

IsoRay, Inc.
Form 10-Q
November 16, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2009

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
(State or other jurisdiction of incorporation or organization)

41-1458152
(I.R.S. Employer Identification No.)

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

99354
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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

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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 13, 2009 |
|---------------------------------|-------------------------------------|
| Common stock, \$0.001 par value | 22,942,088 |

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

| | (Unaudited) September 30, 2009 | June 30, 2009 |
|--|--------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 3,169,376 | \$ 2,990,744 |
| Short-term investments | 959,811 | 1,679,820 |
| Accounts receivable, net of allowance for doubtful accounts of \$115,594 and \$86,931, respectively | 799,436 | 746,568 |
| Inventory | 720,986 | 789,246 |
| Prepaid expenses and other current assets | 175,245 | 151,077 |
| Total current assets | 5,824,854 | 6,357,455 |
| Fixed assets, net of accumulated depreciation and amortization | 4,656,580 | 4,891,484 |
| Deferred financing costs, net of accumulated amortization | 18,111 | 28,186 |
| Licenses, net of accumulated amortization | 8,827 | 11,867 |
| Restricted cash | 179,151 | 178,615 |
| Other assets, net of accumulated amortization | 269,898 | 273,959 |
| Total assets | \$ 10,957,421 | \$ 11,741,566 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | \$ 709,757 | \$ 698,882 |
| Accrued payroll and related taxes | 247,152 | 188,703 |
| Notes payable, due within one year | 155,867 | 161,437 |
| Total current liabilities | 1,112,776 | 1,049,022 |
| Notes payable, due after one year | 164,358 | 176,023 |
| Asset retirement obligation | 566,018 | 553,471 |
| Total liabilities | 1,843,152 | 1,778,516 |
| Shareholders' equity: | | |
| Preferred stock, \$.001 par value; 6,000,000 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 |
| Common stock, \$.001 par value; 194,000,000 shares authorized; | | |
| 22,942,088 shares issued and outstanding | 22,942 | 22,942 |

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| | | |
|--|---------------|---------------|
| Treasury stock, at cost, 13,200 shares | (8,390) | (8,390) |
| Additional paid-in capital | 47,876,130 | 47,818,203 |
| Accumulated deficit | (38,776,472) | (37,869,764) |
| Total shareholders' equity | 9,114,269 | 9,963,050 |
| Total liabilities and shareholders' equity | \$ 10,957,421 | \$ 11,741,566 |

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

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

| | Three months ended September 30, | |
|---|----------------------------------|----------------|
| | 2009 | 2008 |
| Product sales | \$ 1,379,087 | \$ 1,519,582 |
| Cost of product sales | 1,160,089 | 1,448,436 |
| Gross margin | 218,998 | 71,146 |
| Operating expenses: | | |
| Research and development expenses | 68,882 | 218,550 |
| Sales and marketing expenses | 442,899 | 730,774 |
| General and administrative expenses | 602,431 | 780,157 |
| Total operating expenses | 1,114,212 | 1,729,481 |
| Operating loss | (895,214) | (1,658,335) |
| Non-operating income (expense): | | |
| Interest income | 5,867 | 44,786 |
| Loss on impairment of short-term investments | - | (159,200) |
| Financing and interest expense | (17,361) | (20,847) |
| Non-operating (expense) income, net | (11,494) | (135,261) |
| Net loss | \$ (906,708) | \$ (1,793,596) |
| Basic and diluted loss per share | \$ (0.04) | \$ (0.08) |
| Weighted average shares used in computing net loss per share: | | |
| Basic and diluted | 22,942,088 | 22,942,088 |

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

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

| | Three months ended September 30, | |
|---|-------------------------------------|---------------------|
| | 2009 | 2008 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (906,708) | \$ (1,793,596) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | |
| Depreciation and amortization of fixed assets | 242,904 | 303,489 |
| Amortization of deferred financing costs and other assets | 18,191 | 21,493 |
| Amortization of discount on short-term investments | 9 | - |
| Loss on impairment of short-term investments | - | 159,200 |
| Accretion of asset retirement obligation | 12,547 | 11,470 |
| Share-based compensation | 57,927 | 108,714 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (52,868) | 105,220 |
| Inventory | 68,260 | 48,913 |
| Prepaid expenses and other current assets | (25,183) | 10,218 |
| Accounts payable and accrued liabilities | 10,875 | 40,344 |
| Accrued payroll and related taxes | 58,449 | (4,480) |
| Net cash used by operating activities | (515,597) | (989,015) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of fixed assets | (8,000) | (17,107) |
| Additions to licenses and other assets | - | (7,458) |
| Change in restricted cash | (536) | (687) |
| Proceeds from the sale or maturity of short-term investments | 720,000 | - |
| Net cash provided / (used) by investing activities | 711,464 | (25,252) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Principal payments on notes payable | (17,235) | (14,731) |
| Principal payments on capital lease obligations | - | (10,609) |
| Repurchase of Company common stock | - | (4,735) |
| Net cash used by financing activities | (17,235) | (30,075) |
| Net increase / (decrease) in cash and cash equivalents | 178,632 | (1,044,342) |
| Cash and cash equivalents, beginning of period | 2,990,744 | 4,820,033 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 3,169,376 | \$ 3,775,691 |

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

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements
For the three-month periods ended September 30, 2009 and 2008

1. Basis of Presentation

The accompanying 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.

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2009. The financial information is unaudited but reflects all adjustments, consisting only of normal recurring accruals, which are, in the opinion of the Company's management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2009.

2. New Accounting Pronouncements

On July 1, 2009, the Company adopted new accounting provisions which establishes the FASB Accounting Standards Codification™ (the Codification) as the single official source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles (GAAP) other than rules and interpretive releases issued by the Securities and Exchange Commission. The Codification reorganized the literature and changed the naming mechanism by which topics are referenced. The Codification became effective for interim and annual periods ending after September 15, 2009. The Company's accounting policies and amounts presented in the financial statements were not impacted by this change.

On July 1, 2009, the Company adopted new accounting provisions which were delayed from the effective date of fair value accounting for one year for certain nonfinancial assets and nonfinancial liabilities, excluding those that are recognized or disclosed in financial statements at fair value on a recurring basis (that is, at least annually). For purposes of applying the new provisions, nonfinancial assets and nonfinancial liabilities include all assets and liabilities other than those meeting the definition of a financial asset or a financial liability. The Company had previously adopted new standards for fair value accounting on July 1, 2008. The adoption of these new provisions did not have a material effect on the Company but will affect future calculations of asset retirement obligations and long-lived asset impairment.

On July 1, 2009, the Company adopted new accounting provisions for business combinations and for non-controlling interests. The new business combination provisions require an acquirer to measure the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. In addition, the new provisions require that a noncontrolling interest in a subsidiary be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. The adoption of these statements did not have a material effect on the Company's financial statements.

3. Loss per Share

Basic 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. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At September 30, 2009 and 2008, the calculation of diluted weighted average shares did not include 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, 2009 and 2008 were as follows:

| | September 30, | |
|--|------------------|------------------|
| | 2009 | 2008 |
| Preferred stock | 59,065 | 59,065 |
| Common stock warrants | 3,216,644 | 3,245,082 |
| Common stock options | 2,606,769 | 2,469,376 |
| Total potential dilutive securities | 5,882,478 | 5,773,523 |

4. Short-Term Investments

The Company's short-term investments are classified as available-for-sale and recorded at fair market value. The Company's short-term investments consisted entirely of certificates of deposit at various banks as of September 30, 2009 and June 30, 2009. The Company's short-term investments are accounted for and reported at fair value using level 1 inputs.

5. Inventory

Inventory consisted of the following at September 30, 2009 and June 30, 2009:

| | September | |
|-----------------|-------------------|-------------------|
| | 30, 2009 | June 30, 2009 |
| Raw materials | \$ 590,134 | \$ 609,932 |
| Work in process | 123,898 | 155,827 |
| Finished goods | 6,954 | 23,487 |
| | \$ 720,986 | \$ 789,246 |

6. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2009 and 2008:

| | Three months ended September 30, | |
|-------------------------------------|----------------------------------|------------|
| | 2009 | 2008 |
| Cost of product sales | \$ 5,897 | \$ 9,130 |
| Research and development | 162 | 9,921 |
| Sales and marketing expenses | 23,625 | 58,692 |
| General and administrative expenses | 28,243 | 30,971 |
| Total share-based compensation | \$ 57,927 | \$ 108,714 |

As of September 30, 2009, total unrecognized compensation expense related to stock-based options was \$230,202 and the related weighted-average period over which it is expected to be recognized is approximately 0.87 years.

The Company currently provides stock-based compensation under three equity incentive plans approved by the Board of Directors. Options granted under each of the plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2009 were as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|-------------------|---------------------------------|---|---------------------------|
| Outstanding at September 30, 2009 | 2,606,769 | \$ 2.01 | 7.7 | \$ 821,076 |
| Vested and expected to vest at September 30, 2009 | 2,526,559 | \$ 2.07 | 7.7 | \$ 754,390 |
| Vested and exercisable at September 30, 2009 | 2,155,823 | \$ 2.37 | 7.3 | \$ 476,749 |

There were no options exercised during the three months ended September 30, 2009 and 2008, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows:

| | Three months ended September 30, | |
|--|-------------------------------------|----------|
| | 2009(a) | 2008 (b) |
| Weighted average fair value of options granted | \$ 0.51 | \$ 0.51 |
| Key assumptions used in determining fair value: | | |
| Weighted average risk-free interest rate | 2.50% | 3.34% |
| Weighted average life of the option (in years) | 4.00 | 5.33 |
| Weighted average historical stock price volatility | 132.21% | 122.28% |
| Expected dividend yield | -% | -% |

- (a) During the quarter ended September 30, 2009, the Company granted 10,000 stock options.
 (b) During the quarter ended September 30, 2008, the Company granted 45,000 stock options.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Although the Company is using the Black-Scholes option valuation model, management believes that because changes in the subjective input assumptions can materially affect the fair value estimate, this valuation model does not necessarily provide a reliable single measure of the fair value of its stock options. The risk-free interest rate is based on the U.S. treasury security rate in effect as of the date of grant. The expected option lives, volatility, and forfeiture assumptions are based on historical data of the Company.

7. 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.

8. Fair Value Measurements

Effective July 1, 2008, for the financial assets and liabilities of the Company, and effective July 1, 2009, for the non-financial assets and liabilities of the Company, disclosure requirements have been expanded to include the following information for each major category of assets and liabilities that are measured at fair value on a recurring basis: financial assets of the Company include cash and cash equivalents, short-term investments, accounts receivable, net of allowance and restricted cash - these are measured using level 1 inputs. Financial liabilities of the Company include accounts payable and accrued liabilities, accrued payroll and related taxes, notes payable, due within one year and notes payable, due after one year - these are measured using level 1 inputs. Non-financial assets of the Company include inventory, prepaid and other current assets, fixed assets, net, deferred financing costs, net, licenses, net and other assets, net - these are measured using level 2 inputs. Non-financial liabilities of the Company include the asset retirement obligation and this is measured using level 3 inputs. The only change in the valuation of the asset retirement obligation was the accretion in the three months ended September 30, 2009.

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” beginning on page 15 below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2009 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, 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 23, 2009 are those that depend most heavily on these judgments and estimates. As of September 30, 2009, there have been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2009 compared to three months ended September 30, 2008

Revenues. The Company generated revenue of \$1,379,087 during the three months ended September 30, 2009 compared to sales of \$1,519,582 during the three months ended September 30, 2008. The decrease of \$140,495 or 9% was mainly due to decreased overall sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds along with a 36 % decrease in the number of more expensive strand loaded seeds some of which was partially offset by an 12% increase in the number of loose / MICK™ loaded seeds over the prior year.

Approximately 51% of the decrease is due to physicians ordering less seeds per implant as they have become more efficient with use of the isotope and its characteristics. The Company will need to increase the number of total implants to increase sales. Management believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy seed sales. During the three months ended September 30, 2009, the Company sold its Proxcelan seeds to 50 different medical centers as compared to 47 medical centers during the corresponding period of 2008.

Cost of product sales. Cost of product sales was \$1,160,089 for the three months ended September 30, 2009 compared to cost of product sales of \$1,448,436 during the three months ended September 30, 2008. The decrease of \$288,347 or 20% was mainly due to more efficient production operations as the Company continues work to streamline its manufacturing processes. The major components of the decrease were wages, benefits and related taxes, preload expenses and depreciation. Wages, benefits, and related taxes decreased approximately \$79,000 and continue to be directly attributable to a reduced headcount as the Company continues to actively manage its manufacturing staff headcount to effectively respond to sales changes. Preload expenses decreased approximately \$91,000 due to decreased sales volumes, improvements in in-house loading capabilities and the increased utilization of in-house loading by customers. Depreciation contributed additional savings of approximately \$55,000 as the result of a significant piece of production equipment reaching the end of its depreciable life.

Gross margin. Gross margin was \$218,998 for the three month period ended September 30, 2009 compared to a gross margin of \$71,146 for the three month period ended September 30, 2008. The increase of \$147,852 or 208% was due to continued reductions in production costs and efficient use of manufacturing resources despite the decrease in revenues.

Research and development. Research and development expenses for the three month period ended September 30, 2009 were \$68,882 which represents a decrease of \$149,668 or 68% over the research and development expenses of \$218,550 for the three months ended September 30, 2008. The total decrease is a combination of reductions in consulting, isotope research, legal expense, protocol expense, share-based compensation and payroll, benefits and related taxes. Consulting decreased approximately \$10,000 as the Company's spending on its projects to improve efficiency in production processes has been completed with the savings partially offset by the cost of the consulting relationship with the Company's former research and development director. Payroll, benefits and related taxes decreased approximately \$35,000 due to a lower headcount. There were additional savings in protocol expenses of approximately \$60,000 due to the stage the Company's protocols are in at present, share-based compensation of approximately \$10,000, legal expenses of \$17,000 and approximately \$16,000 from isotope research as the Company has discontinued most funding until the final prototype testing trial.

Sales and marketing expenses. Sales and marketing expenses were \$442,899 for the three months ended September 30, 2009. This represents a decrease of \$287,875 or 39% compared to expenditures in the three months ended September 30, 2008 of \$730,774 for sales and marketing. The decrease is mainly due to a decrease in expenses related to conventions and tradeshow, marketing and advertising, share-based compensation, physician training, travel and wages, benefits and related taxes. Wages, benefits and related taxes decreased approximately \$63,000 due to a lower headcount and continued lower base salaries for sales people due to a new compensation plan that was originally introduced in April 2008 and subsequently changed in October 2008. Conventions and tradeshow decreased by approximately \$58,000 due to the sales group attending fewer small conferences and the shift in scheduling of a major conference that occurred in the three months ended September 30, 2008 in FY2009 and will occur instead in the three months ended December 31, 2009 in FY2010. Marketing and advertising expenses decreased approximately \$19,000 as a result of a reduction in the number of trade journals used for advertising. Share-based compensation decreased by approximately \$35,000 as a result of reduced headcounts that resulted in the forfeiture of some options and vesting was completed on other options that were a component of the prior year expense. Physician training expense was reduced by approximately \$16,000 as there was a significant training event in the prior year. Travel expense decreased by approximately \$79,000 due in part to having reduced headcount in the active sales team and associated travel for the major conference discussed above which took place during the three months ended September 30, 2008 in FY2009 but will instead take place during the three months ended December 31, 2009 in FY2010.

General and administrative expenses. General and administrative expenses for the three months ended September 30, 2009 were \$602,431 compared to general and administrative expenses of \$780,157 for the three months ended September 30, 2008. The decrease of \$177,726 or 23% is primarily due to decreases in wages, benefits and related taxes, public company expenses, consulting expense, legal expense and office supply expense partially offset by an increase in audit, SOX and tax expense. Wages, benefits and related taxes decreased approximately \$24,000 mainly due to the reduction in headcount partially offset with the Chief Executive Officer becoming an employee (he was a consultant while serving as interim CEO). Public company expenses decreased approximately \$36,000 due a decrease in board compensation as a result of the interim CEO becoming an employee and reduced investor relations activities. Consulting expenses decreased approximately \$33,000 mainly due to the fact that the interim CEO became an employee. Legal fees decreased by \$78,000 primarily due to the fact that no legal fees were incurred in the three months ended September 30, 2009 for ongoing litigation whereas in the prior year legal fees were incurred in a lawsuit with a former employee. Office supplies expense has decreased by approximately \$16,000 due to the Company's focused effort to minimize purchases of computer software, computer hardware and office supplies.

Operating loss. The Company continues to focus its resources on sales and retaining the administrative infrastructure to increase the level of demand for the Company's product. These objectives and related costs have resulted in the Company not being profitable and generating operating losses since its inception. In the three months ended September 30, 2009, the Company had an operating loss of \$895,214 which is a decrease of \$763,121 or 46% over the operating loss of \$1,658,335 for the three months ended September 30, 2008.

Interest income. Interest income was \$5,867 for the three months ended September 30, 2009. This represents a decrease of \$38,919 or 87% compared to interest income of \$44,786 for the three months ended September 30, 2008. The decrease is due to the Company's lower short-term investment balances and lower interest rates during the quarter ended September 30, 2009 as compared to the quarter ended September 30, 2008. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

Loss on short-term investments. The loss of \$159,200 for the three months ended September 30, 2008 was due to uncertainties in the credit markets that affected the liquidity of the Company's auction rate securities. The loss represented the amount to write-down these securities to their estimated fair market value.

Financing and interest expense. Financing and interest expense for the three months ended September 30, 2009 was \$17,361 or a decrease of \$3,486 or 17% from financing and interest expense of \$20,847 for the corresponding period in 2008. Interest expense was approximately \$7,000 and \$13,000 for the three months ended September 30, 2009 and 2008, respectively. The remaining balance of financing and interest expense represents the amortization of deferred financing costs.

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the three months ended September 30, 2009, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities was approximately \$500,000 for the three months ended September 30, 2009 compared to approximately \$1.0 million for the three months ended September 30, 2008. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash flows from investing activities

Cash provided by investing activities was approximately \$711,000 for the three months ended September 30, 2009 and cash used by investing activities was approximately \$25,000 for the three months ended September 30, 2008. The increase in cash provided by investing activities was a function of short-term investments of \$720,000 maturing in the three months ended September 30, 2009. Cash expenditures for fixed assets were approximately \$8,000 and \$17,000 during the three months ended September 30, 2009 and 2008, respectively.

Cash flows from financing activities

Cash used in financing activities was approximately \$17,000 and \$30,000 for the quarters ended September 30, 2009 and 2008, respectively, and was used mainly for payments of debt and capital leases.

Projected Fiscal Year 2010 Liquidity and Capital Resources

At September 30, 2009, cash and cash equivalents amounted to \$3,169,376 and short-term investments amounted to \$959,811 compared to \$2,990,744 of cash and cash equivalents and \$1,679,820 of short-term investments at June 30, 2009.

The Company had approximately \$2.8 million of cash and cash equivalents and \$960,000 of short-term investments as of November 10, 2009. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$200,000 which represents a significant decrease of approximately \$150,000 from average monthly expenses in fiscal year 2009. Management believes that less than \$100,000 will be spent on capital expenditures for the entire fiscal year 2010, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company's loan with BFEDD matures in fiscal year 2010 and will be paid in full on or about November 13, 2009. The balance of the loan at September 30, 2009 was \$109,629 and is included in current liabilities.

If the Company is able to complete its major research and development project to develop a proprietary separation process to manufacture enriched barium, this process should improve isotope production efficiency during fiscal year 2010. The Company will owe an additional \$56,610 to the contractor upon completion of a successful demonstration of the enrichment process. Once a successful demonstration of the enrichment process has occurred, the Company will have to decide if the smaller test model will produce sufficient quantities of enriched barium or if an additional investment of \$100,000 to \$150,000 will be required to build a larger production model.

During fiscal year 2010, the Company intends to continue its existing protocol studies and begin new protocol studies on lung cancer treatment using Cs-131. Currently, the Company has budgeted approximately \$220,000 in fiscal year 2010 for protocol expenses relating to lung cancer as well as continued work on the dual therapy and mono therapy prostate protocols.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at September 30, 2009 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve months. Management's plans to attain breakeven and generate additional cash flows now include increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), expanding into other market applications which initially will include head and neck implants and lung implants in addition to 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 its revenue targets. Sales in the prostate market have not shown the increases necessary to breakeven during the past two fiscal years and did not improve this quarter. As management is now focused on expanding into head and neck applications and lung applications, management believes the Company will need to raise additional capital for protocols and marketing as it attempts to gain market share. Initially, management plans to seek to sell common stock pursuant to a direct registered offering at a discount to the market price of not more than 15% and has an effective Form S-3 shelf offering registration statement available for this purpose.

If the direct offering of common stock is unsuccessful, the Company expects to finance its future cash needs through solicitation of warrant holders to exercise their warrants, possibly strategic collaborations or debt financing or through other sources that may be dilutive to existing shareholders. Management anticipates that if it raises financing that it will be at a discount to the market price of common stock of not more than 15% and dilutive to shareholders. Of course, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds, it may not be able to market its products as planned or continue development and regulatory approval of its future products.

Long-Term Debt

IsoRay has two loan facilities in place as of September 30, 2009. The first loan is from the Benton-Franklin Economic Development District (BFEDD) in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment that will be paid on or about November 13, 2009. As of September 30, 2009, the principal balance owed was \$109,629. This loan is secured by certain equipment, materials and inventory of the Company, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was originated in June 2006. The loan originally had a total facility of \$1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of \$418,670. The loan bears interest at nine percent and the principal balance owed as of September 30, 2009 was \$210,596. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

Other Commitments and Contingencies

In November 2008, a subsidiary of the Company entered into a written contract with a contractor based in the Ukraine to formalize a research and development project originally begun over two years ago to develop a proprietary separation process to manufacture enriched barium. There is no assurance that this process can be developed. The contract calls for a payment of \$56,610 upon completion of a successful demonstration scheduled for the Fall of 2009 but there is no assurance this testing will occur by then or whether it will be successful. After a successful demonstration, the Company will decide if the prototype model will produce sufficient quantities of enriched barium or if a larger production model will need to be built for an additional \$100,000 to \$150,000.

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company's obligations at its current production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all leasehold improvements.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company has no off-balance sheet arrangements.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, the Company is not required to provide Part I, Item 3 disclosure in this Quarterly Report.

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, 2009. 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 in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. 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.

PART II - OTHER INFORMATION

ITEM 1A – RISK FACTORS

There have been no material changes for the risk factors disclosed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended June 30, 2009.

ITEM 5. OTHER INFORMATION

In lieu of filing a Current Report on Form 8-K under Item 5.02 – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers, the Company is providing the required disclosure under this Item 5.

On November 12, 2009, the Company's Compensation Committee approved a change in the compensation for Dwight Babcock, the Company's Chief Executive Officer. Effective December 1, 2009, Mr. Babcock's salary will increase to \$275,000 annually, and Mr. Babcock will be eligible to receive a \$25,000 bonus should the Company meet goals for fiscal year 2010 that will be established by the Compensation Committee.

ITEM 6. EXHIBITS

Exhibits:

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|------|---|
| 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 |

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 13, 2009

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer
(Principal Executive Officer)

By /s/ Brien Ragle
Brien Ragle, Controller
(Principal Financial and Accounting Officer)