

IsoRay, Inc.  
Form 10-Q  
February 09, 2017

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**Quarterly Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the quarterly period ended December 31, 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 (I.R.S. Employer  
organization) Identification No.)

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

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

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

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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, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer”, and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Smaller reporting company

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

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

| <u>Class</u>                    | <u>Outstanding as of February 7, 2017</u> |
|---------------------------------|-------------------------------------------|
| Common stock, \$0.001 par value | 55,017,419                                |

**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)

|                                                                                            | <b>December<br/>31,<br/>2016</b> | <b>June 30,<br/>2016</b> |
|--------------------------------------------------------------------------------------------|----------------------------------|--------------------------|
|                                                                                            | (unaudited)                      |                          |
| <b>ASSETS</b>                                                                              |                                  |                          |
| Current assets:                                                                            |                                  |                          |
| Cash and cash equivalents                                                                  | \$ 6,668                         | \$10,139                 |
| Certificates of deposit (Note 3)                                                           | 5,279                            | 2,247                    |
| Accounts receivable, net of allowance for doubtful accounts of \$30 and \$30, respectively | 627                              | 605                      |
| Inventory                                                                                  | 381                              | 334                      |
| Prepaid expenses and other current assets                                                  | 224                              | 304                      |
| <br>Total current assets                                                                   | <br>13,179                       | <br>13,629               |
| <br>Property and equipment, net                                                            | <br>779                          | <br>577                  |
| Certificates of deposit, non-current (Note 3)                                              | -                                | 2,973                    |
| Restricted cash                                                                            | 181                              | 181                      |
| Inventory, non-current                                                                     | 568                              | 591                      |
| Other assets, net of accumulated amortization                                              | 278                              | 151                      |
| <br>Total assets                                                                           | <br>\$ 14,985                    | <br>\$18,102             |
| <br><b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>                                            |                                  |                          |
| Current liabilities:                                                                       |                                  |                          |
| Accounts payable and accrued expenses                                                      | \$ 312                           | \$612                    |
| Accrued protocol expense                                                                   | 156                              | 122                      |
| Accrued radioactive waste disposal                                                         | 195                              | 177                      |
| Accrued payroll and related taxes                                                          | 90                               | 72                       |
| Accrued vacation                                                                           | 118                              | 111                      |
| <br>Total current liabilities                                                              | <br>871                          | <br>1,094                |

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|                                                                                                                           |           |           |
|---------------------------------------------------------------------------------------------------------------------------|-----------|-----------|
| Long-term liabilities:                                                                                                    |           |           |
| Warrant derivative liability                                                                                              | -         | 27        |
| Asset retirement obligation                                                                                               | 547       | 580       |
| <br>                                                                                                                      |           |           |
| Total liabilities                                                                                                         | 1,418     | 1,701     |
| Commitments and contingencies (Note 8)                                                                                    |           |           |
| <br>                                                                                                                      |           |           |
| 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;<br>55,017,419 and 55,010,619 shares issued and outstanding | 55        | 55        |
| Additional paid-in capital                                                                                                | 82,901    | 82,788    |
| Accumulated deficit                                                                                                       | (69,389 ) | (66,442)  |
| <br>                                                                                                                      |           |           |
| Total shareholders' equity                                                                                                | 13,567    | 16,401    |
| <br>                                                                                                                      |           |           |
| Total liabilities and shareholders' equity                                                                                | \$ 14,985 | \$ 18,102 |

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

## IsoRay, Inc. and Subsidiaries

## Consolidated Statements of Operations (Unaudited)

(Dollars and shares in thousands, except for per-share amounts)

|                                                               | Three months ended |           | Six months ended |           |
|---------------------------------------------------------------|--------------------|-----------|------------------|-----------|
|                                                               | December 31,       |           | December 31,     |           |
|                                                               | 2016               | 2015      | 2016             | 2015      |
| Product sales, net                                            | \$1,028            | \$1,189   | \$2,109          | \$2,450   |
| Cost of product sales                                         | 1,029              | 1,162     | 2,062            | 2,340     |
| Gross profit / (loss)                                         | (1 )               | 27        | 47               | 110       |
| Operating expenses:                                           |                    |           |                  |           |
| Research and development                                      | 150                | 58        | 322              | 202       |
| Sales and marketing                                           | 496                | 254       | 1,020            | 533       |
| General and administrative                                    | 880                | 1,125     | 1,807            | 1,876     |
| Change in estimate of asset retirement obligation (Note 13)   | (48 )              | -         | (48 )            | -         |
| Total operating expenses                                      | 1,478              | 1,437     | 3,101            | 2,611     |
| Operating loss                                                | (1,479 )           | (1,410 )  | (3,054 )         | (2,501 )  |
| Non-operating income:                                         |                    |           |                  |           |
| Interest income, net                                          | 29                 | 56        | 60               | 112       |
| Change in fair value of warrant derivative liability          | -                  | 43        | 27               | 58        |
| Other income                                                  | -                  | -         | 20               | -         |
| Non-operating income, net                                     | 29                 | 99        | 107              | 170       |
| Net loss                                                      | (1,450 )           | (1,311 )  | (2,947 )         | (2,331 )  |
| Preferred stock dividends                                     | (2 )               | (3 )      | (5 )             | (5 )      |
| Net loss applicable to common shareholders                    | (1,452 )           | (1,314 )  | (2,952 )         | (2,336 )  |
| Basic and diluted loss per share                              | \$(0.03 )          | \$(0.02 ) | \$(0.05 )        | \$(0.04 ) |
| Weighted average shares used in computing net loss per share: |                    |           |                  |           |
| Basic and diluted                                             | 55,017             | 55,014    | 55,014           | 55,013    |

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



## IsoRay, Inc. and Subsidiaries

## Consolidated Statements of Cash Flows (Unaudited)

(In thousands)

|                                                                             | Six months ended December 31, |             |
|-----------------------------------------------------------------------------|-------------------------------|-------------|
|                                                                             | 2016                          | 2015        |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                               |             |
| Net loss                                                                    | \$ (2,947                     | ) \$ (2,331 |
| Adjustments to reconcile net loss to net cash used by operating activities: |                               |             |
| Depreciation expense                                                        | 32                            | 274         |
| Loss on equipment disposals                                                 | 5                             | -           |
| Amortization of other assets                                                | 23                            | 28          |
| Change in fair value of warrant derivative liability                        | (27                           | ) (58       |
| Accretion of asset retirement obligation                                    | 15                            | 43          |
| Change in estimate of asset retirement obligation                           | (48                           | ) -         |
| Share-based compensation                                                    | 122                           | 63          |
| Changes in operating assets and liabilities:                                |                               |             |
| Accounts receivable, gross                                                  | (22                           | ) 74        |
| Inventory                                                                   | (24                           | ) (73       |
| Prepaid expenses and other current assets                                   | 79                            | 73          |
| Accounts payable and accrued expenses                                       | (299                          | ) 183       |
| Accrued protocol expense                                                    | 34                            | (45         |
| Accrued radioactive waste disposal                                          | 18                            | 24          |
| Accrued payroll and related taxes                                           | 18                            | (140        |
| Accrued vacation                                                            | 7                             | (35         |
| Net cash used by operating activities                                       | (3,014                        | ) (1,920    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                               |             |
| Additions to property and equipment                                         | (239                          | ) (35       |
| Additions to other assets                                                   | (151                          | ) (16       |
| Proceeds from maturity of certificates of deposit                           | -                             | 3,527       |
| Purchases of and interest from certificates of deposit                      | (58                           | ) (6,140    |
| Net cash used by investing activities                                       | (448                          | ) (2,664    |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                               |             |
| Preferred dividends paid                                                    | (11                           | ) (11       |
| Proceeds from sales of common stock, pursuant to exercise of options        | 2                             | 47          |
| Net cash provided (used) by financing activities                            | (9                            | ) 36        |
| Net decrease in cash and cash equivalents                                   | (3,471                        | ) (4,548    |



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|                                                |          |        |
|------------------------------------------------|----------|--------|
| Cash and cash equivalents, beginning of period | 10,139   | 5,227  |
| CASH AND CASH EQUIVALENTS, END OF PERIOD       | \$ 6,668 | \$ 679 |

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

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the six months ended December 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, 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, 2016.

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 2017 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 continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2019. This update is not expected to

have a material 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 continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2018.

In November 2015, the FASB issued 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. This update will be effective as of the beginning of fiscal 2018. This update is not expected to have a material impact on the Company's consolidated financial statements.

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. The Company continues to evaluate the new standard and its impact on the Company's consolidated financial statements. This update will be effective as of the beginning of fiscal 2019.

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. Except to indicate an evaluation of a recent pronouncement is in process, the Company does not discuss recent pronouncements that are not anticipated to have potential impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures of the Company.

### 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 December 31, 2016 and June 30, 2016 are as follows (in thousands):

| As of December 31, 2016 |               |                        |                     |
|-------------------------|---------------|------------------------|---------------------|
|                         | Under 90 days | Six months to one year | Greater than 1 year |
| CDARS                   | \$ -          | \$ -                   | \$ 5,279            |

| As of June 30, 2016 |               |                        |                     |
|---------------------|---------------|------------------------|---------------------|
|                     | Under 90 days | Six months to one year | Greater than 1 year |
| CDARS               | \$ -          | \$ 2,247               | \$ 2,973            |

### 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 December 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.

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Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2016 and 2015, were as follows (in thousands):

|                                     | December 31, |       |
|-------------------------------------|--------------|-------|
|                                     | 2016         | 2015  |
| Series B preferred stock            | 59           | 59    |
| Common stock warrants               | 5            | 361   |
| Common stock options                | 2,565        | 2,126 |
| Total potential dilutive securities | 2,629        | 2,546 |

**5. Inventory**

Inventory consisted of the following at December 31, 2016 and June 30, 2016 (in thousands):

|                          | December | June  |
|--------------------------|----------|-------|
|                          | 31,      | 30,   |
|                          | 2016     | 2016  |
| Raw materials            | \$ 167   | \$155 |
| Work in process          | 193      | 161   |
| Finished goods           | 21       | 18    |
| Total inventory, current | \$ 381   | \$334 |

|                              | December<br>31,<br>2016 | June<br>30,<br>2016 |
|------------------------------|-------------------------|---------------------|
| Enriched barium, non-current | \$ 470                  | \$470               |
| Raw materials, non-current   | 98                      | 121                 |
| Total inventory, non-current | \$ 568                  | \$591               |

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 and the enriched barium which will only be utilized if required to obtain volumes of isotope not able to be purchased from an existing source in the short or long-term. Management does not anticipate the need to utilize the enriched barium within the current operating cycle.

## 6. Property and Equipment

Property and equipment consisted of the following at December 31, 2016 and June 30, 2016 (in thousands):

|                               | December<br>31,<br>2016 | June<br>30,<br>2016 |
|-------------------------------|-------------------------|---------------------|
| Land                          | \$ 168                  | \$168               |
| Equipment                     | 3,775                   | 3,606               |
| Leasehold improvements        | 4,130                   | 4,130               |
| Other <sup>1</sup>            | 262                     | 214                 |
| Property and equipment        | 8,335                   | 8,118               |
| Less accumulated depreciation | (7,556 )                | (7,541)             |
| Property and equipment, net   | \$ 779                  | \$577               |

<sup>1</sup> – 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 December 31, 2016 and June 30, 2016 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 December 31, 2016 and 2015 (in thousands):

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|                                     | Three<br>Months<br>ended<br>December<br>31,<br>2016 2015 |       |
|-------------------------------------|----------------------------------------------------------|-------|
| Cost of product sales               | \$ 17                                                    | \$ 18 |
| Research and development expenses   | 7                                                        | 4     |
| Sales and marketing expenses        | 11                                                       | 3     |
| General and administrative expenses | 17                                                       | 6     |
| Total share-based compensation      | \$ 52                                                    | \$ 31 |

The following table presents the share-based compensation expense recognized during the six months ended December 31, 2016 and 2015 (in thousands):

|                                     | Six Months<br>ended<br>December<br>31,<br>2016 2015 |       |
|-------------------------------------|-----------------------------------------------------|-------|
| Cost of product sales               | \$44                                                | \$ 35 |
| Research and development expenses   | 15                                                  | 7     |
| Sales and marketing expenses        | 26                                                  | 6     |
| General and administrative expenses | 37                                                  | 15    |
| Total share-based compensation      | \$ 122                                              | \$ 63 |

As of December 31, 2016, total unrecognized compensation expense related to stock-based options was approximately \$645,000 and the related weighted-average period over which it is expected to be recognized is approximately 1.80 years.

A summary of stock options within the Company's share-based compensation plans as of December 31, 2016 was as follows (in thousands except for exercise prices and terms):

|                             | Number<br>of<br>Options | Weighted<br>Exercise<br>Price | Weighted<br>Average<br>Contractual<br>Term<br>(Years) | Intrinsic<br>Value |
|-----------------------------|-------------------------|-------------------------------|-------------------------------------------------------|--------------------|
| As of December 31, 2016     |                         |                               |                                                       |                    |
| Outstanding                 | 2,565                   | \$ 1.07                       | 6.89                                                  | \$ 83              |
| Vested and expected to vest | 2,492                   | \$ 1.06                       | 6.83                                                  | \$ 82              |
| Vested and exercisable      | 1,615                   | \$ 1.09                       | 5.49                                                  | \$ 82              |

There were 6,800 and 45,994 stock options exercised, with approximately \$3,000 and \$22,000 of intrinsic value associated with these exercises during the six months ended December 31, 2016 and 2015, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 10,000 and 20,000 option awards granted with a fair value of approximately \$4,000 and \$24,000 during the six months ended December 31, 2016 and 2015, respectively.

There were 280,534 and 264,320 stock option awards which expired during six months ended December 31, 2016 and 2015, respectively.

There were 83,005 and 21,608 stock option awards forfeited during six months ended December 31, 2016 and 2015, respectively.

## 8. Commitments and Contingencies

### 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 then-current officers – Dwight Babcock (the Company’s retired CEO) and Brien Ragle (the Company’s former CFO) – 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. On October 16, 2015, an amended complaint was filed with more detailed allegations relating to alleged violations of federal securities laws. On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. On June 1, 2016, the court entered an order denying IsoRay's motion to dismiss, holding that the complaint's allegations, if accepted as true, state a plausible claim to relief. The order did not adjudicate the merits of the lawsuit. No other issues were decided in the ruling.

On June 15, 2016, IsoRay filed its answer to the amended complaint. As IsoRay previously disclosed, on September 23, 2016, the parties entered into a stipulation of settlement which, if it becomes final, will provide for a payment to the plaintiff class of \$3,537,500, which will be paid by our insurers. On October 4, 2016, the stipulation of settlement was filed with the court, along with plaintiffs’ unopposed motion for preliminary approval of the settlement. On October 20, 2016, the court granted preliminary approval of the settlement. Following notice to class members, the class action is subject to final approval by the court. A final approval hearing is scheduled for March 7, 2017. If the proposed settlement is not approved by the court or if IsoRay is otherwise unable to obtain a favorable resolution of the claims set forth in the complaint, the lawsuit could have a material adverse effect on our business, results of operations and financial condition.

### Derivative Complaint related to Shareholder Value

On September 29, 2016, a purported shareholder derivative complaint captioned Kitley v. Babcock, et al., No. 0:16-cv-03297, was filed on behalf of the Company in the United States District Court for the District of Minnesota against certain of the Company's current and former officers and directors. The complaint alleges that the defendants breached their fiduciary duties by causing the Company to issue allegedly false and misleading statements in a May 20, 2015 press release – the same press release at issue in the pending securities class action – concerning the results from a peer reviewed study of the Company's Cesium-131 isotope seeds and mesh product for the treatment of non-small cell lung cancers. The complaint brings claims of breach of fiduciary duty, gross mismanagement, and unjust enrichment, and seeks unspecified compensatory damages, changes in corporate governance, and attorney's fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. The Company may be obligated pursuant to indemnification obligations to advance fees and costs incurred by the individuals defending against the action. The Company has applicable directors and officers insurance policies.

On November 17, 2016, the defendants filed a motion to dismiss Mr. Kitley's complaint. On January 23, 2017, instead of opposing defendants' motion, Mr. Kitley filed an amended complaint. Defendants' response to the amended complaint is due March 9, 2017.

### Irradiation Services Agreement

On November 29, 2016, IsoRay Medical, Inc. (Medical), a wholly owned subsidiary of IsoRay, Inc, entered into an Irradiation Services Agreement (MURR Agreement) with the Curators of the University of Missouri, a public corporation of the State of Missouri, on behalf of its University of Missouri Research Reactor (MURR). The MURR Agreement replaces the month-to-month informal arrangement between Medical and MURR and provides Medical with access to reactor space for the irradiation of natural or enriched barium to produce Ba-131, which is used by Medical to produce Cesium-131 for use in its product. The MURR Agreement has a term of five years concluding November 29, 2021 and will automatically renew for successive twelve-month periods unless terminated by either party, and can be terminated by either party upon three months written notice. The MURR Agreement does not require minimum orders or obligate Medical to future minimum payments.

### Isotope Purchase Agreement

In December 2015, the Company completed negotiations with The Open Joint Stock Company <<Isotope>> (located in Russia) for the purchase of Cesium-131 manufactured by the Institute of Nuclear Materials. The total purchase agreement provides the Company with a one year supply of Cesium-131. The agreement was set to expire on March

31, 2017, however on December 22, 2016, the Company agreed to an addendum extending the expiration period to December 31, 2017.

Operating Lease Agreements

The Company leases office and laboratory space under an operating lease. The lease may be terminated by either party with a six month written notice. The Company agreed to a modification which became effective November 1, 2016 to extend the lease termination date to April 30, 2021. The lease terms require monthly lease payments and include a contractually permitted annual rent increase based on changes in the CPI index. Future minimum lease payments under this operating lease are as follows (in thousands):

| Year ending June 30, | Amount   |
|----------------------|----------|
| 2017                 | \$ 140   |
| 2018                 | 281      |
| 2019                 | 281      |
| 2020                 | 281      |
| 2021                 | 234      |
|                      | \$ 1,217 |

## 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 December 31, 2016 |         |         |         |
|---------------------------|---------------------------------|---------|---------|---------|
|                           | Total                           | Level 1 | Level 2 | Level 3 |
| Cash and cash equivalents | \$6,668                         | \$6,668 | \$ -    | \$ -    |

  

|                              | Fair Value at June 30, 2016 |          |         |         |
|------------------------------|-----------------------------|----------|---------|---------|
|                              | Total                       | Level 1  | Level 2 | Level 3 |
| Cash and cash equivalents    | \$10,139                    | \$10,139 | \$ -    | \$ -    |
| Warrant derivative liability | 27                          | -        | 27      | -       |

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.

The Company's warrant derivative liability is valued using the Black-Scholes option pricing model which requires a variety of inputs. Such instruments are typically included in Level 2.

## 10. Preferred Dividends

On December 12, 2016, 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, 2016 in the amount of approximately \$11,000. The dividends outstanding and cumulative through December 31, 2016 of approximately \$11,000 and through December 31, 2015 of approximately \$11,000 were paid as of those dates.

## 11. Shareholders' Equity

### *Warrants*

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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<br>average<br>exercise<br>price |
|-------------------------------------|-----------|------------------------------------------|
| Outstanding as of June 30, 2016     | 230,087   | \$ 0.94                                  |
| Warrants expired                    | (225,087) | \$ 0.94                                  |
| Outstanding as of December 31, 2016 | 5,000     | \$ 0.98                                  |

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

| <u>Number of Warrants</u> | <u>Exercise Price<sup>1</sup></u> | <u>Expiration Date</u> |
|---------------------------|-----------------------------------|------------------------|
| 5,000                     | \$ 0.98                           | June 2017              |

<sup>1</sup> – Exercise prices have been rounded to the nearest whole cent.

## **12. Related Party Transactions**

In previous fiscal years the Company engaged the services of APEX Data Systems, Inc. (APEX), owned by Dwight Babcock, former Chairman and Chief Executive Officer, to build and maintain a web interfaced data collection application to aggregate patient data in a controlled environment. An alternative vendor began providing these services beginning January 2016.

The cost recorded during six months ended December 31, 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 approximately \$6,000. An additional approximately \$6,000 was spent on the maintenance of Customer Relationship Management (CRM) software in the six months ended December 31, 2015.

During the six months 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 six months ended December 31, 2016, the Company paid approximately \$20,000 to GO for its performance of work related to the agreed upon statement of work. No such services were provided in the six months ended December 31, 2015.

## **13. Asset Retirement Obligation**

The Company has an asset retirement obligation (ARO) associated with the facility it currently leases. The ARO changed as follows (in thousands):

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|                                                       | Six months ended<br>December 31,<br>2016 | Six months ended<br>December 31,<br>2015 |
|-------------------------------------------------------|------------------------------------------|------------------------------------------|
| Beginning balance                                     | \$ 580                                   | \$ 948                                   |
| Accretion of discount                                 | 15                                       | 43                                       |
| Gain on change in ARO estimate due to lease extension | (48)                                     | ) -                                      |
| Ending balance                                        | \$ 547                                   | \$ 991                                   |

**14. 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:

|                                                                                         | Six months ended        |                         |   |
|-----------------------------------------------------------------------------------------|-------------------------|-------------------------|---|
|                                                                                         | December<br>31,<br>2016 | December<br>31,<br>2015 |   |
| Facility                                                                                |                         |                         |   |
| El Camino Hospital of Los Gatos, Fremont Surgery Center & other facilities <sup>1</sup> | 23.10%                  | 24.23                   | % |

<sup>1</sup> – 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.

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

## 15. Subsequent Events

### Property Transaction between Medical and The Port of Benton

Medical has a contract with The Port of Benton to develop property and relocate its manufacturing facility to that property from its present location. Covenants contained in that contract, among others, require certain milestones for construction and minimum headcount.

The Port of Benton Commissioners previously amended the development plan covenants extending to January 31, 2017 the date by which Medical would need to begin construction or be in default. As Medical failed to comply with this covenant, Medical is required to pay the Port the difference in the sales price and the appraised value of the property as of January 31, 2017.

The Benton County 2016 assessed value of the land was approximately \$424,000, 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 and Medical anticipates this approximates the amount that will be payable to the Port. This is subject to a final appraisal which has not been completed.

## **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, 2016.*

*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 9, 2016 are those that depend most heavily on these judgments and estimates. As of December 31, 2016, there had been no material changes to any of the critical accounting policies contained therein.

**Overview**

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 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 tradeshow.

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 December 31, 2016.

**Results of Operations****Three months ended December 31, 2016 and 2015 (in thousands):**

|                                     | Three months ended December 31, |       |          |       |                |
|-------------------------------------|---------------------------------|-------|----------|-------|----------------|
|                                     | 2016                            |       | 2015     |       | 2016 -<br>2015 |
|                                     | Amount                          | % (a) | Amount   | % (a) | %<br>Change    |
| Product sales, net                  | \$ 1,028                        | 100   | \$ 1,189 | 100   | (14 )          |
| Cost of product sales               | 1,029                           | 100   | 1,162    | 98    | (11 )          |
| Gross profit / (loss)               | (1 )                            | -     | 27       | 2     | (104 )         |
| Operating expenses:                 |                                 |       |          |       |                |
| Research and development expenses   | 150                             | 15    | 58       | 5     | 159            |
| Sales and marketing expenses        | 496                             | 48    | 254      | 21    | 95             |
| General and administrative expenses | 880                             | 86    | 1,125    | 95    | (22 )          |
| Change in estimate of ARO           | (48 )                           | (5 )  | -        | -     | 100            |
| Total operating expenses            | 1,478                           | 144   | 1,437    | 121   | (3 )           |

Operating loss (1,479) (144) (1,410) (119) 5

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

**Six months ended December 31, 2016 and 2015 (in thousands):**

|                                     | Six months ended December 31, |       |         |       | 2016 -<br>2015<br>%<br>Change |
|-------------------------------------|-------------------------------|-------|---------|-------|-------------------------------|
|                                     | 2016                          |       | 2015    |       |                               |
|                                     | Amount                        | % (a) | Amount  | % (a) |                               |
| Product sales, net                  | \$2,109                       | 100   | \$2,450 | 100   | (14 )                         |
| Cost of product sales               | 2,062                         | 98    | 2,340   | 95    | (12 )                         |
| Gross profit / (loss)               | 47                            | 2     | 110     | 5     | (57 )                         |
| Operating expenses:                 |                               |       |         |       |                               |
| Research and development expenses   | 322                           | 15    | 202     | 8     | 59                            |
| Sales and marketing expenses        | 1,020                         | 48    | 533     | 22    | 91                            |
| General and administrative expenses | 1,807                         | 86    | 1,876   | 77    | (4 )                          |
| Change in estimate of ARO           | (48 )                         | (2 )  | -       | -     | 100                           |
| Total operating expenses            | 3,101                         | 147   | 2,611   | 107   | 19                            |
| Operating loss                      | (3,054)                       | (145) | (2,501) | (102) | 22                            |

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

**Product Sales**

A continued focus on the maturation of our recently adopted marketing approach and ongoing training and support for sales staff following changes in personnel resulted in lower sales when compared to the prior year's first two quarters.

**Three months ended December 31, 2016 and 2015 (in thousands)**

|                        | Three months ended December 31, |     |         |     |                |
|------------------------|---------------------------------|-----|---------|-----|----------------|
|                        | 2016                            |     | 2015    |     | 2016 -<br>2015 |
|                        | Amount                          | %   | Amount  | %   | %              |
|                        | (a)                             | (a) | (a)     | (a) | Change         |
| Prostate brachytherapy | \$889                           | 86  | \$1,032 | 87  | (14 )          |
| Other brachytherapy    | 139                             | 14  | 157     | 13  | (10 )          |
| Product sales, net     | 1,028                           | 100 | 1,189   | 100 | (14 )          |

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

**Six months ended December 31, 2016 and 2015 (in thousands)**

|                        | Six months ended December 31, |     |         |     |                |
|------------------------|-------------------------------|-----|---------|-----|----------------|
|                        | 2016                          |     | 2015    |     | 2016 -<br>2015 |
|                        | Amount                        | %   | Amount  | %   | %              |
|                        | (a)                           | (a) | (a)     | (a) | Change         |
| Prostate brachytherapy | \$1,855                       | 88  | \$2,148 | 88  | (14 )          |
| Other brachytherapy    | 254                           | 12  | 302     | 12  | (16 )          |
| Product sales, net     | 2,109                         | 100 | 2,450   | 100 | (14 )          |

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

*Prostate Brachytherapy*

Prostate brachytherapy sales were impacted by changes in sales account managers and by the schedules of some key accounts in the first two quarters of the fiscal year. During the quarter ended December 31, 2016, the Company had turnover with sales managers in two territories resulting in fewer sales in those territories. Two new sales account managers were hired in the second quarter bringing to the Company approximately 25 years of combined sales experience. Bolstering the sales team, strengthening relationships with customers and reconnecting with previous customers remains a priority of the Company.

Management believes growth in prostate brachytherapy revenues will be the result of physicians, payors, 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 December 31, 2015.

#### *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 decrease 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 December 31, 2016 and 2015 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 December 31 2016 to research and development from cost of product sales as employees performed research and development work. Also, reduced staffing costs were realized with one employee retiring in the quarter and two others being laid off following process improvements in the production facility.

Contributing to the six months ended December 31, 2016 and 2015 comparison were decreases attributed to a reduction in the accretion expense related to the asset retirement obligation and reduced depreciation expense as several production related assets became fully depreciated.

### **Research and development**

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

Contributing to the quarters ended December 31, 2016 and 2015 comparison were increases associated with increased activity with third party researchers as well as a reallocation of employee costs from cost of product sales as those employees performed work on research and development projects.

Contributing to the six months ended December 31, 2016 and 2015 comparison were increased legal expenses related to maintenance of intellectual property.

### **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 greater staffing continues to increase.

Contributing to the quarters ended December 31, 2016 and 2015 comparison were increases in marketing, website content costs as well as increased consulting costs associated with seeking more favorable reimbursement for sale of Company products. Staffing differences are a major factor in the cost comparison as unfilled positions in the quarter ended December 31, 2015 were filled in periods prior to the quarter ended December 31, 2016.

Contributing to the six months ended December 31, 2016 and 2015 comparison increase were rebranding efforts and a website redesign that launched during the first quarter of fiscal year 2017 and increased costs attributed to filling open positions in the department, including the position of Vice President of Sales and Marketing. Other staffing changes in the comparative periods include adding a Product Manager and a Senior Marketing Consultant, as well as changes to four of the Company's six sales account manager positions.

#### **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 December 31, 2016 and 2015 comparison were decreases in legal costs and the recording of the severance costs associated with the retirement of the Company's former Chief Executive Officer in the quarter ended December 31, 2015. Cost decreases were partially offset by increased travel expenses; increased public company related costs associated with the annual shareholder meeting held in December 2016 this fiscal year as opposed to June 2016 in the prior fiscal year; and increases related to salary, benefits, and share-based compensation associated with the Director of Quality Assurance and Regulatory Affairs, Senior Accountant and Vice President of Human Resources positions being filled. Management continues to assess opportunities to reduce costs and key to that assessment process is utilization of Company personnel.

**Gain on change in estimate of Asset Retirement Obligation (ARO)**

The Company extended the term of the lease on its production facility, resulting in a revision of the estimated cost associated with restoring the facility to its original condition, which will be required when the lease expires and the Company vacates the production facility.

**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 December 31, 2016 and 2015, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

|                                            | Six months<br>ended December<br>31, |            |
|--------------------------------------------|-------------------------------------|------------|
|                                            | 2016                                | 2015       |
| Net cash used by operating activities      | \$(3,014 )                          | \$(1,920 ) |
| Net cash used by investing activities      | (448 )                              | (2,664 )   |
| Net cash provided by financing activities  | (9 )                                | 36         |
| Net decreases in cash and cash equivalents | \$(3,471 )                          | \$(4,548 ) |
| Working capital                            | \$12,373                            | \$13,204   |
| Current ratio                              | 16.35                               | 13.24      |

**Cash flows from operating activities**

Net cash used by operating activities in the six months ended December 31, 2016 was primarily due to a net loss of approximately \$2.9 million, net of approximately \$122,000 in adjustments for non-cash activity such as depreciation and amortization expense, ARO adjustments, the change in fair value of the warrant derivative liability and share-based compensation. Changes in operating assets and liabilities used approximately \$254,000 to fund operating activities; improved effectiveness from accounts receivable collection efforts and reductions in costs for goods and services were offset by the accelerated timing of accounts payable and accrued expenses.



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.

Cash flows from financing activities

Financing activities in the six months ended December 31, 2016 included payment of preferred dividends and proceeds of sales of common stock through option exercises.

Projected 2017 Liquidity and Capital Resources

*Operating activities*

Management forecasts that fiscal 2017 cash requirements will be approximately \$800,000 more than the previous year, the result of filling sales staffing positions which were vacant in fiscal 2016 and increased costs associated with rebranding and marketing the Company's products. 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 the fiscal year. 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 2017 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. There is no assurance that the targeted sales growth will materialize and in spite of the results for the quarter ended December 31, 2016, management remains encouraged by the depth and experience of its restructured sales team.

*Capital expenditures*

Management has nearly 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. The Company anticipates the additional amount due to The Port of Benton as a result of failing to comply with the development plan covenant will be approximately \$256,000 which is the approximate difference between the 2016 assessed value of the land and the purchase price. This final settlement amount could change as it will be subject to an appraisal which has not been completed.

Management is reviewing 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.

Through the quarter ended December 31, 2016, the Company has invested approximately \$190,000 towards the automation of thirteen production processes, three of which have been received, are being tested and evaluated, and were placed in service in the quarter. Management is expecting to invest approximately \$310,000 over the next 12 months on the remaining production process automation 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 December 31, 2016, 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.

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, 2016. There have been no material changes outside of the ordinary course of business in those obligations during the quarter ended December 31, 2016 other than those previously disclosed in Notes 8 and 15 to the interim financial statements contained in this Form 10-Q.

*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 December 31, 2016, 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, 2016.

**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, 2016.

**ITEM 4 – CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of December 31, 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.

## **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). 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.

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 then-current officers – Dwight Babcock (the Company’s retired CEO) and Brien Ragle (the Company’s former CFO) – 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. On October 16, 2015, an amended complaint was filed with more detailed allegations relating to alleged violations of federal securities laws. On December 15, 2015, IsoRay filed a motion to dismiss the complaint altogether. On June 1, 2016, the court entered an order denying IsoRay's motion to dismiss, holding that the complaint's allegations, if accepted as true, state a plausible claim to relief. The order did not adjudicate the merits of the lawsuit. No other issues were decided in the ruling.

On June 15, 2016, IsoRay filed its answer to the amended complaint. As IsoRay previously disclosed, on September 23, 2016, the parties entered into a stipulation of settlement which, if it becomes final, will provide for a payment to the plaintiff class of \$3,537,500, which will be paid by our insurers. On October 4, 2016, the stipulation of settlement was filed with the court, along with plaintiffs’ unopposed motion for preliminary approval of the settlement. On October 20, 2016, the court granted preliminary approval of the settlement. Following notice to class members, the class action is subject to final approval by the court. A final approval hearing is scheduled for March 7, 2017. If the proposed settlement is not approved by the court or if IsoRay is otherwise unable to obtain a favorable resolution of the claims set forth in the complaint, the lawsuit could have a material adverse effect on our business, results of operations and financial condition.

Derivative Complaint related to Shareholder Value

On September 29, 2016, a purported shareholder derivative complaint captioned *Kitley v. Babcock, et al.*, No. 0:16-cv-03297, was filed on behalf of the Company in the United States District Court for the District of Minnesota against certain of the Company’s current and former officers and directors. The complaint alleges that the defendants breached their fiduciary duties by causing the Company to issue allegedly false and misleading statements in a May 20, 2015 press release – the same press release at issue in the pending securities class action – concerning the results from a peer reviewed study of the Company’s Cesium-131 isotope seeds and mesh product for the treatment of non-small cell lung cancers. The complaint brings claims of breach of fiduciary duty, gross mismanagement, and unjust enrichment, and seeks unspecified compensatory damages, changes in corporate governance, and attorney’s fees and costs. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. The Company may be obligated pursuant to indemnification obligations to advance fees and costs incurred by the individuals defending against the action. The Company has applicable directors and officers insurance policies.

On November 17, 2016, the defendants filed a motion to dismiss Mr. Kitley's complaint. On January 23, 2017, instead of opposing defendants' motion, Mr. Kitley filed an amended complaint. Defendants' response to the amended complaint is due March 9, 2017.

## **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, 2016, and is incorporated herein by reference. There have been no material changes in our risk factors since such filing, except for the following:

### *We Rely Heavily On Five Customers*

For the six months ended December 31, 2016 approximately 48% of the Company's revenues were dependent on five customers with approximately 23% being generated by one 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.

**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**

The Company leases office and laboratory space under an operating lease with Energy Northwest. On November 15, 2016, the Company agreed to a contract modification which became effective November 1, 2016 to extend the lease termination date to April 30, 2021. No other terms of the lease, as modified through November 1, 2016, were changed.

**ITEM 6. EXHIBITS**

Exhibits:

- 10.1\* Irradiation Services Agreement, dated November 29, 2016, between The Curators of the University of Missouri and IsoRay Medical, Inc. (confidential treatment requested for redacted portions)
- 10.2\* Contract Modification, entered into on November 15, 2016 with an effective date of November 1, 2016, to Contract No. X-40403 between Energy Northwest and IsoRay Medical, Inc.
- 31.1\* Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer



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

32\*\* Section 1350 Certifications

101.INS\* XBRL Instance Document

101.SCH\* XBRL Taxonomy Extension Schema Document

101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB\* XBRL Taxonomy Extension Label Linkbase Document

101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith

\*\* Furnished herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: February 9, 2017

ISORAY, INC., a Minnesota corporation

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

*/s/ Matthew P. Branson*  
Matthew P. Branson  
Controller  
(Principal Financial and Accounting Officer)