

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

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 February 06, 2013
Common stock, \$0.001 par value	34,611,517

ISORAY, INC.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1	Consolidated Unaudited Financial Statements	1
	Consolidated Balance Sheets	1
	Consolidated Statements of Operations (Unaudited)	2
	Consolidated Statements of Cash Flows (Unaudited)	3
	Notes to Unaudited Consolidated Financial Statements	4
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4	Controls and Procedures	22

PART II OTHER INFORMATION

Item 1A	Risk Factors	22
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 6	Exhibits	24
	Signatures	25

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

	(Unaudited)	
	December 31, 2012	June 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$4,440,703	\$2,672,711
Accounts receivable, net of allowance for doubtful accounts of \$44,127 and \$57,604, respectively	656,168	865,056
Inventory	402,912	444,345
Other receivables	8,011	9,925
Prepaid expenses and other current assets	228,368	144,116
Total current assets	5,736,162	4,136,153
Fixed assets, net of accumulated depreciation and amortization	2,028,682	2,416,853
Restricted cash	181,111	181,027
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	301,074	301,691
Total assets	\$8,716,787	\$7,505,482
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$393,225	\$389,105
Accrued protocol expense	13,750	-
Accrued radioactive waste disposal	76,000	52,000
Accrued payroll and related taxes	129,062	119,881
Accrued vacation	84,776	88,006
Total current liabilities	696,813	648,992
Warrant derivative liability	240,000	314,000
Asset retirement obligation	757,509	724,298
Total liabilities	1,694,322	1,687,290

Commitments and contingencies (Note 6)

Shareholders' equity:

Preferred stock, \$.001 par value; 7,000,000 shares authorized:

Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Common stock, \$.001 par value; 193,000,000 shares authorized; 34,611,517 and 30,950,108 shares issued and outstanding	34,612	30,950
Treasury stock, at cost, 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	57,378,917	54,030,311
Accumulated deficit	(50,382,733)	(48,234,738)
Total shareholders' equity	7,022,465	5,818,192
Total liabilities and shareholders' equity	\$8,716,787	\$7,505,482

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

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

	Three months ended December 31, 2012		Six months ended December 31, 2011	
	2012	2011	2012	2011
Product sales	\$ 975,457	\$ 1,228,655	\$ 2,031,689	\$ 2,442,072
Cost of product sales	1,134,083	1,029,757	2,210,740	2,176,832
Gross profit / (loss)	(158,626)	198,898	(179,051)	265,240
Operating expenses:				
Research and development expenses	149,176	189,661	290,648	440,975
Research and development reimbursement	-	-	-	(50,000)
Sales and marketing expenses	322,094	304,120	638,150	618,538
General and administrative expenses	469,559	497,168	1,114,412	1,150,095
Total operating expenses	940,829	990,949	2,043,210	2,159,608
Operating loss	(1,099,455)	(792,051)	(2,222,261)	(1,894,368)
Non-operating income (expense):				
Interest income	128	268	272	455
Change in fair value of warrant derivative liability	(55,000)	166,000	74,000	166,000
Financing and interest expense	-	(2,962)	(6)	(3,056)
Non-operating income / (expense), net	(54,872)	163,306	74,266	163,399
Net loss	(1,154,327)	(628,745)	(2,147,995)	(1,730,969)
Preferred stock dividends	(2,658)	(2,658)	(5,316)	(5,316)
Net loss applicable to common shareholders	\$ (1,156,985)	\$ (631,403)	\$ (2,153,311)	\$ (1,736,285)
Basic and diluted loss per share	\$ (0.03)	\$ (0.02)	\$ (0.06)	\$ (0.06)
Weighted average shares used in computing net loss per share:				
Basic and diluted	34,604,605	28,593,845	34,238,401	27,540,492

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

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

	Six months ended December 31,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,147,995)	\$ (1,730,969)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(13,477)	(4,020)
Depreciation and amortization of fixed assets	388,171	435,464
Amortization of deferred financing costs and other assets	14,024	16,390
Change in fair value of warrant derivative liability	(74,000)	(166,000)
Accretion of asset retirement obligation	33,211	30,362
Share-based compensation	57,789	66,379
Changes in operating assets and liabilities:		
Accounts receivable, gross	222,365	(32,009)
Inventory	41,433	(56,335)
Other receivables	1,914	405,287
Prepaid expenses and other current assets	(84,252)	34,682
Accounts payable and accrued expenses	4,120	(17,377)
Accrued protocol expense	13,750	(25,243)
Accrued radioactive waste disposal	24,000	24,000
Accrued payroll and related taxes	9,181	(4,808)
Accrued vacation	(3,230)	10,101
Net cash used by operating activities	(1,512,996)	(1,014,096)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	-	(18,048)
Additions to licenses and other assets	(13,407)	(9,491)
Change in restricted cash	(84)	(161)
Net cash used by investing activities	(13,491)	(27,700)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Preferred dividends paid	(10,632)	(10,632)
Proceeds from sales of common stock, pursuant to registered direct offering, net	3,291,977	2,279,701
Proceeds from sales of common stock, pursuant to exercise of warrants, net	1,825	40,244
Proceeds from sales of common stock, pursuant to exercise of options	11,309	1,352
Net cash provided by financing activities	3,294,479	2,310,665

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

Net increase in cash and cash equivalents	1,767,992	1,268,869
Cash and cash equivalents, beginning of period	2,672,711	2,112,254
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 4,440,703	\$ 3,381,123
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ 6	\$ 77
Non-cash investing and financing activities:		
Initial deferral of financing expense	\$ -	\$ 61,511
Initial fair value of warrant liabilities	\$ -	\$ 484,000

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

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three and six months ended December 31, 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-year financial statements have been reclassified to conform to the current year presentation.

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2012, as it may be amended from time to time.

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

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, the reported amounts of revenues and expenses during the reporting period and the disclosures of contingent liabilities. Accordingly, ultimate results could differ materially from those estimates.

2. New Accounting Pronouncements

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

3. Loss per Share

Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At December 31, 2012 and 2011, the calculation of diluted weighted average shares did not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2012 and 2011, were as follows:

	December 31,	
	2012	2011
Preferred stock	59,065	59,065
Common stock warrants	1,957,033	4,482,786
Common stock options	2,312,072	2,318,506
Total potential dilutive securities	4,328,170	6,860,357

4. Inventory

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

	December 31, 2012	June 30, 2012
Raw materials	\$ 130,889	\$261,835
Work in process	216,360	114,124
Finished goods	55,663	68,386
	\$ 402,912	\$444,345

In June 2007, the Company purchased \$469,758 of enriched barium that will be used in future production of its isotope. The enriched barium is held at an off-site storage location in Richland, Washington and was included in raw materials at June 30, 2011, and is now classified as inventory, non-current at June 30, 2012 and December 31, 2012. The Company reclassified the material based on revised plans of management for utilizing the material.

5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and six months ended December 31, 2012 and 2011:

Three months ended December 31,		Six months ended December 31,	
2012	2011	2012	2011

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

Cost of product sales	\$ 10,164	\$ 12,090	\$ 20,328	\$ 24,180
Research and development expenses	8,717	7,630	17,435	15,260
Sales and marketing expenses	1,523	2,606	3,182	5,211
General and administrative expenses	8,422	10,864	16,844	21,728
Total share-based compensation	\$ 28,826	\$ 33,190	\$ 57,789	\$ 66,379

As of December 31, 2012, total unrecognized compensation expense related to stock-based options was \$109,561 and the related weighted-average period over which it is expected to be recognized is approximately 0.79 years.

The Company currently provides stock-based compensation under three equity incentive plans approved by the Board of Directors. Options granted under each of the plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

A summary of stock options within the Company's share-based compensation plans as of December 31, 2012 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2012	2,312,072	\$ 1.82	5.12	\$ 283,372
Vested and expected to vest at December 31, 2012	2,221,210	1.87	5.07	\$ 258,411
Vested and exercisable at December 31, 2012	2,037,064	\$ 1.93	4.84	\$ 280,472

	Outstanding	Vested and expected to vest	Vested and exercisable
Beginning of period (June 30, 2012)	2,381,306	2,283,968	2,102,964
Forfeited	(37,534)	(35,480)	(36,422)
Exercised	(31,700)	(27,278)	(29,478)
End of period (December 31, 2012)	2,312,072	2,221,210	2,037,064

There were 31,700 options exercised during the six months ended December 31, 2012 and 5,200 options exercised during the six months ended December 31, 2011. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised during the six months ended December 31, 2012 and 2011 was \$ 13,866 and \$2,964, respectively.

No stock option awards were granted during the six months ended December 31, 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.

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 December 31, 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 December 31, 2012	Balance at June 30, 2012	Input Hierarchy Level
Assets:			
Cash and cash equivalents	\$ 4,440,703	\$ 2,672,711	Level 1
Restricted cash	181,111	181,027	Level 1
Liabilities:			
Derivative warrant liability	\$ 240,000	\$ 314,000	Level 2

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

8. Preferred Dividends

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

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 as described in the table below:

	Three months ended December 31, 2012	Six months ended December 31, 2012
Change in fair value	\$ (55,000) \$ 74,000

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.	650,033	0.720	1.049	2.05	85.02	0.278	(118,000)
12/31/2012	Fair Value Adjust.	650,003	0.780	1.049	1.81	100.96	0.220	50,000
Fair value of warrant liability from registered direct offering:								\$218,000

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)
12/31/2012	Fair Value Adjust.	63,598	0.78	1.049	1.941	98.25	0.220	5,000

Fair value of warrant liability from over-allotment offering:	\$ 22,000
Total fair value of warrant liability at December 31, 2012:	\$ 240,000

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, 2012	1,959,799	\$ 1.3800
Warrants exercised	(2,766)	0.6472
Outstanding as of December 31, 2012	1,957,033	\$ 1.3800

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

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

10. Related Party Transaction

During the six months ended December 31, 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 Board of Directors approved the use of the ongoing services of APEX Data Systems. Mr. Babcock recused himself due to his conflict of interest. The cost recorded during the six months ended December 31, 2012 and 2011 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection application was \$8,960 and \$5,200.

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

Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we

believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under “Risk Factors” under Part II, Item 1A below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2012 that may cause actual results to differ materially.

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

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 28, 2012 are those that depend most heavily on these judgments and estimates. As of December 31, 2012, there had been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended December 31, 2012 compared to three months ended December 31, 2011.

Revenues.

Prostate Brachytherapy.

The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole. Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity-Modulated Radiation Therapy (IMRT) and robotic-assisted surgery but that combination treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have the potential to continue to increase.

Other Brachytherapy including Brain and Lung.

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 partially mitigate the lost revenue from the prostate brachytherapy segment. The timeline of developing and bringing new products from concept to revenue

production in the pharmaceutical/medical device segment is lengthy and is typically measured in years. The probability of any new cancer treatment product reaching the stage at which it produces revenue is very low.

Company management has been investing in development of alternative uses for the Company's brachytherapy seed that management believes have the ability to generate revenue in the near-term to offset development costs. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible. The products being implemented by the Company are very dependent on first adopters as a source of revenue, and there is initially a steep growth in revenue that will reach a plateau due to capacity until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. Management strategy includes soliciting the use of other applications for the Company's brachytherapy seeds at major medical institutions that are more likely to publish their outcomes and that are training the next generation of decision makers. Company management intends to actively pursue alternative uses for the Company's brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments.

GliaSite Radiation Therapy System.

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

During the three months ended December 31, 2012, a customer returned five catheters that had been purchased as part of a sale of six catheters for a procedure performed in the three months ended September 30, 2012. The Company historically has sold catheters in sets of six (two of each size) to its customers with all the catheters to be paid up front and the unused catheters to be held by the hospital in its inventory for future use. Typically, the hospital will replace the consumed catheter to have on-hand two of each size in its inventory for use in its next procedure. As there were no sales of product in the three months ended December 31, 2012, the return of these catheters resulted in an overall reduction in revenue.

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 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$ 840,819	\$ 1,037,867	\$ (197,048)	(19)%
Product Sales (Brain)	33,868	46,220	(12,352)	(27)%
Product Sales (Lung)	108,865	83,953	24,912	30 %
Product Sales (GliaSite)	(15,750)	34,035	(49,785)	(146)%
Product Sales (Other)	7,655	26,580	(18,925)	(71)%
Total product sales	\$ 975,457	\$ 1,228,655	\$ (253,198)	(21)%

Cost of product sales.

Cost of product sales was influenced to a large degree by two key operating factors, amortization and depreciation expense and material cost, while overall costs increased approximately 10% or \$104,000 during the three months ended December 31, 2012 compared to the three months ended December 31, 2011.

The two key operating factors that changed in the three months ended December 31, 2012 as compared to the three months ended December 31, 2011 were amortization and depreciation expense and materials expense. Amortization and depreciation expense decreased as the direct result of fixed assets reaching the end of their depreciable lives. During the three months ended December 31, 2012, materials cost increased primarily as a result of the Company's Russian isotope supplier providing a non-recurring reduction in both quantity and cost of isotope during the three months ended December 31, 2011 which was not provided in the three months ended December 31, 2012. Management negotiated this temporary reduction in isotope cost during the three months ended December 31, 2011 to allow the Company to recover the additional isotope cost that was incurred during the three months ended September 30, 2011 as the result of an unscheduled outage at the Russian supplier's reactor facility that resulted in the Company having to build an inventory of irradiated Ba-130 to supply a volume of Cs-131 to cover the supply shortfall.

Key operating factors

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Amortization and depreciation	\$ 176,403	\$ 216,615	\$ (40,212)	(19)%
Materials	472,692	361,764	110,928	31 %
Other cost of product sales (Seeds)	463,811	431,200	32,611	8 %
GliaSite RTS	21,177	20,178	999	5 %
Total cost of product sales	\$ 1,134,083	\$ 1,029,757	\$ 104,326	10 %

Gross profit/(loss). Gross profit for the three months ended December 31, 2012 decreased compared to the three month period ended December 31, 2011 as a result of reduced revenue from product sales combined with an increase in isotope cost as the result of the non-recurring reduction in isotope cost that was recorded in the three months ended December 31, 2011 which was partially offset by a decrease in amortization and depreciation expense. Management continues to seek to control variable costs, however, at this time most remaining production costs are of a fixed nature and related to minimum personnel costs to meet peak demand orders.

Key operating factor

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Gross profit / (loss)	\$ (158,626)	\$ 198,898	\$ (357,524)	(180)%
Gross profit / (loss) percentage	(16)%	16 %		

Research and development. Research and development costs were influenced by a single key operating factor for the three months ended December 31, 2012 compared to the three months ended December 31, 2011. This key operating

factor was payroll and benefit expense which decreased as the result of a decrease in payroll and benefits expense through the decrease in allocation of salary, tax and benefits expenses from other operating departments toward research and development projects.

Key operating factors

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Payroll and benefit expense	\$ 74,927	\$ 100,808	\$ (25,881)	(26)%
Research and development (Other)	74,249	88,853	(14,604)	(16)%
Total research and development	\$ 149,176	\$ 189,661	\$ (40,485)	(21)%

12

Sales and marketing expenses. Sales and marketing expenses increased in the three months ended December 31, 2012 compared to the three months ended December 31, 2011 primarily as the result of a single operating factor.

This single operating factor influencing the increase in sales and marketing expenses was payroll and benefits expense which includes share-based compensation which was primarily created by the increased number of sales employees in the field during the three months ended December 31, 2012 when compared to the three months ended December 31, 2011.

Key operating factors

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)	
Payroll and benefits	\$ 209,330	\$ 190,047	\$ 19,283	10	%
Sales and marketing (Other)	112,764	114,073	(1,309)	(1)%
Total sales and marketing	\$ 322,094	\$ 304,120	\$ 17,974	6	%

General and administrative expenses. General and administrative expenses decreased in the three months ended December 31, 2012 compared to the three months ended December 31, 2011 with no individual expense creating the overall decrease in cost.

Key operating factors

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)	
General and administrative (Other)	\$ 469,559	\$ 497,168	\$ (27,609)	(6)%
Total general and administrative	\$ 469,559	\$ 497,168	\$ (27,609)	(6)%

Operating loss. Operating loss for the three months ended December 31, 2012 increased compared to the three months ended December 31, 2011. The increase in cost was primarily as a result of the continued decrease in product sales from prostate brachytherapy coupled with an increase in materials cost as the result of the temporary and non-recurring discount on isotope cost from the Company's Russian supplier that only occurred in the three months ended December 31, 2011, which was partially offset by the decrease in operating expenses.

Key operating factor

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Operating loss	\$ (1,099,455)	\$ (792,051)	\$ (307,404)	39 %

Interest income. Interest income for the three months ended December 31, 2012 was reduced compared to the three months ended December 31, 2011 as a direct result of reduced cash and cash equivalent balances when coupled with reduced short-term interest rates.

Key operating factor

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Interest income	\$ 128	\$ 268	\$ (140)	(52)%

Change in fair value of warrant liability. During the three months ended December 31, 2012 and December 31, 2011, there were warrant liabilities established upon issuance of warrants during October 2011 and December 2011 to the purchasers and underwriters in the Company's registered public offering and warrants issued to the purchaser in the Company's registered public offering during November 2010. Per ASC 820, the warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2012 and December 31, 2011, the Company evaluated the fair value of the warrant liability using the Black-Scholes option pricing model on which the original warrant liability was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of December 31, 2012 and December 31, 2011.

Key operating factor

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Change in fair value of warrant liability	\$ (55,000)	\$ 166,000	\$ (221,000)	(133)%

Financing and interest expense. Financing and interest expense for the three months ended December 31, 2012 decreased when compared to the three months ended December 31, 2011 as a direct result of the October 2011, December 2011 and November 2010 equity transactions and their related amortization of deferred offering costs throughout the life of the warrant liability.

Key operating factor

Description	Three months ended 12-31-12	Three months ended 12-31-11	Variance (\$)	Variance (%)
Deferred financing expense	\$ -	\$ (2,962)	\$ 2,962	100 %
Total financing and interest expense	\$ -	\$ (2,962)	\$ 2,962	100 %

Six months ended December 31, 2012 compared to six months ended December 31, 2011.

Revenues.

Prostate Brachytherapy.

The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole. Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity-Modulated Radiation Therapy (IMRT) and robotic-assisted surgery but that combination treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have the potential to continue to increase.

Other Brachytherapy including Brain and Lung.

During the six months ended December 31, 2012, the strategy implemented by management in the prior year of diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to partially mitigate the lost revenue from the prostate brachytherapy segment which in total remains unchanged from the six months ended December 31, 2011. The timeline of developing and bringing new products from concept to revenue production in the pharmaceutical/medical device segment is lengthy and is typically measured in years. The probability of any new cancer treatment product reaching the stage at which it produces revenue is very low.

Company management has been investing in development of alternative uses for the Company's brachytherapy seed that management believes have the ability to generate revenue in the near-term to offset the development costs. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible. The products being implemented by the Company are very dependent on first adopters as a source of revenue, and there is initially a steep growth in revenue that will reach a plateau due to capacity until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. Management strategy includes soliciting the use of other applications for the Company's brachytherapy seeds at major medical institutions that are more likely to publish their outcomes and that are training the next generation of decision makers. Company management intends to actively pursue alternative uses for the Company's brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments.

GliaSite Radiation Therapy System.

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

During the six months ended December 31, 2012, revenue from the GliaSite RTS has increased by approximately 32% or \$11,000 compared to the six months ended December 31, 2011. The timeline of developing and bringing new products from concept to revenue production in the pharmacy – medical device segment is lengthy, typically measured in years, and the success rate for each product reaching the stage at which it produces revenue is very low. The GliaSite RTS is in the early stages of adoption and the Company is actively soliciting medical institutions to serve as the first adopters to facilitate the wider adoption of the product. The conversion of prospects to new GliaSite RTS customers has been a longer process than was 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	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$ 1,722,675	\$ 2,134,345	\$ (411,670)	(19)%
Product Sales (Brain)	58,442	62,171	(3,729)	(6)%
Product Sales (Lung)	172,865	178,779	(5,914)	(3)%

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

Product Sales (GliaSite)	45,054	34,035	11,019	32	%
Product Sales (Other)	32,653	32,742	(89)	0
Total product sales	\$ 2,031,689	\$ 2,442,072	\$ (410,383)	(17)%

15

Cost of product sales. Cost of product sales related to brachytherapy seed sales increased for the six months ended December 31, 2012 compared to the six months ended December 31, 2011. Two cost segments that largely offset each other were a decrease in depreciation and amortization and an increase in payroll and benefits expense as detailed in the table below. Depreciation and amortization expense decreased as the result of fixed assets reaching the end of their depreciable lives which was offset by an increase in payroll and benefits as the result of a reduced allocation of cost to research and development costs. Cost of product sales related to the GliaSite RTS segment increased as the result of an expired inventory of catheters being expensed in the six months ended December 31, 2012 when compared to the six months ended December 31, 2011.

Key operating factors

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Depreciation and amortization	\$ 377,186	\$ 434,632	\$ (57,446)	(13)%
Payroll and benefits	441,596	373,982	67,614	18 %
Cost of product sales (Other)	1,354,992	1,347,928	7,064	1 %
GliaSite RTS	36,966	20,290	16,676	82 %
Total cost of product sales	\$ 2,210,740	\$ 2,176,832	\$ 33,908	2 %

Gross profit/(loss). Gross profit for the six month period ended December 31, 2012 decreased compared to the six month period ended December 31, 2011 primarily as a result of the previously discussed reduction in sales in the prostate market, a lack of continued growth in the sales of non-prostate applications and inability to decrease fixed costs required regardless of revenue levels. Most remaining production costs are of a fixed nature and related to minimum personnel costs required to meet peak demand orders.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Gross profit / (loss)	\$ (179,051)	\$ 265,240	\$ (444,291)	(168)%
Gross profit / (loss) percentage	(9)%	11 %		

Research and development. Research and development costs were decreased by three key operating factors for the six months ended December 31, 2012 compared to the six months ended December 31, 2011. The first key operating factor was payroll and benefits which decreased as a result of the cost of production staff no longer being used in research and development on projects. The second key operating factor was protocol expense which decreased as the result of the Company having a temporary no cost period on one of the protocol agreements. The third key operating

factor that decreased was other organ research cost, as the significant effort that was undertaken in the six months ended December 31, 2011 in the areas of brain and lung applications did not recur in the six months ended December 31, 2012. During the six months ended December 31, 2012 and December 31, 2011, the Company accrued protocol costs in accordance with its agreements with participating facilities.

Key operating factors

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)	
Payroll and benefits	\$ 144,173	\$ 243,628	\$ (99,455)	(41)%
Other organ research	12,486	39,469	(26,983)	(68)%
Protocol expense	41,191	64,746	(23,555)	(36)%
Research and development (Other)	92,798	93,132	(334)	0	%
Total research and development	\$ 290,648	\$ 440,975	\$ (150,327)	(34)%

Research and development reimbursement. Research and development reimbursement costs were influenced by a single key operating factor for the six months ended December 31, 2012 compared to the six months ended December 31, 2011. This key operating factor was a reimbursement recorded in the amount of \$50,000 in the six months ended December 31, 2011 that did not recur in the six months ended December 31, 2012. This reimbursement amount represents the amount of cost sharing that was negotiated with the future distributor of the GliaSite RTS. This amount was invoiced and received from the future distributor during the three months ended September 30, 2011 even though the distribution agreement was not executed until October.

Key operating factors

Description	Six months ended 12-31-12	Six months ended 12-31-11	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 in the six months ended December 31, 2012 compared to the six months ended December 31, 2011 with no individual expense creating the overall increase in cost as shown in the table below.

Key operating factors

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)	
Sales and marketing (Other)	\$ 638,150	\$ 618,538	\$ 19,612	3	%
Total sales and marketing	\$ 638,150	\$ 618,538	\$ 19,612	3	%

General and administrative expenses. General and administrative expenses decreased in the six months ended December 31, 2012 compared to the six months ended December 31, 2011 primarily as a result of one key operating factor. The key operating factor was legal expense which decreased due to the Company's due diligence and negotiation of various potential alternative additional equity investments in the Company that did not result in an equity investment and which resulted in additional legal costs being charged to current period expense instead of being netted against an equity investment in the six months ended December 31, 2011.

Key operating factors

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Legal expense	\$ 65,346	\$ 100,797	\$ (35,451)	(35)%
General and administrative (Other)	1,049,066	1,049,298	(232)	0 %
Total general and administrative	\$ 1,114,412	\$ 1,150,095	\$ (35,683)	(3)%

Operating loss. Operating loss for the six months ended December 31, 2012 increased compared to the six months ended December 31, 2011 primarily as a result of reduced sales and an increase in cost of product sales, partially offset by an overall decrease in operating expenses.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Operating loss	\$ (2,222,261)	\$ (1,894,368)	\$ (327,893)	17 %

Interest income. Interest income for the six months ended December 31, 2012 was reduced compared to the six months ended December 31, 2011 as a direct result of reduced cash and cash equivalent balances when coupled with reduced short-term interest rates.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Interest income	\$ 272	\$ 455	\$ (183)	(40)%

Change in fair value of warrant liability. During the six months ended December 31, 2012 and December 31, 2011, there were warrant liabilities established upon issuance of warrants to the purchasers and underwriters in the Company's registered public offering during October 2011 and December 2011 and the registered public offering during November 2010. Per ASC 820, the warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2012 and December 31, 2011, the Company evaluated the fair value of the warrant liability using the Black-Scholes option pricing model on which the original warrant liability was based and applied updated inputs as of those dates. The resulting change in fair value was recorded as of December 31, 2012 and December 31,

2011.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Change in fair value of warrant liability	\$ 74,000	\$ 166,000	\$ (92,000)	(55)%

Financing and interest expense. Financing and interest expense for the six months ended December 31, 2012 decreased when compared to the six months ended December 31, 2011 as a direct result of the October 2011, December 2011 and November 2010 equity transactions and the related amortization of deferred offering costs throughout the life of the warrant liability.

18

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Interest expense	\$ 6	\$ 94	\$ (88)	(94)%
Deferred financing expense	-	2,962	(2,962)	(100)%
Total financing and interest expense	\$ 6	\$ 3,056	\$ (3,050)	(100)%

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the six months ended December 31, 2012 and December 31, 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. The increase in net cash used in operating activities for the six months ended December 31, 2012 when compared to the six months ended December 31, 2011 is primarily the result of the increased net loss that is primarily the result of decreased revenues. Management has continued to maintain prior reductions of expenses that consumed cash in operating activities through a combination of cost reductions and operational efficiencies that were previously identified and implemented in operations. The remaining increase in cash used by operating activities is the net of an increase from the changes in operating assets and liabilities partially reduced by the decrease in non-cash operating expenses.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Net loss	\$ (2,147,995)	\$ (1,730,969)	\$ (417,026)	24 %
Non-cash items	405,718	378,575	27,143	7 %
Non-cash changes in operating assets and liabilities	229,281	338,298	(109,017)	(32)%
Net cash used by operating activities	\$ (1,512,996)	\$ (1,014,096)	\$ (498,900)	49 %

Cash flows from investing activities

Cash used by investing activities during the six months ended December 31, 2012 was primarily related to the capitalization of costs related to other assets and in the six months ended December 31, 2011 was primarily that required to bring the GliaSite RTS to market.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Purchases of fixed assets	\$ -	\$ (18,048)	\$ 18,048	(100)%
Additions to licenses and other assets	(13,407)	(9,491)	(3,916)	41 %
Change in restricted cash	(84)	(161)	77	(48)%
Net cash used by investing activities	\$ (13,491)	\$ (27,700)	\$ 14,209	(51)%

Cash flows from financing activities

Cash provided by financing activities in the six months ended December 31, 2012 and December 31, 2011 was the result of sales of common stock in a registered direct offering through warrant exercises and option exercises. Cash used during the six months ended December 31, 2012 was the result of dividend payments to the preferred shareholders. Cash used during the six months ended December 31, 2011 was the result of dividend payments to the preferred shareholders.

Key operating factor

Description	Six months ended 12-31-12	Six months ended 12-31-11	Variance (\$)	Variance (%)
Preferred dividend payments	\$ (10,632)	\$ (10,632)	\$ -	0 %
Proceeds from sale of common stock	3,305,111	2,321,297	983,814	42 %
Net cash provided by financing activities	\$ 3,294,479	\$ 2,310,665	\$ 983,814	43 %

Projected Fiscal Year 2013 Liquidity and Capital Resources

At December 31, 2012, the Company held cash and cash equivalents of \$4,440,703 as compared to \$2,672,711 of cash and cash equivalents at June 30, 2012.

The Company had approximately \$4.06 million of cash and cash equivalents and no short-term investments as of February 5, 2013. The Company's monthly required cash operating expenditures were approximately \$252,000 in the six months ended December 31, 2012, which represents a 49% increase or approximately \$83,000 from average monthly cash operating expenditures in the six months ended December 31, 2011. The increased use of cash in operating activities of approximately \$499,000 is primarily the result of the increased net loss of approximately \$417,000 which was driven by the continued decrease in revenue from prostate treatments of approximately \$412,000. Management believes that less than \$100,000 will be spent on capital expenditures during the final six months of 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 and inter-cranial cancer treatments using Cesium-131 brachytherapy seeds and the GliaSite Radiation Therapy System. 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, inter-cranial cancer and both dual therapy and mono therapy prostate cancer protocols, but there is no assurance that unanticipated needs for additional protocols in support of the

development of new applications of our existing products may not arise.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments of approximately \$4.06 million on hand at February 5, 2013 will be sufficient to meet our anticipated cash requirements for operations and capital expenditure requirements through at least the next twelve months.

Management plans to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), increasing sales of the Company's GliaSite RTS, expanding into other market applications which initially will include inter-cranial, head and neck, and lung implants, while maintaining the Company's focus on cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain increases in its revenue. Sales in the prostate market have not shown the increases necessary to breakeven during the past five fiscal years and continued to decrease during the six months ended December 31, 2012.

For the six months ended December 31, 2012, revenue from other treatment modalities with brachytherapy seeds has decreased by 4% when compared to the six months ended December 31, 2011. When including the revenue from the sale of GliaSite RTS, revenue from non-prostate treatments is unchanged in the six months ended December 31, 2012 compared to the six months ended December 31, 2011. As management is focused on increasing revenue from head and neck, colorectal, lung and brain applications of Cesium-131 brachytherapy seeds in addition to increasing the number of cases treated with of the GliaSite RTS, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it works to gain market share.

Offering description	Period	Net proceeds	Remaining net proceeds
Registered direct offering	November 2010	\$ 2,219,306	\$ -
Registered direct offering	October / December 2011	2,274,486	312,105
Registered direct offering	July 2012	3,291,977	3,291,977
Total remaining proceeds		\$ 7,785,769	\$ 3,604,082

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

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

The Company has no off-balance sheet arrangements.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 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 six months ended December 31, 2012 is as follows:

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

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

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

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the consolidated financial statements for the three and six months ended December 31, 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 for the risk factors disclosed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2012, except as follows:

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

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

Use of Proceeds from Registered Securities

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

There was no material change in the use of proceeds from our October 2011 public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b) on October 13, 2011. Through December 31, 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.

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 December 31, 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 the 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 as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on July 17, 2012. Through December 31, 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 December 31, 2012, none of the proceeds from the warrant exercise had been used.

On November 26, 2012, the holder of the Series C warrants issued in the November 2010 offering exercised Series C warrants in the exercise amount of \$34.92 in exchange for 100 shares of common stock with an exercise price of \$0.3497. As of December 31, 2012, none of the proceeds from the warrant exercise had been used.

Proceeds used in the six months ended December 31, 2012:

Indirect payments to directors and officers for database maintenance and development	\$7,960
Direct payments of compensation to directors	66,000
Direct payments of salaries to officers	352,393
Working capital	1,099,456
Total proceeds used in the six months ended December 31, 2012	\$1,525,809

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: February 14, 2013

ISORAY, INC., a Minnesota corporation

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

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