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

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File No. 001-33407

**ISORAY, INC.**

(Exact name of registrant as specified in its charter)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Smaller reporting company ¨

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

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

| Class | Outstanding as of November 6, 2015 |
|---|---|
| Common stock, $0.001 par value | 55,013,553 |

**ISORAY, INC.**

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**PART I – FINANCIAL INFORMATION**

**ITEM 1 – FINANCIAL STATEMENTS**

**IsoRay, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

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

| | | |
|---|---|---|
| Total current liabilities | 931,384 | 1,092,194 |
| Long-term liabilities: | | |
| Warrant derivative liability | 166,000 | 181,000 |
| Asset retirement obligation | 969,336 | 947,849 |
| Total liabilities | 2,066,720 | 2,221,043 |
| Commitments and contingencies (Note 8) | | |
| Shareholders' equity: | | |
| Preferred stock, $.001 par value; 7,001,671 shares authorized: | | |
| Series A: 1,000,000 shares allocated; no shares issued and outstanding | - | - |
| Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding | 59 | 59 |
| Series C: 1,000,000 shares allocated; no shares issued and outstanding | - | - |
| Series D: 1,671 and 1,671 shares allocated; no shares issued and outstanding | - | - |
| Common stock, $.001 par value; 192,998,329 shares authorized; 55,013,553 and 54,967,559 shares issued and outstanding | 55,014 | 54,968 |
| Treasury stock, at cost, 13,200 shares | (8,390) | (8,390) |
| Additional paid-in capital | 82,546,112 | 82,467,111 |
| Accumulated deficit | (62,750,617) | (61,731,507) |
| Total shareholders' equity | 19,842,178 | 20,782,241 |
| Total liabilities and shareholders' equity | $ 21,908,898 | $ 23,003,284 |

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

**IsoRay, Inc. and Subsidiaries**

**Consolidated Statements of Operations**

**(Unaudited)**

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

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

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**IsoRay, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**

**(Unadudited)**

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

| | | |
|---|---|---|
| Net cash provided by financing activities | 46,735 | 215,686 |
| Net decrease in cash and cash equivalents | (3,639,731) | (5,604,756) |
| Cash and cash equivalents, beginning of period | 5,226,740 | 7,680,073 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 1,587,009 | $ 2,075,317 |
| Non-cash investing and financing activities: | | |
| Reclassification of derivative warrant liability to equity upon exercise | $ - | $ (17,000) |

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

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the three months ended September 30, 2015 and 2014**

## 1. Basis of Presentation

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

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

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

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

## 2. New Accounting Pronouncements

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

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

**3. Certificates of deposit**

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

| | As of September 30, 2015 | | | |
|---|---|---|---|---|
| | Under 90 Days | 91 days to six months | Six months to 1 year | Greater than 1 year |
| CDARS | $6,528,858 | $ - | $ 5,362,454 | $5,135,116 |

| | As of June 30, 2015 | | | |
|---|---|---|---|---|
| | Under 90 Days | 91 days to six months | Six months to 1 year | Greater than 1 year |
| CDARS | $3,523,167 | $ 500,064 | $ 5,339,343 | $5,106,775 |

**4. Loss per Share**

Basic and diluted earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. At September 30, 2015 and 2014, the calculation of diluted weighted average shares did not include convertible preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2015 and 2014, were as follows:

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

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

**5. Inventory**

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

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

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

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

**6. Fixed Assets**

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

Depreciation expense related to property and equipment for the three months ended September 30, 2015 and 2014 was $136,668 and $169,970, respectively.

**7. Share-Based Compensation**

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2015 and 2014:

| | Three months ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Cost of product sales | $ 17,558 | $ 7,972 |
| Research and development expenses | 3,565 | 3,117 |
| Sales and marketing expenses | 3,492 | 2,158 |
| General and administrative expenses | 7,697 | 8,206 |
| Total share-based compensation | $ 32,312 | $ 21,453 |

As of September 30, 2015, total unrecognized compensation expense related to stock-based options was $381,596 and the related weighted-average period over which it is expected to be recognized is approximately 1.56 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2015 was as follows:

| | Number of Options | Weighted Exercise Price (Years) | Weighted Average Contractual Term | Intrinsic Value |
|---|---|---|---|---|
| Outstanding at September 30, 2015 | 2,364,346 | $ 1.93 | 4.52 | $591,185 |
| Vested and expected to vest at September 30, 2015 | 2,267,045 | $ 1.94 | 4.40 | $570,238 |
| Vested and exercisable at September 30, 2015 | 1,967,880 | $ 1.96 | 3.55 | $583,083 |

There were 45,994 options exercised during the three months ended September 30, 2015 and 133,564 options exercised during the three months ended September 30, 2014. The Company's current policy is to issue new shares to satisfy option exercises. The intrinsic value of the employee options exercised in the three months ended September 30, 2015 and 2014 was $21,654 and $252,308, respectively.

There were no stock option awards granted during the three months ended September 30, 2015 and 2014, respectively.

**8. Commitments and Contingencies**

Patent and Know-How Royalty License Agreement

The Company is the holder of an exclusive license to use certain "know-how" developed by one of the founders of a predecessor to the Company and licensed to the Company by the Lawrence Family Trust, a Company shareholder. The terms of this license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty based on Net Factory Sales Price, as defined in the agreement, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and therefore no royalty is

due pursuant to the terms of the agreement. Management believes that ultimately no royalties should be paid under this agreement as there is no intent to use this “know-how” in the future.

The licensor of the “know-how” has disputed management’s contention that it is not using this “know-how”. On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

Class Action Lawsuit Related to Press Release

On May 22, 2015, a class action complaint for violation of the federal securities laws was filed in U.S. District Court against IsoRay, Inc., our CEO/Chairman and our CFO. The complaint related to a press release issued by the Company on May 20, 2015 and is purportedly brought on behalf of all purchasers of IsoRay, Inc. common stock from May 20, 2015 through and including May 21, 2015.

On October 16, 2015, an amended class action complaint for violation of the federal securities laws was filed in U.S District Court for Eastern District of Washington against IsoRay, Inc. and our CEO/Chairman. The class period remains unchanged at 27 hours and our CFO was dropped as a defendant. The Company has until December 15, 2015 to respond to the amended complaint.

The complaint, as amended, asserts that the purchasers were misled by the press release, and seeks, among other things, damages and costs and expenses. We cannot predict the outcome of such proceedings or an estimate of damages, if any. We believe that these claims are without merit and intend to defend them vigorously.

Property Transaction between Medical and The Port of Benton

*Initial Property Transaction*

On September 10, 2015, the Company's operating subsidiary, Medical, entered into a Real Estate Purchase and Sale Agreement with The Port of Benton, a municipal corporation of the State of Washington. The Agreement is for the sale of undeveloped real property of approximately 4.2 acres located adjacent to the Company's existing manufacturing facility and corporate offices. The purchase price for the property is One Hundred Sixty-Eight Thousand Dollars ($168,000) which is payable on October 30, 2015, the original expected date of closing prior to the First Addendum/Amendment.

In addition to the feasibility studies required on all aspects of the property required by Medical to close, Medical is also bound to comply with a Development Plan for a ten year period which requirements include but are not limited to the following:

(1) Certain specified site configurations and design with a minimum of 12,000 square feet of warehouse and production space and 4,000 square feet of office space;

(2) Completion of all construction in two years;

(3) Use of facility as primary production facility for ten (10) years; and

(4) Provision of jobs for not less than 25 full time employees.

Failure to comply with these covenants will result in a breach of the Agreement and if not cured, will obligate Medical to pay the Port the difference in the sales price and the appraised value of the property at the time of default.

*First Addendum / Amendment to Property Transaction*

On October 15, 2015, the Company's operating subsidiary, Medical, entered into a First Addendum / Amendment to Real Estate Purchase & Sale Agreement to the Real Estate Purchase and Sale Agreement with The Port of Benton, a municipal corporation of the State of Washington, that was entered into on September 10, 2015.

This addendum modified the following:

(1) Extended the feasibility contingency from a period of sixty (60) days to one hundred and twenty (120) days to expire on or before January 8, 2016 with no further extensions.

(2) Extended the closing of sale to on or before February 5, 2016.

All other terms and conditions of said Real Estate Purchase & Sale Agreement dated September 10, 2015 remained the same and continue in full force and effect.

**9. Fair Value Measurements**

The table below sets forth the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of September 30, 2015 and June 30, 2015, respectively, and the fair value calculation input hierarchy level the Company has determined applies to each asset and liability category.

Fair value at September 30, 2015

| | Total | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Cash and cash equivalents | $1,587,009 | $1,587,009 | $- | $ - |
| Warrant derivative liability | 166,000 | - | 166,000 | - |

Fair value at June 30, 2015

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

**10. Preferred Dividends**

On December 17, 2014, 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, 2014 in the amount of $10,632. The dividends outstanding and cumulative through December 31, 2014 of $10,632 and through December 31, 2013 of $10,632 were paid as of those dates.

As of September 30, 2015, there were accrued but undeclared dividends on Series B Preferred Stock outstanding in the amount of $7,974.

**11. Shareholders' Equity**

*Warrant derivative liability*

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

Change in fair value of the warrant derivative liability is as follows.

| | Three months ended September 30, 2015 | Three months ended September 30, 2014 |
|---|---|---|
| Change in fair value of warrant derivative liability: | $ (15,000) | $ (323,000) |

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

| | Quantity[1] | Amount |
|---|---|---|
| Balance at June 30, 2014 | 238,696 | $573,000 |
| Change in fair value | | (374,605) |
| Warrants exercised | (13,209) | (17,395) |
| Balance at June 30, 2015 | 225,087 | $181,000 |
| Change in fair value | | (15,000) |
| Balance at September 30, 2015 | 225,087 | $166,000 |

[1] Quantity of warrants either issued or outstanding as of the date of valuation.

*Warrants*

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

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

The following table summarizes additional information about the Company's common warrants outstanding as of September 30, 2015:

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

**12. Related Party Transaction**

During the three months ended September 30, 2015 and 2014, the Company continued to engage the services of APEX Data Systems, Inc., owned by Dwight Babcock, the Company's Chairman and Chief Executive Officer, to modify and maintain the Company's web interfaced data collection application to aggregate patient data in a controlled environment. The cost recorded during the three months ended September 30, 2015 and 2014 from APEX Data Systems, Inc. for the maintenance of the web interfaced data collection applications in combination with the updating of the Company website was $3,000 and $3,000 respectively. An additional $3,000 was spent on the implementation of Customer Relationship Management (CRM) software in the three months ended September 30, 2015 and 2014.

**13. Concentrations of Credit and Other Risks**

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

For the three months ended September 30, 2015 and 2014, there were two and one customers that each represented 10% or more of total net revenue, respectively.

At September 30, 2015, two customers each accounted for 10% of the Company's total accounts receivable with a single customer (a group of seven legal entities) that represents 30% of total accounts receivable. At June 30, 2014, one customer (a group of seven legal entities) accounted for 27% of total accounts receivable.

Accounts receivable are typically not collateralized. The Company maintains ongoing dialogue with its customers about invoice payments. Some of our customers are small outpatient surgery centers that pay invoices for our products at the time they receive a decision regarding payment by the insurer providing benefits which in the case of prostate cancer is predominately Medicare. A qualitative review of outstanding customer balances is performed at least quarterly and the allowance for doubtful accounts is adjusted based on historical performance of the customer and management knowledge regarding specific invoices. Accounts are charged against the allowance for doubtful accounts once collection efforts are deemed unsuccessful.

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

**ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

***Caution Regarding Forward-Looking Information***

*In addition to historical information, this Form 10-Q contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 ("PSLRA"). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.*

*All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under "Risk Factors"*

*under Part II, Item 1A below and in the "Risk Factors" section of our Form 10-K for the fiscal year ended June 30, 2015 that may cause actual results to differ materially.*

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

**Critical Accounting Policies and Estimates**

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, derivative liabilities and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 30, 2015 are those that depend most heavily on these judgments and estimates. As of September 30, 2015, there had been no material changes to any of the critical accounting policies contained therein.

**Overview**

**Products and Market.**

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

These brachytherapy seeds utilize Cesium-131, with a 9.7 day half-life, as their radiation source. The Company believes that it is the unique combination of the short half-life and the energy of the isotope that are yielding the beneficial treatment results that have been published in peer reviewed journal articles and presented in various forms at conferences and tradeshows. In the case of the GliaSite® RTS, the Company believes that in the long-term, Cesitrex®, which is Cesium-131-based, is the best isotope solution for this treatment, but it continues to offer Iotrex®, an Iodine-125 based isotope solution, as it works to reestablish the market for this product. To date, Iotrex® is the primary isotope solution utilized in the GliaSite® RTS; Cesitrex® is available for sale and only utilized in U.S. treatment.

The Company continues to enter into distribution agreements outside of the United States through its subsidiary IsoRay International LLC. These distributors are responsible for obtaining regulatory clearance to sell the Company's products in their territories, with the support of the Company. As of September 30, 2015, the Company had distributors in Australia and New Zealand, Germany which includes rights to Austria, Switzerland, and Luxembourg as well, Italy, and the Russian Federation.

Management is encouraged by the growth trend in our core business of treating prostate cancer, with four of the past five fiscal quarters experiencing increases over the same quarter in the prior fiscal year and with growth in total revenue during the past three fiscal quarters over the same quarters in the prior fiscal year. As the Company has a very small share of the overall prostate brachytherapy market, there is significant opportunity for expansion.

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

When brachytherapy seeds are implanted during a surgical procedure for brain cancer, lung cancer and certain other non-prostate cancers, under Medicare, the brachytherapy seeds are not separately reimbursed when surgery is performed and the patient is admitted to the hospital. External beam radiation treatments for these same cancers are reimbursed separately following surgery. While the cost of external beam radiation is significantly greater than the cost of brachytherapy at the time of surgery, this separate reimbursement for external beam radiation treatments results in the hospital receiving a payment in addition to payment for the surgical procedure itself. With brachytherapy performed concurrent with the surgery, the hospital receives the same reimbursement for the surgical procedure whether seeds are implanted or not, resulting in brachytherapy treatment being a "cost" and not a source of additional revenue for the hospital.

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

- Increased awareness by physicians of the benefits of utilizing Proxcelan ® Cesium-131 brachytherapy seeds;
- The Affordable Care Act (ACA) implementing cost containment measures in the evaluation of treatment methodologies and reimbursement, particularly in prostate cancer where costly intensity-modulated radiation therapy (IMRT) treats an increasing percentage of the overall U.S. prostate cancer treatment market and growth in the market is expected with the increase in men younger than Medicare age obtaining health insurance;
- Increased patient awareness of the comparability and benefits of low dose rate (LDR) brachytherapy when compared to external beam radiation therapy, including comparable urinary symptoms, fewer bowel toxicities, and better sexual function, with respect to which management believes that the Company's Cs-131 brachytherapy provides improved outcomes in these areas when compared to other types of LDR brachytherapy;
-

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

- Changes in the reimbursement methodology regarding the utilization of brachytherapy seeds in the treatment of brain cancer, lung cancer and other cancers;
- Continued evolution in protocols demonstrating the safety, efficacy and other benefits of using Proxcelan® Cesium-131 brachytherapy seeds to treat tumors throughout the body;
- Continued publication of peer reviewed journal articles and presentations at society meetings about the treatment outcomes achieved utilizing Proxcelan® Cesium-131 brachytherapy seeds in the treatment of prostate cancer, brain cancer, lung cancer, gynecological cancer and other tumors throughout the body;
- Expanded sales through distributors into other countries particularly those in which external beam radiation has not established a significant presence; and
- Continued ability of the Company to deliver product that meets the standards of the Company and the expectations of its customers.

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

- Implementation of a protocol to support the publication of peer reviewed journal articles and presentations at society meetings about the treatment outcomes achieved utilizing GliaSite® RTS;
- Greater awareness among doctors of the historical use of GliaSite® RTS and the treatment outcomes achieved;
- Greater awareness of the availability of Cesitrex® as an alternative isotope to Iotrex®; and
- Recovery of foreign economies and currencies to increase the overall market.

**Results of Operations**

**Three months ended September 30, 2015 compared to three months ended September 30, 2014.**

| | Three months ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2015 | | 2014 | | 2015-2014 |
| | Amount | % (a) | Amount | % (a) | % Change |
| Product sales, net | $1,261,322 | 100 | $1,042,101 | 100 | 21 |
| Cost of product sales | 1,177,863 | 93 | 1,096,903 | 105 | 7 |
| Gross profit / (loss) | 83,459 | 7 | (54,802) | (5) | 252 |
| | | | | | |
| Research and development expenses | 143,903 | 11 | 176,610 | 17 | (19) |
| Sales and marketing expenses | 278,421 | 22 | 353,743 | 34 | (21) |
| General and administrative expenses | 751,712 | 60 | 575,951 | 55 | 31 |
| Net loss attributable to shareholders | $(1,021,768) | (30) | $(788,520) | (76) | (30) |

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

**Revenues.** Total revenue from product sales increased approximately $219,000 or 21% in the three months ended September 30, 2015 when compared to the three months ended September 30, 2014. The 21% growth during the three months ended September 30, 2015 compared to the three months ended September 30, 2014 was the result of an increase of approximately $244,000 or 24% overall growth in seed brachytherapy treatments which more than offset the 100% decrease in GliaSite® revenues. During the three months ended September 30, 2015, 100% of product sales came from brachytherapy seed treatments compared with 98% during the three months ended September 30, 2014.

*Prostate Brachytherapy.*

During the three months ended September 30, 2015 and 2014, respectively, prostate brachytherapy was 88% of total revenues. The growth in revenue from prostate brachytherapy of 22% was the result of a 16% increase in the total number of seeds sold combined with the change in product mix ordered by physicians during the three months ended September 30, 2015 compared to the three months ended September 30, 2014. Physicians ordered 18% more seeds configured into strands and pre-loaded in needles and 20% more seeds configured in Mick® cartridges during the three months ended September 30, 2015 compared to the three months ended September 30, 2014. These configurations result in more revenue than alternative configurations.

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

*Other Brachytherapy.*

The strategy implemented by management in diversifying the number of body sites being actively treated with the Proxcelan® Cs-131 brachytherapy seed has continued to provide an additional source of revenue. While individually these treatment sites do not represent a significant contribution to revenue, the sites as a group increased their revenue contribution by 44% during the three months ended September 30, 2015 when compared to the three months ended September 30, 2014. The largest revenue contributions in this classification came from brain cancer and lung cancer treatments. During the three months ended September 30, 2015 and 2014, respectively, other brachytherapy represented approximately $146,000 or 12% and approximately $101,000 or 10% of total revenue growth, or a 44% increase. These other brachytherapy treatments continue to be subject to the influence of a small pool of innovative physicians who are the early adopters of the technology who also tend to be faculty at teaching hospitals training the next generation of physicians. This causes the revenue created by these types of treatment applications to be more volatile and vary significantly from quarter to quarter.

*GliaSite® Radiation Therapy System.*

All product sales are generated by brachytherapy seeds and their related methods of application except for the revenue generated by sales of GliaSite® RTS, which come from sale of the liquid isotope, catheter trays and access trays. Product sales from GliaSite® RTS decreased 100%, with no revenue in the three months ended September 30, 2015 compared to revenue of $25,000 in the three months ended September 30, 2014. While the recovery of past sales levels will be dependent on economic recovery in Europe, the Company expects to see some mild recovery of prior sales levels based on discussions with its German distributor, however, these sales may not materialize. The lack of sales was partially impacted by the change in the exchange rate between the US dollar and the Euro as the dollar continued to be stronger during fiscal year 2016 compared with fiscal year 2015, which effectively increased the cost to European customers as all transactions are conducted in the US dollar.

The conversion of prospects to new GliaSite® RTS customers has been a longer process than originally anticipated by the Company. The Company has experienced lengthy timelines in the internal processes of medical facilities in reviewing and approving the use of the product at the request of their physician(s). These longer than anticipated internal processes are compounded by uncertain timelines and delays in receiving the approval for the requested modification of each facility's nuclear materials license, which is required to begin using GliaSite® RTS and is dependent on external government regulators.

**Cost of product sales.**

The cost of product sales for the production of brachytherapy seeds increased by approximately $81,000 or 7% during the three months ended September 30, 2015 when compared to the three months ended September 30, 2014. The increase in cost of products for the production of brachytherapy seeds was the result of increased material consumption of approximately $98,000 or 23%, partially offset by a reduction in depreciation and amortization expense of approximately $31,000 or 19%. The increased material costs are the result of the additional costs related to producing the 16% increase in the number of brachytherapy seeds produced and the related changes in configuration, with the ability to produce those seeds within the existing isotope that was purchased to ensure the ability of the Company to produce orders on a weekly basis that were previously expensed as the isotope decayed and was unable to generate future revenue. The decrease in depreciation and amortization is the result of reduced depreciation expense as equipment has continued to reach the end of its depreciable life without requiring replacement. Although not required by our contract with our Russian isotope supplier, we purchase isotope in 20 curie lots weekly and therefore incur this cost regardless of usage. The Company is a just in time manufacturer of brachytherapy seeds which is the result of the unique properties of Cesium-131, primarily the half-life or decay rate of 9.7 days. The Company requires isotope on-hand to meet known orders as well as anticipated orders which may or may not materialize. The Company does not manufacture to inventory as other brachytherapy seed manufacturers may. When the Company has isotope available for production in excess of the current demand, manufacturing of orders due to ship in the near future will be manufactured to allow future flexibility in the manufacturing cycle.

During the three months ended September 30, 2015 compared to the three months ended September 30, 2014, the decrease in the cost of product sales for the GliaSite® RTS was primarily the result of decreased isotope consumption which was the result of there being no orders for this product in the three months ended September 30, 2015.

**Gross profit / (loss).** Gross profit for the three months ended September 30, 2015 improved by approximately $138,000 or 252% compared to the gross loss for the three months ended September 30, 2014, primarily as a result of the increased product sales, with minimal incremental costs related to materials and labor to increase seed production outputs. This increase in gross profit was significantly impacted by the ability of the Company to utilize isotope that was already purchased to ensure an adequate supply of isotope on a weekly basis to produce orders and that would have otherwise been expensed as it decayed during the operating cycle.

**Research and development.** Research and development costs decreased by approximately $33,000 or 19% in the three months ended September 30, 2015 compared to the three months ended September 30, 2014, primarily as a result of the decrease in legal expense related to the protection of intellectual property.

**Sales and marketing expenses.** Sales and marketing expenses decreased by approximately $75,000 or 21% during the three months ended September 30, 2015 compared to the three months ended September 30, 2014, primarily as the result of decreased conventions and tradeshow expenses of approximately $41,000 or 84% as the American Society for Radiation Oncology (ASTRO) convention occurred in October 2015 versus September 2014. The Company also had an expected temporary reduction in travel expenses and payroll related expenses of approximately $17,000 or 29% and approximately $13,000 or 6% related to the open national sales director and territory sales manager positions that were unfilled during the three months ended September 30, 2015.

**General and administrative expenses.** General and administrative expenses increased by $176,000 or 31% in the three months ended September 30, 2015 compared to the three months ended September 30, 2014. The significant increases were in auditing, Sarbanes-Oxley and tax compliance of approximately $28,000 or 93%, legal expense of approximately $92,000 or 219%, and occupancy expense of approximately $16,000 or 160%. The auditing, Sarbanes-Oxley and tax compliance cost increased as the result of the Company’s change from a smaller reporting company to an accelerated filer June 30, 2015 and the related reporting and compliance obligations that came as the result of the filing status change. Legal expense increased from a combination of the expanded reporting obligations related to the Company filing status change from a smaller reporting company to an accelerated filer June 30, 2015 and the cost of legal counsel in defending the Company and its executive officers against a class action shareholder lawsuit. Occupancy expense increased as the allocation of cost changed in the three months ended September 30, 2015 compared to the three months ended September 30, 2014. The overall rent did not change, however, the amount of cost being allocated to general and administrative functions did change, resulting in reductions to other functions which offset this increase to general and administrative.

**Operating loss.** Operating loss for the three months ended September 30, 2015 decreased approximately $71,000 or 6% compared to the three months ended September 30, 2014, primarily as a result of an increase in product sales partially offset by an increase in cost of product sales and general and administrative expenses.

**Interest income.** Interest income decreased approximately $15,000 or 21% during the three months ended September 30, 2015 when compared to the three months ended September 30, 2014 due to a decrease in the available excess cash to invest in laddered CDs in the Certificate of Deposit Account Registry Service® (CDARS) and which are in amounts that are fully insured by the Federal Deposit Insurance Corporation (FDIC).

**Change in fair value of warrant derivative liability.** The warrant derivative liability requires periodic evaluation for changes in fair value. As required at September 30, 2015 and September 30, 2014, the Company evaluated the fair value of the warrant derivative liability using the Black-Scholes option pricing model and applied updated inputs as of those dates. The resulting change in fair value was recorded as of September 30, 2015 and September 30, 2014.

**Liquidity and capital resources**. The Company has historically financed its operations through selling stock to investors. During the three months ended September 30, 2015 and September 30, 2014, the Company used existing cash reserves to fund its operations and capital expenditures.

Our cash flows for the three months ended September 30, 2015 and 2014, respectively, are summarized as follows:

| | Three months ended September 30, | |
|---|---|---|
| | 2015 | 2014 |
| Net cash used by operating activities | $ (1,109,572) | $ (1,143,186) |
| Net cash used by investing activities | (2,576,894) | (4,677,256) |
| Net cash provided by financing activities | 46,735 | 215,686 |
| Net decrease in cash and cash equivalents | $ (3,639,731) | $ (5,604,756) |

*Cash flows from operating activities*

Net cash used by operating activities in the three months ended September 30, 2015 was $1.11 million as compared to $1.14 million used in the three months ended September 30, 2014.

Net cash used by operating activities in the three months ended September 30, 2015:

- Net loss of $1.02 million;
- Net loss was increased by non-cash items of approximately $15,000 related to the change in fair value of derivative warrant liability;
- Net loss was decreased by non-cash items of approximately $211,000 related to depreciation of fixed assets; amortization of other assets; accretion of the asset retirement obligation and share-based compensation expense;
- Increase in accounts receivable of approximately $81,000, the result of the increase in product sales of approximately $219,000 when compared to the same quarter in the prior fiscal year;
- Increase in inventory of approximately $57,000, the result of purchases of inventory, consisting of titanium lids, titanium tubing and gold wire produced to the specifications of the Company, in quantities to obtain best pricing;

- Decrease in accounts payable and accrued expenses of approximately $87,000, the result of the timing of paying operating expenses; and
- Decrease in the accrued payroll and related taxes expense of approximately $83,000, the result of the number of days of unpaid payroll and related taxes in combination with the payment of commissions due that were accrued but unpaid at the end of the prior fiscal year.

Net cash used by operating activities in the three months ended September 30, 2014:

- Net loss of approximately $786,000;
- Net loss was increased by non-cash items of approximately $306,000 related to change in fair value of derivative warrant liability and allowance for doubtful accounts;
- Net loss was decreased by non-cash items of approximately $207,000 related to depreciation of fixed assets; amortization of other assets; accretion of the asset retirement obligation and share-based compensation expense;
- Increase in accounts receivable of approximately $38,000, the result of delayed payments from customers;
- Increase in inventory of $48,000, the result of increased raw materials and work in process on-hand at period end;
- Decrease in other receivables of approximately $48,000, the result of receiving a refund of overpaid payroll taxes from the third party processor of the Company payroll related to the exercise of non-qualified employee stock options;
- Increase in prepaid expenses and other current assets of approximately $46,000 which was the result of prepayment of directors and officers insurance;
- Increase in accounts payable and accrued expenses of approximately $65,000, the result of the timing of paying operating expenses; and
- Increase in the accrued payroll and related taxes expense of $131,000, the result of the number of days of unpaid payroll and related taxes.

*Cash flows from investing activities*

Net cash used by investing activities in the three months ended September 30, 2015 was $2.58 million as compared to $4.68 million used in the three months ended September 30, 2014.

Net cash used by investing activities in the three months ended September 30, 2015:

- Increased by purchases of fixed assets of approximately $4,000;
- Increased by additions to licenses and other assets of approximately $16,000;
- Decreased by proceeds from certificates of deposit that matured of $3.53 million;
- Increased by purchases of certificates of deposit of $6.06 million;
  - Approximately $3.53 million of the cash used for the certificates of deposit purchased came from certificates of deposit that reached maturity during the three months ended September 30, 2015;
  - $2.5 million of the cash used for the purchase of certificates of deposit came certificates of deposit that matured during June 2015 and were in cash and cash equivalents at June 30, 2015;
  - The remaining cash used for the purchase of certificates of deposit was from interest earned during the period and added to the existing certificates of deposit; and
- Increased by purchases of certificates of deposit, non-current of approximately $28,000.

Net cash used by investing activities in the three months ended September 30, 2014:

- Increased by purchases of fixed assets of approximately $7,000;
- Increased by purchases of certificates of deposit of approximately $22,000; and
- Increased by purchases of certificates of deposit, non-current of $4.65 million.

*Cash flows from financing activities*

Net cash provided by financing activities in the three months ended September 30, 2015:

- Increase from the sale of common stock from the exercise of stock options of approximately $47,000.

Net cash provided by financing activities in the three months ended September 30, 2014:

- Increase from the sale of common stock from the exercise of warrants of approximately $70,000; and
- Increase from the sale of common stock from the exercise of stock options of approximately $145,000.

*Projected Fiscal Year 2016 Liquidity and Capital Resources*

At September 30, 2015, the Company held cash and cash equivalents of $1.59 million, CDARS of $11.89 million that mature in the current operating cycle and CDARS of $5.14 million that mature within the next twenty-four months.

| | Amount |
|---|---|
| Cash and cash equivalents | $1,587,009 |
| Certificates of deposit maturing in less than 90 days | 6,528,858 |
| Certificates of deposit maturing greater than six months and less than one year | 5,362,454 |
| Certificates of deposit maturing greater than one year and less than two years | 5,135,116 |
| Cash, cash equivalents and certificates of deposit total | $18,613,437 |

The Company had approximately $1.72 million of cash and cash equivalents, $11.90 million of certificates of deposit and $5.14 million of certificates of deposit, non-current as of November 3, 2015. The short-term investments have maturities in December 2015, January 2016 and June 2016. At the time of maturity, Company management will assess the cash requirements of the Company and reinvest excess cash as it deems appropriate. The Company's monthly required cash operating expenditures were approximately $361,000 and $381,000 during the three months ended September 30, 2015 and 2014, respectively, which represents a 5% improvement.

Management forecasts that fiscal year 2016 cash consumed in production operations will be similar to the prior fiscal year. Company management is early in the design process of the future facility and with the goal of constructing a facility that will have non-cash depreciation that is less than the current monthly rental cost of the current facility while providing long-term security for future of the Company. It is expected that the long-term production facility will be owned by the Company or a wholly-owned subsidiary of the Company.

*Capital expenditures*

- The Company has not required significant capital equipment investment despite many of the significant items of manufacturing equipment having reached or reaching their depreciable lives this fiscal year. Management believes less than $200,000 will be required to be invested in manufacturing or other capital equipment related to Company

operations during fiscal year 2016, but there is no assurance that unanticipated needs for capital equipment or a yet to be determined capital project may not arise; and

- The Company has placed $25,000 in escrow on raw land as disclosed in financial statement footnote 8 Commitments and Contingencies under the section “Property Transaction between Medical and The Port of Benton”. An additional amount of less than $175,000 including closing costs and due diligence is expected to be spent in fiscal 2016 if the purchase of the real property closes. Future cash requirements related to construction of and moving into the new facility are difficult to project until designs, architectural drawings and contractor estimates of construction costs have been made, but management does not expect to spend more than $50,000 beyond the amounts needed to close the purchase prior to breaking ground on the new facility.

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

Based on the foregoing assumptions, management believes that the cash and cash equivalents of approximately $1.72 million, short-term investments of $11.90 million and investments – other of $5.14 million at November 3, 2015 will be sufficient to meet our anticipated cash needs assuming both revenue and expenses remain at current levels for the next three years.

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

For the three months ended September 30, 2015, revenue from other treatment modalities with both brachytherapy seeds and GliaSite® RTS has increased 44% when compared to the three months ended September 30, 2014. These newer brachytherapy product sales (including brain, lung and those reported as other) remain in the early stages of adoption and application in the clinical setting and their purchasing patterns are subject to the influence of a few key physicians who can significantly influence revenue from quarter to quarter. There were no sales of GliaSite® RTS in the three months ended September 30, 2015.

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, 2015, the Company had used the net proceeds raised through the March 2014 offering as described in the table below and held the remaining net proceeds in cash and cash equivalents and certificates of deposit. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

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

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

*Other Commitments and Contingencies*

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

*Off-Balance Sheet Arrangements*

The Company has no off-balance sheet arrangements.

*Critical Accounting Policies and Estimates*

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

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

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

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

**ITEM 4 – CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of September 30, 2015. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

**Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

**PART II - OTHER INFORMATION**

**ITEM 1 – LEGAL PROCEEDINGS**

On October 16, 2015, an amended class action complaint for violation of the federal securities laws was filed in U.S District Court for Eastern District of Washington against IsoRay, Inc. and our CEO/Chairman. This amends the complaint originally filed on May 22, 2015. The class includes purchasers of IsoRay, Inc. common stock from May 20, 2015 through and including May 21, 2015 and our CFO was dropped as a defendant. The complaint asserts that the purchasers were misled by a press release issued by the Company on May 20, 2015. The complaint seeks, among other things, damages and costs and expenses. We cannot predict the outcome of such proceedings or an estimate of damages, if any. We believe that these claims are without merit and intend to defend them vigorously. The Company has until December 15, 2015 to respond to the complaint.

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

**ITEM 1A – RISK FACTORS**

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

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

None.

**ITEM 3 – DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM4 - MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5 – OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

Exhibits:

| | |
|---|---|
| 31.1* | Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer |
| 31.2* | Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer |
| 32** | Section 1350 Certifications |
| 101.INS* | XBRL Instance Document |

101.SCH* XBRL Taxonomy Extension Schema Document

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Dated: November 9, 2015

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer

(Principal Executive Officer)

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

(Principal Financial and Accounting Officer)

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