IsoRay, Inc.
Form 10-Q
May 10, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

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

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

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:

Class	Outstanding as of May 6, 2016
Common stock, $0.001 par value	55,010,619

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

IsoRay, Inc. and Subsidiaries

Consolidated Balance Sheets

	(Unaudited) March 31, 2016	June 30, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$5,694,339	$5,226,740
Certificates of deposit	5,910,756	9,362,574
Accounts receivable, net of allowance for doubtful accounts of $30,000 and $30,000, respectively	883,702	1,049,041
Inventory	457,291	403,955
Other receivables	5,098	19,615
Prepaid expenses and other current assets	288,977	263,597
Total current assets	13,240,163	16,325,522
Property and equipment, net	415,675	574,840
Certificates of deposit, non-current	5,191,960	5,106,775
Restricted cash	181,368	181,262
Inventory, non-current	544,363	569,854
Other assets, net of accumulated amortization	222,529	245,031
Total assets	$19,796,058	$23,003,284
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$732,018	$498,253
Accrued protocol expense	97,679	124,131
Accrued radioactive waste disposal	164,544	129,500
Accrued payroll and related taxes	119,165	212,795
Accrued vacation	98,874	127,515
Total current liabilities	1,212,280	1,092,194

Long-term liabilities:		
Warrant derivative liability	45,000	181,000
Asset retirement obligation	1,013,782	947,849
Total liabilities	2,271,062	2,221,043
Commitments and contingencies		
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;		
55,010,619 and 54,967,559 shares issued and outstanding	55,010	54,968
Treasury stock, at cost, 0 and 13,200 shares, respectively	-	(8,390)
Additional paid-in capital	82,727,429	82,467,111
Accumulated deficit	(65,257,502)	(61,731,507)
Total shareholders' equity	17,524,996	20,782,241
Total liabilities and shareholders' equity	$19,796,058	$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 March 31,		Nine months ended March 31,	
	2016	2015	2016	2015
Product sales	$ 1,198,701	$ 1,158,109	$ 3,649,031	$ 3,265,795
Cost of product sales	1,132,397	1,102,912	3,472,357	3,303,364
Gross profit (loss)	66,304	55,197	176,674	(37,569)
Operating expenses:				
Research and development	183,187	141,399	385,325	458,636
Sales and marketing	300,995	374,876	833,887	1,032,402
General and administrative	909,144	589,934	2,785,539	1,703,825
Total operating expenses	1,393,326	1,106,209	4,004,751	3,194,863
Operating loss	(1,327,022)	(1,051,012)	(3,828,077)	(3,232,432)
Non-operating income (expense):				
Interest income	53,725	68,954	167,032	214,009
Change in fair value of warrant derivative liability	78,000	28,605	136,000	375,605
Financing and interest expense	-	(100)	(950)	(3,551)
Non-operating income (expense), net	131,725	97,459	302,082	586,063
Net loss	(1,195,297)	(953,553)	(3,525,995)	(2,646,369)
Preferred stock dividends	(2,658)	(2,658)	(7,974)	(7,974)
Net loss applicable to common shareholders	$ (1,197,955)	$ (956,211)	$ (3,533,969)	$ (2,654,343)
Basic and diluted loss per share	$ (0.02)	$ (0.02)	$ (0.06)	$ (0.05)
Weighted average shares used in computing net loss per share:				
Basic and diluted	55,022,668	54,883,551	55,010,619	54,878,297

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

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IsoRay, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended March 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,525,995)	$ (2,646,369)
Adjustments to reconcile net loss to net cash used by operating activities:		
Allowance for doubtful accounts	-	(8,607)
Depreciation expense	412,170	439,223
Loss on equipment disposals	6,512	-
Writeoff of inventory associated with discontinued product	72,200	-
Amortization of other assets	25,494	34,923
Change in fair value of derivative warrant liability	(136,000)	(375,605)
Accretion of asset retirement obligation	65,933	60,278
Share-based compensation	229,442	64,360
Changes in operating assets and liabilities:		
Accounts receivable, gross	165,339	(116,817)
Inventory	(125,536)	(104,818)
Other receivables	14,517	43,154
Prepaid expenses and other current assets	111	(9,171)
Accounts payable and accrued expenses	233,765	(135,198)
Accrued protocol expense	(26,452)	38,031
Accrued radioactive waste disposal	35,044	(23,469)
Accrued payroll and related taxes	(93,630)	(146,746)
Accrued vacation	(28,641)	(5,633)
Net cash used by operating activities	(2,675,727)	(2,892,464)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Payments for property and equipment	(259,517)	(77,963)
Additions to licenses and other assets	(2,992)	(14,016)
Proceeds from maturity of certificates of deposit	9,558,812	10,031,758
Purchases of certificates of deposit	(6,106,994)	(9,110,673)
Purchases of certificates of deposit, non-current	(85,185)	(4,744,580)
Change in restricted cash	(106)	(40)
Net cash provided (used) by investing activities	3,104,018	(3,915,514)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Preferred dividends paid	(10,632)	(10,632)

Proceeds from sales of common stock, pursuant to exercise of warrants, net	-	70,789
Proceeds from sales of common stock, pursuant to exercise of options	49,940	145,274
Net cash provided by financing activities	39,308	205,431
Net increase (decrease) in cash and cash equivalents	467,599	(6,602,547)
Cash and cash equivalents, beginning of period	5,226,740	7,680,073
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 5,694,339	$ 1,077,526
Non-cash investing and financing activities:		
Retirement of treasury stock	$ 8,390	$ -
Reclassification of derivative warrant liability to equity upon exercise	$ -	$ 17,395

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 nine months ended March 31, 2016 and 2015

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 the consolidation. In the opinion of management, all adjustments necessary for the fair presentation of the consolidated financial statements have been included. 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 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.

Certain prior period amounts have been reclassified to conform to the current period's presentation. The results of operations for the periods presented may not be indicative of those which may be expected for a full year. 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 March 31, 2016			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	$5,910,756	$ -	$ -	$5,191,960

	As of June 30, 2015			
	Under 90	91 days to	Six months to	Greater

	Days	six months	1 year	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 are 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 March 31, 2016 and 2015, 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 March 31, 2016 and 2015, were as follows:

	March 31, 2016	2015
Series B preferred stock	59,065	59,065
Common stock warrants	360,800	396,174
Common stock options	2,355,060	2,057,620
Total potential dilutive securities	2,774,925	2,512,859

5. Inventory

Inventory consisted of the following at March 31, 2016 and June 30, 2015:

	March 31, 2016	June 30, 2015
Raw materials	$223,588	$143,669
Work in process	225,978	204,760
Finished goods	7,725	55,526
	$457,291	$403,955

	March 31, 2016	June 30, 2015
Enriched barium, non-current	$469,758	$469,758
Raw materials, non-current	74,605	100,096
Total inventory, non-current	$544,363	$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. As of March 31, 2016, the Company discontinued the GliaSite® RTS product line resulting in a write-off of GliaSite® RTS related inventory totaling $72,200.

6. Property and Equipment

	March 31, 2016	June 30, 2015
Land	$168,459	$-
Equipment	3,560,891	3,553,774
Leasehold improvements	4,129,977	4,129,977
Other	38,793	5,925
Property and equipment	7,898,120	7,689,676

Less accumulated depreciation	(7,482,445)	(7,114,836)
Property and equipment , net	$415,675	$574,840

7. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months and nine months ended March 31, 2016 and 2015:

	Three months ended March 31,		Nine months ended March 31,	
	2016	2015	2016	2015
Cost of product sales	$17,757	$7,972	$52,947	$23,917
Research and development expenses	3,567	3,117	10,699	9,352
Sales and marketing expenses	3,744	2,158	10,230	6,475
General and administrative expenses	140,998	8,205	155,556	24,616
Total share-based compensation	$166,066	$21,452	$229,442	$64,360

As of March 31, 2016, total unrecognized compensation expense related to stock-based options was $337,350 and the related weighted-average period over which it is expected to be recognized is approximately 1.34 years.

A summary of stock options within the Company's share-based compensation plans as of March 31, 2016 was as follows:

	Number of Options	Weighted Exercise Price (Years)	Weighted Average Contractual Term	Intrinsic Value
Outstanding at March 31, 2016	2,380,060	$ 1.48	5.71	$289,393
Vested and expected to vest at March 31, 2016	2,294,065	$ 1.48	5,66	$282,800
Vested and exercisable at March 31, 2016	1,966,762	$ 1.46	5.01	$274,200

There were 56,260 and 133,564 stock options exercised and $27,469 and $145,275 of intrinsic value associated with these exercises during the nine months ended March 31, 2016 and 2015, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 482,500 and no stock option awards granted during the nine months ended March 31, 2016 and 2015, respectively. Included in the 482,500 options were 20,000 that were issued in the first quarter of fiscal 2016 and 462,500 issued in the three months ended March 31, 2016.

	For the nine months ended March 31, 2016
Options issued	482,500
Weighted average exercise price	$0.64 to $1.53
Expected term (in years)	1 to 5
Risk free rate	0.51% to 1.51%
Weighted average volatility	106.21% to 108.26%

There were 442,854 and 39,002 stock option awards which expired during nine months ended March 31, 2016 and 2015, respectively.

There were 21,608 and 84,236 stock option awards forfeited during nine months ended March 31, 2016 and 2015, 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 (the Company's retired CEO) 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 was scheduled on this motion on April 2016 but was rescheduled at the request of the plaintiff's attorney to May 12, 2016.

On April 1, 2016, IsoRay filed a reply in Support of Motion to Dismiss Amended Complaint for Violations of the Federal Securities Laws. 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 ("Port"), 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. Medical finalized the purchase of the land in the third quarter of fiscal 2016 and has begun design work on a new production facility.

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

(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 March 31, 2016 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 March 31, 2016			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$5,694,339	$5,694,339	$-	$ -
Warrant derivative liability	45,000	-	45,000	-

	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[1]	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
Change in fair value	-	(78,000)
Balance at March 31, 2016	225,087	$45,000

[1] 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 by 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 March 31, 2016	360,800	$ 1.17

The following table summarizes additional information about the Company's common warrants outstanding as of March 31, 2016:

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 nine months ended March 31, 2016 and 2015, 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 nine months ended March 31, 2016 and 2015 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 nine months ended March 31, 2016 and 2015, respectively. At March 31, 2016 and 2015, services during the prior month had been accrued and remained unpaid in the amount of none and $2,000, respectively. 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 nine months ended March 31, 2016 and 2015, there was a single customer (which was a group of customers supported by a single physician group) that represented between 5% and 10% or more of total net revenue, respectively.

At March 31, 2016, one customer accounted for 10% or more of the Company’s total accounts receivable with that customer (a group of seven legal entities) representing 22% 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 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 nine to twelve months, management intends to vet, test and modify where appropriate the Company’s current plan as required to ensure this capability.

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 that 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" sections of our Form 10-K for the fiscal year ended June 30, 2015 and our Form 10-Q for the fiscal quarter ended December 31, 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 March 31, 2016, 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 a single medical device that can be delivered to the physician in multiple configurations as prescribed for the treatment of cancers in multiple body sites. The Company manufactures and sells this product as the Proxcelan® Cesium-131 brachytherapy seed. Each brachytherapy seed order is manufactured to the physician's specifications for a named patient on a specific treatment date.

The Proxcelan® brachytherapy seed utilizes Cesium-131, with a 9.7 day half-life, as its 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.

The Company has 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 the date of this Report, the Company had distributors in Australia and New Zealand, and the Russian Federation, with revenues from all distributors combined approximating $17,000 in the nine months ended March 31, 2016.

Management is encouraged by the overall growth in revenue from sales of the Company's Proxcelan® 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 20% with minimum revenue growth of 4% and maximum revenue growth of 45%.

Management is encouraged by the growth trend in our core business of treating prostate cancer, with three of the past four 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 18% growth with a maximum revenue decrease of 1% and maximum revenue growth of 44%. The Company has a very small share of the overall prostate brachytherapy market; as such management believes there is significant opportunity for expansion.

Net revenue from other treatments utilizing the Proxcelan® brachytherapy seeds during the prior four fiscal quarters has averaged revenue growth of 36% when compared to the same quarter in the prior fiscal year with minimum revenue growth of 18% 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 32% with minimum revenue growth of 9% and maximum revenue growth of 139%. Although 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 current revenue growth is the result of additional peer-reviewed articles that share treatment experiences. These publications are building awareness in, and communicating the treatment advantages of, our products. Management also believes that as the impact of the Affordable Care Act’s cost containment measures continue 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® Cesium-131 brachytherapy seed is dependent on a number of factors including the following:

- Increased awareness by physicians of the benefits of utilizing Proxcelan® 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® 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® 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 a product that meets the standards of the Company and the expectations of its customers.

As of April 12 , 2016, management had provided a notice of termination of all agreements related to the patent license, supply, manufacture and distribution of its GliaSite® Radiation Therapy System (GliaSite® RTS). The GliaSite® RTS had only resulted in marginal sales but it was the first delivery system available to the Company to deliver brachytherapy radiation in the treatment of brain cancer. Management believes that application of the

Cesium-131 brachytherapy seed in a braided suture and using other delivery systems which are being developed by others utilizing the Company's Cesium-131 brachytherapy seed are showing greater success and acceptance in the treatment of brain cancer.

Results of Operations

Three and nine months ended March 31, 2016 and 2015.

	Three months ended March 31,				
	2016		2015		2016 - 2015
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	$1,198,701	100	$1,158,109	100	4
Cost of product sales	1,132,397	94	1,105,912	95	3
Gross profit / (loss)	66,304	6	55,197	5	20
Research and development expenses	183,187	15	141,399	12	30
Sales and marketing expenses	300,995	25	374,876	32	(20)
General and administrative expenses	909,144	76	589,934	51	54
Net loss	$(1,195,297)	(100)	$(953,553)	(83)	25

	Nine months ended March 31,				
	2016		2015		2016 - 2015
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	$3,649,031	100	$3,265,795	100	12
Cost of product sales	3,472,357	95	3,303,364	101	5
Gross profit / (loss)	176,674	5	(37,569)	(1)	570
Research and development expenses	385,325	11	458,636	14	(16)
Sales and marketing expenses	833,887	23	1,032,402	32	(19)
General and administrative expenses	2,785,539	76	1,703,825	51	63
Net loss	$(3,525,995)	(97)	$(2,646,369)	(81)	(33)

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

Revenues.

Product sales consist primarily of Proxcelan® Cesium-131 brachytherapy seeds manufactured and configured to the physician's specification. Also included in product sales are GliaSite® RTS device sales.

Revenue from product sales for the three months ended March 31, 2016 increased approximately $41,000 or 4% when compared to the three months ended March 31, 2015. Increases in revenue from product sales were due to an increase in the number of brachytherapy seed treatments. No revenue was derived from GliaSite® RTS during the three months ended March 31, 2016. During the three months ended March 31, 2016 and 2015, nearly 100% of product sales came from brachytherapy seed treatments.

Revenue from product sales for the nine months ended March 31, 2016 increased approximately $383,000 or 12% when compared to the nine months ended March 31, 2015. Increases in revenue from product sales were primarily related to an increase in the number of brachytherapy seed treatments. GliaSite® RTS revenues for the nine months ended March 31, 2016 were approximately $17,000. During the nine months ended March 31, 2016, nearly 100% of product sales came from brachytherapy seed treatments compared with 98% during the nine months ended March 31, 2015.

Prostate Brachytherapy.

During the three months ended March 31, 2016 and 2015, respectively, prostate brachytherapy was 87% and 86% of total revenues. During the nine months ended March 31, 2016 and 2015, respectively, prostate brachytherapy was 88% and 87% of total revenues. Management believes 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 anticipates that additions in sales and marketing during the three months ended March 31, 2016 will enhance growth in this segment including the addition of a Vice-President of Sales and Marketing with over 15 years of experience in the prostate cancer treatment market. Management also believes the data that has been published in peer-reviewed journal articles on treatment outcomes achieved with low-dose-rate (LDR) prostate brachytherapy with the Company's Proxcelan® Cesium-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® Cesium-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 March 31, 2016 when compared to the three months ended March 31, 2015. The largest revenue contributions in this classification came from brain cancer and gynecological cancer treatments. During the three months ended March 31, 2016 and 2015, respectively, other brachytherapy represented approximately $139,000 or 12% of total revenue and approximately $118,000 or 11% of total revenue.

These treatment sites as a group increased their revenue contribution by 30% during the nine months ended March 31, 2016 when compared to the nine months ended March 31, 2015. The largest revenue contributions in this classification came from brain cancer and gynecological cancer treatments. During the nine months ended March 31, 2016 and 2015, 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.

Cost of product sales.

Cost of product sales consists primarily of the costs of manufacturing and distributing the Company's products.

Cost of product sales for the three months ended March 31, 2016 increased approximately $30,000 or 3% when compared to the three months ended March 31, 2015.

Cost of product sales for the nine months ended March 31, 2016 increased approximately $169,000 or 5% when compared to the nine months ended March 31, 2015.

Included in the increase in cost of product sales for the three and nine months ended March 31, 2016 were increased payroll, benefits and share-based compensation which were partially offset by a decrease in medical device tax. In addition, for the nine months ended March 31, 2016 material and third-party seed loading costs increased but were partially offset by decreased occupancy and depreciation expenses.

The Company purchases an excess supply of isotope to meet not only known customer orders but also enough to fill anticipated orders which may or may not materialize. Excess isotope is utilized in the production of upcoming orders where possible considering the decay rates of Cesuim-131. Loss of isotope to decay is also included as a cost of production.

Gross profit / (loss).

Gross profit for the three months ended March 31, 2016 improved by approximately $11,000 or 20% when compared to the gross profit for the three months ended March 31, 2015.

Gross profit for the nine months ended March 31, 2016 improved by approximately $214,000 or 570% when compared to the gross loss for the nine months ended March 31, 2015.

Gross profit improvements for the three and nine months were due primarily to increased product sales that required only minimal increases in labor costs, raw material consumption and utilized isotope that was already available at current purchasing levels to support growth and other fluctuations in demand.

Research and development.

Research and development consists primarily of the costs related to employee and third party research and development activities.

Research and development costs for the three months ended March 31, 2016 increased approximately $42,000 or 30% when compared to the three months ended March 31, 2015.

Research and development costs for the nine months ended March 31, 2016 increased approximately $73,000 or 16% when compared to the nine months ended March 31, 2015.

Included in research and development costs for the three and nine months ended March 31, 2016 were increases in legal expenses related to intellectual property and increased payroll related to the short-term appointment of the Company Vice-President of Research and Development as interim Chief Executive Officer. In addition, for the nine months ended March 31, 2016 cost increases were partially offset by an adjustment to protocol costs.

Sales and marketing expenses.

Sales and marketing expenses consists primarily of the costs related to the internal and external activities of the Company’s sales, marketing and customer service.

Sales and marketing costs for the three months ended March 31, 2016 decreased approximately $74,000 or 20% when compared to the three months ended March 31, 2015.

Sales and marketing costs for the nine months ended March 31, 2016 decreased approximately $199,000 or 19% when compared to the nine months ended March 31, 2015.

Included in sales and marketing costs for the three and nine months ended March 31, 2016 were decreases in payroll, benefits and travel expenses related to unfilled positions. The Company filled a senior marketing position in February 2016 and the Vice President of Sales and Marketing position in March 2016. The open territory manager position remained vacant as of March 31, 2016 but was filled in April 2016.

General and administrative expenses.

General and administrative expenses consist primarily of the costs related to the executive, quality assurance/regulatory affairs departments, finance, and information technology of the Company.

General and administrative costs for the three months ended March 31, 2016 increased approximately $319,000 or 54% when compared to the three months ended March 31, 2015.

General and administrative costs for the nine months ended March 31, 2016 increased approximately $1,082,000 or 63% when compared to the nine months ended March 31, 2015.

Included in general and administrative costs for the three months ended March 31, 2016 were approximately $60,000 in increased legal expenses related to the retirement of the Company CEO, the appointment of an interim CEO and the hiring of a new CEO as well as payroll and benefit expenses related to the retirement of the Company CEO and the hiring of a new CEO; approximately $134,000 in option-based compensation for the new CEO; and approximately $79,000 in costs associated with discontinuing the GliaSite® RTS product.

In addition, for the nine months ended March 31, 2016, cost increases included approximately $234,000 in legal fees related to the class action shareholder suit; approximately $300,000 in severance costs related to the retirement of the former CEO; approximately $51,000 in occupancy expense due to a change in allocation of costs; $27,000 in information technology upgrades including computer hardware, computer software and office supplies that are below the capitalization threshold; approximately $26,000 in audit and other services from British Standards Institute, the notified body for the Company related to the quality system; and approximately $21,000 in public company expenses.

Operating loss.

Operating loss for the three months ended March 31, 2016 increased approximately $276,000 or 26% when compared to the operating loss for the three months ended March 31, 2015.

Operating loss for the nine months ended March 31, 2016 increased by approximately $596,000 or 18% when compared to the operating loss for the nine months ended March 31, 2015.

Operating losses for the three and nine months increased primarily due to general and administrative cost increases as previously discussed.

Interest income.

Interest income for the three months ended March 31, 2016 decreased approximately $15,000 or 22% when compared to the interest income for the three months ended March 31, 2015.

Interest income for the nine months ended March 31, 2016 decreased by approximately $47,000 or 22% when compared to the interest income for the nine months ended March 31, 2015.

Interest income decreases for the three and nine months ending March 31, 2016 were due primarily the excess cash available to invest in laddered CDs in the Certificate of Deposit Account Registry Service® (CDARS) and 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 as of March 31, 2016 and March 31, 2015, 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 March 31, 2016 and March 31, 2015.

Liquidity and capital resources. The Company assesses its liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company has historically financed its operations through selling equity to investors. During the nine months ended March 31, 2016 and March 31, 2015, the Company used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Net loss was approximately $3.53 million compared to $2.65 million and net cash used by operating activities was $2.68 million and $2.89 million, for the nine months ended March 31, 2016 and 2015, respectively. The decrease in net cash used by operating activities was due to several factors including unfilled positions within the Company and timing of paying operating expenses. Other factors are as follows:

- Decrease in cash used by accounts receivable of approximately $165,000, the result of the increased collection effectiveness;
- Increase in cash used by inventory of approximately $126,000, the result of purchases of inventory, consisting of raw materials produced to the specifications of the Company, in quantities to obtain best pricing, pre-loading materials and work in process;
- Decrease in cash used by inventory, a significant portion of the change is the result of a $72,000 write-off of GliaSite® RTS inventory; and
- Decrease in cash used by accounts payable and accrued expenses of approximately $234,000, 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.

Cash flows from investing activities

Net cash provided by investing activities was $3.10 million as compared to net cash used by investing activities of $3.92 million for the nine months ended March 31, 2016 and 2015, respectively. Investing activities primarily consist

of transactions related to the purchase and subsequent maturity of certificates of deposit totaling approximately $3.4 million, with transactional categories showing separately on the statement of cash flows. Other factors are as follows:

- Increase in cash used in purchases of equipment of approximately $91,000; and
- Increase in cash used in purchase of land of approximately $169,000.

Cash flows from financing activities

Net cash provided by financing activities was $40,000 and $205,000 for the nine months ended March 31, 2016 and 2015, respectively. The decrease was primarily due to fewer warrants and stock option exercises.

Projected Fiscal Year 2016 Liquidity and Capital Resources

At March 31, 2016, the Company held cash and cash equivalents of $5,694,339, CDARS of $5,910,756 million that mature in the current operating cycle and CDARS of $5,191,960 million that mature within the next seventeen months.

	Amount
Cash and cash equivalents	$5,694,339
Certificates of deposit maturing in less than 90 days	5,910,756
Certificates of deposit maturing greater than one year and less than two years	5,191,960
Cash, cash equivalents and certificates of deposit total	$16,797,055

The Company had approximately $4.50 million of cash and cash equivalents, $6.40 million of certificates of deposit and $5.19 million of certificates of deposit, non-current as of May 6, 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 approximate monthly required cash operating expenditures were $298,000 and $321,000 during the nine months ended March 31, 2016 and 2015, respectively, which represents a 7% decrease. As we have filled several open positions both in senior management and sales and marketing and have engaged other third-party experts in marketing and medical reimbursement, 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 with the goal of constructing a facility that will have depreciation cost that is less than the monthly rental 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 $144,000 was paid to close on the real property. Future cash requirements related to the construction of and moving into the new facility are difficult to project until designs, architectural drawings and contractor estimates of construction costs have been completed. Prior to construction, management has contracted to spend approximately $165,000 to receive a final design, architectural drawings and an estimate of cost to construct the new facility. 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 $4.50 million, short-term investments of $6.40 million and investments – other of $5.19 million at May 6, 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 sales in other market applications which include brain, gynecologic, 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 nine months ended March 31, 2016.

For the nine months ended March 31, 2016, revenue from other treatment modalities with brachytherapy seeds increased 30% when compared to the nine months ended March 31, 2015. These newer brachytherapy product sales (including brain, gynecological, head and neck, 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 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 March 31, 2016, 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 are 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 nine months ended March 31, 2016, 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 March 31, 2016. 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 are 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

The Company may, in the ordinary course of business, be subject to various legal proceedings. Legal proceedings are discussed in Note 8 of Notes to Condensed Consolidated Financial Statements (Unaudited), which is incorporated by reference in Part 1, Item 1. We refer you to that discussion for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought. We provide the following additional information concerning those legal proceedings, including the name of the lawsuit, the court in which the lawsuit is pending, and the date on which the petition commencing the lawsuit was filed.

In Re IsoRay, Inc. Securities Litigation: U.S. District Court for the Eastern District of Washington, filed October 16, 2015.

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 in Part II, Item 1A of our Form 10-Q for the quarter ended December 31, 2015, and is incorporated herein by reference. There have been no material changes in our risk factors since such filings, except for the following:

Our Revenues Depend Upon One Product. As we discontinued sale of our GliaSite® RTS product, our revenues depend solely upon the successful production, marketing, and sales of the Proxcelan® Cesium-131 brachytherapy seed. The rate and level of market acceptance of this product varies depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of competing products, if any; the clinical outcomes of the patients treated; the effectiveness of our sales and marketing efforts or those of our distributors in the United States, Australia, New Zealand and the Russian Federation; any unfavorable publicity concerning our product or similar products; our product's price relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third-party payers; regulatory developments related to the manufacture or continued use of the product; availability of sufficient supplies of barium for Cesium-131 seed production; ability to produce sufficient quantities of Cesium-131; the ability of physicians to apply the correct dosage of seeds and avoid excessive levels of radiation to patients; and the ability to use this product to treat multiple types of cancers in various organs. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

We Rely Heavily On Five Customers And Have a Single Customer With A Large Payable. Approximately fifty-one percent (51%) of the Company's revenues are dependent on five customers and approximately twenty-two percent (22%) 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.

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.

ITEM 6. EXHIBITS

Exhibits:

31.1* Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer

31.2* Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer

32** Section 1350 Certifications

101.INS* XBRL Instance Document

101.SCH* XBRL Taxonomy Extension Schema Document

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

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: May 10, 2016

ISORAY, INC., a Minnesota corporation

By /s/ Thomas C. LaVoy
Thomas C. LaVoy, Chief Executive Officer

(Principal Executive Officer)

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

(Principal Financial and Accounting Officer)