

IsoRay, Inc.  
Form 10-Q  
November 09, 2015

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 September 30, 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

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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:

<u>Class</u>	<u>Outstanding as of November 6, 2015</u>
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) September 30, 2015	June 30, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,587,009	\$ 5,226,740
Certificates of deposit (Note 3)	11,891,312	9,362,574
Accounts receivable, net of allowance for doubtful accounts of \$30,000 and 30,000, respectively	1,130,540	1,049,041
Inventory	460,557	403,955
Other receivables	10,406	19,615
Prepaid expenses and other current assets	260,549	263,597
<b>Total current assets</b>	<b>15,340,373</b>	<b>16,325,522</b>
Fixed assets, net of accumulated depreciation		
Certificates of deposit, non-current (Note 3)	441,890	574,840
Restricted cash	5,135,116	5,106,775
Inventory, non-current	181,262	181,262
Other assets, net of accumulated amortization	569,854	569,854
	240,403	245,031
<b>Total assets</b>	<b>\$ 21,908,898</b>	<b>\$ 23,003,284</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 411,032	\$ 498,253
Accrued protocol expense	152,465	124,131
Accrued radioactive waste disposal	141,500	129,500
Accrued payroll and related taxes	129,540	212,795
Accrued vacation	96,847	127,515

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Total current liabilities	931,384	1,092,194
Long-term liabilities:		
Warrant derivative liability	166,000	181,000
Asset retirement obligation	969,336	947,849
Total liabilities	2,066,720	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 and 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	82,546,112	82,467,111
Accumulated deficit	(62,750,617	) (61,731,507 )
Total shareholders' equity	19,842,178	20,782,241
Total liabilities and shareholders' equity	\$ 21,908,898	\$ 23,003,284

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

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

	Three months ended September 30,	
	2015	2014
Product sales, net	\$ 1,261,322	\$ 1,042,101
Cost of product sales	1,177,863	1,096,903
Gross profit / (loss)	83,459	(54,802 )
Operating expenses:		
Research and development	143,903	176,610
Sales and marketing	278,421	353,743
General and administrative	751,712	575,951
Total operating expenses	1,174,036	1,106,304
Operating loss	(1,090,577 )	(1,161,106 )
Non-operating income (expense):		
Interest income	57,417	72,695
Change in fair value of warrant derivative liability	15,000	306,000
Interest expense	(950 )	(3,451 )
Non-operating income (expense), net	71,467	375,244
Net loss	(1,019,110 )	(785,862 )
Preferred stock dividends	(2,658 )	(2,658 )
Net loss applicable to common shareholders	\$ (1,021,768 )	\$ (788,520 )
Basic and diluted loss per share	\$ (0.02 )	\$ (0.01 )
Weighted average shares used in computing net loss per share:		
Basic and diluted	55,012,901	54,868,053

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



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

	Three months ended September 30,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,019,110	) \$ (785,862 )
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	-	(11,321 )
Depreciation of fixed assets	136,668	169,970
Amortization of other assets	20,725	7,734
Change in fair value of derivative warrant liabilities	(15,000 )	(306,000 )
Accretion of asset retirement obligation	21,487	19,644
Share-based compensation	32,312	21,453
Changes in operating assets and liabilities:		
Accounts receivable, gross	(81,499 )	(37,889 )
Inventory	(56,602 )	(47,742 )
Other receivables	9,209	47,824
Prepaid expenses and other current assets	3,048	(46,136 )
Accounts payable and accrued expenses	(87,221 )	(65,167 )
Accrued protocol expense	28,334	14,029
Accrued radioactive waste disposal	12,000	12,000
Accrued payroll and related taxes	(83,255 )	(130,779 )
Accrued vacation	(30,668 )	(4,944 )
Net cash used by operating activities	(1,109,572 )	(1,143,186 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(3,718 )	(7,453 )
Additions to licenses and other assets	(16,097 )	(2,296 )
Proceeds from the maturity of certificates of deposit	3,526,999	-
Purchases of certificates of deposit	(6,055,737 )	(22,355 )
Purchases of certificates of deposit - non-current	(28,341 )	(4,645,139 )
Change in restricted cash	-	(13 )
Net cash used by investing activities	(2,576,894 )	(4,677,256 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sales of common stock, pursuant to exercise of warrants	-	70,411
Proceeds from sales of common stock, pursuant to exercise of options	46,735	145,275



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Net cash provided by financing activities	46,735	215,686
Net decrease in cash and cash equivalents	(3,639,731 )	(5,604,756 )
Cash and cash equivalents, beginning of period	5,226,740	7,680,073
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 1,587,009</b>	<b>\$ 2,075,317</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 financial statements.

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the three months ended September 30, 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.

### 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 September 30, 2015

	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$6,528,858	\$ -	\$ 5,362,454	\$5,135,116

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 September 30, 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 September 30, 2015 and 2014, were as follows:

	September 30,	
	2015	2014
Series B preferred stock	59,065	59,065
Common stock warrants	360,800	396,574

Common stock options	2,364,346	2,180,858
Total potential dilutive securities	2,784,211	2,636,497

## 5. Inventory

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

	September 30, 2015	June 30, 2015
Raw materials	\$ 264,900	\$ 143,669
Work in process	156,759	204,760
Finished goods	38,898	55,526
	\$ 460,557	\$ 403,955

	September 30, 2015	June 30, 2015
Enriched barium, non-current	\$ 469,758	\$469,758
Raw materials, non-current	100,096	100,096
Total inventory, non-current	\$ 569,854	\$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

	September 30, 2015	June 30, 2015
Production equipment	\$ 3,180,933	\$3,180,933
Office equipment	226,995	224,576
Furniture and fixtures	148,265	148,265
Leasehold improvements	4,129,977	4,129,977
Other	7,224	-
	7,718,394	7,689,676
Less accumulated depreciation	(7,251,504 )	(7,114,836)
Fixed assets, net	\$ 441,890	\$574,840