

IsoRay, Inc.
Form 10-Q
February 16, 2010

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

FORM 10-Q

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

For the quarterly period ended December 31, 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	41-1458152	(I.R.S. Employer Identification No.)
(State or other jurisdiction of incorporation or organization)		
350 Hills St., Suite 106, Richland, Washington	99354	(Zip Code)
(Address of principal executive offices)		

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

Edgar Filing: IsoRay, Inc. - Form 10-Q

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

Class	Outstanding as of February 8, 2009
Common stock, \$0.001 par value	22,942,088

ISORAY, INC.

Table of Contents

PART I	FINANCIAL INFORMATION	
Item 1	Consolidated Unaudited Financial Statements	1
	Consolidated Balance Sheets	1
	Consolidated Statements of Operations (Unaudited)	2
	Consolidated Statements of Cash Flows (Unaudited)	3
	Notes to Unaudited Consolidated Financial Statements	4
Item 2	Management’s Discussion and Analysis of Financial Condition and Results of Operations	9
Item 3	Quantitative and Qualitative Disclosures About Market Risk	16
Item 4	Controls and Procedures	16
PART II	OTHER INFORMATION	
Item 1A	Risk Factors	17
Item 4	Submission of Matters to a Vote of Security Holders	17
Item 6	Exhibits	18
	Signatures	19

PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

	(Unaudited) December 31, 2009	June 30, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,105,584	\$ 2,990,744
Short-term investments	-	1,679,820
Accounts receivable, net of allowance for doubtful accounts of \$130,748 and \$86,931, respectively	921,435	746,568
Inventory	753,885	789,246
Prepaid expenses and other current assets	154,034	151,077
Total current assets	4,934,938	6,357,455
Fixed assets, net of accumulated depreciation and amortization	4,424,912	4,891,484
Deferred financing costs, net of accumulated amortization	14,383	28,186
Restricted cash	179,664	178,615
Other assets, net of accumulated amortization	271,544	285,826
Total assets	\$ 9,825,441	\$ 11,741,566
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 705,636	\$ 698,882
Accrued payroll and related taxes	187,554	188,703
Notes payable, due within one year	47,283	161,437
Total current liabilities	940,473	1,049,022
Notes payable, due after one year	155,846	176,023
Asset retirement obligation	578,849	553,471
Total liabilities	1,675,168	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
Treasury stock, at cost, 13,200 shares	(8,390)	(8,390)

Edgar Filing: IsoRay, Inc. - Form 10-Q

Additional paid-in capital	47,862,001	47,818,203
Accumulated deficit	(39,726,339)	(37,869,764)
Total shareholders' equity	8,150,273	9,963,050
Total liabilities and shareholders' equity	\$ 9,825,441	\$ 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 December		Six months ended December	
	2009	31, 2008	2009	31, 2008
Product sales	\$ 1,368,347	\$ 1,326,703	\$ 2,747,434	\$ 2,846,285
Cost of product sales	1,100,193	1,724,225	2,260,282	3,172,661
Gross income / (loss)	268,154	(397,522)	487,152	(326,376)
Operating expenses:				
Research and development expenses	59,078	306,056	127,960	524,606
Sales and marketing expenses	603,980	620,700	1,046,879	1,351,474
General and administrative expenses	550,009	758,822	1,152,440	1,538,979
Total operating expenses	1,213,067	1,685,578	2,327,279	3,415,059
Operating loss	(944,913)	(2,083,100)	(1,840,127)	(3,741,435)
Non-operating income (expense):				
Interest income	2,944	37,562	8,811	82,348
Gain on fair value of short-term investments	-	433,200	-	274,000
Financing and interest expense	(7,898)	(20,769)	(25,259)	(41,616)
Non-operating income (expense), net	(4,954)	449,993	(16,448)	314,732
Net loss	(949,867)	(1,633,107)	(1,856,575)	(3,426,703)
Preferred stock dividends	(36,679)	-	(36,679)	-
Net loss applicable to common shareholders	\$ (986,546)	\$ (1,633,107)	\$ (1,893,254)	\$ (3,426,703)
Basic and diluted loss per share	\$ (0.04)	\$ (0.07)	\$ (0.08)	\$ (0.15)
Weighted average shares used in computing net loss per share:				
Basic and diluted	22,942,088	22,942,088	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)

	Six months ended December 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (1,856,575)	\$ (3,426,703)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	484,572	604,651
Impairment of IBt license (see Note 4)	-	425,434
Amortization of deferred financing costs and other assets	29,100	44,144
Gain on fair value of short-term investments	-	(274,000)
Realized (gains) / losses on short-term investments	-	-
Accretion of asset retirement obligation	25,378	23,201
Share-based compensation	80,477	199,782
Changes in operating assets and liabilities:		
Accounts receivable, net	(174,867)	186,387
Inventory	35,361	11,694
Prepaid expenses and other current assets	(3,972)	51,443
Accounts payable and accrued expenses	6,754	(15,529)
Accrued payroll and related taxes	(1,149)	(75,601)
Net cash used by operating activities	(1,374,921)	(2,245,097)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(18,000)	(32,396)
Additions to licenses and other assets	-	(7,458)
Change in restricted cash	(1,049)	(1,586)
Proceeds from the sale or maturity of short-term investments	1,679,820	-
Net cash provided (used) by investing activities	1,660,771	(41,440)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(134,331)	(30,102)
Principal payments on capital lease obligations	-	(14,783)
Preferred dividends paid	(36,679)	-
Repurchase of Company common stock	-	(4,735)
Net cash used by financing activities	(171,010)	(49,620)
Net increase (decrease) in cash and cash equivalents	114,840	(2,336,157)
Cash and cash equivalents, beginning of period	2,990,744	4,820,033
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 3,105,584	\$ 2,483,876

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

IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements
For the periods ended December 31, 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 December 31, 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 December 31, 2009 and 2008 were as follows:

	December 31,	
	2009	2008
Preferred stock	59,065	59,065
Common stock warrants	3,216,644	3,245,082
Common stock options	2,412,236	2,458,708
Total potential dilutive securities	5,687,945	5,762,855

4. Impairment of IBt License

In December 2008, the Company reevaluated its license agreement with International Brachytherapy SA (IBt) in connection with an overall review of its present cost structure and projected market and manufacturing strategies. Management determined through this review that it does not currently intend to utilize the IBt license as part of its market strategy due to the cost of revamping its manufacturing process to incorporate the technology and as there can be no assurance that physicians would accept this new technology without extensive education and marketing costs. However, the Company does not intend to cancel the license agreement at this time; therefore, the license was reviewed in terms of an "abandoned asset" for purposes of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, it was determined that the entire value should be written off. Therefore, the Company recorded an impairment charge of \$425,434 that is included in cost of product sales for the three and six months ended December 31, 2008.

5. 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 December 31, 2009 and June 30, 2009. The Company's short-term investments are accounted for and reported at fair value using level 1 inputs.

6. Inventory

Inventory consisted of the following at December 31, 2009 and June 30, 2009:

	December 31, 2009	June 30, 2009
Raw materials	\$ 594,378	\$ 609,932
Work in process	147,112	155,827
Finished goods	12,395	23,487
	\$ 753,885	\$ 789,246

7. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and six months ended December 31, 2009 and 2008:

	Three months ended December 31,		Six months ended December 31,	
	2009	2008	2009	2008
Cost of product sales	\$ 5,375	\$ 4,780	\$ 11,272	\$ 13,910
Research and development expenses	174	9,568	336	19,489
Sales and marketing expenses	27,460	46,291	51,085	104,983
General and administrative expenses	(10,459)	30,429	17,784	61,400
Total share-based compensation	\$ 22,550	\$ 91,068	\$ 80,477	\$ 199,782

As of December 31, 2009, total unrecognized compensation expense related to stock-based options was \$126,100 and the related weighted-average period over which it is expected to be recognized is approximately 0.97 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 December 31, 2009 were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2009	2,412,236	\$ 2.02	7.4	\$ 716,604
Vested and expected to vest at December 31, 2009	2,335,146	\$ 2.08	7.3	\$ 652,538
Vested and exercisable at December 31, 2009	1,975,157	\$ 2.39	7.0	\$ 383,925

There were no options exercised during the six months ended December 31, 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 December 31,		Six months ended December 31,	
	2009(a)	2008(b)	2009(c)	2008(b)
Weighted average fair value of options granted	\$ -	\$ 0.25	\$ 0.51	\$ 0.37
Key assumptions used in determining fair value:				
Weighted average risk-free interest rate	-%	1.99%	2.50%	2.63%
Weighted average life of the option (in years)	-	6.00	4.00	5.68
Weighted average historical stock price volatility	-%	252.93%	132.21%	191.04%
Expected dividend yield	-%	0.00%	0.00%	0.00%

- (a) During the three months ended December 31, 2009, the Company did not grant any stock options.
- (b) During the three months ended December 31, 2008, the Company granted 50,000 stock options.
- (c) During the six months ended December 31, 2009, the Company granted 10,000 stock options
- (d) During the six months ended December 31, 2008, the Company granted 95,000 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.

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.

9. 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, deferred financing costs, licenses and other assets which 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. Per ASC 410, the only change in the valuation of the asset retirement obligation was the accretion expense in the six months ended December 31, 2009.

10. Preferred Dividends

On December 11, 2009, 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, 2009. Dividends on the Series B Preferred Stock were last paid on February 15, 2007 for dividends outstanding and cumulative through December 31, 2006. The dividends outstanding and cumulative through December 31, 2009 of \$36,679 were paid as of that date.

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 17 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 December 31, 2009, there have been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended December 31, 2009 compared to three months ended December 31, 2008

Revenues. The Company generated revenue of \$1,368,347 during the three months ended December 31, 2009 compared to revenue of \$1,326,703 during the three months ended December 31, 2008. The increase of \$41,644 or 3% was mainly due to an overall increase in the quantity of Proxcelan Cs-131 brachytherapy seeds sold and the addition of new configurations to the product line. The total number of cases for the three months ended December 31, 2009 as compared to the three months ended December 31, 2008 remains relatively unchanged. The nominal revenue increase is primarily related to orders for the new treatment modalities such as head and neck, lung and colorectal cancers.

During the three months ended December 31, 2009, the Company sold its Proxcelan seeds to 44 different medical centers as compared to 49 different medical centers during the three months ended December 31, 2008. The Company attributes the decrease of 5 medical centers ordering seeds in the three months ended December 31, 2009 when compared to the three months ended December 31, 2008 to the overall decrease of the prostate brachytherapy market. Management believes that the overall market for prostate brachytherapy has received increased pressure from other treatment options with higher reimbursement rates such as IMRT.

Cost of product sales. Cost of product sales was \$1,100,193 for the three months ended December 31, 2009 compared to cost of product sales of \$1,724,225 during the three months ended December 31, 2008. While the Company continues to streamline manufacturing processes, the reduction of cost of product sales of \$624,032 or 36% for the three months ended December 31, 2009 as compared to the three months ended December 31, 2008 is primarily due to a one-time charge for the impairment of the IBt license (note 4) in the amount of \$425,434. The one-time impairment charge represents approximately 68% of the overall period to period cost reduction of \$624,032.

The remaining approximately 32% of the overall period to period cost reduction of \$624,032 or \$198,598 was composed of decreased wages, benefits and related taxes cost of \$60,000, decreased preload expenses of \$78,000, decreased depreciation expense of \$55,000, decreased consulting expense of \$25,000, and decreased occupancy costs of \$34,000, which was partially offset by increased material cost of \$54,000. The Company has achieved a \$199,000 reduction in production costs as a result of a focused effort in analyzing and improving the efficiencies in all areas of production. These efforts have resulted in improving production processes, better utilization of labor, performing functions internally in lieu of using consultants and increased use of internal seed loading capabilities instead of external seed loading services, all of which were offset by contractual obligations to purchase some materials in quantities that exceed the need for those materials at current sales volumes.

Gross margin. Gross margin was \$268,154 for the three month period ended December 31, 2009 compared to a gross loss of (\$397,522) for the three month period ended December 31, 2008. The improvement of \$665,676 was due to the one-time impairment charge in the three month period ended December 31, 2008, as well as continued reductions in production costs and more efficient use of manufacturing resources.

Research and development. Research and development expenses for the three month period ended December 31, 2009 were \$59,078 which represents a decrease of \$246,978 or approximately 81% over the research and development expenses of \$306,056 for the three month period ended December 31, 2008. The cost savings of approximately \$247,000 were primarily a function of a reduction of \$133,000 in protocol expense as the major cost for the monotherapy protocol has been completed and consulting costs were reduced by \$29,000 as several production projects were completed related to both production automation and to bring delivery methods to treat head and neck, lung, and colorectal cancers to market. There were additional temporary savings of \$44,000 achieved in payroll, benefits, related taxes and share-based compensation during a transition period between R&D personnel.

Sales and marketing expenses. Sales and marketing expenses were \$603,980 for the three months ended December 31, 2009. This represents a decrease of \$16,720 or 3% compared to expenditures in the three months ended December 31, 2008 of \$620,700. The decrease of approximately \$17,000 is primarily the net result of a temporary decrease in wages, benefits, related taxes and share-based compensation of \$77,000 that is related to attrition as a result of the incentive compensation plan and a temporary increase in conventions and tradeshow activity of \$58,000 due to the scheduling of the same major conference in the three month period ended December 31, 2009 versus the three month period ended September 30, 2008.

General and administrative expenses. General and administrative expenses for the three months ended December 31, 2009 were \$550,009 compared to general and administrative expenses of \$758,822 for the three months ended December 31, 2008. The decrease of \$208,813 or 28% is primarily due to decreases in wages, benefits and related taxes, consulting expense, legal expense and share-based compensation. Wages, benefits and related taxes decreased approximately \$77,000 mainly due to the reduction in headcount and were partially offset when our Chief Executive Officer, previously a consultant, was hired as an employee. Consulting expenses decreased approximately \$24,000 mainly due to the interim CEO becoming an employee. Legal fees decreased by \$66,000 primarily due to costs associated with settling a lawsuit with a former employee in the three months ended December 31, 2008. Share-based compensation was reduced by approximately \$41,000 and this was primarily a function of the reduced headcount and the related options that were forfeited.

Operating loss. In the three months ended December 31, 2009, the Company had an operating loss of \$944,913 which is a reduction of \$1,138,187 or 55% less than the operating loss of \$2,083,100 for the three months ended December 31, 2008. The Company's operating loss reduction of \$1.14 million was primarily achieved through a decrease in cost of product sales of \$199,000, research and development savings of \$246,000, a general and administrative decrease of \$209,000 and a non-recurring one-time impairment charge of \$425,000.

Interest income. Interest income was \$2,944 for the three months ended December 31, 2009. This represents a decrease of \$34,618 or 92% compared to interest income of \$37,562 for the three months ended December 31, 2008. The decrease is due to the Company's lower short-term investment balances and lower interest rates during the three months ended December 31, 2009 as compared to the three months ended December 31, 2008. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

Gain on fair value of short-term investments. There was no gain on short-term investments for the three months ended December 31, 2009 as compared to a gain of \$433,820 for the three months ended December 31, 2008. The gain of \$433,200 for the three months ended December 31, 2008 was due to the receipt of auction rate security rights (Rights) issued by the Company's broker in October 2008. The gain was calculated as the fair value amount of the Rights estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's auction rate securities (ARS).

Financing and interest expense. Financing and interest expense for the three months ended December 31, 2009 was \$7,898 or a decrease of \$12,871 or 62% from financing and interest expense of \$20,769 for the three months ended December 31, 2008. Interest expense was approximately \$4,000 and \$12,000 for the three months ended December 31, 2009 and 2008, respectively. The remaining balance of financing and interest expense represents the amortization of deferred financing costs.

Six months ended December 31, 2009 compared to six months ended December 31, 2008

Revenues. The Company generated revenue of \$2,747,434 during the six months ended December 31, 2009 compared to revenue of \$2,846,285 during the six months ended December 31, 2008. The decrease of \$98,851 or 3.5% was due to a decrease in the quantity of Proxcelan Cs-131 brachytherapy seeds sold. The total number of cases for the six months ended December 31, 2009 as compared to the six months ended December 31, 2008 declined 3.7% while total revenue decreased 3.5%. The total revenue decrease was partially mitigated by the revenue provided from the growth in orders for the new treatment modalities such as head and neck, lung and colorectal cancers.

During the six months ended December 31, 2009, the Company sold its Proxcelan seeds to 55 different medical centers as compared to 60 different medical centers during the six months ended December 31, 2008. The Company attributes the overall decrease of 5 medical centers ordering seeds in the six months ended December 31, 2009 when compared to the six months ended December 31, 2008 to the overall decrease of the prostate brachytherapy market. Management believes that the overall market for prostate brachytherapy has received increased pressure from other treatment options with higher reimbursement rates such as IMRT.

Cost of product sales. Cost of product sales was \$2,260,282 for the six months ended December 31, 2009 compared to cost of product sales of \$3,172,661 during the six months ended December 31, 2008. While the Company continues to streamline manufacturing processes, the reduction of cost of product sales of \$912,379 or 29% for the six months ended December 31, 2009 as compared to the six months ended December 31, 2008, was substantially impacted by a one-time impairment charge in the amount of \$425,434. The one-time impairment charge was approximately 47% of the overall period to period cost reduction of \$912,379.

The remaining approximately 53% of the overall period to period cost reduction of \$912,379 or \$486,945 was composed of decreased wages, benefits and related taxes cost of \$139,000, decreased preload expenses of \$169,000, decreased depreciation expense of \$111,000, decreased consulting expense of \$20,000, decreased occupancy costs of \$47,000. The Company achieved a \$487,000 reduction in production costs as a result of a focused effort in analyzing and improving the efficiencies in all areas of production. These efforts have resulted in improving production processes, better utilization of labor, performing functions internally in lieu of using consultants and increased use of internal seed loading capabilities instead of external seed loading services.

Gross margin. Gross margin was \$487,152 for the six month period ended December 31, 2009 compared to a gross loss of \$326,376 for the six month period ended December 31, 2008. The improvement of \$813,528 was due to the one-time impairment charge in the six month period ended December 31, 2008, as well as continued reductions in production costs and more efficient use of manufacturing resources.

Research and development. Research and development expenses for the six month period ended December 31, 2009 were \$127,960 which represents a decrease of \$396,646 or approximately 76% over the research and development expenses of \$524,606 for the six month period ended December 31, 2008.

The cost savings of approximately \$397,000 were primarily a function of a reduction of \$194,000 in protocol expense as the major cost for the monotherapy protocol has been completed and consulting costs were reduced by \$39,000 as several production projects were completed related to both production automation and to bring delivery methods to treat head and neck, lung, and colorectal cancers to market. There were additional temporary savings of \$89,000 achieved in payroll, benefits, related taxes and share-based compensation during a transition period between R&D personnel.

Sales and marketing expenses. Sales and marketing expenses were \$1,046,879 for the six months ended December 31, 2009. This represents a decrease of approximately \$305,000 or 23% compared to expenditures in the six months ended December 31, 2008 of \$1,351,474 for sales and marketing. The savings of \$305,000 is primarily the net result of a temporary decrease in wages, benefits, related taxes and share-based compensation of \$164,000 that is related to attrition as a result of the incentive compensation plan and forfeiture of related stock, and a decrease of \$77,000 in travel that is the result of both the temporary attrition and improved trip planning. Marketing and advertising expense was reduced by \$33,000 by reducing the number of trade journals that were used for advertising.

General and administrative expenses. General and administrative expenses for the six months ended December 31, 2009 were \$1,152,440 compared to general and administrative expenses of \$1,538,979 for the six months ended December 31, 2008. The decrease of \$386,539 or 25% is primarily due to decreases in wages, benefits and related taxes, consulting expense, legal expense, public company expense and share-based compensation. Wages, benefits and related taxes decreased approximately \$101,000 mainly due to the reduction in headcount and were partially offset when our Chief Executive Officer, previously a consultant, was hired as an employee. Consulting expenses decreased approximately \$57,000 primarily due to the interim CEO becoming an employee. Legal fees decreased by \$144,000 primarily due to the legal fees incurred in the six months ended December 31, 2008 related to settling a lawsuit with a former employee. Public company expense was reduced by \$47,000, due to a decrease in board compensation as a result of the interim CEO becoming an employee in addition to reduced investor relations cost. Share-based compensation was reduced by approximately \$44,000, and this was primarily a function of the reduced headcount and the related options that were forfeited.

Operating loss. In the six months ended December 31, 2009, the Company had an operating loss of \$1,840,127 which is a decrease of \$1,901,308 or 51% less than the operating loss of \$3,741,435 for the six months ended December 31, 2008. . The Company operating loss reduction of \$1.9 million was primarily achieved through a savings in cost of product sales of \$487,000, research and development savings of \$397,000, sales and marketing savings of \$305,000 and a general and administrative decrease of \$387,000 in addition to a non-recurring one-time impairment charge of \$425,000.

Interest income. Interest income was \$8,811 for the six months ended December 31, 2009. This represents a decrease of \$73,537 or 89% compared to interest income of \$82,348 for the six months ended December 31, 2008. The decrease is due to the Company's lower short-term investment balances and lower interest rates during the six months ended December 31, 2009 as compared to the six months ended December 31, 2008. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

Gain on fair value of short-term investments. There was no gain on short-term investments for the six months ended December 31, 2009 as compared to a gain of \$274,000 for the six months ended December 31, 2008. The gain of \$274,000 for the six months ended December 31, 2008 was due to the receipt of Rights issued by the Company's broker in October 2008. The gain was calculated as the fair value amount of the Rights estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's ARS.

Financing and interest expense. Financing and interest expense for the six months ended December 31, 2009 was \$25,259 or a decrease of \$16,357 or 39% from financing and interest expense of \$41,616 for the six months ended December 31, 2008. Interest expense was approximately \$11,000 and \$25,000 for the six months ended December 31, 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 six months ended December 31, 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 \$1.38 million for the six months ended December 31, 2009 compared to approximately \$2.25 million for the six months ended December 31, 2008. Cash used by operating activities is the net loss adjusted for non-cash items and changes in operating assets and liabilities. A significant reduction in cash consumed in operating activities of \$870,000 was achieved through a combination of cost reductions and operational efficiencies identified in the results of operations that resulted in a reduction in net loss of \$1,570,000 which was reduced by the non-cash items and changes in operating assets and liabilities of \$700,000 for the six months ended December 31, 2009 when compared to the six months ended December 31, 2008. The reduction in cash consumed by operating activities of \$870,000 was negatively impacted by revenue being generated later in the quarter for the six months ended December 31, 2009 when compared to the six months ended December 31, 2008. Since during the quarter ended December 31, 2008, a larger percentage of the quarter's sales occurred during October and thus were generally paid by customers before the end of the quarter, the Company had more cash from revenues available during the quarter to meet operating expenses. However, in the quarter ended December 31, 2009, a larger percentage of sales occurred during December, which resulted in less cash being received from these sales before the end of the quarter and correspondingly higher accounts receivable at the end of the quarter ended December 31, 2009. The reduced amount of incoming cash payments during the three months ended December 31, 2009 resulted in additional cash being consumed by operations and thus increased the negative impact of the change in the operating assets.

Cash flows from investing activities

Cash provided by investing activities was approximately \$1.66 million for the six months ended December 31, 2009 and cash used by investing activities was approximately \$41,000 for the six months ended December 31, 2008. The increase in cash provided by investing activities was a function of short-term investments of \$1.68 million maturing in the six months ended December 31, 2009. Cash expenditures for fixed assets were approximately \$18,000 and \$32,000 during the six months ended December 31, 2009 and 2008, respectively.

Cash flows from financing activities

Cash used in financing activities was approximately \$171,000 and \$50,000 for the quarters ended December 31, 2009 and 2008, respectively. \$134,000 and \$45,000 was used mainly for payments of debt and capital leases in the six months ended December 31, 2009 and 2008 respectively. Approximately, \$108,000 of the \$134,000 in cash that was used for payments of debt and capital leases in the six months ended December 31, 2009 was to retire the loan facility with Benton-Franklin Council of Governments (BFEDD). The remaining \$37,000 in cash consumed in financing activities was related to the payment of preferred dividends.

Projected Fiscal Year 2010 Liquidity and Capital Resources

At December 31, 2009, the Company held cash and cash equivalents amounted to \$3,142,263 and no short-term investments as 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 \$2.9 million of cash and cash equivalents and no short-term investments as of February 8, 2010. The Company's monthly required cash operating expenditures were approximately \$230,000 in the six months ended December 31, 2009, which represents a 39% decrease of approximately \$145,000 from average monthly cash operating expenditures in fiscal year 2009, which is primarily a result of improved operating performance from fiscal year 2009 to fiscal year 2010. Management believes that less than \$100,000 will be spent on capital expenditures for the fiscal year 2010, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company's loan facility with BFEDD matured during the six months ended December 31, 2009 and the full amount due of approximately \$108,000 was paid on November 13, 2009 to settle the loan facility. The Company has only one remaining loan facility outstanding with HAEIFC, with a principal balance of approximately \$203,000 of which approximately \$47,000 will be due in the next 12 months.

While management has seen some indication that the proprietary separation process to manufacture enriched barium may have viability on smaller scale projects to date there has been no indication that it will work on a larger production model. Therefore, the Company does not believe that any more payments will be made to its contractor located in the Ukraine.

The Company has significantly decreased its protocol studies in the prostate market as management believes the studies conducted to date are adequate. Management is in the process of determining whether the approximately \$225,000 originally budgeted for protocol expenses relating to lung cancer and the ongoing protocols still needed for dual therapy and monotherapy prostate protocols is adequate.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at December 31, 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 by 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, colorectal 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 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 during the six months ended December 31, 2009. As management is now focused on expanding into head and neck, colorectal and lung applications, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it attempts to gain market share. Initially, management plans to seek to sell common stock pursuant to either an "at the market" underwritten offering or through 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 underwriting at market or direct offering of common stock below market is unsuccessful, the Company expects to finance its future cash needs through solicitation of warrant holders to exercise their warrants, possible strategic collaborations, 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

Edgar Filing: IsoRay, Inc. - Form 10-Q

IsoRay has a single loan facility in place as of December 31, 2009 from the Hanford Area Economic Investment Fund Committee (HAEIFC), which 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 December 31, 2009 was \$203,129. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

Other Commitments and Contingencies

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 previously disclosed a contingency related to its research and development project underway in the Ukraine to develop a proprietary separation process to manufacture enriched barium. As the prototype has not been successfully demonstrated and is not expected to be, the Company does not intend to make the final payment to the contractor, as the final payment was only due following a successful demonstration of the prototype.

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 December 31, 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On December 11, 2009, the Company held its Annual Meeting of Shareholders at which our shareholders elected four Directors and ratified the appointment of our independent registered public accounting firm for the fiscal year ending June 30, 2010. The two other proposals were not approved.

(a) Election of Directors. All nominees for election as Directors were unopposed and elected as follows:

Director	For	Withhold
Dwight Babcock	16,715,177	392,436
Robert R. Kauffman	16,540,193	567,420
Thomas C. LaVoy	16,980,904	126,709
Albert Smith	16,235,893	872,720

(b) Appointment of our independent registered public accounting firm. Proposal to ratify the appointment of DeCoria, Maichel & Teague, P.S. as independent registered public accounting firm of the Company for the fiscal year ending June 30, 2010 was approved as follows:

For	Against	Abstain
16,620,440	301,467	185,705

(c) Approval of the Additional Share Issuance at a Discount. Proposal to approve, for purposes of the NYSE Amex Company Guide Sec. 713, the issuance to investors of not to exceed 10 million to be registered shares of our common stock, \$0.001 par value (the "Common Stock") which may include shares received upon exercise of warrants, to be sold at a discount that will not exceed fifteen percent (15%) of the greater of the book value or market value at the time of issuance, was not approved as follows:

For	Against	Abstain
2,872,591	452,599	98,098

(d) Approval of the Additional Share Issuance at a Discount. Proposal to approve, for purposes of the NYSE Amex Company Guide Sec. 713, the issuance of rights to purchase not to exceed 10 million shares of Common Stock and the underlying Common Stock issuable upon exercise of shareholder rights which may be granted to shareholders by the Board of Directors in the future pursuant to a to be registered offering, at an exercise price per share that will include a discount of not to exceed fifteen percent (15%) of the greater of book value or market value at the time of issuance, was not approved as follows:

For	Against	Abstain
2,902,572	422,618	98,098

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

SIGNATURES

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

Dated: February 15, 2010

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)