

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

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

xQUARTERLY Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended December 31, 2013

or

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

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota 41-1458152
(State or other jurisdiction of incorporation or (I.R.S. Employer
organization) Identification No.)

350 Hills St., Suite 106, Richland, Washington 99354
(Address of principal executive offices) (Zip Code)

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

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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 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 No

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

Large accelerated filer Accelerated filer Non-accelerated filer

Smaller reporting company

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

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

<u>Class</u>	<u>Outstanding as of February 6, 2014</u>
Common stock, \$0.001 par value	41,540,982

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries

Consolidated Balance Sheets

	(Unaudited)	
	December	June 30,
	31,	2013
	2013	2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$4,414,572	\$2,899,927
Accounts receivable, net of allowance for doubtful accounts of \$32,515 and \$52,598, respectively	917,222	923,780
Inventory	426,333	405,571
Other receivables	10,064	11,502
Prepaid expenses and other current assets	156,365	202,880
Total current assets	5,924,556	4,443,660
Fixed assets, net of accumulated depreciation and amortization	1,349,469	1,684,282
Restricted cash	181,181	181,149
Inventory, non-current	469,758	469,758
Other assets, net of accumulated amortization	262,698	276,507
Total assets	\$8,187,662	\$7,055,356
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$430,293	\$432,566
Accrued protocol expense	46,973	25,305
Accrued radioactive waste disposal	124,000	100,000
Accrued payroll and related taxes	141,082	127,419
Accrued vacation	104,932	107,578
Total current liabilities	847,280	792,868
Warrant derivative liability	23,000	104,000
Asset retirement obligation	828,568	792,242

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Total liabilities	1,698,848	1,689,110
Commitments and contingencies (Note 6)		
Shareholders' equity:		
Preferred stock, \$.001 par value; 7,001,671 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series D: 1,671 and 0 shares allocated; 1,670 & 0 shares issued and outstanding	2	-
Common stock, \$.001 par value; 192,998,329 & 193,000,000 shares authorized; 38,419,502 and 34,618,517 shares issued and outstanding	38,420	34,618
Treasury stock, at cost, 13,200 shares	(8,390)	(8,390)
Additional paid-in capital	60,747,935	57,431,293
Accumulated deficit	(54,289,212)	(52,091,334)
Total shareholders' equity	6,488,814	5,366,246
Total liabilities and shareholders' equity	\$8,187,662	\$7,055,356

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,		Six months ended December 31,	
	2013	2012	2013	2012
Product sales	\$ 1,085,408	\$ 975,457	\$ 2,135,323	\$ 2,031,689
Cost of product sales	1,119,314	1,134,083	2,246,537	2,210,740
Gross loss	(33,906)	(158,626)	(111,214)	(179,051)
Operating expenses:				
Research and development expenses	170,030	149,176	317,020	290,648
Sales and marketing expenses	326,467	322,094	685,652	638,150
General and administrative expenses	513,964	469,559	1,165,000	1,114,412
Total operating expenses	1,010,461	940,829	2,167,672	2,043,210
Operating loss	(1,044,367)	(1,099,455)	(2,278,886)	(2,222,261)
Non-operating income (expense):				
Interest income	481	128	835	272
Change in fair value of warrant derivative liability	117,000	(55,000)	81,000	74,000
Financing and interest expense	(86)	-	(827)	(6)
Non-operating income / (expense), net	117,395	(54,872)	81,008	74,266
Net loss	(926,972)	(1,154,327)	(2,197,878)	(2,147,995)
Preferred stock deemed dividends (Note 9)	-	-	(726,378)	-
Preferred stock dividends	(2,658)	(2,658)	(5,316)	(5,316)
Net loss applicable to common shareholders	\$ (929,630)	\$ (1,156,985)	\$ (2,929,572)	\$ (2,153,311)
Basic and diluted loss per share	\$ (0.02)	\$ (0.03)	\$ (0.08)	\$ (0.06)
Weighted average shares used in computing net loss per share:				
Basic and diluted	38,419,502	34,604,605	37,133,875	34,238,401

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,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(2,197,878)	\$(2,147,995)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	(20,083)	(13,477)
Depreciation and amortization of fixed assets	349,232	388,171
Amortization of deferred financing costs and other assets	15,371	14,024
Change in fair value of warrant derivative liability	(81,000)	(74,000)
Accretion of asset retirement obligation	36,326	33,211
Share-based compensation	51,786	57,789
Changes in operating assets and liabilities:		
Accounts receivable, gross	26,641	222,365
Inventory	(20,762)	41,433
Other receivables	1,438	1,914
Prepaid expenses and other current assets	46,515	(84,252)
Accounts payable and accrued expenses	(2,273)	4,120
Accrued protocol expense	21,668	13,750
Accrued radioactive waste disposal	24,000	24,000
Accrued payroll and related taxes	13,663	9,181
Accrued vacation	(2,646)	(3,230)
Net cash used by operating activities	(1,738,002)	(1,512,996)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(14,419)	-
Additions to licenses and other assets	(1,562)	(13,407)
Change in restricted cash	(32)	(84)
Net cash used by investing activities	(16,013)	(13,491)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Preferred dividends paid	(10,632)	(10,632)
Proceeds from sales of preferred stock, pursuant to underwritten offering, net	1,478,712	-
Proceeds from sales of common stock, pursuant to underwritten offering, net	1,800,580	-
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	-	1,825
Proceeds from sales of common stock, pursuant to exercise of options	-	11,309

Net cash provided by financing activities	3,268,660	3,294,479
Net increase in cash and cash equivalents	1,514,645	1,767,992
Cash and cash equivalents, beginning of period	2,899,927	2,672,711
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$4,414,572	\$4,440,703

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, 2013 and 2012

1. Basis of Presentation

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

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2013, 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, 2013 and 2012, the calculation of diluted weighted average shares did not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities, presented on an as-converted to common stock basis, not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2013 and 2012, were as follows:

	December 31,	
	2013	2012
Series B preferred stock	59,065	59,065
Series D preferred stock	3,121,480	-
Common stock warrants	7,605,771	1,957,033
Common stock options	2,370,072	2,312,072
Total potential dilutive securities	13,156,388	4,328,170

4. Inventory

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

	December 31, 2013	June 30, 2013
Raw materials	\$ 168,731	\$ 167,671
Work in process	212,726	195,323
Finished goods	44,876	42,577
Total inventory	\$ 426,333	\$ 405,571

5. Share-Based Compensation

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

	Three months ended December 31, 2013		Six months ended December 31, 2012	
	2013	2012	2013	2012
Cost of product sales	\$4,499	\$10,164	\$8,921	\$20,328
Research and development expenses	3,482	8,717	6,965	17,435
Sales and marketing expenses	879	1,523	1,757	3,182
General and administrative expenses	4,572	8,422	34,141	16,844

Total share-based compensation	\$13,432	\$28,826	\$51,784	\$57,789
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As of December 31, 2013, total unrecognized compensation expense related to stock-based options was \$42,626 and the related weighted-average period over which it is expected to be recognized is approximately 0.82 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, 2013 was as follows:

	Average Number of Options	Weighted Remaining Exercise Price	Weighted Average Aggregate Contractual Term	Intrinsic Value
Outstanding at December 31, 2013	2,370,072	\$ 1.79	4.57	\$ 125,884
Vested and expected to vest at December 31, 2013	2,278,260	\$ 1.84	4.50	\$ 114,801
Vested and exercisable at December 31, 2013	2,080,064	\$ 1.90	4.13	\$ 125,784

There were no options exercised during the six months ended December 31, 2013 and 31,700 options exercised during the six months ended December 31, 2012. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised during the six months ended December 31, 2012 was \$13,866.

There were 65,000 stock option awards granted and no stock option awards granted during the six months ended December 31, 2013 and 2012, respectively.

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

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

6. Commitments and Contingencies

Patent and Know-How Royalty License Agreement

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

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

7. Fair Value Measurements

The table below sets forth the Company’s financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2013 and June 30, 2013, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Description	Balance at December 31, 2013	Balance at June 30, 2013	Input Hierarchy Level
Assets:			
Cash and cash equivalents	\$4,414,572	\$2,899,927	Level 1
Restricted cash	181,181	181,149	Level 1
Liabilities:			
Warrant liability	\$23,000	\$104,000	Level 2

8. Preferred Dividends

On December 19, 2013, the Board of Directors declared a dividend on the Series B Preferred Stock of all currently payable and accrued outstanding and cumulative dividends through December 31, 2013 in the amount of \$10,632. Dividends on the Series B Preferred Stock were last paid on December 31, 2012 as declared by the Board of Directors on December 21, 2012 in the amount of \$10,632. The dividends outstanding and cumulative through December 31, 2013 of \$10,632 and through December 31, 2012 of \$10,632 were paid as of those dates.

9. Shareholders’ Equity

Common and preferred stock transactions

On August 29, 2013, the Company entered into an agreement to sell 3,800,985 common units, each consisting of 1 share of common stock and a warrant to purchase 0.816 shares of common stock (the “Common Units”), and 1,670 preferred units, each consisting of 1 share of Series D Convertible Preferred Stock and a warrant to purchase 1,525.23

shares of common stock (the "Preferred Units") on a firm commitment underwritten basis. The Common Units were sold at an initial per unit purchase price of \$0.535 and the Preferred Units were sold at an initial per unit purchase price of \$1,000. The warrants are all exercisable at \$0.72 per share, are callable, and have a twenty-four month term, with the exercise price and term subject to reduction if shareholder approval is obtained, and are not exercisable until March 1, 2014. Each share of the Series D Convertible Preferred Stock is convertible into 1,869.15 shares of common stock at any time at the option of the holder, subject to adjustment, provided that the holder will be prohibited from converting Series D Convertible Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with affiliates, would own more than 9.99% of the total shares of the Company's common stock then issued and outstanding. The preferred shares which are convertible into shares of common stock contain a beneficial conversion feature of \$726,378 which was recognized as a deemed dividend to the Series D preferred shareholders on the date of issuance. This public offering resulted in gross proceeds of \$3.7 million. The offering yielded approximately \$3,279,292 in cash after expenses.

Series D

Series D convertible preferred shares are entitled to dividends in the same form as dividends actually paid on shares of common stock. Series D convertible preferred shares are convertible into shares of common stock at the rate of 1,869.15 shares of common stock for each share of Series D convertible preferred stock (subject to adjustment as provided in the certificate of designation for the Series D Convertible Preferred Stock), and are subject to conversion limitations if the conversion would result in the holder together with its affiliates, beneficially owning more than 9.99% of the total number of shares of our common stock then issued and outstanding. Series D convertible preferred shareholders shall not have the right to vote on any matter other than those set forth in the Certificate of Designation with the potential to specifically adversely affect the Series D Convertible Preferred Stock.

Upon the execution of a fundamental transaction which effects a merger or other change of control transaction of the Company a holder will have the right to receive, upon any subsequent conversion of a share of Series D Convertible Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such fundamental transaction if it had been, immediately prior to such fundamental transaction, the holder of the shares of common stock into which such holder's shares of Series D Convertible Preferred Stock is then convertible.

Gross proceeds from public offering	\$3,703,527
Underwriting discount	(185,176)
Legal and accounting expense	(184,514)
Listing expense	(48,500)
Other expense	(6,045)
Net proceeds	3,279,292

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 fair value as described in the table below:

Change in fair value of the derivative warrant liability for the three months ended December 31, 2013 and 2012, respectively.

	Three months ended December 31, 2013	Three months ended December 31, 2012
Change in fair value	\$ (117,000) \$ 55,000

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on October 19, 2011.

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	Three months ended December 31, 2013		Three months ended December 31, 2012	
	Quantity ¹	Amount	Quantity ¹	Amount
Balance, beginning of period	650,003	\$127,000	650,003	\$168,000
Change in fair value	650,003	(107,000)	650,003	50,000
Warrants exercised	-	-	-	-
Balance, end of period	650,003	\$20,000	650,003	\$218,000

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on December 7, 2011.

	Three months ended December 31, 2013		Three months ended December 31, 2012	
	Quantity ¹	Amount	Quantity ¹	Amount
Balance, beginning of period	63,598	\$13,000	63,598	\$17,000
Change in fair value	63,598	(10,000)	63,598	5,000
Warrants exercised	-	-	-	-
Balance, end of period	63,598	\$3,000	63,598	\$22,000
Total fair value of warrant derivative liability at December 31, 2013 and 2012		\$23,000		\$240,000

Change in fair value of the derivative warrant liability for the six months ended December 31, 2013 and 2012, respectively.

	Six months ended December 31, 2013	Six months ended December 31, 2012
Change in fair value	\$(81,000)	\$(74,000)

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on October 19, 2011.

Six months ended Six months ended

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	December 31, 2013		December 31, 2012	
	Quantity ¹	Amount	Quantity ¹	Amount
Balance, beginning of period	650,003	\$94,000	650,003	\$286,000
Change in fair value	650,003	(74,000)	650,003	(68,000)
Warrants exercised	-	-	-	-
Balance, end of period	650,003	\$20,000	650,003	\$218,000

Change in fair value of the derivative warrant liability for purchaser warrants and underwriter warrants contained in an equity transaction on December 7, 2011.

	Six months ended December 31, 2013		Six months ended December 31, 2012	
	Quantity ¹	Amount	Quantity ¹	Amount
Balance, beginning of period	63,598	\$ 10,000	63,598	\$ 28,000
Change in fair value	63,598	(7,000)	63,598	(6,000)
Warrants exercised	-	-	-	-
Balance, end of period	63,598	\$ 3,000	63,598	\$ 22,000
Total fair value of warrant derivative liability at December 31, 2013 and 2012		\$ 23,000		\$ 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, 2013	1,957,033	\$ 1.38
Warrants issued	5,648,738	0.72
Outstanding as of December 31, 2013	7,605,771	\$ 0.89

Warrants outstanding as of December 31, 2013

Quantity	Expiration date	Exercise price
6,000	June 8, 2015	\$ 1.18
25,000	July 27, 2015	2.00
5,648,738	August 25, 2015	0.72
1,207,832	November 21, 2015	1.56
650,003	October 19, 2016	1.043
63,198	December 7, 2016	1.043
5,000	June 27, 2017	0.98
7,605,771		\$ 0.89

10. Related Party Transaction

During the six months ended December 31, 2013 and 2012, the Company continued to engage the services of APEX Data Systems, Inc., owned by Dwight Babcock, the Company's Chairman and Chief Executive Officer, to modify and maintain the Company's web interfaced data collection application to aggregate patient data in a controlled environment. The Audit Committee and Board of Directors approved the use of the ongoing services of APEX Data Systems. Mr. Babcock recused himself from the Board vote due to his conflict of interest. The cost recorded during the six months ended December 31, 2013 and 2012 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection application was \$9,720 and \$8,960, respectively. An additional \$6,000 was spent on the implementation of Customer Relationship Management software in the six months ended December 31, 2013.

11. Subsequent Event

In January 2014, the holder of the 1,670 shares of Series D convertible preferred stock fully exercised its right to convert the 1,670 shares of Series D convertible preferred stock into 3,121,480 shares of common stock which resulted in an increase in shares of common stock outstanding from 38,419,502 to 41,540,982. Subsequent to the conversion, no shares of Series D convertible preferred stock remain outstanding.

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

Caution Regarding Forward-Looking Information

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

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words “believe,” “expect,” “anticipate,” “intends,” “estimate,” “forecast,” “project,” and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under “Risk Factors” under Part II, Item 1A below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2013 that may cause actual results to differ materially.

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

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 30, 2013 are those that depend most heavily on these judgments and estimates. As of December 31, 2013, there had been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended December 31, 2013 compared to three months ended December 31, 2012.

Revenues. During the three months ended December 31, 2013, total revenue increased from the three months ended December 31, 2012. Revenue generated by prostate brachytherapy and non-prostate related treatments which is described below as Product Sales – (Other) both increased. The increase in revenue from prostate brachytherapy treatments is the result of a new physician being added to a key physician group that resulted in nearly doubling of revenue at an existing treatment facility and the addition of a new treatment facility at which the new physician treated a significant volume of patients as well. While the overall revenue produced by Product Sales – (Other) continued to increase in the three months ended December 31, 2013 when compared to the three months ended December 31, 2012, there continued to be significant variances in utilization of the GliaSite® Radiation Therapy System (the “GliaSite RTS”) and in treating brain cancer and lung cancer with brachytherapy seeds. The newer brachytherapy product sales reported as “other” represent more developmental applications of our product which may not lead to either a long-term revenue source or a significant product line and therefore revenue fluctuation in this segment is expected to be subject to more significant variation from quarter to quarter. Company management intends to actively pursue alternative uses for the Company’s brachytherapy seeds in treatments consistent with the FDA clearance granted permitting the Company to utilize other FDA cleared application methods as a means of administering the treatments. New treatments such as those being initiated by the Company can be expected to experience a staged entry to market in which primary adopters demonstrate the suitability of a treatment, after which wider adoption is possible. The products being implemented by the Company are very dependent on first adopters as a source of revenue which assists in offsetting some of the developmental cost, and there is initially a significant change in revenue period over period that is expected to reach a plateau due to treatment capacity and quantity of cases available to the first adopters until the mainstream adoption occurs, when and if there is favorable publication of the experiences and treatment outcomes of the first adopters. However, to date the Company has only experienced minimal sales to first adopters. Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity –Modulated Radiation Therapy (IMRT) and Robotics but management believes that combining treatments incorporating brachytherapy with other modalities in the prostate, the addition of new treatment facilities and treatment of other body sites with brachytherapy have the potential to continue to increase revenue. During the three months ended December 31, 2013 and 2012, respectively, all product sales were generated by the brachytherapy seeds and the related methods of application except for the revenue generated by the sales of GliaSite RTS which include the sale of the Iotrex solution, catheter trays and access trays. The conversion of prospects to new GliaSite RTS customers has been a longer process than originally anticipated by the Company. The Company has experienced lengthy timelines in the internal processes of the medical facilities in reviewing and approving the use of the product at the request of their physician(s). These longer than anticipated internal processes are compounded by uncertain timelines and delays in receiving the approval for the requested modification of each facility's nuclear materials license, which is required to begin using GliaSite RTS and is dependent on external government regulators.

Key operating factors

Description	Three months ended 12-31-13	Three months ended 12-31-12	Variance (\$)	Variance (%)
Product Sales (Prostate)	\$937,296	\$840,819	\$96,477	11%
Product Sales (Other)	148,112	134,638	13,474	10%
Total product sales	\$1,085,408	\$975,457	\$109,951	11%

Cost of product sales.

Cost of product sales nominally decreased during the three months ended December 31, 2013 compared to the three months ended December 31, 2012.

The two key operating factors that changed significantly in the three months ended December 31, 2013 as compared to the three months ended December 31, 2012 were the addition of the medical device tax and an increase in production costs of the GliaSite RTS. The addition of the medical device tax expense was the result of the implementation of the Affordable Care Act in calendar year 2013. The increase in the GliaSite RTS production costs was the result of additional Iotrex solution required to meet the increased revenue. Additionally, there was a reduction in overall pre-loading costs through a reduction in third-party loading cost, as the Company is loading nearly 100% of its orders in-house, and an improved utilization of pre-loading materials. There was a reduction in other expense as the result of six months property tax expense being recorded during the three months ended December 31, 2012 while there was three months expense recorded during the three months ended December 31, 2013. Nominal changes in other categories of seed production expenses are summarized as Other cost of product sales (Seeds).

Key operating factors

Description	Three months ended 12-31-13	Three months ended 12-31-12	Variance (\$)	Variance (%)
Medical device tax expense	\$23,612	\$-	\$23,612	100%
Pre-loading production expense	64,147	80,033	(15,886)	(20%)
Other expense	17,784	32,547	(14,763)	(45%)
Other cost of product sales (Seeds)	975,589	998,477	(22,888)	(2%)
GliaSite RTS	38,182	23,026	15,156	66%
Total cost of product sales	\$1,119,314	\$1,134,083	\$(14,769)	(1%)

Gross loss. Gross loss for the three months ended December 31, 2013 decreased compared to the three month period ended December 31, 2012 as a result of increased revenue from product sales reduced by a minimal increase in cost of product sales. Management continued 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 12-31-13	Three months ended 12-31-12	Variance (\$)	Variance (%)
Gross loss	\$ (33,906)			