IsoRay, Inc.
Form 10-Q
November 14, 2017
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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, 2017

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 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 No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)
	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided

pursuant to Section 13(a) of the Exchange Act.

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

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

Class	Outstanding as of November 10, 2017
Common stock, $0.001 par value	55,017,419

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ISORAY, INC.

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PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands, except shares)

	September 30, 2017 (unaudited)	**June 30, 2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,956	$5,932
Certificates of deposit (Note 3)	3,300	3,039
Accounts receivable, net of allowance for doubtful accounts of $26 and $26, respectively	743	726
Inventory	453	323
Prepaid expenses and other current assets	414	271
Total current assets	8,866	10,291
Property and equipment, net	1,090	1,054
Restricted cash	181	181
Inventory, non-current	427	513
Other assets, net of accumulated amortization	217	230
Total assets	$ 10,781	$12,269
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 811	$630
Accrued protocol expense	65	75
Accrued radioactive waste disposal	11	125
Accrued payroll and related taxes	34	138
Accrued vacation	146	138
Total current liabilities	1,067	1,106
Long-term liabilities:		
Asset retirement obligation	568	561
Total liabilities	1,635	1,667
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	-	-
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; 55,017,419 and 55,017,419 shares issued and outstanding	55	55
Additional paid-in capital	83,241	83,151
Accumulated deficit	(74,150)	(72,604)
Total shareholders' equity	9,146	10,602
Total liabilities and shareholders' equity	$ 10,781	$ 12,269

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

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IsoRay, Inc. and Subsidiaries
Consolidated Statements of Operations (Unaudited)
(Dollars and shares in thousands, except for per-share amounts)

	Quarter ended September 30,	
	2017	**2016**
Product sales, net	$1,211	$1,081
Cost of product sales	946	1,033
Gross profit	265	48
Operating expenses:		
Research and development		
Propriety research and development	287	172
Collaboration arrangement, net of reimbursement	75	-
Total research and development	362	172
Sales and marketing	614	524
General and administrative	841	927
Total operating expenses	1,817	1,623
Operating loss	(1,552)	(1,575)
Non-operating income:		
Interest income, net	6	30
Change in fair value of warrant derivative liability	-	27
Other income	-	20
Non-operating income, net	6	77
Net loss	(1,546)	(1,498)
Preferred stock dividends	(3)	(3)
Net loss applicable to common shareholders	(1,549)	(1,501)
Basic and diluted loss per share	$(0.03)	$(0.03)
Weighted average shares used in computing net loss per share:		
Basic and diluted	55,017	55,011

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)
(In thousands)

	Quarter ended September 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(1,546)	$(1,498)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	18	16
Loss on equipment disposals	-	5
Amortization of other assets	13	10
Change in fair value of warrant derivative liability	-	(27)
Accretion of asset retirement obligation	7	7
Share-based compensation	90	70
Changes in operating assets and liabilities:		
Accounts receivable, gross	(17)	31
Inventory	(44)	(39)
Prepaid expenses and other current assets	(143)	41
Accounts payable and accrued expenses	181	(118)
Accrued protocol expense	(10)	28
Accrued radioactive waste disposal	(114)	12
Accrued payroll and related taxes	(104)	98
Accrued vacation	8	11
Net cash used by operating activities	(1,661)	(1,353)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(54)	(147)
Additions to other assets	-	(151)
Proceeds from maturity of certificates of deposit	3,043	-
Purchases of and interest from certificates of deposit	(3,304)	(29)
Net cash used by investing activities	(315)	(327)
Net decrease in cash and cash equivalents	(1,976)	(1,680)
Cash and cash equivalents, beginning of quarter	5,932	10,139
CASH AND CASH EQUIVALENTS, END OF QUARTER	$3,956	$8,459

The accompanying notes are an integral part of

these
consolidated
financial
statements.

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IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three months ended September 30, 2017 and 2016

1. Basis of Presentation

The accompanying unaudited interim consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries, referred to herein as "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, 2017.

The unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). 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 2018 will be 0%.

2. New Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 Revenue Recognition, replacing guidance currently codified in Subtopic 605-10 Revenue Recognition-Overall with various SEC Staff Accounting Bulletins providing interpretive guidance. The guidance establishes a new five step principle-based framework in an effort to significantly enhance comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets. The standard will be effective for the Company in the first quarter of its fiscal year 2019, but early adoption is permitted starting in the first quarter of fiscal year 2018. The Company intends to adopt the new standard in the first quarter of fiscal year 2019 and expects to use the modified retrospective method. The Company has evaluated the impact of the future adoption of ASU 2014-09 on its consolidated financial statements and does not currently expect significant changes in the timing of revenue recognition compared to the existing methodology.

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 ASU became effective for the Company on July 1, 2017. This update did not have a material impact on the Company's consolidated financial statements upon adoption.

In November 2015, the FASB issued an ASU 2015-17 to simplify the balance sheet classification of deferred taxes. This update requires all deferred tax assets and liabilities to be reported as non-current in the consolidated balance sheets. The ASU became effective for the Company on July 1, 2017. This update did not to have a material impact on the Company's consolidated financial statements upon adoption.

In February 2016, the FASB issued ASU 2016-02 Leases (Subtopic 842), which will require lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by most leases. The update is effective for annual and interim reporting periods beginning after December 15, 2018. Early adoption is permitted. The ASU will be effective for the Company in the first quarter of fiscal year 2020. We are currently evaluating the impact of the guidance on the Company's consolidated financial statements.

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In August 2016, the FASB issued ASU No. 2016-15 Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The update provides guidance on classification for cash receipts and payments related to eight specific issues. The update is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of implementing this update on the consolidated financial statements.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

3. Certificates of Deposit

Certificate of Deposit Account Registry Service (CDARS) 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). That institution utilizes the CDARS system to purchase certificates of deposit at other financial institutions while keeping the investment at each institution fully insured by the FDIC. CDARS held by the Company as of September 30, 2017 and June 30, 2017 mature as follows (in thousands):

	As of September 30, 2017			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	$825	$ 825	$ 1,650	$ -

	As of June 30, 2017			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	$3,039	$ -	$ -	$ -

4. Loss per Share

Basic and diluted earnings (loss) 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 September 30, 2017 and 2016, 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, 2017 and 2016, were as follows (in thousands):

	September 30,	
	2017	2016
Series B preferred stock	59	59
Common stock warrants	-	230
Common stock options	3,395	2,609
Total potential dilutive securities	3,454	2,898

5. Inventory

Inventory consisted of the following at September 30, 2017 and June 30, 2017 (in thousands):

	September 30, 2017	June 30, 2017
Raw materials	$ 339	$191
Work in process	94	121
Finished goods	20	11
Total inventory, current	$ 453	$323

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	September 30, 2017	June 30, 2017
Enriched barium, non-current	$ 347	$470
Raw materials, non-current	80	43
Total inventory, non-current	$ 427	$513

Inventory, non-current is raw materials that were ordered in quantities to obtain volume cost discounts which based on current and anticipated sales volumes will not be consumed within an operating cycle.

On August 25, 2017, IsoRay Medical, Inc. (“Medical”) entered into a Consignment Agreement and related Services Agreement with MedikorPharma-Ural LLC (“Medikor”). Pursuant to the Consignment Agreement, Medical has consigned its inventory of enriched barium carbonate to Medikor. It is expected that beginning in November, 2017, Medikor will use the barium carbonate consigned by Medical and contract with a third-party manufacturer to produce Cesium-131. Pursuant to the Service Agreement, Medical will perform certain qualitative and quantitative chemical analyses on the resulting Cesium-131. It is further expected that a separate third-party contractor will receive the Cesium-131 produced by the third-party manufacturer and will sell the Cesium-131 exclusively to Medical. Medical anticipates obtaining enough Cesium-131 under this arrangement to obtain over 4,000 curies of Cesium-131 over a ten-year period but there is no assurance as to whether the agreements will be terminated before this full amount is obtained and other supply sources are used, nor is there assurance that the agreements with the third-party Cesium-131 suppliers will be periodically executed over this time period.

6. Property and Equipment

Property and equipment consisted of the following at September 30, 2017 and June 30, 2017 (in thousands):

	September 30, 2017	June 30, 2017
Land	$ 366	$366
Equipment	3,776	3,776
Leasehold improvements	4,134	4,130
Other[1]	422	373
Property and equipment	8,698	8,645
Less accumulated depreciation	(7,608)	(7,591)
Property and equipment, net	$ 1,090	$1,054

[1] – Represents items that meet the capitalization threshold or which management believes will meet the threshold at the time of completion and which have yet to be placed into service as of the date of the balance sheet. Also included at

September 30, 2017 and June 30, 2017 are costs associated with automation of production processes and advance planning and design work on the Company's new production facility.

7. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2017 and 2016 (in thousands):

	Three Months ended September 30,	
	2017	2016
Cost of product sales	$ 16	$ 27
Research and development expenses	19	8
Sales and marketing expenses	17	15
General and administrative expenses	38	20
Total share-based compensation	$ 90	$ 70

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As of September 30, 2017, total unrecognized compensation expense related to stock-based options was approximately $807,000 and the related weighted-average period over which it is expected to be recognized is approximately 1.39 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2017 was as follows (in thousands except for exercise prices and terms):

As of September 30, 2017	Number of Options	Weighted Exercise Price	Weighted Average Contractual Term (Years)	Intrinsic Value
Outstanding	3,395	$ 0.76	7.71	$ 67
Vested and expected to vest	3,290	$ 0.76	7.66	$ 67
Vested and exercisable	1,760	$ 0.90	5.82	$ 67

There were no stock options exercised during the three months ended September 30, 2017 and 2016, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 75,000 and no option awards granted with a fair value of approximately $33,000 and $0 during the three months ended September 30, 2017 and 2016, respectively.

There were no and 280,534 stock option awards which expired during three months ended September 30, 2017 and 2016, respectively.

There were 59,666 and 35,336 stock option awards forfeited during three months ended September 30, 2017 and 2016, respectively.

8. Commitments and Contingencies

Isotope Purchase Agreement

In December 2015, the Company completed negotiations with The Open Joint Stock Company (located in Russia) for the purchase of Cs-131 manufactured by the Institute of Nuclear Materials. The purchase agreement provided the Company with one year's supply of Cs-131. The original agreement was due to expire on March 31, 2017, but in December 2016 an addendum was signed extending it until December 31, 2017. On October 23, 2017, the Company, together with The Open Joint Stock Company signed an addendum to the contract to include Cs-131 manufactured at SSC RIAR and extending it until December 31, 2018.

Research and Development - Collaborative Arrangement

On March 13, 2017, Medical entered into a Collaborative Development Agreement (CDA) with GammaTile, LLC to further develop a brachytherapy medical device for the treatment of cancerous tumors in the brain and to seek regulatory approval for the new product. As the project manager, Medical will incur all costs in connection with the collaboration project which has been shared equally by both parties as of November 8, 2016 when they informally began the collaboration. The start of the formal collaboration has been extended from December 2017 until March 2018. In accordance with ASC 808 "Collaborative Arrangements", this activity is accounted for as a collaborative arrangement and related costs are incurred, shared, and separately stated in connection with a collaborative research and development project. These costs are reported on the financial statements under "Research and development: Collaboration arrangements, net of reimbursement." The Company collaborated with GammaTile LLC in filing applications to the U.S. Food and Drug Administration (FDA) to clear GammaTile™ for clinical use, and a New Technology Add-on Payment (NTAP) to the Center for Medicare and Medicaid Services (CMS) seeking re-imbursement for the GammaTile™ treatment in the in-patient setting. The application with the FDA is ongoing, however, the NTAP was filed in October 2017.

During the quarter ended September 30, 2017 and June 30, 2017, costs incurred in connection with the collaboration agreement were $147,000 and $65,000, respectively.

As of September 30, 2017 and June 30, 2017, the Company had outstanding receivables from GammaTile LLC of $68,000 and $66,000 respectively.

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Derivative Complaint related to Shareholder Value

On September 29, 2016, David M. Kitley, purportedly on behalf of IsoRay, filed a derivative lawsuit in the United States District Court for the District of Minnesota under the case caption Kitley v. IsoRay, Inc., Case No. 0:16-cv-03297-DTS. The complaint named as defendants current and former IsoRay directors Dwight Babcock, Thomas LaVoy, Philip J. Vitale and Michael W. McCormick, alleging that they violated their fiduciary duties to IsoRay in connection with a press release allegedly containing false and misleading statements concerning the results from a peer reviewed study of its Cesium-131 isotope seeds for the treatment of non-small cell lung cancers, thereby artificially inflating the price of IsoRay stock. The complaint sought unspecified damages, in an amount not presently determinable, among other forms of relief.

On November 17, 2016, IsoRay moved to dismiss the complaint, arguing that plaintiff was not entitled to pursue his derivative claims due to his failure to serve a pre-suit demand on IsoRay's board. Rather than respond to the motion to dismiss, plaintiff filed an amended complaint on January 23, 2017. The amended complaint alleged the same derivative claims as the original, and added IsoRay director Alan Hoffmann as a defendant. Plaintiff sought an award of damages and an order directing IsoRay to undertake reforms of its corporate governance and internal procedures. IsoRay moved to dismiss the amended complaint on March 9, 2017. Plaintiff responded on April 20, 2017, and IsoRay replied on May 17, 2017. The court heard oral argument on the motion on August 22, 2017, and took the matter under advisement at that time. On October 19, 2017, the court granted IsoRay's motion to dismiss. The matter is now resolved.

9. Fair Value Measurements

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement (in thousands):

	Fair Value at September 30, 2017			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$3,956	$3,956	$ -	$ -

	Fair Value at June 30, 2017			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$5,932	$5,932	$ -	$ -

The Company's cash and cash equivalent instruments are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices.

10. Related Party Transactions

During the quarter ended June 30, 2016, the Company engaged GO Intellectual Capital, LLC (GO) for marketing services in support of the Company's rebranding effort. Michael McCormick, a member of the Company Board of Directors, is a 1/3 owner of GO. A statement of work was developed defining the scope of the effort and the deliverables to the Company including a new logo with brand messaging and communication tools including a website, sales presentation tools and a public relations strategy. For the quarter ended September 30, 2016, the Company paid approximately $15,000 to GO for its performance of work related to the agreed upon statement of work. No such services were provided in the quarter ended September 30, 2017.

11. Concentrations of Credit and Other Risks

One group of customers, facilities or physician practices has revenues that aggregate to greater than 10% of total Company product sales:

	Three months ended	
	September 30, 2017	September 30, 2016
Facility		
El Camino Hospital of Los Gatos, Fremont Surgery Center & other facilities [1]	25.98%	22.33 %

[1] – This group of facilities individually each comprise less than 10% of total Company product sales. They are serviced by the same physician group, one of whom is our Medical Director.

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The Company routinely assesses the financial strength of its customers and provides an allowance for doubtful accounts as necessary.

12. Subsequent Events

Media Advertising Agreement

On October 3, 2017, IsoRay, Inc. (“IsoRay”) entered into a Media Advertising Agreement (the “Agreement”) with Al & J Media Inc., a corporation incorporated in the State of New York (the “Consultant”).

Pursuant to the Agreement, the Consultant will introduce IsoRay to potential sources of media, marketing agreements, and/or strategic alliances, including but not limited to radio and television media advertising, various media publications, and Internet podcasts. The Consultant does not promote IsoRay as part of the Agreement; it is only a media agent for advertising. The services are expected to be complete in 180 days. IsoRay may cancel the Agreement after the first 90 days.

As compensation for the services, IsoRay will pay the Consultant $120,000 of which $20,000 is payable upon execution of the Agreement, and $20,000 is payable 30, 60, 90, 120, and 150 days after execution of the Agreement. Additionally, the Consultant will receive 250,000 warrants upon execution of the Agreement, which vest immediately, entitling the Consultant to purchase shares of IsoRay common stock, exercisable on or before October 3, 2020, at an exercise price of $0.54 per share, and 250,000 at the market warrants 90 days after execution of the Agreement, at a price based on the issuance date.

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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 revenue, 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 Item 1A - Risk Factors beginning on page 23 below 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 GAAP. 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 SEC on September 28, 2017 are those that depend most heavily on these judgments and estimates. As of September 30, 2017 there had been no material changes to any of the critical accounting policies contained therein.

Overview

IsoRay 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 Cesium-131 brachytherapy seed.

The 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.

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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 Italy and the Russian Federation, with no reported revenues in the quarter ended September 30, 2017.

Results of Operations

Three months ended September 30, 2017 and 2016 (in thousands):

	Three months ended September 30,				
	2017		2016		2017 - 2016
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	$ 1,211	100	$ 1,081	100	12
Cost of product sales	946	78	1,033	96	(8)
Gross profit	265	22	48	4	452
Operating expenses:					
Research and development expenses - proprietary	287	24	172	16	67
Research and development expenses – collaboration agreement, net of reimbursement	75	6			
Sales and marketing expenses	614	51	524	48	17
General and administrative expenses	841	69	927	86	(9)
Total operating expenses	1,817	150	1,623	150	12
Operating loss	(1,552)	(128)	(1,575)	(146)	(2)

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

Product Sales

Changes in sales personnel and implementation of a revitalized sales and marketing strategy in the second quarter of fiscal 2017 has resulted in positive sales growth in the first quarter of fiscal 2018 when compared to prior year first quarter. Ongoing training and support of new sales personnel has led to not only new accounts but also reconnecting with and receiving orders from prior accounts.

Three months ended September 30, 2017 and 2016 (in thousands)

	Three months ended September 30,				
	2017		2016		2017 - 2016
	Amount	% (a)	Amount	% (a)	% Change
Prostate brachytherapy	$1,084	89	$966	89	12
Other brachytherapy	127	11	115	11	10
Product sales, net	1,211	100	1,081	100	12

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

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Prostate Brachytherapy

Prostate brachytherapy sales were impacted by changes in sales account managers and by the schedules of some key accounts in the first quarter of the fiscal year. During the quarter ended September 30, 2017, the Company had a full sales team in place contributing to the increase in sales. Also, website improvements and significant investments in product support literature, social media and public relations are increasing the awareness of the Company in the prostate brachytherapy treatment markets providing the Company opportunities to develop new customers and reconnect with past customers.

Management believes growth in prostate brachytherapy revenues will be the result of physicians, payers, and patients increasingly considering overall brachytherapy treatment advantages including costs, better treatment outcomes and improvement in the quality of life for patients, when compared with non-brachytherapy treatments.

Management believes increased pressure to deliver effective healthcare in both terms of outcome and cost drove treatment options, and accordingly drove the Company's prostate revenues, in the quarter ended September 30, 2017.

Other Brachytherapy

Other brachytherapy includes, but is not limited to, brain, lung, head/neck, and gynecological treatments. Initial applications for these other brachytherapy treatments are primarily used in recurrent cancer treatments or salvage cases that are generally difficult to treat aggressive cancers where other treatment options are either ineffective or unavailable.

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. This volatility resulted in the increase from the prior year.

Cost of product sales

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

Contributing to the quarters ended September 30, 2017 and 2016 comparison were decreases attributed to cost savings initiatives that resulted in lower procurement costs of goods and services. Some costs shifted in the quarter ended September 30, 2017 to research and development from cost of product sales as employees performed research and development work. Also, reduced staffing costs were realized with decreased head count. These decreases were partially offset by increased supply of isotope from MURR which increased total cost of product sales but resulted in lower supply cost per curie of Cesium-131.

Gross Profit

Contributing to the three months ended September 30, 2017 and 2016 gross profit comparison were increased sales as well as reductions in cost of product sales due to cost savings initiatives and reduced staffing costs including utilization of production personnel on research and development projects.

Research and development

Research and development – proprietary

Proprietary research and development consists primarily of employee and third-party costs related to research and development activities.

Contributing to the quarters ended September 30, 2017 and 2016 proprietary research and development comparison were increases associated with participation in new protocols, device development activities, as well as a reallocation of employee costs from cost of product sales as those employees performed work on research and development projects. These increases were partially offset by decreased legal fees.

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Research and development – collaborative arrangement

Collaboration arrangement related costs are incurred, shared, and separately stated in connection with a collaborative research and development project (see footnote 8 of Notes to unaudited consolidated financial statements contained in this filing). For the quarter ended September 30, 2017 the collaborative arrangement incurred total costs of approximately $147,000 net of approximately $72,000 in shared cost reimbursements.

Sales and marketing expenses

Sales and marketing expenses consist primarily of the costs related to the internal and external activities of the Company's sales, marketing and customer service functions of the Company. As the Company increasingly focuses on improving sales, the cost associated with marketing and additional staffing continues to increase.

Contributing to the quarters ended September 30, 2017 and 2016 comparison were increased advertising and public relations costs as part of the revitalized marketing plan. Staffing differences are a major factor in the cost comparison as open positions in the quarter ended September 30, 2016 were filled in periods prior to the quarter ended September 30, 2017 with increased salaries.

General and administrative expenses

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

Contributing to the quarters ended September 30, 2017 and 2016 comparison were cost decreases from the prior year. Those include decreases to payroll as a result of the re-organization of the finance department with reduced head count, decreased legal expenses, audit fees, and public company related fees. These cost decreases were partially offset in the quarter ended September 30, 2017 by increases associated with share-based compensation, and employment hiring expenses related to the hiring of the Controller.

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 quarters ended September 30, 2017 and 2016, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

	Three months ended September 30,	
	2017	2016
Net cash used by operating activities	$(1,661)	$(1,353)
Net cash provided (used) by investing activities	(315)	(327)
Net increase (decrease) in cash and cash equivalents	$(1,976)	$(1,680)
Working capital	$7,799	$13,801
Current ratio	8.31	13.28

Cash flows from operating activities

Net cash used by operating activities in the three months ended September 30, 2017 was primarily due to a net loss of approximately $1.55 million, net of approximately $128,000 in adjustments for non-cash activity such as depreciation and amortization expense, and share-based compensation. Changes in operating assets and liabilities used approximately $243,000 to fund operating activities; increases to prepaid expenses and other current assets, along with decreases to accrued radioactive waste disposal and accrued payroll and related taxes, were partially offset by decreases in accounts receivable resulting from improved collections as well as an increase in accounts payable and accrued expenses resulting from better cash management procedures to more effectively utilize payment terms.

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Cash flows from investing activities

Investing activities consisted of transactions related to the purchase of fixed assets, including automation of production processes and advance planning and design work on the Company's new production facility, as well as the purchase and subsequent maturity of certificates of deposit. Management will continue to invest in technology and machinery that improves and streamlines production processes and to invest maturing certificates of deposit in low-risk investment opportunities that safeguard assets and provide greater assurance those resources will be liquid and available for business needs as they arise.

Projected 2018 liquidity and capital resources

Operating activities

Management forecasts that current cash and cash equivalents along with certificates of deposit will be sufficient to meet projected operating cash needs for the remainder of fiscal 2018. Assuming no extraordinary expenses occur (whether operating or capital), if management is successful at implementing its strategy of renewed emphasis on driving the consumer to the prostate market, meets or exceeds its annual growth targets of twenty percent increase in revenue in fiscal 2018 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. Although the Company did not reach that target of twenty percent increased revenue in the first quarter of fiscal 2018, the Company is continuing to project revenue growth in fiscal 2018 of at least twenty percent over fiscal 2017. There is no assurance that targeted sales growth will materialize over the next three to five years. However, management is encouraged by the results for the quarter ended September 30, 2017 and with the depth and experience of its restructured sales team.

Capital expenditures

Management has completed the design of a future production and administration facility. If financing is obtained and the facility constructed, it is believed that the new facility will have non-cash depreciation cost equal to or greater than the monthly rental cost of the current facility.

Management is reviewing and implementing changes in all aspects of production operations (including process automation), 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 product sales.

During the quarter ended September 30, 2017, the Company invested approximately $44,000 in the automation of thirteen production processes, three of which have been received, tested and evaluated, and were placed in service in the quarter. One additional machine has been received and is currently being tested. Beginning in fiscal 2017 and continuing through September 30, 2017, the Company has invested approximately $349,000 in these automation projects and management is expecting to invest approximately $260,000 more over the next 11 months on the remaining projects. This investment is designed to allow the Company to significantly increase the output of Cs-131 brachytherapy seeds, while allowing the Company to decrease the labor costs related to seed production and also improving the overall safety of our operations.

Financing activities

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 September 30, 2017, the Company had used the net proceeds raised through the March 2014 offering as described in the public offering. 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.

On August 25, 2015, the Company filed a registration statement on Form S-3 to register securities up to $20 million in value for future issuance in our capital raising activities. The registration statement became effective on November 19, 2015, and the SEC file number assigned to the registration statement is 333-206559.

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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.

The Company’s common stock is currently listed on the NYSE American stock exchange, which will consider delisting a company’s securities if, among other things, a company fails to maintain minimum stockholder's equity. With the Company’s existing cash reserves we believe we will not be able to maintain our listing on the NYSE American unless we raise capital in the next six to nine months assuming we maintain our projected budgeted expenses and contemplated level of revenues.

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, 2017. There have been no material changes outside of the ordinary course of business in those obligations during the quarter ended September 30, 2017 other than those previously disclosed in footnotes 8 and 12 of Notes to unaudited consolidated financial statements contained in this filing.

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 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 quarter ended September 30, 2017, there have been no changes to the critical accounting policies and estimates discussed in Part II, Item 7 of our Form 10-K for the year ended June 30, 2017.

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, 2017.

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) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of September 30, 2017. 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.

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PART II - OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

The Company may, in the ordinary course of business, be subject to various legal proceedings. Some legal proceedings are discussed in footnote 8 of Notes to Unaudited Consolidated Financial Statements contained in this filing. We refer you to that footnote for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought.

Derivative Complaint related to Shareholder Value

On September 29, 2016, David M. Kitley, purportedly on behalf of IsoRay, filed a derivative lawsuit in the United States District Court for the District of Minnesota under the case caption Kitley v. IsoRay, Inc., Case No. 0:16-cv-03297-DTS. The complaint named as defendants current and former IsoRay directors Dwight Babcock, Thomas LaVoy, Philip J. Vitale and Michael W. McCormick, alleging that they violated their fiduciary duties to IsoRay in connection with a press release allegedly containing false and misleading statements concerning the results from a peer reviewed study of its Cesium-131 isotope seeds for the treatment of non-small cell lung cancers, thereby artificially inflating the price of IsoRay stock. The complaint sought unspecified damages, in an amount not presently determinable, among other forms of relief.

On November 17, 2016, IsoRay moved to dismiss the complaint, arguing that plaintiff was not entitled to pursue his derivative claims due to his failure to serve a pre-suit demand on IsoRay's board. Rather than respond to the motion to dismiss, plaintiff filed an amended complaint on January 23, 2017. The amended complaint alleged the same derivative claims as the original, and added IsoRay director Alan Hoffmann as a defendant. Plaintiff sought an award of damages and an order directing IsoRay to undertake reforms of its corporate governance and internal procedures. IsoRay moved to dismiss the amended complaint on March 9, 2017. Plaintiff responded on April 20, 2017, and IsoRay replied on May 17, 2017. The court heard oral argument on the motion on August 22, 2017, and took the matter under advisement at that time. On October 19, 2017, the court granted IsoRay's motion to dismiss. The matter is now resolved.

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 annual report on Form 10-K for the year ended June 30, 2017, 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 Four Customers

For the three months ended September 30, 2017 approximately 54% of the Company's revenues were dependent on five customers with approximately 26% being generated by one physician group. The loss of any of these customers would have a material adverse effect on the Company's revenues that may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments.

We May Need Additional Capital In The Future To Maintain Our NYSE American Listing And For Acquisitions And Expansion Into Other Markets.

Our common stock is currently listed on the NYSE American stock exchange which will consider delisting a company's securities if, among other things, a company fails to maintain minimum stockholder's equity. With our existing cash reserves we believe we will not be able to maintain our listing on the NYSE American unless we raise capital in the next six to nine months assuming we maintain our projected budgeted expenses and contemplated level of revenues. In the event that our common stock is delisted from the NYSE American, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock. We may also need to raise capital for strategic acquisitions or expansion into other markets and there is no assurance management will not pursue this additional capital if available.

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.

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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

*** Denotes Management Contract or Compensatory Plan or Arrangement

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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: November 14, 2017

ISORAY, INC., a Minnesota corporation

/s/ *Thomas C. LaVoy*
Thomas C. LaVoy
Chief Executive Officer
(Principal Executive Officer)

/s/ *Mark J. Austin*
Mark J. Austin
Controller
(Principal Financial and Accounting Officer)