

IsoRay, Inc.  
Form 10-Q  
February 09, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**Quarterly Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended December 31, 2015

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)

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was

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required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

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

Yes x No "

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

Large accelerated filer " Accelerated filer x 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 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 8, 2016
Common stock, \$0.001 par value	55,013,553

**ISORAY, INC.**

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**PART I – FINANCIAL INFORMATION****ITEM 1 – FINANCIAL STATEMENTS****IsoRay, Inc. and Subsidiaries****Consolidated Balance Sheets**

	(Unaudited)	
	December 31, 2015	June 30, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 678,906	\$ 5,226,740
Certificates of deposit (Note 3)	11,918,558	9,362,574
Accounts receivable, net of allowance for doubtful accounts of \$30,000 and 30,000, respectively	975,342	1,049,041
Inventory	476,749	403,955
Other receivables	8,715	19,615
Prepaid expenses and other current assets	224,819	263,597
<b>Total current assets</b>	<b>14,283,089</b>	<b>16,325,522</b>
Fixed assets, net of accumulated depreciation		
Certificates of deposit, non-current (Note 3)	335,753	574,840
Restricted cash	5,163,615	5,106,775
Inventory, non-current	181,277	181,262
Other assets, net of accumulated amortization	547,287	569,854
	233,011	245,031
<b>Total assets</b>	<b>\$ 20,744,032</b>	<b>\$ 23,003,284</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 681,312	\$ 498,253
Accrued protocol expense	78,703	124,131
Accrued radioactive waste disposal	153,500	129,500
Accrued payroll and related taxes	72,545	212,795
Accrued vacation	92,653	127,515
<b>Total current liabilities</b>	<b>1,078,713</b>	<b>1,092,194</b>

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Long-term liabilities:		
Warrant derivative liability	123,000	181,000
Asset retirement obligation	991,310	947,849
Total liabilities	2,193,023	2,221,043
Commitments and contingencies (Note 8)		
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 shares allocated; no shares issued and outstanding	-	-
Common stock, \$.001 par value; 192,998,329 shares authorized; 55,013,553 and 54,967,559 shares issued and outstanding	55,014	54,968
Treasury stock, at cost, 13,200 shares	(8,390 )	(8,390 )
Additional paid-in capital	82,566,531	82,467,111
Accumulated deficit	(64,062,205 )	(61,731,507)
Total shareholders' equity	18,551,009	20,782,241
Total liabilities and shareholders' equity	\$ 20,744,032	\$ 23,003,284

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,	
	2015	2014	2015	2014
Product sales	\$ 1,189,008	\$ 1,065,585	\$ 2,450,330	\$ 2,107,686
Cost of product sales	1,162,097	1,103,549	2,339,960	2,200,452
Gross profit / (loss)	26,911	(37,964 )	110,370	(92,766 )
Operating expenses:				
Research and development	58,235	140,627	202,138	317,237
Sales and marketing	254,471	303,783	532,892	657,526
General and administrative	1,124,683	537,940	1,876,395	1,113,891
Total operating expenses	1,437,389	982,350	2,611,425	2,088,654
Operating loss	(1,410,478 )	(1,020,314 )	(2,501,055 )	(2,181,420 )
Non-operating income (expense):				
Interest income	55,890	72,360	113,307	145,055
Change in fair value of warrant derivative liability	43,000	41,000	58,000	347,000
Financing and interest expense	-	-	(950 )	(3,451 )
Non-operating income / (expense), net	98,890	113,360	170,357	488,604
Net loss	(1,311,588 )	(906,954 )	(2,330,698 )	(1,692,816 )
Preferred stock dividends	(2,658 )	(2,658 )	(5,316 )	(5,316 )
Net loss applicable to common shareholders	\$ (1,314,246 )	\$ (909,612 )	\$ (2,336,014 )	\$ (1,698,132 )
Basic and diluted loss per share	\$ (0.02 )	\$ (0.02 )	\$ (0.04 )	\$ (0.03 )
Weighted average shares used in computing net loss per share: Basic and diluted	55,013,553	54,883,445	55,013,227	54,875,749

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,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,330,698 )	\$ (1,692,816 )
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	-	(8,607 )
Depreciation of fixed assets	274,200	305,147
Amortization of other assets	28,098	15,469
Change in fair value of derivative warrant liability	(58,000 )	(347,000 )
Accretion of asset retirement obligation	43,461	39,734
Share-based compensation	63,363	42,907
Changes in operating assets and liabilities:		
Accounts receivable, gross	73,700	124,275
Inventory	(72,794 )	(51,683 )
Other receivables	10,899	42,104
Prepaid expenses and other current assets	61,345	(15,120 )
Accounts payable and accrued expenses	183,059	(86,534 )
Accrued protocol expense	(45,428 )	9,947
Accrued radioactive waste disposal	24,000	(33,524 )
Accrued payroll and related taxes	(140,250 )	(89,537 )
Accrued vacation	(34,862 )	(12,387 )
Net cash used by operating activities	(1,919,907 )	(1,757,625 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(35,113 )	(48,657 )
Additions to licenses and other assets	(16,078 )	(2,296 )
Proceeds from maturity of certificates of deposit	3,526,999	5,013,694
Purchases of certificates of deposit	(6,082,983 )	(5,058,080 )
Purchases of certificates of deposit - non-current	(56,840 )	(4,695,282 )
Change in restricted cash	(15 )	(27 )
Net cash used by investing activities	(2,664,030 )	(4,790,648 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Preferred dividends paid	(10,632 )	(10,632 )
Proceeds from sales of common stock, pursuant to exercise of warrants, net	46,735	70,411
Proceeds from sales of common stock, pursuant to exercise of options	-	145,274



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Net cash provided by financing activities	36,103	205,053
Net increase (decrease) in cash and cash equivalents	(4,547,834 )	(6,343,220 )
Cash and cash equivalents, beginning of period	5,226,740	7,680,073
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 678,906</b>	<b>\$ 1,336,853</b>
Non-cash investing and financing activities:		
Reclassification of derivative warrant liability to equity upon exercise	\$ -	\$ 17,000

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, 2015 and 2014**

**1. Basis of Presentation**

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

In the opinion of management, the accompanying unaudited interim consolidated financial statements and notes to the interim consolidated financial statements contain all adjustments, consisting of normal recurring items, necessary to present fairly, in all material respects, the financial position of IsoRay, Inc. and its wholly-owned subsidiaries. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company's annual report filed on Form 10-K for the year ended June 30, 2015.

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

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, the reported amounts of revenues and expenses during the reporting period, and the disclosures of contingent liabilities. Accordingly, ultimate results could differ materially from those estimates. The Company anticipates that as the result of continuing operating losses and the significant net operating losses available from prior fiscal years, its effective income tax rate for fiscal year 2016 will be 0%.

**2. New Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes the revenue recognition requirements in FASB Accounting Standards Codification (ASC) Topic 605, Revenue Recognition. The guidance requires that an entity recognize revenue in a way that depicts the transfer of promised goods or services to customers in the amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods and services. The guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11 – Inventory. The guidance requires an entity's management to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01 – Financial Instruments – Overall. The guidance requires an entity’s management to measure equity investments except those accounted for under the equity method of accounting or those that result in consolidation of the investee to be measured at fair value; simplifies the impairment assessment of equity investments; eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for non-public entities; eliminates the requirement for a public entity to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (that is, securities or loans and receivables) on the balance sheet or the accompanying notes to the financial statements; and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity’s other deferred tax assets. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early application is not permitted except as contained in the early adoption guidance. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial statements.

### 3. Certificates of deposit

The Company has maintained all excess cash in certificates of deposit at certain banks in certificates of deposit and through the Certificate of Deposit Account Registry Service (CDARS), which is a system that allows the Company to invest in certificates of deposit through a single financial institution that exceed the \$250,000 limit to be fully insured by the Federal Deposit Insurance Corporation (FDIC). The Company ensures that principal amounts of certificates of deposit are fully insured. There may from time to time be short periods following maturity that amounts held in the money market account at the CDARS host bank will exceed FDIC coverage. In cases where the period that uninsured amounts will be held beyond ten banking days, the funds will be transferred to the primary operating account of the Company’s operating subsidiary, IsoRay Medical, Inc. (Medical), that incorporates a sweep function that keeps the funds FDIC insured during that time.

As of December 31, 2015

	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$6,031,813	\$5,886,745	\$ -	\$5,163,615

As of June 30, 2015

	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$3,523,167	\$500,064	\$5,339,343	\$5,106,775

#### **4. Loss per Share**

Basic and diluted earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. At December 31, 2015 and 2014, the calculation of diluted weighted average shares did not include convertible preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2015 and 2014, were as follows:

	December 31,	
	2015	2014
Series B preferred stock	59,065	59,065
Common stock warrants	360,800	396,574
Common stock options	2,126,360	2,180,858
Total potential dilutive securities	2,546,225	2,636,497

## 5. Inventory

Inventory consisted of the following at December 31, 2015 and June 30, 2015:

	December 31, 2015	June 30, 2015
Raw materials	\$ 275,456	\$ 143,669
Work in process	165,726	204,760
Finished goods	35,567	55,526
	\$ 476,749	\$ 403,955

	December 31, 2015	June 30, 2015
Enriched barium, non-current	\$ 469,758	\$ 469,758
Raw materials, non-current	77,529	100,096
Total inventory, non-current	\$ 547,287	\$ 569,854

Inventory, non-current is (i) raw materials that were ordered in quantities to obtain volume cost discounts for key components of our brachytherapy seed including titanium lids, titanium tubes, gold wires that are used for imaging markers, and our proprietary seed core, which were ordered based on current and anticipated sales volumes and will not be consumed within an operating cycle, and (ii) enriched barium, which is classified as non-current, and is only expected to be utilized if required to obtain volumes of isotope that is not able to be purchased from an existing source in either the short- or long-term. Management does not anticipate the need to utilize the enriched barium within the current operating cycle unless there is an unanticipated interruption to the isotope supply that requires its use. If such a need were to occur, then management would evaluate the need to reclassify some or all of the inventory as a current asset.

**6.Fixed Assets**

	December 31, 2015	June 30, 2015
Production equipment	\$ 3,186,857	\$3,180,933
Office equipment	248,857	224,576
Furniture and fixtures	152,238	148,265
Leasehold improvements	4,129,977	4,129,977
Other	6,860	5,925
	7,724,789	7,689,676
Less accumulated depreciation	(7,389,036 )	(7,114,836)
Fixed assets, net	\$ 335,753	\$574,840

Depreciation expense related to fixed assets for the three and six months ended December 31, 2015 was \$137,531 and \$274,200, respectively. Depreciation expense related to fixed assets for the three and six months ended December 31, 2014 was \$135,176 and \$305,147, respectively.

## 7. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended December 31, 2015 and 2014:

	Three months ended December 31,	
	2015	2014
Cost of product sales	\$ 17,632	\$ 7,972
Research and development expenses	3,567	3,117
Sales and marketing expenses	2,994	2,158
General and administrative expenses	6,858	8,206
Total share-based compensation	\$ 31,051	\$ 21,453

The following table presents the share-based compensation expense recognized during the six months ended December 31, 2015 and 2014:

	Six months ended December 31,	
	2015	2014
Cost of product sales	\$35,190	\$15,945
Research and development expenses	7,132	6,235
Sales and marketing expenses	6,486	4,317
General and administrative expenses	14,555	16,410
Total share-based compensation	\$63,363	\$42,907

As of December 31, 2015, total unrecognized compensation expense related to stock-based options was \$372,627 and the related weighted-average period over which it is expected to be recognized is approximately 1.32 years.

A summary of stock options within the Company's share-based compensation plans as of December 31, 2015 was as follows:



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	Number of Options	Weighted Exercise Price (Years)	Weighted Average Contractual Term	Intrinsic Value
Outstanding at December 31, 2015	2,126,360	\$ 1.88	4.89	\$235,064
Vested and expected to vest at December 31, 2015	2,026,059	\$ 1.90	4.77	\$226,839
Vested and exercisable at December 31, 2015	1,709,894	\$ 1.91	3.85	\$231,563

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There were 45,994 and 133,564 stock options exercised and \$21,654 and \$252,308 of intrinsic value associated with these exercises during the six months ended December 31, 2015 and December 31, 2014, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 20,000 and no stock option awards granted during the six months ended December 31, 2015 and 2014, respectively.

There were 264,320 and 39,002 stock option awards which expired during the six months ended December 31, 2015 and 2014, respectively.

There were 21,608 and 84,236 stock option awards forfeited during the six months ended December 31, 2015 and 2014, respectively.

## **8. 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.

### Class Action Lawsuit Related to Press Release

On May 22, 2015, the first of three lawsuits was filed against IsoRay, Inc. and two of its officers – Dwight Babcock and Brien Ragle – related to a press release on May 20, 2015 regarding a May 19 online publication of the peer-reviewed article in the journal Brachytherapy titled “Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-Stage Lung Cancer” by Dr. Bhupesh Parashar, et al. The lawsuits are class actions alleging violations of the federal securities laws. By Order dated August 17, 2015, all of the pending lawsuits were consolidated into one case – In re IsoRay, Inc. Securities Litigation; Case No. 4:15-cv-05046-LRS, in the US District Court for the Eastern District of Washington. IsoRay retained Wilson Sonsini Goodrich & Rosati as its and its officers’ defense counsel.

On October 16, 2015, an amended complaint was filed with more detailed allegations relating to violations of federal securities laws and requesting damages through a jury trial. Mr. Ragle was dismissed from the complaint. On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. Oral argument is scheduled on this motion on April 21, 2016.

IsoRay believes the lawsuit is without merit and is seeking its dismissal.

Property Transaction between Medical and The Port of Benton

On September 10, 2015, the Company's operating subsidiary, Medical, entered into a Real Estate Purchase and Sale Agreement with The Port of Benton, a municipal corporation of the State of Washington. The Agreement is for the sale of undeveloped real property of approximately 4.2 acres located adjacent to the Company's existing manufacturing facility and corporate offices. The purchase price for the property is One Hundred Sixty-Eight Thousand Dollars (\$168,000) which is payable on closing.

On October 15, 2015, the Agreement was amended through an addendum, which extended the closing date to February 5, 2016.

The Company placed a \$25,000, non-refundable deposit in escrow with the title company and closed on the property on Friday, February 5, 2016, remitting the balance of \$143,000 at the time of closing.

Medical is bound to comply with a Development Plan for a ten year period, which requirements include but are not limited to the following:

- (1) Certain specified site configurations and design with a minimum of 12,000 square feet of warehouse and production space and 4,000 square feet of office space;
- (2) Completion of all construction in two years;
- (3) Use of facility as primary production facility for ten (10) years; and
- (4) Provision of jobs for not less than 25 full time employees.

The purchase price for the property was adjusted in consideration of the Development Plan's covenants. Failure to comply with these covenants will result in a breach of the Agreement and if not cured, will obligate Medical to pay the Port the difference in the sales price and the appraised value of the property at the time of default. The Benton County 2015 assessed value of the land was \$423,720, and management believes this approximates the current

appraised value. The difference in the sales price and management's estimate of the current appraised value of the property is approximately \$256,000. This is subject to subsequent changes in valuation of the property.

## **9. 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, 2015 and June 30, 2015, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

## Fair value at December 31, 2015

	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$678,906	\$678,906	\$-	\$ -
Warrant derivative liability	123,000	-	123,000	-

## Fair value at June 30, 2015

	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$5,226,740	\$5,226,740	\$-	\$ -
Warrant derivative liability	181,000	-	181,000	-

**10. Preferred Dividends**

On December 10, 2015, 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, 2015 in the amount of \$10,632. The dividends outstanding and cumulative through December 31, 2015 of \$10,632 and through December 31, 2014 of \$10,632 were paid as of those dates.

**11. Shareholders' Equity***Warrant derivative liability*

Based on the guidance contained in ASC 815 "Derivatives and Hedging", management has concluded that the warrants issued in the 2011 offering should be classified as a derivative liability and has recorded a liability at fair value.

A summary of the change in fair value of derivative warrant liability is as follows for the fiscal years presented.

	Quantity <sup>1</sup>	Amount
Balance at June 30, 2014	238,696	\$573,000
Change in fair value		(374,605)
Warrants exercised	(13,209 )	(17,395 )
Balance at June 30, 2015	225,087	\$181,000
Change in fair value		(15,000 )
Balance at September 30, 2015	225,087	166,000
Change in fair value	(43,000 )	

Balance at December 31, 2015    225,087    \$123,000

<sup>1</sup> Quantity of warrants either issued or outstanding as of the date of valuation.

*Warrants*

The following table summarizes all warrants outstanding as of the beginning of the fiscal year, all activity related to warrants issued, cancelled, exercised or expired during the period and weighted average prices for each category.

	Warrants	Weighted average exercise price
Outstanding as of June 30, 2015	385,800	\$ 1.22
Warrants expired	(25,000 )	2.00
Outstanding as of December 31, 2015	360,800	\$ 1.17

The following table summarizes additional information about the Company's common warrants outstanding as of December 31, 2015:

Number of Warrants	Exercise Prices	Expiration Date
130,713	1.56	May 2016
199,437	0.94	October 2016
25,650	0.94	December 2016
5,000	0.98	June 2017
360,800		

## 12. Related Party Transaction

During the six months ended December 31, 2015 and 2014, the Company continued to engage the services of APEX Data Systems, Inc., owned by Dwight Babcock, the Company's former Chairman and Chief Executive Officer, to modify and maintain the Company's web interfaced data collection application to aggregate patient data in a controlled environment. The cost recorded during the six months ended December 31, 2015 and 2014 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection applications in combination with the updating of the Company website was \$6,000 and \$6,000 respectively. An additional \$6,000 was spent on the maintenance of Customer Relationship Management (CRM) software in the six months ended December 31, 2015 and 2014, respectively. At December 31, 2015 and 2014, services during the prior month had been accrued and remained unpaid in the amount of \$2,000. These amounts were each paid in the subsequent month.

## 13. Concentrations of Credit and Other Risks

The Company's cash, cash equivalents and investments are deposited with several financial institutions with FDIC coverage. At times, deposits for a limited period of time in these institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses in such accounts and believes that it is not exposed to any significant risk on these balances.

For the six months ended December 31, 2015 and 2014, there were one and two customers (one of which was a group of customers supported by a single physician group) that each represented 10% or more of total net revenue, respectively.

At December 31, 2015, a single customer accounted for 10% or more of the Company's total accounts receivable with a single customer (a group of seven legal entities) that represents 35% of total accounts receivable. At June 30, 2015, one customer (a group of seven legal entities) accounted for 27% of total accounts receivable.



Accounts receivable are typically not collateralized. The Company maintains ongoing dialogue with its customers about invoice payments. Some of our customers are small outpatient surgery centers that pay invoices for our products at the time they receive a decision regarding payment by the insurer providing benefits which in the case of prostate cancer is predominately Medicare. A qualitative review of outstanding customer balances is performed at least quarterly and the allowance for doubtful accounts is adjusted based on historical performance of the customer and management knowledge regarding specific invoices. Accounts are charged against the allowance for doubtful accounts once collection efforts are deemed unsuccessful. Prior to utilizing an external collection agency and interrupting the supply of our product, customers may be provided the opportunity to continue purchasing product on the basis of pre-paying via guaranteed funds the amount due on their current order prior to producing and shipping the order plus the amount due on their oldest outstanding invoice.

Single source suppliers presently provide the Company with several components. Management believes that it would be able to locate other sources for these components subject to any regulatory qualifications, if required.

During the three months ended December 31, 2015, the Company experienced an unplanned supply disruption of radioisotope from its Russian supplier. No customer orders were missed or delayed while the Company increased production at its second supplier to compensate for the unplanned outage. This event has led management to conduct a review of the Company's current supply interruption plan in such a situation to ensure its ability to continue to produce a sufficient supply of radioisotope at either facility in the case of an extended supply interruption at either reactor. Over the next six to twelve months, management will completely vet, test and modify where appropriate the Company's current plan as required to ensure this capability.

#### **14. Subsequent Events**

On January 6, 2016, Dwight Babcock, the Company's Chairman and CEO, informed the Board of his retirement from all positions held with the Company and its subsidiaries, including from Board service, effective as of January 7, 2016. In connection with his retirement, on January 6, 2016, Mr. Babcock entered into a Severance Agreement, Waiver and Release (the "Agreement") with the Company and its subsidiaries, which was amended and restated on January 12, 2016. Pursuant to the Agreement, Mr. Babcock will continue to receive his base salary through January 6, 2017, and Mr. Babcock has agreed to a waiver and release of claims. The Company recorded a liability of approximately \$300,000 in the quarter ended December 31, 2015 relating to the Agreement.

The Board appointed William Cavanagh III, the Company's Vice President, Research and Development, as interim CEO, and elected Thomas LaVoy, Chair of the Audit Committee, as Chairman, each of whom took office on January 7, 2016. On January 13, 2016, the Board appointed Thomas LaVoy as CEO, to take office on February 15, 2016.

Effective January 13, 2016, the Board, on the recommendation of the Nominating Committee, appointed Alan Hoffmann, CPA to the Board to fill the vacancy created by Mr. Babcock's departure. Mr. Hoffmann will stand for re-election at the Company's fiscal 2016 annual meeting. Mr. Hoffmann was appointed to serve on the Nominations and Corporate Governance Committee and the Compensation Committee, and to chair the Audit Committee.

## **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, 2015 that may cause actual results to differ materially.*

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

### **Critical Accounting Policies and Estimates**

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, derivative liabilities and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 14, 2015 are those that depend most heavily on these judgments and estimates. As of December 31, 2015, there had been no material changes to any of the critical accounting policies contained therein.

### **Overview**

#### **Products and Market.**

IsoRay, Inc. is a brachytherapy device manufacturer with FDA clearance and CE marking for two medical devices that can be delivered to the physician in multiple configurations as prescribed. The Company manufactures and sells these products as the Proxcelan® Cesium-131 brachytherapy seed and the GliaSite® Radiation Therapy System (GliaSite® RTS). Each brachytherapy seed order is manufactured to the physician's specifications for a named patient on a specific treatment date. The GliaSite® RTS utilizes a balloon catheter system, which allows the physician to later place a specified dose of radioisotope (either Cesitrex® or Iotrex® solution) in the treatment location.

The Proxcelan® brachytherapy seeds utilize Cesium-131, with a 9.7 day half-life, as their radiation source. The Company believes that it is the unique combination of the short half-life and the energy of the Cesium-131 isotope

that are yielding the beneficial treatment results that have been published in peer reviewed journal articles and presented in various forms at conferences and tradeshows. In the case of the GliaSite® RTS, the Company believes that in the long-term, Cesitrex®, which is Cesium-131-based, is the best radioisotope solution for this treatment, but it continues to offer Iotrex®, an Iodine-125 based isotope solution, as it works to re-establish the market for this product. To date, Iotrex® has been the primary isotope solution utilized in the GliaSite® RTS; Cesitrex® is available for sale and only utilized in U.S. treatment.

The Company continues to enter into distribution agreements outside of the United States through its subsidiary IsoRay International LLC. These distributors are responsible for obtaining regulatory clearance to sell the Company's products in their territories, with the support of the Company. As of December 31, 2015, the Company had distributors in Australia and New Zealand, Germany (which includes rights to Austria, Switzerland, and Luxembourg as well), Italy, and the Russian Federation.

Management is encouraged by the overall growth in revenue from sales of the Company's Proxcelan<sup>®</sup> brachytherapy seeds during the prior four consecutive fiscal quarters. The growth from the sales of brachytherapy seeds during the prior four fiscal quarters compared to the same quarters in the prior fiscal year has averaged 21% with minimum revenue growth of 7% and maximum revenue growth of 45%.

Management is encouraged by the growth trend in our core business treating prostate cancer, with five of the past six fiscal quarters experiencing increases over the same quarter in the prior fiscal year. During the prior four fiscal quarters, the prostate segment growth has averaged 21% growth with the minimum revenue growth of 7% and maximum revenue growth of 44%. As the Company has a very small share of the overall prostate brachytherapy market, there is significant opportunity for expansion.

Net revenue from other treatments utilizing the Proxcelan<sup>®</sup> brachytherapy seeds during the prior four fiscal quarters have averaged revenue growth of 27% when compared to the same quarter in the prior fiscal year with minimum revenue growth of 9% and maximum revenue growth of 49% during that period. Growth in revenue from treating brain cancer during the preceding four consecutive fiscal quarters compared to the same quarters during the prior fiscal year has averaged 79% with minimum revenue growth of 9% and maximum revenue growth of 258%. While these treatments are still heavily dependent on the purchasing behaviors of key physicians which has created volatility in revenue, management is encouraged by the upward trend in revenues.

Management believes that the current growth is the result of additional peer-reviewed articles that share the treatment experience and these publications are building awareness of and communicating the treatment advantages of our products. Management also believes that as the impact of the Affordable Care Act's cost containment measures continues to be felt, the payors will have to react by modifying methods of reimbursement to encourage facilities to utilize other modalities that offer equal or better results with a lower total cost of treatment. Management expects cost containment decisions to be favorable to seed brachytherapy as external beam radiation makes up the majority of the overall treatment market for prostate cancer and a significant portion of the market in other body sites in which the Company competes for business.

When brachytherapy seeds are implanted during a surgical procedure for brain cancer, lung cancer and certain other non-prostate cancers, under Medicare, the brachytherapy seeds are not separately reimbursed when surgery is performed and the patient is admitted to the hospital. Management is developing a strategy to address this gap in the payment system in consultation with consultants experienced in healthcare reimbursement, representatives of the

facilities utilizing our products and the final payors for our products. External beam radiation treatments for these same cancers are reimbursed in addition to the cost of surgery as they are administered as separate treatments following surgery with a significantly greater cost of treatment, increased duration of treatment and decreased convenience for the patient. While the cost of external beam radiation is significantly greater than the cost of brachytherapy procedures, the separate reimbursement for external beam radiation treatments results in the hospital receiving a payment in addition to payment for the surgical procedure itself. With brachytherapy performed concurrent with the surgery, the hospital receives the same reimbursement for the surgical procedure whether seeds are implanted or not, resulting in brachytherapy treatment being an additional cost for the hospital.

The Company believes that long-term success of the Proxcelan<sup>®</sup> Cesium-131 brachytherapy seed is dependent on a number of factors including the following:

- Increased awareness by physicians of the benefits of utilizing Proxcelan<sup>®</sup> Cesium-131 brachytherapy seeds; The Affordable Care Act (ACA) implementing cost containment measures in the evaluation of treatment methodologies and reimbursement, particularly in prostate cancer where costly intensity-modulated radiation therapy (IMRT) treats an increasing percentage of the overall U.S. prostate cancer treatment market and growth in the market is expected with the increase in men younger than Medicare age obtaining health insurance;

Increased patient awareness of the comparability and benefits of low dose rate (LDR) brachytherapy when compared to external beam radiation therapy, including comparable urinary symptoms, fewer bowel toxicities, and better sexual function;

Increased attention by payors and patients to the increased cost being paid for IMRT and the potential conflict of interest resulting from the in-office referral of prostate cancer patients for IMRT utilizing equipment in which the physician has an ownership interest, which can be allowed through an exception, for in-office ancillary services, to the federal laws that generally prohibit self-referrals;

Changes in the reimbursement methodology regarding the utilization of brachytherapy seeds in the treatment of brain cancer, lung cancer and other cancers;

Continued evolution in protocols demonstrating the safety, efficacy and other benefits of using Proxcelan<sup>®</sup> Cesium-131 brachytherapy seeds to treat tumors throughout the body;

Continued publication of peer reviewed journal articles and presentations at society meetings about the treatment outcomes achieved utilizing Proxcelan<sup>®</sup> Cesium-131 brachytherapy seeds in the treatment of prostate cancer, brain cancer, lung cancer, gynecological cancer and other tumors throughout the body;

- Expanded sales through distributors into other countries particularly those in which external beam radiation has not established a significant presence; and

Continued ability of the Company to deliver product that meets the standards of the Company and the expectations of its customers.

Revenue from GliaSite<sup>®</sup> RTS during the prior four consecutive fiscal quarters compared to the same quarters in the previous year has decreased by an average of 65% with the decreases ranging from a maximum of (100%) to a minimum of (25%). This has been the result of reduced purchases from foreign distributors as the US dollar has strengthened against the Euro making the product increasingly more expensive for those distributors. Domestic adoption of the GliaSite<sup>®</sup> RTS has been slower than anticipated by management and a clinical study has not been conducted to aggregate outcomes for publication in peer reviewed journals.

The Company believes that long-term success of the GliaSite<sup>®</sup> RTS is dependent on a number of factors including the following:

- Implementation of a protocol to support the publication of peer reviewed journal articles and presentations at society meetings about the treatment outcomes achieved utilizing GliaSite<sup>®</sup> RTS;

- Greater awareness among doctors of the historical use of GliaSite<sup>®</sup> RTS and the treatment outcomes achieved;

- Greater awareness of the availability of Cesitrex<sup>®</sup> as an alternative isotope to Iotrex<sup>®</sup>; and

- Recovery of foreign economies and currencies to increase the overall market.



**Results of Operations****Three and six months ended December 31, 2015 and 2014.**

	Three months ended December 31,				2015-	
	2015		2014		2014	
	Amount	% (a)	Amount	% (a)	% Change	
Product sales, net	\$1,189,008	100	\$1,065,585	100	12	
Cost of product sales	1,162,097	98	1,103,549	104	5	
Gross profit / (loss)	26,911	2	(37,964 )	(4 )	171	
Research and development expenses	58,235	5	140,627	13	(59 )	
Sales and marketing expenses	254,471	21	303,783	29	(16 )	
General and administrative expenses	1,124,683	95 %	537,940	50	-109 %	
Net loss attributable to shareholders	\$(1,314,246)	-111 %	\$(909,612 )	(85 )	-44 %	
	Six months ended December 31,				2015-	
	2015		2014		2014	
	Amount	% (a)	Amount	% (a)	% Change	
Product sales, net	\$2,450,330	100	\$2,107,686	100	16	
Cost of product sales	2,339,960	95	2,200,452	104	6	
Gross profit / (loss)	110,370	5	(92,766 )	(4 )	219	
Research and development expenses	202,138	8	317,237	15	(36 )	
Sales and marketing expenses	532,892	22	657,526	31	(19 )	
General and administrative expenses	1,876,395	77 %	1,113,891	53	-68 %	
Net loss attributable to shareholders	\$(2,336,014)	-95 %	\$(1,698,132)	(81 )	-38 %	

(a) Expressed as a percentage of product sales, net

**Revenues.**

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Total revenue from product sales increased approximately \$123,000 or 12% in the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. The 12% growth during the three months ended December 31, 2015 as compared to the three months ended December 31, 2014 was the result of an increase of approximately \$137,000 or 13% overall growth in seed brachytherapy treatments which more than offset the 44% decrease in GliSite® revenues. During the three months ended December 31, 2015, 99% of product sales came from brachytherapy seed treatments compared with 97% during the three months ended December 31, 2014.

Total revenue from product sales increased approximately \$343,000 or 16% in the six months ended December 31, 2015 as compared to the six months ended December 31, 2014. The 16% growth during the six months ended December 31, 2015 as compared to the six months ended December 31, 2014 was the result of an increase of approximately \$382,000 or 19% overall growth in seed brachytherapy treatments which more than offset the 69% decrease in GliSite<sup>®</sup> revenues. During the six months ended December 31, 2015, 99% of product sales came from brachytherapy seed treatments compared with 97% during the six months ended December 31, 2014.

*Prostate Brachytherapy.*

During the three months ended December 31, 2015 and 2014, respectively, prostate brachytherapy was 87% and 86% of total revenues. The growth in revenue from prostate brachytherapy of 13% was the result of a 7% increase in the total number of seeds sold combined with the change in product mix ordered by physicians during the three months ended December 31, 2015 compared to the three months ended December 31, 2014. Physicians ordered 18% fewer seeds configured into strands and/or pre-loaded in needles, 45% fewer seeds in a loose seed configuration, 38% fewer seeds for calibration applications, 389% more seeds pre-loaded using C4 spacers, and 15% more seeds configured in Mick<sup>®</sup> cartridges during the three months ended December 31, 2015 compared to the three months ended December 31, 2014. Pre-loaded configurations result in more revenue per seed than loose seeds.

During the six months ended December 31, 2015 and 2014, respectively, prostate brachytherapy was 88% and 87% of total revenues. The growth in revenue from prostate brachytherapy of 17% was the result of a 12% increase in the total number of seeds sold combined with the change in product mix ordered by physicians during the six months ended December 31, 2015 compared to the six months ended December 31, 2014. Physicians ordered 9% fewer seeds configured into strands and/or pre-loaded in needles, 52% fewer seeds in a loose seed configuration, 14% fewer seeds for calibration applications, 786% more seeds pre-loaded using C4 spacers, and 17% more seeds configured in Mick<sup>®</sup> cartridges during the six months ended December 31, 2015 compared to the six months ended December 31, 2014. Pre-loaded configurations result in more revenue per seed than loose seeds.

Management believes that the growth in the Company's prostate brachytherapy revenue is the result of physicians, payors and patients increasingly considering overall treatment cost in combination with treatment outcomes and quality of life. Management also believes the recent publication of additional data in peer reviewed journal articles on treatment outcomes achieved with low-dose-rate (LDR) prostate brachytherapy with the Company's Proxcelar<sup>®</sup> Cs-131 brachytherapy seeds, indicating it is more cost effective, has faster resolution of urinary side effects and a reduced impact on the healthy tissue surrounding the tumor, when compared to competing treatments such as high-dose-rate brachytherapy and intensity modulated radiation therapy, is a driver of the recent growth in the Company's prostate brachytherapy revenue. There is no assurance this trend will continue.

*Other Brachytherapy.*

The strategy implemented by management in diversifying the number of body sites being actively treated with the Proxcelan<sup>®</sup> Cs-131 brachytherapy seed has continued to provide an additional source of revenue. While individually these treatment sites do not represent a significant contribution to revenue, the sites as a group increased their revenue contribution by 18% during the three months ended December 31, 2015 when compared to the three months ended December 31, 2014. The largest revenue contributions in this classification came from brain cancer and gynecological cancer treatments. During the three months ended December 31, 2015 and 2014, respectively, other brachytherapy represented approximately \$139,000 or 12% of total revenue and approximately \$118,000 or 11% of total revenue.

These sites as a group increased their revenue contribution by 30% during the six months ended December 31, 2015 when compared to the six months ended December 31, 2014. The largest revenue contributions in this classification came from brain cancer and gynecological cancer treatments. During the six months ended December 31, 2015 and 2014, respectively, other brachytherapy represented approximately \$285,000 or 12% of total revenue and approximately \$219,000 or 10% of total revenue.

These other brachytherapy treatments continue to be subject to the influence of a small pool of innovative physicians who are the early adopters of the technology who also tend to be faculty at teaching hospitals training the next generation of physicians. This causes the revenue created by these types of treatment applications to be more volatile and vary significantly from quarter to quarter.

*GliaSite® Radiation Therapy System.*

All product sales are generated by brachytherapy seeds and their related methods of application except for the revenue generated by sales of GliaSite® RTS, which come from sale of the liquid isotope, catheter trays and access trays. Product sales from GliaSite® RTS decreased 44%, with revenue of \$17,000 in the three months ended December 31, 2015 compared to revenue of \$31,000 in the three months ended December 31, 2014.

Product sales from GliaSite® RTS decreased 69%, with revenue of \$17,000 in the six months ended December 31, 2015 compared to revenue of \$56,000 in the six months ended December 31, 2014.

The lack of sales was partially impacted by the unfavorable change in the exchange rate between the US dollar and the Euro as the dollar continued to be stronger during fiscal year 2016 compared with fiscal year 2015, which effectively increased the cost to European customers as all transactions are conducted in the US dollar.

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 medical facilities in reviewing and approving the use of the product at the request of their physician(s).

**Cost of product sales.**

The cost of product sales for the production of brachytherapy seeds increased by approximately \$61,000 or 6% during the three months ended December 31, 2015 when compared to the three months ended December 31, 2014. The increase in cost of products for the production of brachytherapy seeds was the result of increased payroll, benefits and share-based compensation of approximately \$29,000 or 13% and increased third-party seed loading cost of approximately \$29,000 or 288%. The increased payroll, benefits and share-based compensation expense are the result of the additional costs related to producing the 9% increase in the number of brachytherapy seeds produced and the related changes in configuration along with the additional expense related to the employee stock options issued in June 2015 to production employees. The increased cost of third-party seed loading expense is the result of the increased quantity of seeds ordered by physicians at MD Anderson Cancer Center utilizing the C4 marker. Until the

volume of C4 markers is sufficient to justify the additional cost of adding an in-house loading and sterilization capability, they will be loaded via a third-party seed loader.

The cost of product sales for the production of brachytherapy seeds increased by approximately \$140,000 or 6% during the six months ended December 31, 2015 when compared to the six months ended December 31, 2014. The increase in cost of products for the production of brachytherapy seeds was the result of increased cost of materials of approximately \$104,000 or 12% and increased third-party seed loading cost of approximately \$50,000 or 372%, partially offset by decreased occupancy expense of approximately \$24,000 or 16%. The increased cost of materials was a function of increased isotope cost, increased consumption of raw materials and work in process to produce the increased quantity of seeds ordered. The increased cost of third-party seed loading expense is the result of the increased quantity of seeds ordered by physicians at MD Anderson Cancer Center utilizing the C4 marker. These increases were partially offset by a decrease in occupancy costs that was the result of a change in the allocation of rent and utility expenses.

Although not required by our contract with our Russian isotope supplier, we purchase isotope at specific volumes on a weekly basis to provide additional certainty of our ability to meet forecasted demands based on the lead times required in the ordering of isotope and therefore incur this cost regardless of usage. The Company is a just in time manufacturer of brachytherapy seeds which is the result of the unique properties of Cesium-131, primarily the half-life or decay rate of 9.7 days. The Company requires isotope on-hand to meet known orders as well as anticipated orders which may or may not materialize. The Company does not manufacture to inventory as other brachytherapy seed manufacturers may. When the Company has isotope available for production in excess of the current demand, orders due to ship in the near future will be manufactured early to maximize the number of viable seeds that can be manufactured from any given lot of radioisotope.

During the three and six months ended December 31, 2015 compared to the three and six months ended December 31, 2014, the decrease in the cost of product sales for the GliSite<sup>®</sup> RTS was an immaterial amount as there has not been significant activity related to this product line.

#### **Gross profit / (loss).**

Gross profit for the three months ended December 31, 2015 improved by approximately \$65,000 or 171% compared to the gross loss for the three months ended December 31, 2014, primarily as a result of the increased product sales, with minimal incremental costs related to materials and labor to increase seed production outputs.

Gross profit for the six months ended December 31, 2015 improved by approximately \$203,000 or 219% compared to the gross loss for the six months ended December 31, 2014, primarily as a result of the increased product sales, with minimal incremental costs related to materials and labor to increase seed production outputs.

Both increases in gross profit were significantly impacted by the ability of the Company to utilize isotope that was already purchased to ensure an adequate supply of isotope on a weekly basis to produce orders and that would have otherwise been expensed as it decayed during the operating cycle.

#### **Research and development.**

Research and development costs decreased by approximately \$82,000 or 59% in the three months ended December 31, 2015 compared to the three months ended December 31, 2014, primarily as an adjustment to the accrued cost of protocols for on-going activities.

Research and development costs decreased by approximately \$115,000 or 36% in the six months ended December 31, 2015 compared to the six months ended December 31, 2014, primarily as an adjustment to the accrued cost of protocols for on-going activities in combination with the reduced legal expense related to intellectual property.

**Sales and marketing expenses.**

Sales and marketing expenses decreased by approximately \$49,000 or 16% during the three months ended December 31, 2015 compared to the three months ended December 31, 2014. The Company had an expected temporary reduction in travel expenses and payroll related expenses of approximately \$30,000 or 47% and approximately \$21,000 or 11% related to the open national sales director and territory sales manager positions that were unfilled during the three months ended December 31, 2015, partially offset by a tradeshow expense in October 2015.



Sales and marketing expenses decreased by approximately \$125,000 or 19% during the six months ended December 31, 2015 compared to the six months ended December 31, 2014, primarily as the result of decreased conventions and tradeshow expenses of approximately \$24,000 or 41% as the American Society for Radiation Oncology (ASTRO) convention costs were decreased year over year along with not having a national sales meeting in fiscal year 2016. The Company also had a planned temporary reduction in travel expenses and payroll related expenses of approximately \$47,000 or 39% and approximately \$34,000 or 8% related to the open national sales director and territory sales manager positions that were unfilled during the six months ended December 31, 2015.

### **General and administrative expenses.**

General and administrative expenses increased by \$587,000 or 109% in the three months ended December 31, 2015 compared to the three months ended December 31, 2014. Approximately \$488,000 or 83% of the \$587,000 increase in general and administrative expense was the result of non-recurring legal fees related to the class action shareholder suit and the accrual of the severance costs of approximately \$300,000 associated with the retirement of the CEO. The Company has incurred \$213,000 of legal expense applicable to our deductible of \$250,000. Ongoing costs of defense in excess of an additional \$37,000 will be covered by our insurance carrier up to our policy limits. Public company expense increased approximately \$25,000 from the addition of a third independent board member as part of the change to being an accelerated filer as defined by the US Securities and Exchange Commission, increased costs of being a listed company on the NYSE MKT and increased investor relations expenses.

General and administrative expenses increased by 763,000 or 68% in the six months ended December 31, 2015 compared to the six months ended December 31, 2014. Approximately \$519,000 or 68% of the \$763,000 increase in general and administrative expense was the result of non-recurring costs for legal fees related to the class action shareholder suit and the accrual of the severance costs of approximately \$300,000 associated with the retirement of the CEO. The other increases in expense were in consulting expense of \$22,000, office expenses of \$22,000, occupancy expense of \$34,000 and public company expense of approximately \$28,000. Legal expense increased from a combination of the expanded reporting obligations related to the Company's filing status change from a smaller reporting company to an accelerated filer effective June 30, 2015 and the legal fees related to the class action shareholder lawsuit. Consulting expense increased from audit and other services from British Standards Institute who is the notified body for the Company related to the quality system. The notified body is the party that audits the quality system of the Company for compliance with the applicable standards for medical devices to be sold in the European Economic Area (EEA). Office expenses increased as part of an information technology upgrade including computer hardware, computer software and office supplies that are below the capitalization threshold. Occupancy expense increased as the allocation of cost changed in the three months ended September 30, 2015 compared to the three months ended September 30, 2014. Although the overall rent did not change, the amount of cost being allocated to general and administrative functions did change, resulting in reductions to other functions which offset this increase to general and administrative. Public company expense increased from the addition of a third independent board member, additional costs of being a listed company on the NYSE MKT and increased investor relations expenses.

**Operating loss.**

Operating loss for the three months ended December 31, 2015 increased approximately \$390,000 or 38% compared to the three months ended December 31, 2014, primarily as a result of the substantial increase in general and administrative expenses which is primarily related to the \$179,000 in legal fees related to the class action shareholder lawsuit and the accrual of severance cost of approximately \$300,000 associated with the retirement of the CEO.

Operating loss for the six months ended December 31, 2015 increased approximately \$320,000 or 15% compared to the six months ended December 31, 2014. Operating loss would have substantially declined but for the increase in general and administrative expenses which is primarily related to the \$218,000 in legal fees related to the class action shareholder lawsuit and the accrual of severance cost of approximately \$300,000 associated with the retirement of the CEO.

**Interest income.**

Interest income decreased approximately \$16,000 or 23% during the three months ended December 31, 2015 when compared to the three months ended December 31, 2014 due to a decrease in the available excess cash to invest in laddered CDs in the Certificate of Deposit Account Registry Service® (CDARS) and which are in amounts that are fully insured by the Federal Deposit Insurance Corporation (FDIC).

Interest income decreased approximately \$32,000 or 22% during the six months ended December 31, 2015 when compared to the six months ended December 31, 2014 due to a decrease in the available excess cash to invest in laddered CDs in the Certificate of Deposit Account Registry Service® (CDARS) and which are in amounts that are fully insured by the Federal Deposit Insurance Corporation (FDIC).

**Change in fair value of warrant derivative liability.**

The warrant derivative liability requires periodic evaluation for changes in fair value. As required at December 31, 2015 and December 31, 2014, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model and applied updated inputs as of those dates. The resulting change in fair value was recorded as of December 31, 2015 and December 31, 2014.

**Liquidity and capital resources.** The Company has historically financed its operations through selling stock to investors. During the six months ended December 31, 2015 and December 31, 2014, the Company used existing cash reserves to fund its operations and capital expenditures.

Our cash flows for the six months ended December 31, 2015 and 2014, respectively, are summarized as follows:

	Six months ended December 31,	
	2015	2014
Net cash used by operating activities	\$ (1,919,907 )	\$ (1,757,625 )
Net cash used by investing activities	(2,664,030 )	(4,790,648 )
Net cash provided by financing activities	36,103	205,053
Net decrease in cash and cash equivalents	\$ (4,547,834 )	\$ (6,343,220 )

*Cash flows from operating activities*

Net cash used by operating activities in the six months ended December 31, 2015 was \$1.92 million as compared to \$1.76 million used in the six months ended December 31, 2014.

Net cash used by operating activities in the six months ended December 31, 2015:

Net loss of approximately \$2.33 million;

Net loss was offset by non-cash items of approximately \$351,000 related to the depreciation of fixed assets, amortization of other assets, change in fair value of derivative warrant liability, accretion of asset retirement obligation and share-based compensation;

Decrease in accounts receivable of approximately \$74,000, the result of the increased collection effectiveness during the six months ended December 31, 2015;

Increase in inventory of approximately \$73,000, the result of purchases of inventory, consisting of titanium lids, titanium tubing and gold wire produced to the specifications of the Company, in quantities to obtain best pricing;

Decrease in other receivables of \$11,000, which is related to the timing of collecting on non-revenue receivables;

Decrease in prepaid expenses and other current assets of \$61,000, which represent the difference in timing on payments issued for vendor invoices due after month end and paid prior to month end;

Decrease in accounts payable and accrued expenses of approximately \$183,000, the result of the timing of paying operating expenses and the accrual of severance cost of approximately \$300,000 associated with the retirement of the CEO;

Increase in accrued protocol expense of \$45,000 which represents a timing difference between incurring an expense and payment;

Decrease in radioactive waste disposal expense of \$24,000 which represents a timing difference between incurring an expense and payment;

Increase in accrued payroll and related taxes expense of approximately \$140,000 which represents a timing difference; and

Increase in accrued vacation of \$35,000 which represent the timing difference of employees accruing vacation and the actual payment when the vacation is used.

Net cash used by operating activities in the six months ended December 31, 2014:

Net loss of approximately \$1.69 million;

Net loss was offset by non-cash items of approximately \$47,000 related to the allowance for doubtful accounts, depreciation of fixed assets, amortization of other assets, change in fair value of derivative warrant liability, accretion of asset retirement obligation and share-based compensation;

Decrease in accounts receivable of approximately \$124,000, the result of the increased collection effectiveness during the six months ended December 31, 2014;

Increase in inventory of approximately \$52,000, the result of purchases of inventory, consisting of titanium lids, titanium tubing and gold wire produced to the specifications of the Company, in quantities to obtain best pricing;

Decrease in other receivables of \$42,000, which is related to the timing of collecting on non-revenue receivables;

Increase in prepaid expenses and other current assets of \$15,000, which represent the difference in timing on payments issued for vendor invoices due after month end and paid prior to month end;

Increase in accounts payable and accrued expenses of approximately \$87,000, the result of the timing of paying operating expenses;

Decrease in accrued protocol expense of \$10,000 which represents a timing difference between incurring an expense and payment;

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Increase in radioactive waste disposal expense of \$34,000 which represents a timing difference between incurring an expense and payment;  
Increase in accrued payroll and related taxes expense of approximately \$90,000 which represents a timing difference;  
and  
Increase in accrued vacation of \$12,000 which represent the timing difference of employees accruing vacation and the actual payment when the vacation is used.

*Cash flows from investing activities*

Net cash used by investing activities in the six months ended December 31, 2015 was \$2.66 million as compared to \$4.79 million used in the six months ended December 31, 2014.

Net cash used by investing activities in the six months ended December 31, 2015:

- Increased by purchases of fixed assets of approximately \$35,000;
- Increased by additions to licenses and other assets of approximately \$16,000;
- Decreased by proceeds from certificates of deposit that matured of \$3.53 million;
- Increased by purchases of certificates of deposit of \$6.06 million;

Approximately \$3.53 million of the cash used for the certificates of deposit purchased came from certificates of deposit that reached maturity during the six months ended December 31, 2015;

\$2.5 million of the cash used for the purchase of certificates of deposit came from certificates of deposit that matured during June 2015 and were in cash and cash equivalents at June 30, 2015;

The remaining cash used for the purchase of certificates of deposit of approximately \$56,000 was from interest earned during the period and added to the existing certificates of deposit; and

Increased by purchases of certificates of deposit, non-current of approximately \$57,000 which came from the interest earned.

Net cash used by investing activities in the six months ended December 31, 2014:

- Increased by purchases of fixed assets of approximately \$49,000;
- Decreased by maturity of certificates of deposit of approximately \$5.01 million
- Increased by purchases of certificates of deposit of approximately \$5.06 million; and
- Increased by purchases of certificates of deposit, non-current of \$4.70 million.

*Cash flows from financing activities*

Net cash provided by financing activities in the six months ended December 31, 2015 was \$36,000 as compared to \$205,000 provided in the six months ended December 31, 2014.

Net cash provided by financing activities in the six months ended December 31, 2015:

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- Decreased by payment of preferred dividends of approximately \$11,000; and
- Increased from the sale of common stock from the exercise of stock options of approximately \$47,000.

Net cash provided by financing activities in the six months ended December 31, 2014:

- Decreased by payment of preferred dividends of approximately \$11,000;
- Increased from the sale of common stock from the exercise of warrants of approximately \$70,000; and
- Increased from the sale of common stock from the exercise of stock options of approximately \$145,000.

*Projected Fiscal Year 2016 Liquidity and Capital Resources*

At December 31, 2015, the Company held cash and cash equivalents of \$679,000, CDARS of \$11.92 million that mature in the current operating cycle and CDARS of \$5.16 million that mature within the next twenty months.

	Amount
Cash and cash equivalents	\$678,906
Certificates of deposit maturing in less than 90 days	6,031,813
Certificates of deposit maturing greater than 90 days and less than six months	5,886,745
Certificates of deposit maturing greater than one year and less than two years	5,163,615
Cash, cash equivalents and certificates of deposit total	\$17,761,079

The Company had approximately \$6.35 million of cash and cash equivalents, \$5.89 million of certificates of deposit and \$5.16 million of certificates of deposit, non-current as of February 5, 2016. The short-term investments mature in June 2016. At the time of maturity, Company management will assess the cash requirements of the Company and reinvest excess cash as it deems appropriate.

The Company's monthly required cash operating expenditures were approximately \$320,000 and \$293,000 during the six months ended December 31, 2015 and 2014, respectively, which represents a 9% increase. As we intend to fill several open positions and hire additional management personnel, our monthly cash operating expenses are expected to show a long term increase from historical levels.

Management forecasts that fiscal year 2016 cash consumed in production operations will be similar to the prior fiscal year. Company management is early in the design process of the future facility and with the goal of constructing a facility that will have non-cash depreciation that is less than the current monthly rental cost of the current facility. Management is reviewing all aspects of production operations, research and development, sales and marketing, and general and administrative functions to evaluate the most efficient deployment of capital to ensure that the appropriate materials, systems and personnel are available to support and drive sales.

#### *Capital expenditures*

The Company has not required significant capital equipment investment despite many of the significant items of manufacturing equipment having reached or reaching their depreciable lives this fiscal year. Management believes less than \$200,000 will be required to be invested in manufacturing or other capital equipment related to Company operations during fiscal year 2016, but there is no assurance that unanticipated needs for capital equipment or a yet to be determined capital project may not arise; and

The Company placed \$25,000 in escrow on raw land as disclosed in financial statement footnote 8 Commitments and Contingencies under the section "Property Transaction between Medical and The Port of Benton". On February 5, 2016, an additional amount of \$143,000 was paid to close on the real property. Future cash requirements related to construction of and moving into the new facility are difficult to project until designs, architectural drawings and contractor estimates of construction costs have been made, but management does not expect to spend more than \$50,000 beyond the amounts already paid prior to incurring construction costs. If the covenants associated with the raw land are not fully complied with in a timely manner, the Company would be required to pay the difference between the purchase price and the appraised value of the property, which management has estimated to be \$256,000



as of the date of this Report, but this difference is subject to change with changes in the appraised value.

Management intends to continue its existing protocol studies and to begin new protocol studies on brain and lung cancer treatment using Cesium-131. Management believes that approximately \$150,000 in expense will be incurred during fiscal year 2016 in protocol expenses relating to lung cancer, inter-cranial cancer and both dual therapy and monotherapy prostate protocols, but there is no assurance that unanticipated needs for additional protocols in support of the development of new applications of our existing products may not arise.

Based on the foregoing assumptions, management believes that the cash and cash equivalents of approximately \$6.35 million, short-term investments of \$5.89 million and investments – other of \$5.16 million at February 5, 2016 will be sufficient to meet our anticipated cash needs assuming both revenue and expenses remain at current levels for the next three years.

Management plans to attempt to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers in the prostate market (through our direct sales channels and through our distributors), and expanding into other market applications which include brain, head and neck, and lung implants, while maintaining the Company's focus on cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain increases in its revenue. Total product sales have not shown the increases necessary to breakeven during the past seven fiscal years ended June 30, 2015 or for the six months ended December 31, 2015.

For the six months ended December 31, 2015, revenue from other treatment modalities with brachytherapy seeds increased 30% when compared to the six months ended December 31, 2014. These newer brachytherapy product sales (including brain, lung and those reported as other) remain in the early stages of adoption and application in the clinical setting and their purchasing patterns are subject to the influence of a few key physicians who can significantly influence revenue from quarter to quarter. There were approximately \$17,000 and \$56,000 sales of GliaSite® RTS in the six months ended December 31, 2015 and 2014, respectively.

There was no material change in the use of proceeds from our public offering as described in our final prospectus supplement filed with the SEC pursuant to Rule 424(b) on March 24, 2014. Through December 31, 2015, the Company had used the net proceeds raised through the March 2014 offering as described in the table below and held the remaining net proceeds in cash and cash equivalents and certificates of deposit. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Offering description	Period	Net proceeds	Remaining net proceeds
Registered direct offering	March 2014	\$ 13,814,742	\$ 13,814,742

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

#### *Other Commitments and Contingencies*

The Company presented its other commitments and contingencies in our Annual Report on Form 10-K for the fiscal year ended June 30, 2015. There have been no material changes outside of the ordinary course of business in those obligations during the current quarter.

*Off-Balance Sheet Arrangements*

The Company has no off-balance sheet arrangements.

*Critical Accounting Policies and Estimates*

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. The Company evaluates its estimates and judgments on an ongoing basis. The Company bases its estimates on historical experience and on various other factors the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Actual results could therefore differ materially from those estimates if actual conditions differ from our assumptions.

During the six months ended December 31, 2015, there have been no changes to the critical accounting policies and estimates, as discussed in Part II, Item 7 of our Form 10-K for the year ended June 30, 2015.

### **ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There have been no material changes to the disclosure in the “Quantitative and Qualitative Disclosures about Market Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2015.

### **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, 2015. 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.

#### **Inherent Limitations of Internal Control Over Financial Reporting**

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

## **PART II - OTHER INFORMATION**

### **ITEM 1 – LEGAL PROCEEDINGS**

On May 22, 2015, the first of three lawsuits was filed against IsoRay, Inc. and two of its officers – Dwight Babcock and Brien Ragle – related to a press release on May 20, 2015 regarding a May 19 online publication of the peer-reviewed article in the journal Brachytherapy titled “Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-Stage Lung Cancer” by Dr. Bhupesh Parashar, et al. The lawsuits are class actions alleging violations of the federal securities laws. By Order dated August 17, 2015, all of the pending lawsuits were consolidated into one case – In re IsoRay, Inc. Securities Litigation; Case No. 4:15-cv-05046-LRS, in the US District Court for the Eastern District of Washington. IsoRay retained Wilson Sonsini Goodrich & Rosati as its and its officers’ defense counsel.

On October 16, 2015, an amended complaint was filed with more detailed allegations relating to violations of federal securities laws and requesting damages through a jury trial. Mr. Ragle was dismissed from the complaint.

On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. Oral argument is scheduled on this motion on April 21, 2016.

IsoRay believes the lawsuit is without merit and is seeking its dismissal, but there can be no assurance as to the outcome of this proceeding.

From time to time we are also involved in legal proceedings arising in the ordinary course of our business.

### **ITEM 1A – RISK FACTORS**

A description of the risk factors associated with our business is included under “Risk Factors” contained in Part I, Item 1A of our Form 10-K for the year ended June 30, 2015, and is incorporated herein by reference. There have been no material changes in our risk factors since such filing, except for the following:

*We Rely Heavily On Five Customers And Have a Single Customer With A Large Payable.* Approximately fifty-four percent (54%) of the Company's revenues are dependent on five customers and approximately thirty-five percent (35%) of our payables are owed by a single customer. The loss of any of these customers would have a material adverse effect on the Company's revenues which may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments. Failure to successfully collect our large outstanding payables would have a material adverse effect on our revenues.

*We Rely Heavily On A Limited Number Of Suppliers.* Some materials used in our products are currently available only from a limited number of suppliers. In fiscal 2015, approximately eighty-three percent (83%) of our Cesium-131 was supplied through JSC INM from a reactor located in Russia and this reliance is continuing in fiscal 2016. Management is evaluating other reactors that meet current specifications to yield Cesium-131 of the purity that the Company requires for use in its products. In November 2015, we experienced a complete shutdown of our Russian supplier and management relied on a combination of inventory from JSC INM and MURR for about a three week period. We believe MURR cannot solely supply our needs for isotope. Management does not believe we could operate for greater than three to four weeks without access to our Russian supplier, and is actively exploring other possible solutions, but there can be no assurance a solution will be found.

Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which can be subject to unanticipated shutdowns and political or civil unrest. Failure to obtain deliveries of Cesium-131 from multiple sources could have a material adverse effect on seed production and there may be a significant delay before we could locate alternative suppliers beyond the two currently used.

We may not be able to locate additional suppliers outside of Russia, other than MURR (which we now believe can only provide supply in combination with inventory from our Russian supplier for three to four weeks), capable of producing the level of output of cesium at the quality standards we require. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our suppliers' control. Failure to deliver products based on lack of supply of our isotope could have a material adverse effect on our business and our reputation.

*We Have A Single Russian Supplier For Our Cesium-131.* In January 2015, the Company entered into an agreement with The Open Joint Stock Company <<Institute of Nuclear Materials>> (JSC INM) to purchase Cesium-131 directly from the Institute of Nuclear Materials (INM) which expired on January 31, 2016. On December 15, 2015, the Company entered into an agreement with The Open Joint Stock Company <<Isotope>> (JSC Isotope) to purchase Cesium. This new agreement expires on March 31, 2017. As a result, the Company relies on JSC Isotope to obtain Cesium-131 from its single Russian reactor source, which is INM. Through the new Agreement, we have obtained fixed pricing for our Russian Cesium-131 through the termination of the contract on March 31, 2017. There can be no guarantee that JSC Isotope will always be able to supply us with sufficient Cesium-131 or will renew our existing contract on favorable terms in March 2017, which could be due in part to risks associated with foreign operations and beyond either our or JSC Isotope's control. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cesium-131 could be reduced significantly unless we have a source of enriched barium for utilization in domestic reactors beyond the quantity that we already own. The Company has performed a search for enriched barium as part of its annual impairment testing for its existing inventory of enriched barium and has found no other entity that could supply the required quantities of enriched barium. While recent testing of regions within the reactor at MURR has found that Cesium-131 can be produced in economically viable quantities at a viable price, there is no assurance that we can obtain the increased quantity of isotope at the pricing and quantities that the Company requires and we now believe that we would only have three to four weeks to rely on MURR based on supply issues with our Russian supplier that occurred in November 2015. We no longer believe we can rely on our prior plan to utilize our supply of enriched barium to expand into other irradiation sites within MURR or at another reactor to supplement our supply of Cs-131. Management believes that, during the next six to twelve months, a viable radiochemistry process must be developed; it must use an acceptable level of enriched barium for the reactor; and the new process must be validated by performing test runs on actual irradiated targets and by performing the radiochemistry process. Management is actively pursuing alternative solutions beyond those at MURR to meet our needs in the event of a prolonged shutdown of the Russian supplier. There is no assurance as to finding a viable solution or if a solution is found, when it can be implemented.

## **ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

## **ITEM 3 – DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4 - MINE SAFETY DISCLOSURES**



Not applicable.

**ITEM 5 – OTHER INFORMATION**

None.

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**ITEM 6. EXHIBITS**

Exhibits:

- 10.87\* Amended and Restated Severance Agreement, Waiver and Release by and among IsoRay Medical, Inc., IsoRay International LLC, IsoRay, Inc., and Dwight Babcock dated January 12, 2016.
- 10.88\* Employment Agreement by and between Thomas C. LaVoy and IsoRay, Inc. dated January 13, 2016 with an effective date of February 15, 2016.
- 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.

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 9, 2016

ISORAY, INC., a Minnesota corporation

By/s/ William Cavanagh, III  
William Cavanagh, III, Interim Chief Executive Officer

(Principal Executive Officer)

By/s/ Brien Ragle  
Brien Ragle, Chief Financial Officer

(Principal Financial and Accounting Officer)