IsoRay, Inc.
Form 10-Q
November 14, 2012

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, 2012

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 (State or other jurisdiction of incorporation or organization)	41-1458152 (I.R.S. Employer Identification No.)
350 Hills St., Suite 106, Richland, Washington (Address of principal executive offices)	99354 (Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

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

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

Smaller reporting company 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, 2012
Common stock, $0.001 par value	34,597,717

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries

Consolidated Balance Sheets

	(Unaudited) September 30, 2012	June 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$5,028,727	$2,672,711
Accounts receivable, net of allowance for doubtful accounts of $109,076 and $57,604, respectively	845,098	865,056
Inventory	410,464	444,345
Other receivables	11,140	9,925
Prepaid expenses and other current assets	200,948	144,116
Total current assets	6,496,377	4,136,153
Fixed assets, net of accumulated depreciation and amortization	2,210,460	2,416,853
Restricted cash	181,069	181,027
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	301,439	301,691
Total assets	$9,659,103	$7,505,482
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	347,606	389,105
Accrued radioactive waste disposal	64,000	52,000
Accrued payroll and related taxes	73,457	119,881
Accrued vacation	93,322	88,006
Total current liabilities	578,385	648,992
Warrant derivative liability	185,000	314,000
Asset retirement obligation	740,717	724,298
Total liabilities	1,504,102	1,687,290

Commitments and contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,000,000 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Common stock, $.001 par value; 193,000,000 shares authorized; 34,597,717 and 30,950,108 shares issued and outstanding	34,598	30,950
Treasury stock, at cost 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	57,357,140	54,030,311
Accumulated deficit	(49,228,406)	(48,234,738)
Total shareholders' equity	8,155,001	5,818,192
Total liabilities and shareholders' equity	$9,659,103	$7,505,482

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,	
	2012	2011
Product sales	$1,056,232	$1,213,417
Cost of product sales	1,076,657	1,147,075
Gross profit / (loss)	(20,425)	66,342
Operating expenses:		
Research and development expenses	141,472	251,314
Research and development reimbursement	-	(50,000)
Sales and marketing expenses	316,056	314,418
General and administrative expenses	644,853	652,927
Total operating expenses	1,102,381	1,168,659
Operating loss	(1,122,806)	(1,102,317)
Non-operating income (expense):		
Interest income	144	187
Change in fair value of warrant derivative liability	129,000	-
Financing and interest expense	(6)	(94)
Non-operating income / (expense) , net	129,138	93
Net loss	(993,668)	(1,102,224)
Preferred stock dividends	(2,658)	(2,658)
Net loss applicable to common shareholders	$(996,326)	$(1,104,882)
Basic and diluted loss per share	$(0.03)	$(0.04)
Weighted average shares used in computing net loss per share:		
Basic and diluted	33,866,563	26,487,140

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,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (993,668)	$ (1,102,224)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	51,472	46,165
Depreciation and amortization of fixed assets	206,393	216,806
Amortization of deferred financing costs and other assets	7,079	6,714
Change in fair value of warrant derivative liabilities	(129,000)	-
Accretion of asset retirement obligation	16,419	15,011
Share-based compensation	28,963	33,189
Changes in operating assets and liabilities:		
Accounts receivable	(31,514)	(225,759)
Inventory	33,881	(12,057)
Other receivables	(1,215)	406,537
Prepaid expenses, other current assets and other assets	(56,832)	(70,703)
Accounts payable and accrued expenses	(41,499)	176,545
Accrued protocol expense	-	3,378
Accrued radioactive waste disposal	12,000	8,307
Accrued payroll and related taxes	(46,424)	(52,346)
Accrued vacation	5,316	8,351
Net cash used by operating activities	(938,629)	(542,086)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	-	(6,795)
Additions to licenses and other assets	(6,827)	(9,001)
Change in restricted cash	(42)	(71)
Net cash used by investing activities	(6,869)	(15,867)
CASH FLOWS FROM FINANCING ACTIVITIES:		
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	40,244
Proceeds from cash sales of common stock, pursuant to exercise of options	7,746	
Net cash provided by financing activities	3,301,514	40,244
Net increase (decrease) in cash and cash equivalents	2,356,016	(517,709)

Cash and cash equivalents, beginning of period	2,672,711	2,112,254
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 5,028,727	$ 1,594,545
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 6	$ 94

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, 2012 and 2011

1. Basis of Presentation

The accompanying consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries (IsoRay or the Company). All significant intercompany accounts and transactions have been eliminated in consolidation. Certain amounts in the prior-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, 2012.

The results of operations for the periods presented may not be indicative of those which may be expected for a full year. The unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been condensed or omitted pursuant to those rules and regulations, although we believe that the disclosures are adequate for the information not to be misleading.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, the reported amounts of revenues and expenses during the reporting period and the disclosures of contingent liabilities. Accordingly, ultimate results could differ materially from those estimates. The Company anticipates that as the result of continuing operating losses and the significant net operating losses available from prior fiscal years, its effective income tax rate for fiscal year 2013 will be 0%.

2. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standards setting bodies that are adopted by us as of the specified effective dates. Unless otherwise discussed, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position, results of operations and cash flows upon adoption.

3. Loss per Share

Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. At September 30, 2012 and 2011, 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, 2012 and 2011, were as follows:

	September 30,	
	2012	2011
Preferred stock	59,065	59,065
Common stock warrants	1,957,133	3,784,185
Common stock options	2,325,772	2,318,706
Total potential dilutive securities	4,341,970	6,161,956

4. Inventory

Inventory consisted of the following at September 30, 2012 and June 30, 2012:

	September 30, 2012	June 30, 2012
Raw materials	$ 142,640	$261,835
Work in process	218,408	114,124
Finished goods	49,416	68,386
	$ 410,464	$444,345

5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2012 and 2011:

	Three months ended September 30,	
	2012	2011
Cost of product sales	$ 10,164	$ 12,090
Research and development expenses	8,718	7,630
Sales and marketing expenses	1,659	2,605
General and administrative expenses	8,422	10,864
Total share-based compensation	$ 28,963	$ 33,189

As of September 30, 2012, total unrecognized compensation expense related to stock-based options was $138,388 and the related weighted-average period over which it is expected to be recognized is approximately 0.86 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2012 were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Aggregate Remaining Contractual Term (Years)	Average Intrinsic Value
Outstanding at September 30, 2012	2,325,772	$ 1.81	5.38	$253,608
Vested and expected to vest at September 30, 2012	2,232,855	$ 1.86	5.33	$230,622
Vested and exercisable at September 30, 2012	2,050,764	$ 1.92	5.10	$251,308

	Outstanding	Vested and expected to vest	Vested and exercisable
Beginning of period- 06-30-12	2,381,306	2,283,968	2,102,964
Forfeited	(37,534)	(32,480)	(34,200)
Exercised	(18,000)	(18,633)	(18,000)
End of period – 09-30-12	2,325,772	2,232,855	2,050,764

There were 18,000 options exercised during the three months ended September 30, 2012 and no options exercised during the three months ended September 30, 2011. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised was $ 11,400.

No stock option awards were granted during the three months ended September 30, 2012 and 2011.

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, 2012 and June 30, 2012, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Description	Balance at September 30, 2012	Balance at June 30, 2012	Input Hierarchy Level
Assets:			
Cash and cash equivalents	$ 5,028,727	$ 2,672,711	Level 1
Restricted cash	181,069	181,027	Level 1
Liabilities:			
Warrant derivative liability	$ 185,000	$ 314,000	Level 2

8. Preferred Dividends

On December 16, 2011, 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, 2011 in the amount of $10,632. Dividends on the Series B Preferred Stock were last paid on December 30, 2011 as declared by the Board of Directors on December 16, 2011 in the amount of $10,632. The dividends outstanding and cumulative through December 31, 2011 of $10,632 and through December 31, 2010 of $10,632 were paid as of those dates.

As of September 30, 2012, there were accrued but undeclared dividends on Series B Preferred Stock outstanding in the amount of $7,974.

9. Shareholders' Equity

Common stock transactions

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

cash after expenses.

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

Warrant liability and related offering cost deferral

Based on the guidance contained in ASC 815 “Derivatives and Hedging”, management has concluded that the warrants issued in the October 13, 2011 underwritten registered offering of 2,500,000 shares of common stock should be classified as a derivative liability and has recorded a liability at fair value. The Company determined the fair value of the warrants using the Black-Scholes fair value model. The Company determined the fair value of the warrants on the date of the offering to be as disclosed in the tables below. The Company has recognized a change in the change in fair value of $129,000 in the three months ended September 30, 2012.

The inputs to the Black-Scholes fair value model are listed in the table below:

Issue Date	Type	Quantity	Initial Fair Value
10/19/2011	Purchaser Warrants	500,003	$ 343,000
10/19/2011	Underwriter Warrants	150,000	103,000
12/07/2011	Purchaser Warrants	63,598	38,000
Total		713,601	$ 484,000

Transaction Date	Description	Quantity[1]	Stock Price	Exercise Price	Est. Term	Expected Volatility	Risk-Free Rate	Valuation
10/19/2011	Registered offering	650,003	$0.900	$ 1.058	3	141.07 %	0.460 %	$446,000
12/31/2011	Fair Value Adjust.	650,003	0.660	1.058	3	129.98	0.360	(156,000)
03/31/2012	Fair Value Adjust.	650,003	0.480	1.058	2.48	85.20	0.510	(194,445)
06/30/2012	Fair Value Adjust.	650,003	1.010	1.058	2.30	78.04	0.345	190,445
09/30/2012	Fair Value Adjust.	650,003	0.720	1.049	2.05	85.02	0.278	(118,000)
Fair value of warrant liability from registered direct offering:								$168,000

Transaction Date	Description	Quantity[1]	Stock Price	Exercise Price	Est. Term	Expected Volatility	Risk-Free Rate	Valuation
12/07/2011	Over-allotment	63,598	$0.820	$ 1.058	3	133.00 %	0.360 %	$ 38,000
12/31/2011	Fair Value Adjust.	63,598	0.660	1.058	3	129.98	0.360	(10,000)
03/31/2012	Fair Value Adjust.	63,598	0.480	1.058	2.48	85.20	0.510	(18,650)
06/30/2012	Fair Value Adjust.	63,598	1.010	1.058	2.44	77.16	0.345	18,650
09/30/2012	Fair Value Adjust.	63,598	0.720	1.049	2.19	84.53	0.278	(11,000)
Fair value of warrant liability from over-allotment offering:								$ 17,000

Total fair value of warrant liability at September 30, 2012: $ 185,000

[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.

Weighted average

	Warrants	exercise price
Outstanding as of June 30, 2012	1,959,799	$ 1.3800
Warrants exercised	(2,666)	0.6715
Outstanding as of September 30, 2012	1,957,133	$ 1.3800

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

10. Related Party Transaction

During the three months ended September 30, 2012 and 2011, 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, 2012 and 2011 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 $4,960 and $5,200 respectively.

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

Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under "Risk Factors" under Part II, Item 1A below and in the "Risk Factors" section of our Form 10-K for the fiscal year ended June 30, 2012 that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the

Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, 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 28, 2012 are those that depend most heavily on these judgments and estimates. As of September 30, 2012, there had been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2012 compared to three months ended September 30, 2011.

Revenues. The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole, however, the strategy implemented by management in the prior year in diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to mitigate some of the decreased revenue from the prostate segment of the business. 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. During the three months ended September 30, 2012, the Company had one of the physicians that utilized brachytherapy seeds in the treatment of lung cancer take an extended amount of leave, decreasing that physician's purchases compared to the three months ended September 30, 2011. There was increased utilization of brachytherapy seeds in the treatment of brain cancer by physicians that were not using the treatment during the three months ended September 30, 2011. 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.

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.

The Company made the first U.S. sales of its recently FDA cleared GliaSite Radiation Therapy System (GliaSite RTS) for use in clinical treatment during the three months ended December 31, 2011. During the three months ended September 30, 2012, 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. In April 2012, the Company received its CE mark clearing its and its distributor's ability to sell and distribute the GliaSite RTS in the European Union. The initial sale of GliaSite RTS related components into the European Union was made in July 2012 to the Company's distributor Karlheinz Goehl-Medizintechnik Goehl based in Germany.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Product Sales (Prostate)	$ 881,856	$ 1,096,728	$ (214,872)	(20)%
Product Sales (Brain)	24,574	-	24,574	100 %
Product Sales (Lung)	64,100	94,826	(30,726)	(32)%
Product Sales (GliaSite)	60,804	-	60,804	100 %
Product Sales (Other)	24,898	21,863	3,035	14 %
Total product sales	$ 1,056,232	$ 1,213,417	$ (157,185)	(13)%

Cost of product sales.

The cost of product sales for the production of brachytherapy seeds decreased in the three months ended September 30, 2012 when compared to the three months ended September 30, 2011. The decrease in brachytherapy seed cost of products was influenced by five key operating factors, which were depreciation and amortization, material cost, payroll and benefits cost, pre-loading expense and other costs.

Depreciation and amortization expense decreased as assets utilized in production reached the end of their useful lives without requiring replacement, materials cost decreased primarily as the result of using the traditional blend of isotope sources during the current quarter as well as a reduced consumption of production supplies, inventory and other costs as well as a reduced cost of pre-loading seeds as production was decreased in response to the reduction in revenue. A partial offset of the reduction in cost of product sold was an increase in payroll and benefits expense primarily as there was not an allocation of labor related to research and development expense to that department.

The cost of product sales for the GliaSite RTS related products was segregated from cost of product sales related to brachytherapy seed production during the three months ended September 30, 2012. Sales of the GliaSite RTS products and related production did not begin until the three months ended December 31, 2011.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Material	$ 418,773	$ 499,017	$ (80,244)	(16)%
Payroll and benefits	228,357	176,600	51,757	29 %

Pre-load	75,395	100,653	(25,258	)	(25)%
Depreciation	200,783	218,017	(17,234	)	(8)%
Other cost of product sales (Seeds)	138,109	152,788	(14,679	)	(10)%
GliaSite RTS	15,240	-	15,240		100 %
Total cost of product sales	$ 1,076,657	$ 1,147,075	$ (70,418	)	(6)%

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Gross profit / (loss). Gross profit for the three month period ended September 30, 2012 decreased compared to the three month period ended September 30, 2011 primarily as a result of the decreased brachytherapy seed revenue from prostate cancer treatment and the addition of the production costs of the GliaSite RTS.

Key operating factor

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Gross profit / (loss)	$ (20,425)	$ 66,342	$ (86,767)	(131)%
Gross profit percentage	(2)%	5 %		

Research and development. Research and development costs were decreased by three key operating factors for the three months ended September 30, 2012 compared to the three months ended September 30, 2011. Key operating factors consisting of other organ research expense, protocol expense and payroll and benefits expense decreased in the three months ended September 30, 2012.

Research and development expense decreased primarily as the result of a decrease in protocol activity as some efforts have reached their conclusion, payroll and benefits expense decreased as fewer production staff were being used on research and development projects resulting in decreased cost being transferred from other departments and other organ research expense was reduced as the result of projects reaching their conclusion.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Other organ research expense	11,636	25,143	(13,507)	(54)%
Protocol expense	16,858	37,789	(20,931)	(55)%
Payroll and benefits expense	69,246	142,820	(73,574)	(52)%
Other research - development expense	43,732	45,562	(1,830)	(4)%
Total research and development	$ 141,472	$ 251,314	$ (109,842)	(44)%

Research and development reimbursement. The research and development reimbursement was influenced by a single key operating factor for the three months ended September 30, 2012 compared to the three months ended September 30, 2011. This key operating factor was the existence of a reimbursement from the European GliaSite RTS

distributor for the reimbursement of some research and development expenses related to returning the GliaSite RTS to market which was completed in the fiscal year ended June 30, 2012.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Research and development reimbursement	$ -	$ (50,000)	$ 50,000	(100)%
Total research and development reimbursement	$ -	$ (50,000)	$ 50,000	(100)%

Sales and marketing expenses. Sales and marketing expenses increased overall by an immaterial amount in the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily as the result of changes in three operating factors.

The three operating factors that influenced the increase in sales and marketing expenses were conventions and tradeshows, as the sales force expanded the number of events that were attended in order to increase the number of new market segments to which the expanded product offerings were exposed, hiring expense increased as the Company replaced a salesperson, while payroll and benefits expense decreased as the result of the commission expense being reduced as a function of the decreased revenue.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Conventions and tradeshows	$ 16,892	$ 9,197	$ 7,695	84 %
Hiring expense	8,218	-	8,218	100 %
Payroll and benefits expense	197,591	213,031	(15,440)	(7)%
Other sales – marketing expense	93,355	92,190	1,165	1 %
Total sales and marketing	$ 316,056	$ 314,418	$ 1,638	1 %

General and administrative expenses. General and administrative expenses decreased by an immaterial amount in the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily as a result of changes in two key operating factors that net to an immaterial decrease in cost.

The primary changes in general and administrative expense are a decrease in legal expense that is partially offset by an increase in payroll and benefits expense and other general and administrative expense.

Legal expense during the three months ended September 30, 2012 compared to the three months ended September 30, 2011 decreased as the result of a non-recurring cost of legal services related to a financing that was not completed during the three months ended September 30, 2011. Payroll and benefits expense increased as the result of annual payroll changes, related payroll taxes and medical benefits.

Key operating factors

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Legal expense	$ 32,331	$ 69,143	$ (36,812)	(53)%
Payroll and benefits expense	279,012	265,254	15,344	6 %
General and administrative (Other)	333,510	318,530	14,980	5 %
Total general and administrative	$ 644,853	$ 652,927	$ (6,488)	(1)%

Operating loss. Operating loss for the three months ended September 30, 2012 increased compared to the three months ended September 30, 2011 as a result of decreased revenue generated from the sales of brachytherapy seeds for the treatment of prostate cancer with the addition of revenue from the GliaSite RTS partially mitigating that revenue decrease. The decrease in both cost of product sales and an overall reduction in research and development spending net of reimbursements led to an overall reduction in operating expenses.

Key operating factor

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Operating loss	$ (1,122,806)	$ (1,102,317)	$ (22,075)	2 %

Change in fair value of warrant derivative liability. During the three months ended September 30, 2012, 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, 2012, 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, 2012.

Key operating factor

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Change in fair value of warrant derivative liability	$ 129,000	$ -	$ 129,000	100 %

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the three months ended September 30, 2012 and September 30, 2011, 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 cash consumed in operating activities through maintaining a combination of cost reductions and operational efficiencies that have been previously identified in the results of operations that together resulted in a decrease in the net loss, which when increased by the non-cash items and non-cash changes in operating assets and liabilities, resulted in an overall increase in net cash used by operating activities for the three months ended September 30, 2012 when compared to the three months ended September 30, 2011. The three months ended September 30, 2011 included the collection of the grant receivable from the Internal Revenue Service in the non-cash changes in operating assets and liabilities which represents the difference in net cash used by operating activities between the three months ended September 30, 2012 and September 30, 2011. The net cash used in operating activities in three months ended September 30, 2012 and the three months ended September 30,

2011 would have been materially the same when the impact of the cash received from the IRS grant was removed from the three months ended September 30, 2011.

Key operating factor

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Net loss	$ (993,668)	$ (1,102,224)	$ 106,970	10 %
Non-cash items	181,326	317,885	(134,973)	(42)%
Non-cash changes in operating assets and liabilities	(126,287)	242,253	(368,540)	(152)%
Net cash used by operating activities	$ (938,629)	$ (542,086)	$ (396,543)	73 %

Cash flows from investing activities

Cash used by investing activities during the three months ended September 30, 2012 and in the three months ended September 30, 2011 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 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Purchases of fixed assets	$ -	$ (6,795)	$ 6,795	(100)%
Additions to licenses and other assets	(6,827)	(9,001)	2,174	(24)%
Change in restricted cash	(42)	(71)	29	(41)%
Net cash used by investing activities	$ (6,869)	$ (15,867)	$ 8,998	(57)%

Cash flows from financing activities

Cash provided by financing activities in the three months ended September 30, 2012 and September 30, 2011 was the result of sales of common stock in a registered direct offering, through warrant exercises, and through option exercises.

Key operating factor

Description	Three months ended 09-30-2012	Three months ended 09-30-2011	Variance ($)	Variance (%)
Proceeds from sale of common stock	$ 3,301,514	$ 40,244	$ 3,261,270	8,104 %
Net cash provided by financing activities	$ 3,301,514	$ 40,244	$ 3,261,270	8,104 %

Projected Fiscal Year 2013 Liquidity and Capital Resources

At September 30, 2012, the Company held cash and cash equivalents of $5,028,727 as compared to $2,672,711 at June 30, 2012.

The Company had approximately $4.83 million of cash and cash equivalents and no short-term investments as of November 9, 2012. The Company's monthly required cash operating expenditures were approximately $313,000 during the three months ended September 30, 2012, which represents a 73% increase of approximately $132,000 in average monthly cash operating expenditures from the three months ended September 30, 2011. The three months ended September 30, 2011 included the collection of the grant receivable from the Internal Revenue Service in the non-cash changes in operating assets and liabilities which represents the difference in net cash used by operating activities between the three months ended September 30, 2012 and September 30, 2011. Without the cash inflow in the three months ended September 30, 2011 from the grant receivable the cash consumed in operations would have been approximately $316,000. When adjusted for the cash from the grant receivable, the actual change is a decrease of $3,000 to $313,000 during the three months ended September 30, 2012. Management forecasts that cash consumed in operation will be similar to the prior fiscal year for the remainder of the 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 2013, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company intends to continue its existing protocol studies and to begin new protocol studies on lung cancer treatment using Cesium-131. The Company continues to believe that approximately $200,000 in expense will be incurred during fiscal year 2013 related to protocol expenses relating to lung cancer and 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 $4.83 million on hand at November 9, 2012 will be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements through at least the next twelve months assuming both revenue and expenses remain at current levels.

Management plans to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), increasing sales of 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. Sales in the prostate market have not shown the increases necessary to breakeven during the past five fiscal years and continued to decrease during the three months ended September 30, 2012.

For the three months ended September 30, 2012, revenue from other treatment modalities with brachytherapy seeds has decreased 3% when compared to the three months ended September 30, 2011. 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. When including the revenue from the sale of GliaSite RTS, revenue from non-prostate treatments increased 49% in the three months ended September 30, 2012 compared to the three months ended September 30, 2011.

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 November 24, 2010, December 28, 2010, October 13, 2011 and July 17, 2012. Through September 30, 2012, the Company had used the net proceeds raised through the November 2010 offering, October and December 2011 offering and the July 2012 offering as described in the table below and had invested 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	Nov 2010	$ 2,219,306	$ -
Registered direct offering	Oct & Dec 2011	2,274,486	900,162

Registered direct offering	July 2012	3,291,977	3,291,977
Total remaining net proceeds		$ 7,785,769	$ 4,192,139

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, 2012. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals

under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

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

The Company is continuing the process of developing and implementing the remediation plan to address the material weakness and significant deficiency identified in its Form 10-K for the fiscal year ended June 30, 2012.

Progress made on this plan in the three months ended September 30, 2012 is as follows:

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

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

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the consolidated financial statements for the three months ended September 30, 2012 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 from the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2012.

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

Use of Proceeds from Registered Securities

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

There was no material change in the use of proceeds from our October 2011 registered public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) on October 13, 2011. Through September 30, 2012, we had begun to use the net proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) and as further described in the table below, and invested the remaining net proceeds in cash and cash equivalents.

Proceeds used in the three months ended September 30, 2012:	
Indirect payments to directors and officers for database development	$4,960
Direct payments of compensation to directors	33,000

Direct payments of salaries to officers	187,059
Working capital	712,733
Total proceeds used in the three months ended September 30, 2012:	$937,752

There was no material change in the use of proceeds from the December 7, 2011 over-allotment closing for the October 2011 registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on October 13, 2011. Through September 30, 2012, we had not begun to use the net proceeds from this registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) and had invested all net proceeds in cash and cash equivalents.

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, 2012, we had not begun to use the net proceeds from this registered offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) and had invested all net proceeds in cash and cash equivalents.

On September 12, 2012, the holder of the Series C warrants issued in the November 2010 offering exercised Series C warrants in the exercise amount of $1,791 in exchange for 2,666 shares of common stock with an exercise price of $0.6715. As of September 30, 2012, none of the proceeds from the warrant exercise had been used.

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

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, 2012

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer
(Principal Executive Officer)

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