IsoRay, Inc.
Form 10-Q
November 14, 2013

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, 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 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 6, 2013
Common stock, $0.001 par value	38,419,502

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries

Consolidated Balance Sheets

	(Unaudited) September 30, 2013	June 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	$5,284,163	$2,899,927
Accounts receivable, net of allowance for doubtful accounts of $47,597 and $52,598, respectively	962,256	923,780
Inventory	436,244	405,571
Other receivables	9,293	11,502
Prepaid expenses and other current assets	210,404	202,880
Total current assets	6,902,360	4,443,660
Fixed assets, net of accumulated depreciation	1,510,009	1,684,282
Restricted cash	181,167	181,149
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	271,394	276,507
Total assets	$9,334,688	$7,055,356
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$653,390	$432,566
Accrued protocol expense	8,306	25,305
Accrued radioactive waste disposal	112,000	100,000
Accrued payroll and related taxes	84,933	127,419
Accrued vacation	111,276	107,578
Total current liabilities	969,905	792,868
Warrant derivative liability	140,000	104,000
Asset retirement obligation	810,202	792,242
Total liabilities	1,920,107	1,689,110

Commitments and contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,001,671 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 and 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; 1,670 and 0 shares issued and outstanding	2	-
Common stock, $.001 par value; 192,998,329 and 193,000,000 shares authorized; 38,419,502 and 34,618,517 shares issued and outstanding	38,420	34,618
Treasury stock, at cost 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	60,746,730	57,431,293
Accumulated deficit	(53,362,240)	(52,091,334)
Total shareholders' equity	7,414,581	5,366,246
Total liabilities and shareholders' equity	$9,334,688	$7,055,356

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

IsoRay, Inc. and Subsidiaries

Consolidated Statements of Operations

(Unaudited)

	For the three months ended September 30,	
	2013	2012
Product sales	$1,049,915	$1,056,232
Cost of product sales	1,127,223	1,076,657
Gross loss	(77,308)	(20,425)
Operating expenses:		
Research and development expenses	146,990	141,472
Sales and marketing expenses	359,185	316,056
General and administrative expenses	651,036	644,853
Total operating expenses	1,157,211	1,102,381
Operating loss	(1,234,519)	(1,122,806)
Non-operating income (expense):		
Interest income	354	144
Change in fair value of warrant derivative liability	(36,000)	129,000
Financing and interest expense	(741)	(6)
Non-operating income / (expense) , net	(36,387)	129,138
Net loss	(1,270,906)	(993,668)
Preferred stock deemed dividends (Note 9)	(726,378)	-
Preferred stock dividends	(2,658)	(2,658)
Net loss applicable to common shareholders	$(1,999,942)	$(996,326)
Basic and diluted loss per share	$(0.06)	$(0.03)
Weighted average shares used in computing net loss per share:		
Basic and diluted	35,921,712	33,866,563

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

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IsoRay, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(Unaudited)

	Three months ended September 30,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,270,906)	$ (993,668)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(5,001)	51,472
Depreciation and amortization of fixed assets	176,314	206,393
Amortization of deferred financing costs and other assets	7,685	7,079
Change in fair value of warrant derivative liability	36,000	(129,000)
Accretion of asset retirement obligation	17,960	16,419
Share-based compensation	38,353	28,963
Changes in operating assets and liabilities:		
Accounts receivable	(33,475)	(31,514)
Inventory	(30,673)	33,881
Other receivables	2,209	(1,215)
Prepaid expenses, other current assets and other assets	(7,524)	(56,832)
Accounts payable and accrued expenses	220,824	(41,499)
Accrued protocol expense	(16,999)	-
Accrued radioactive waste disposal	12,000	12,000
Accrued payroll and related taxes	(42,486)	(46,424)
Accrued vacation	3,698	5,316
Net cash used by operating activities	(892,021)	(938,629)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(2,041)	-
Additions to licenses and other assets	(2,572)	(6,827)
Change in restricted cash	(18)	(42)
Net cash used by investing activities	(4,631)	(6,869)
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 registered direct offering, net	-	3,291,977
Proceeds from sales of common stock, pursuant to exercise of warrants, net	-	1,791
Proceeds from cash sales of common stock, pursuant to exercise of options	-	7,746
Net cash provided by financing activities	3,280,888	3,301,514

Net increase in cash and cash equivalents	2,384,236	2,356,016
Cash and cash equivalents, beginning of period	2,899,927	2,672,711
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 5,284,163	$ 5,028,727

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

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three months ended September 30, 2013 and 2012

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-year presentation.

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2013.

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 2014 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. At September 30, 2013 and 2012, 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, 2013 and 2012, were as follows:

	September 30,	
	2013	2012
Series B preferred stock	59,065	59,065
Series D preferred stock	3,121,481	-
Common stock warrants	7,605,771	1,957,133
Common stock options	2,370,072	2,325,772
Total potential dilutive securities	13,156,389	4,341,970

4. Inventory

Inventory consisted of the following at September 30, 2013 and June 30, 2013:

	September 30, 2013	June 30, 2013
Raw materials	$ 161,011	$ 167,671
Work in process	214,386	195,323
Finished goods	60,847	42,577
	$ 436,244	$ 405,571

5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2013 and 2012:

	Three months ended September 30,	
	2013	2012
Cost of product sales	$ 4,422	$ 10,164
Research and development expenses	3,482	8,718
Sales and marketing expenses	879	1,659
General and administrative expenses	29,570	8,422
Total share-based compensation	$ 38,353	$ 28,963

As of September 30, 2013, total unrecognized compensation expense related to stock-based options was $56,060 and the related weighted-average period over which it is expected to be recognized is approximately 0.85 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2013 were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at September 30, 2013	2,370,072	$ 1.79	4.82	$ 222,581
Vested and expected to vest at September 30, 2013	2,278,260	$ 1.84	4.75	$ 203,244
Vested and exercisable at September 30, 2013	2,080,064	$ 1.90	4.38	$ 219,581

There were no options exercised during the three months ended September 30, 2013 and 18,000 exercised during the three months ended September 30, 2012. 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, 2012 was $11,400.

There were 65,000 stock option awards granted and no stock option awards granted during the three months ended September 30, 2013 and 2012, respectively.

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

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

6. Commitments and Contingencies

Patent and Know-How Royalty License Agreement

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

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

7. Fair Value Measurements

The table below sets forth the Company’s financial assets and liabilities that were accounted for at fair value on a recurring basis as of September 30, 2013 and June 30, 2013, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Description	Balance at September 30, 2013	Balance at June 30, 2013	Input Hierarchy Level
Assets:			
Cash and cash equivalents	$ 5,284,163	$ 2,899,927	Level 1
Restricted cash	181,167	181,149	Level 1
Liabilities:			
Warrant derivative liability	$ 140,000	$ 104,000	Level 2

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. 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 September 30, 2013, there were accrued but undeclared dividends on Series B Preferred Stock outstanding in the amount of $7,974.

9. 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 an initial per unit purchase price of $0.535 and the Preferred Units were sold at an initial per unit purchase price of $1,000. The warrants are all exercisable at $0.72 per share and have a twenty-four month term, with the exercise price and term subject to reduction if shareholder approval is obtained. 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, provided that the holder will be prohibited from converting Series D Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with affiliates, would own more than 9.99% of the total shares of the Company's common stock then issued and outstanding. The preferred shares which are convertible into shares of common stock contain a beneficial conversion feature of $726,378 which was recognized as a deemed dividend to the Series D preferred shareholders on the date of issuance. This public offering resulted in gross proceeds of $3.7 million. The offering yielded approximately $3,280,888 in cash after expenses.

Gross proceeds from public offering	$3,703,527
Underwriter discount	(185,176)
Legal and accounting expense	(182,917)
Listing expense	(48,500)
Other expense	(6,046)
Net proceeds	$3,280,888

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, 2013
Change in fair value of warrant derivative liability:	$ (36,000)

Purchaser and underwriter warrants issued in October 2011:

	Three months ended September 30, 2013	
	Qty[1]	Amount
Balance, beginning of period	650,003	$94,000
Change in fair value	650,003	33,000
Warrants exercised	-	-
Balance, end of period	650,003	$127,000

Purchaser warrants issued in December 2011:

	Three months ended September 30, 2013	
	Qty[1]	Amount
Balance, beginning of period	63,598	$10,000
Change in fair value	63,598	3,000
Warrants exercised	-	-
Balance, end of period	63,598	$13,000

Total fair value of warrant derivative liability at September 30, 2013:	$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, 2013	1,957,033	$ 1.38
Warrants issued	5,648,738	0.72
Outstanding as of September 30, 2013	7,605,771	$ 0.89

10. Related Party Transaction

During the three months ended September 30, 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 cost recorded during the three months ended September 30, 2013 and 2012 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 $4,120 and $4,960 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, 2013 that may cause actual results to differ materially.

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

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related

disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, 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, 2013 are those that depend most heavily on these judgments and estimates. As of September 30, 2013, there had been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2013 compared to three months ended September 30, 2012.

Revenues. During the three months ended September 30, 2013, total revenue was materially unchanged from the three months ended September 30, 2012. While revenue generated by prostate brachytherapy continued to decrease, the decrease was materially offset by the continued growth of non-prostate related treatments which is described below as Product Sales – (Other). The continued decrease in revenue from prostate brachytherapy treatments is consistent with revenue decreases experienced by this segment of the industry as a whole. While overall revenue produced by Product Sales – (Other) continued to increase in the three months ended September 30, 2013 when compared to the three months ended September 30, 2012, there continued to be significant variances in utilization by several key physicians in treating brain cancer, lung cancer and the GliaSite Radiation Therapy System (the "GliaSite RTS"). The newer brachytherapy product sales reported as "other" represent more developmental applications of our product which may not lead to either a long-term revenue source or a significant product line and therefore revenue fluctuation in this segment is expected to be subject to more significant variation from quarter to quarter. Company management 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 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. However, to date the Company has only experienced minimal sales to first adopters.

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

During the three months ended September 30, 2013 and 2012, respectively, all product sales were generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of GliaSite RTS which include the sale of the Iotrex solution, catheter trays and access trays.

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

dependent on external government regulators.

Key operating factors

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Product Sales (Prostate)	$ 852,753	$ 881,856	$ (29,103)	(3)%
Product Sales (Other)	197,162	174,376	22,786	13 %
Total product sales	$ 1,049,915	$ 1,056,232	$ (6,317)	(1)%

Cost of product sales.

The cost of product sales for the production of brachytherapy seeds increased in the three months ended September 30, 2013 when compared to the three months ended September 30, 2012. The increase in brachytherapy seed cost of products was influenced by two key operating factors, depreciation and amortization and miscellaneous cost of product sales (COPS) seeds.

Depreciation and amortization expense decreased as assets utilized in the production of brachytherapy seeds reached the end of their useful lives without requiring replacement while miscellaneous cost of product sales (COPS) increased as the result of the addition of the medical device tax, which became effective in January 2013, in combination with an increase in property tax expense.

During the three months ended September 30, 2013 compared to the three months ended September 30, 2012, the increase in the cost of product sales for the GliaSite RTS related products was segregated from cost of product sales related to brachytherapy seed production. GliaSite RTS cost of product sales increased primarily as the result of increased materials consumed in producing the products which created the additional GliaSite RTS revenue.

Key operating factors

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Depreciation & amortization (Seeds)	$ 172,315	$ 200,783	$ (28,468)	(14)%
Miscellaneous COPS (Seeds)	39,539	2,312	37,227	1,610 %
Other COPS (Seeds)	872,480	858,322	14,158	2 %
GliaSite RTS	42,889	15,240	27,649	181 %
Total cost of product sales	$ 1,127,223	$ 1,076,657	$ 50,566	5 %

Gross (loss). Gross loss for the three months ended September 30, 2013 increased compared to the three months ended September 30, 2012 primarily as a result of the addition of the medical device tax, an increase in property tax and an increase in the production costs of the GliaSite RTS, which was partially offset by a decrease in depreciation and amortization.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Gross loss	$ (77,308)	$ (20,425)	$ (56,883)	(279)%
Gross loss percentage	(7)%	(2)%		

Research and development. Research and development costs increased by an immaterial amount in the three months ended September 30, 2013 compared to the three months ended September 30, 2012 primarily as a result of changes in three key operating factors that net to an immaterial increase in cost.

During the three months ended September 30, 2013, research and development expense increased as the result of increased spending on protocol expenses which was partially offset by a decrease in payroll, benefits and share-based compensation expense, primarily as the result of option grants that have reached the end of their amortization, and a decrease in other organ research when compared to the three months ended September 30, 2012.

Key operating factors

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)	
Total research and development	$ 146,990	$ 141,472	$ 5,518	4	%

Sales and marketing expenses. Sales and marketing expenses increased overall during the three months ended September 30, 2013 compared to the three months ended September 30, 2012 primarily as the result of the change in a single operating factor.

The single operating factor that influenced the increase in sales and marketing expenses was the maintenance of a sales force at the levels established at the end of the fiscal year ended June 30, 2013 during the three months ended September 30, 2013 when compared to the three months ended September 30, 2012.

Key operating factors

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)	
Payroll, benefits and share-based compensation expense	$ 237,059	$ 197,591	$ 39,468	20	%
Other sales – marketing expense	122,126	118,465	3,661	3	%
Total sales and marketing	$ 359,185	$ 316,056	$ 43,129	14	%

General and administrative expenses. General and administrative expenses increased by an immaterial amount in the three months ended September 30, 2013 compared to the three months ended September 30, 2012 primarily as a result of changes in two key operating factors that net to an immaterial increase in cost.

Payroll, benefits and share-based compensation expense increased primarily as the result of option grants made in the three months ended September 30, 2013 which was offset by a reduction in bad debt expense when compared to the three months ended September 30, 2012.

Key operating factors

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Total general and administrative	$ 651,036	$ 644,853	$ 6,183	1 %

Operating loss. Operating loss for the three months ended September 30, 2013 increased compared to the three months ended September 30, 2012 primarily as a result of an increase in both cost of product sales and in sales and marketing expenses.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Operating loss	$ (1,234,519)	$ (1,122,806)	$ (111,713)	10%

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 liability requires periodic evaluation for changes in fair value. As required at September 30, 2013, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model and applied updated inputs as of those dates. The resulting change in fair value was recorded as of September 30, 2013.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Change in fair value of warrant derivative liability	$ (36,000)	$ 129,000	$ (165,000)	(128)%

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the three months ended September 30, 2013 and September 30, 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. Management continued to maintain or reduce the controllable cash consumed in operating activities through maintaining a combination of cost reductions and operational efficiencies that were previously identified and implemented in operations, however, the net loss increased during the three months ended September 30, 2013 when compared to the three months ended September 30, 2012. The key items that created the increase in the net loss were from cost of production, of which approximately 70% of the increase was related to the addition of the medical device tax and an increase in property tax expense, from sales and marketing which was attributable to the additional payroll and tax expense and travel expense which increased with the additional number of sales people in the field, and from the change in fair value of the warrant liability derivative.

The net loss was adjusted by an increase in both the non-cash items and non-cash changes in operating assets and liabilities, resulted in an overall decrease in net cash used by operating activities for the three months ended September 30, 2013 when compared to the three months ended September 30, 2012.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)	
Net loss	$ (1,270,906)	$ (993,668)	$ (277,238)	28	%
Non-cash items	271,311	181,326	89,985	50	%
Non-cash changes in operating assets and liabilities	107,574	(126,287)	233,861	(185)	)%
Net cash used by operating activities	$ (892,021)	$ (938,629)	$ 46,608	(5)	)%

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Cash flows from investing activities

Cash used by investing activities during the three months ended September 30, 2013 and in the three months ended September 30, 2012 was immaterial and primarily related to the acquisition of fixed assets, the amortization of licenses and other assets and the increase in restricted cash.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	Variance ($)	Variance (%)
Purchases of fixed assets	$ (2,041)	$ -	$ (2,041)	100%
Additions to licenses and other assets	(2,572)	(6,827)	4,255	(62)%
Change in restricted cash	(18)	(42)	24	(57)%
Net cash used by investing activities	$ (4,631)	$ (6,869)	$ 2,238	(33)%

Cash flows from financing activities

Cash provided by financing activities in the three months ended September 30, 2013 and September 30, 2012 was the result of sales of common and preferred stock in two public offerings, through warrant exercises, and through option exercises.

Key operating factor

Description	Three months ended 09-30-2013	Three months ended 09-30-2012	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	3,301,514	(1,500,057)	(45)%
Net cash provided by financing activities	$ 3,280,888	$ 3,301,514	$ (20,626)	(1)%

Projected Fiscal Year 2014 Liquidity and Capital Resources

At September 30, 2013, the Company held cash and cash equivalents of $5,284,163 as compared to $2,899,927 at June 30, 2013.

The Company had approximately $4.91 million of cash and cash equivalents and no short-term investments as of November 12, 2013. The Company's monthly required cash operating expenditures were approximately $297,000 during the three months ended September 30, 2013, which represents a 5% decrease of approximately $16,000 in average monthly cash operating expenditures from the three months ended September 30, 2012. Management forecasts that cash consumed in operations will be similar to the prior fiscal year for the remainder of the current fiscal year, however, this is largely impacted by the realized revenue and the timing of payments being received from our customers. 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 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 $180,000 in expense will be incurred during fiscal year 2014 related to protocol expenses relating to lung cancer, inter-cranial cancer and both dual therapy and mono therapy 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 cash and cash equivalents of approximately $4.91 million on hand at November 12, 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 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. Neither sales in the prostate market nor increases in the other markets have shown the increases necessary to breakeven during the past six fiscal years and sales in the prostate market continued to decrease during the three months ended September 30, 2013.

For the three months ended September 30, 2013, revenue from other treatment modalities with brachytherapy seeds and GliaSite RTS has increased 13% when compared to the three months ended September 30, 2012. 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 only increased by approximately 32% during the three months ended September 30, 2013 when compared to the three months ended September 30, 2012.

These non-prostate brachytherapy treatments are in the early stages of application in the clinical setting and the purchasing patterns are subject to the influence of a few key physicians which can significantly influence revenue from quarter to quarter.

There was no material change in the use of proceeds from our public offerings as described in our final prospectus supplements filed with the SEC pursuant to Rule 424(b) on July 17, 2012 and August 29, 2013. Through September 30, 2013, the Company had used the net proceeds raised through the July 2012 and August 2013 offerings as described in the table below and held the remaining net proceeds in cash and cash equivalents. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Offering description	Period	Net proceeds	Remaining net proceeds
Registered direct offering	July 2012	$ 3,291,977	$ 2,001,450
Underwritten offering	August 2013	3,280,888	3,280,888
		$ 6,572,865	$ 5,282,338

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. 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 September 30, 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 remediating the single deficiency which constituted a material weakness identified in its Form 10-K for the fiscal year ended June 30, 2013.

Progress made on this remediating the single deficiency which constituted a material weakness in the three months ended September 30, 2013 is as follows:

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

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the accompanying unaudited interim consolidated financial statements for the three months ended September 30, 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, 2013.

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

Use of Proceeds from Registered Securities

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

There was no material change in the use of proceeds from the July 17, 2012 registered public offering closing for the July 2012 registered public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 17, 2012. Through September 30, 2013, we had begun to use the net proceeds from this registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) and had invested all remaining net proceeds in cash and cash equivalents.

On May 13, 2013, we filed a registration statement on Form S-3 to register securities up to $20 million in value for future issuance in our capital raising activities. The registration statement became effective on June 14, 2013 and the Commission file number assigned to the registration statement is 333-188579.

There was no material change in the use of proceeds from the August 29, 2013 public offering closing for the August 2013 underwritten public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on August 29, 2013. Through September 30, 2013, we had not begun to use the net proceeds from this underwritten 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.

The proceeds used during the three months ended September 30, 2013 were from the July 17, 2012 registered public offering and no proceeds from the August 29, 2013 underwritten offering were used.

Proceeds used in the three months ended September 30, 2013:

Indirect payments to directors and officers for database development	$6,840
Direct payments of compensation to directors	33,000
Direct payments of salaries to officers	163,399
Working capital	693,413
Total proceeds used in the three months ended September 30, 2013:	$896,652

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: November 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, Chief Financial Officer
(Principal Financial and Accounting Officer)