999
	$ 407,479	$359,737

6. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2014 and 2013:

	Three months ended September 30,	
	2014	2013
Cost of product sales	$ 7,972	$ 4,422
Research and development expenses	3,117	3,482
Sales and marketing expenses	2,158	879
General and administrative expenses	8,206	29,570
Total share-based compensation	$ 21,453	$ 38,353

As of September 30, 2014, total unrecognized compensation expense related to stock-based options was $319,044 and the related weighted-average period over which it is expected to be recognized is approximately 2.15 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2014 were as follows:

	Number of Options	Weighted Average Exercise Price (Years)	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2014	2,180,858	$ 2.05	4.45	$ 933,618
Vested and expected to vest at September 30, 2014	2,112,233	$ 2.07	4.36	$ 896,932
Vested and exercisable at September 30, 2014	1,760,312	$ 2.15	3.52	$ 774,655

There were 133,564 options exercised during the three months ended September 30, 2014 and no options exercised during the three months ended September 30, 2013. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised in the three months ended September 30, 2014 was $252,308.

There were no stock option awards granted and 65,000 stock option awards granted during the three months ended September 30, 2014 and 2013, respectively.

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

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

7. Commitments and Contingencies

Patent and Know-How Royalty License Agreement

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

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

8. Fair Value Measurements

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

Description	Balance at September 30, 2014	Balance at June 30, 2014	Input Hierarchy Level
Assets:			
Cash and cash equivalents	$ 2,075,317	$ 7,680,073	Level 1
Restricted cash	181,221	181,208	Level 1
Liabilities:			
Warrant derivative liability	$ 250,000	$ 573,000	Level 2

9. 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. 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.

As of September 30, 2014, there were accrued but undeclared dividends on Series B Preferred Stock outstanding in the amount of $7,974.

10. Shareholders’ Equity

Common and preferred stock transactions

On August 29, 2013, the Company entered into an agreement to sell 3,800,985 common units, each consisting of 1 share of our 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 a per unit purchase price of $0.535 and the Preferred Units were sold at a per unit purchase price of $1,000. The warrants are all exercisable at $0.72 per share and have a twenty-four month term. Each share of the Series D Convertible Preferred Stock is convertible into 1,869.15 shares of common stock at any time at the option of the holder, subject to adjustment. 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
Underwriter discount	(185,176)
Legal and accounting expense	(184,514)
Listing expense	(48,500)
Other expense	(6,045)
Net proceeds	$3,279,292

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 fair value as described in the table below:

	Three months ended September 30, 2014	Three months ended September 30, 2013
Change in fair value of warrant derivative liability:	$ (306,000)	$ 36,000

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

	Three months ended September 30, 2014		Three months ended September 30, 2013	
	Qty[1]	Amount	Qty[1]	Amount
Balance, beginning of period	238,296	$573,000	713,601	$104,000
Change in fair value		(306,000)		36,000
Warrants exercised	(8,435)	(17,000)		-
Balance, end of period	229,861	$250,000	713,601	$140,000
Total fair value of warrant derivative liability at period end:		$250,000		$140,000

[1] 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, 2014	444,747	$ 1.43
Warrants exercised	(48,173)	1.45
Outstanding as of September 30, 2014	396,574	$ 1.22

Warrants Outstanding as of September 30, 2014

Quantity	Expiration date	Exercise Price
6,000	June 8, 2015	$ 1.18
25,000	July 27, 2015	2.00
130,713	November 21, 2015	1.56
204,211	October 19, 2016	0.944
25,650	December 7 2016	0.944
5,000	June 27, 2017	$ 0.98
396,574	Total	

11. Related Party Transaction

During the three months ended September 30, 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 cost recorded during the three months ended September 30, 2014 and 2013 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection applications in combination with the updating of the Company website was $3,000 and $4,120 respectively. An additional $3,000 was spent on the implementation of Customer Relationship Management (CRM) software in the three months ended September 30, 2013.

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

Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning *proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under "Risk Factors" under Part II, Item 1A below and in the "Risk Factors" section of our Form 10-K for the fiscal year ended June 30, 2014 that may cause actual results to differ materially.*

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

Critical Accounting Policies and Estimates

The discussion and analysis of the Company’s financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, derivative liabilities and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company’s annual report on Form 10-K as filed with the Securities and Exchange Commission on September 30, 2014 are those that depend most heavily on these judgments and estimates. As of September 30, 2014, there had been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2014 compared to three months ended September 30, 2013.

Revenues. During the three months ended September 30, 2014, total revenue was materially unchanged from the three months ended September 30, 2013. As revenue generated by prostate brachytherapy increased, the increase was able to offset the majority of the decrease in revenue from the non-prostate treatments. The non-prostate applications continued to show inconsistent sales. Management continues to believe that these non-prostate treatments are primarily purchased by early adopting physicians whose purchases are inconsistent. Until mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters, revenue results from non-prostate treatments will fluctuate dramatically. 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. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible.

The continued purchase and use of Cs-131 brachytherapy seeds after the completion of protocols by physicians while awaiting publication of the protocol outcomes is viewed by management as a positive indicator of the experience using the Company products by ordering physicians.

Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity –Modulated Radiation Therapy (IMRT) and Robotics but management believes that combining treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have the potential to continue to increase.

During the three months ended September 30, 2014 and 2013, respectively, all product sales were generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of the GliaSite® Radiation Therapy System (GliaSite RTS) which include the sale of the Iotrex solution, Cesitrex solution, catheter trays and access trays.

The conversion of prospects to new GliaSite RTS customers has been a longer process than originally anticipated by the Company. The Company has experienced lengthy timelines in the internal processes of the medical facilities in reviewing and approving the use of the product at the request of their physician(s). These longer than anticipated internal processes are compounded by uncertain timelines and delays in receiving the approval for the requested modification of each facility's nuclear materials license, which is required to begin using GliaSite RTS and is dependent on external government regulators.

Key operating factors

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Product Sales (Prostate)	$ 915,627	$ 852,753	$ 62,874	7 %
Product Sales (Other)	126,474	197,162	(70,688)	(36)%
Total product sales	$ 1,042,101	$ 1,049,915	$ (7,814)	(1)%

Cost of product sales.

The cost of product sales for the production of brachytherapy seeds was materially unchanged in the three months ended September 30, 2014 when compared to the three months ended September 30, 2013. The immaterial increase in brachytherapy seed cost of products was the result of offsetting immaterial changes to individual cost categories.

During the three months ended September 30, 2014 compared to the three months ended September 30, 2013, the decrease in the cost of product sales for the GliaSite RTS was primarily the result of decreased isotope consumption which was the result of the decrease in orders.

Key operating factors

	Three months	Three months

Description	ended 09-30-2014	ended 09-30-2013	Variance ($)	Variance (%)
Seed COPS	$ 1,085,000	$ 1,084,334	$ 666	(0)%
GliaSite RTS	11,903	42,889	(30,986)	(72)%
Total cost of product sales	$ 1,096,903	$ 1,127,223	$ (30,320)	(3)%

Gross loss. Gross loss for the three months ended September 30, 2014 decreased compared to the three months ended September 30, 2013 primarily as a result of the decreased cost of product sales related to GliaSite RTS, which was partially offset by a decrease in product sales.

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance(%)
Gross loss	$ (54,802)	$ (77,308)	$ 22,506	29 %
Gross loss percentage	(5)%	(7)%		

Research and development. Research and development costs increased in the three months ended September 30, 2014 compared to the three months ended September 30, 2013 primarily as a result of the increase in legal expense related to intellectual property.

13

Key operating factors

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Legal expense	$ 32,469	$ 1,032	$ 31,437	3,046 %
Research and development – other	144,141	145,958	(1,817)	(1)%
Total research and development	$ 176,610	$ 146,990	$ 29,620	20 %

Sales and marketing expenses. Sales and marketing expenses were materially unchanged during the three months ended September 30, 2014 compared to the three months ended September 30, 2013 primarily as the result of a combination of insignificant changes in multiple cost categories.

The single operating factor with significant increase was conventions and tradeshow expense during the three months ended September 30, 2014 when compared to the three months ended September 30, 2013. This was the direct result of the cost of the Company having organized and hosted presentations by researchers who have participated in several of the Company protocols to discuss their results with other physicians during the American Society of Therapeutic Radiation Oncology (ASTRO) meeting during September 2014.

Key operating factors

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Conventions and tradeshow expense	$ 48,890	$ 21,063	$ 27,827	132 %
Other sales – marketing expense	304,853	$ 338,122	$ (33,269)	(10)%
Total sales and marketing	$ 353,743	$ 359,185	$ (5,442)	(2)%

General and administrative expenses. General and administrative expenses decreased in the three months ended September 30, 2014 compared to the three months ended September 30, 2013, primarily as a result of changes in two key operating factors that net to an insignificant increase in cost.

Consulting expense decreased as the result of existing Company employees performing work that was previously done by external consultants. Payroll, benefits and share-based compensation expense decreased primarily as the result of no option grants being made in the three months ended September 30, 2014 compared to the three months ended September 30, 2013 during which options were granted to purchase 65,000 shares, of which 50,000 were immediately vested and the full expense recognized in that period.

Key operating factors

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Consulting expense	64,956	86,714	(21,758)	(25)%
Payroll, benefits and share-based compensation expense	266,789	315,164	(48,375)	(15)%
Other general and administrative expense	244,206	249,158	(4,952)	(2)%
Total general and administrative	$ 575,951	$ 651,036	$ (75,085)	(12)%

14

Operating loss. Operating loss for the three months ended September 30, 2014 decreased compared to the three months ended September 30, 2013 primarily as a result of an increase in both research and development expenses offset by the decrease in general and administrative expenses and the reduction in cost of product sales related to GliaSite RTS created by the decreased volume of GliaSite RTS product sales.

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Operating loss	$ (1,161,106)	$ (1,234,519)	$ 73,413	(6)%

Interest income. Interest income increased during the three months ended September 30, 2014 when compared to the three months ended September 30, 2013 as the result of the investment of excess cash in laddered CDs in the Certificate of Deposit Account Registry Service® (CDARS) and which are in amounts that are fully insured by the Federal Deposit Insurance Corporation (FDIC).

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Interest income	$ 72,695	$ 354	$ 72,341	20,435 %

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 in the Company's registered offering. The warrant derivative liability requires periodic evaluation for changes in fair value. As required at September 30, 2014, 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 September 30, 2014.

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)

Change in fair value of warrant derivative liability	$ 306,000	$ (36,000)	$ 342,000	950 %

Liquidity and capital resources. The Company has historically financed its operations through selling stock to investors. During the three months ended September 30, 2014 and September 30, 2013, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

15

Cash flows from operating activities

The net loss was adjusted by an increase in both the non-cash items and non-cash changes in operating assets and liabilities, which resulted in an overall increase in net cash used by operating activities for the three months ended September 30, 2014 when compared to the three months ended September 30, 2013. The decreased net loss during the three months ended September 30, 2014 when compared to the three months ended September 30, 2013 was primarily the result of the non-cash change in fair value of derivative warrant liabilities coupled with increased cash consumed in satisfying operational liabilities. The change in the fair value of the warrant liability is a model driven item contained in the statement of operations which is primarily impacted by the market price of the stock, the volatility of the market price and the remaining life of the warrant derivative liability. Cash used by operating activities adjusted for the change in the fair value of the derivative warrant liability improved during the three months ended September 30, 2014 compared to the three months ended September 30, 2013. The item that created the increased use of cash in operating activities was the payment of operational liabilities which increased during the three months ended September 30, 2014 compared to the three months ended September 30, 2013.

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Net loss	$ (785,862)	$ (1,270,906)	$ 485,044	(38)%
Non-cash items	(98,520)	271,311	(369,831)	(136)%
Non-cash changes in operating assets and liabilities	(258,804)	107,574	(366,378)	(341)%
Net cash used by operating activities	$ (1,143,186)	$ (892,021)	$ (251,165)	28 %

Cash flows from investing activities

Cash used by investing activities during the three months ended September 30, 2014 and in the three months ended September 30, 2013 was primarily related to the additional investment of excess cash in both short-term and long-term CDARS.

Key operating factor

Three months Three months

Description	ended 09-30-2014	ended 09-30-2013	Variance ($)	Variance (%)
Purchases of fixed assets	$ (7,453)	$ (2,041)	$ (5,412)	265 %
Additions to licenses and other assets	(2,296)	(2,572)	276	(11)%
Purchases of short term investments	(22,355)	-	(22,355)	100 %
Purchases of investments – other	(4,645,139)	-	(4,645,139)	100 %
Change in restricted cash	(13)	(18)	5	(28)%
Net cash used by investing activities	$ (4,677,256)	$ (4,631)	$ (4,672,625)	100,899 %

Cash flows from financing activities

Cash provided by financing activities in the three months ended September 30, 2014 and September 30, 2013 was the result of sales of common and preferred stock through one public offering in the three months ended September 30, 2013 and through warrant and option exercises during the three months ended September 30, 2014.

Key operating factor

Description	Three months ended 09-30-2014	Three months ended 09-30-2013	Variance ($)	Variance (%)
Proceeds from sale of preferred stock, net	$ -	$ 1,479,431	$(1,479,431)	(100)%
Proceeds from sale of common stock, net	-	1,801,457	(1,801,457)	(100)%
Proceeds from sales of common stock, pursuant to exercise of warrants	70,411	-	70,411	100 %
Proceeds from sales of common stock, pursuant to exercise of options	145,275	-	145,275	100 %
Net cash provided by financing activities	$ 215,686	$ 3,280,888	$3,065,202	(93)%

Projected Fiscal Year 2014 Liquidity and Capital Resources

At September 30, 2014, the Company held cash and cash equivalents of $2,075,317 as compared to $7,680,073 at June 30, 2014 with the additional investment of cash in investments with a maturity beyond one year.

The Company had approximately $1.87 million of cash and cash equivalents, $10.03 million of short-term investments and $10.06 million of investments - other as of October 31, 2014. The short-term investments have maturities in December 2014 and June 2015. At the time of maturity, Company management will assess the cash requirements of the Company and reinvest excess cash as it deems appropriate. The Company's average monthly required cash operating expenditures were approximately $381,000 during the three months ended September 30, 2014, which represents a 28% increase of approximately $84,000 in average monthly cash operating expenditures from the three months ended September 30, 2013. Management forecasts that fiscal year 2015 cash consumed in operations will be similar to the prior fiscal year. The change is largely impacted by the realized revenue and the timing of payments being received from our customers and the timing of the payment of liabilities. Management forecasts that less than $200,000 will be spent on capital expenditures for fiscal year 2014, but there is no assurance that unanticipated needs for capital equipment or a yet to be determined capital project may not arise.

Management intends to continue its existing protocol studies and to begin new protocol studies on lung cancer treatment using Cesium-131. Management believes that approximately $150,000 in expense will be incurred during fiscal year 2015 in protocol expenses relating to lung cancer, inter-cranial cancer and both dual therapy and monotherapy prostate protocols but there is no assurance that unanticipated needs for additional protocols in support of the development of new applications of our existing products may not arise.

Based on the foregoing assumptions, management believes that the cash and cash equivalents of approximately $1.87 million, short-term investments of $10.03 million and investments – other of $10.06 million at October 31, 2014 will be sufficient to meet our anticipated cash needs, assuming both revenue and expenses remain at current levels, for at least the next five years.

Management plans to attempt 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 its GliaSite RTS, and expanding into other market applications which initially will include brain, 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. Total product sales have not shown the increases necessary to breakeven during the past seven fiscal years.

For the three months ended September 30, 2014, revenue from other treatment modalities with brachytherapy seeds and GliaSite RTS has decreased 36% when compared to the three months ended September 30, 2013. These newer brachytherapy product sales (including brain, lung and those reported as other) remain in the early stages of adoption and application in the clinical setting and their purchasing patterns are subject to the influence of a few key physicians who can significantly influence revenue from quarter to quarter. The revenue from the sale of GliaSite RTS decreased by approximately 69% during the three months ended September 30, 2014 when compared to the three months ended September 30, 2013.

There was no material change in the use of proceeds from our public offerings as described in our final prospectus supplements filed with the SEC pursuant to Rule 424(b) on August 29, 2013 and March 24, 2014. Through September 30, 2014, the Company had used the net proceeds raised through the August 2013 and March 2014 offerings as described in the table below and held the remaining net proceeds in cash and cash equivalents and investments. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Offering description	Period	Net proceeds	Remaining net proceeds
Underwritten offering	August 2013	$3,279,292	$ 1,894,454
Registered direct offering	March 2014	13,814,742	13,814,742
		$17,094,034	$ 15,709,196

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

Other Commitments and Contingencies

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

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its products. The Company also carries product liability insurance to help protect it from this risk.

The Company has no off-balance sheet arrangements.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2014. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

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

PART II - OTHER INFORMATION

ITEM 1A – RISK FACTORS

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

ITEM 6. EXHIBITS

Exhibits:

31.1 Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer

31.2 Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer

32* Section 1350 Certifications

101.INS XBRL Instance Document

101.SCH XBRL Taxonomy Extension 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

* Furnished herewith.

SIGNATURES

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

Dated: November 14, 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)