IsoRay, Inc.
Form 10-Q
November 15, 2010

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

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2010

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from __________ to ____________

Commission File No. 001-33407

ISORAY, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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 x No ¨

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o
Smaller reporting company x

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

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

Class	Outstanding as of November 10, 2010
Common stock, $0.001 par value	23,566,825

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

		(Unaudited) September 30, 2010		June 30, 2010
ASSETS				
Current assets:				
Cash and cash equivalents	$	1,024,569	$	1,678,869
Accounts receivable, net of allowance for doubtful accounts of $32,068 and $36,390, respectively		833,343		896,266
Inventory		678,588		681,677
Prepaid expenses and other current assets		305,495		259,975
Total current assets		2,841,995		3,516,787
Fixed assets, net of accumulated depreciation and amortization		3,737,347		3,959,983
Deferred financing costs, net of accumulated amortization		12,724		13,277
Restricted cash		180,368		180,154
Other assets, net of accumulated amortization		269,997		272,594
Total assets	$	7,042,431	$	7,942,795
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable and accrued liabilities	$	426,961	$	404,401
Accrued protocol expense		212,331		242,029
Accrued radioactive waste disposal		72,060		60,060
Accrued payroll and related taxes		125,016		186,513
Accrued vacation		70,281		68,525
Notes payable, due within one year		50,575		49,445
Total current liabilities		957,224		1,010,973
Notes payable, due after one year		117,501		130,550
Asset retirement obligation		619,115		605,391
Total liabilities		1,693,840		1,746,914
Commitments and contingencies (Note 6)				
Shareholders' equity:				
Preferred stock, $.001 par value; 6,000,000 shares authorized:				
Series A: 1,000,000 shares allocated; no shares issued and outstanding		-		-
		59		59

Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding				
Common stock, $.001 par value; 194,000,000 shares authorized; 23,048,754 shares issued and outstanding		23,049		23,049
Treasury stock, at cost, 13,200 shares		(8,390)		(8,390)
Additional paid-in capital		48,109,375		48,084,783
Accumulated deficit		(42,775,502)		(41,903,620)
Total shareholders' equity		5,348,591		6,195,881
Total liabilities and shareholders' equity	$	7,042,431	$	7,942,795

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

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

	Three months ended September 30,	
	2010	2009
Product sales	$ 1,327,127	$ 1,379,087
Cost of product sales	1,111,527	1,160,089
Gross margin	215,600	218,998
Operating expenses:		
Research and development expenses	114,522	68,882
Sales and marketing expenses	373,425	442,899
General and administrative expenses	596,133	602,431
Total operating expenses	1,084,080	1,114,212
Operating loss	(868,480)	(895,214)
Non-operating income (expense):		
Interest income	1,061	5,867
Financing and interest expense	(4,463)	(17,361)
Non-operating income (expense), net	(3,402)	(11,494)
Net loss	(871,882)	(906,708)
Preferred stock dividends	(2,658)	(2,658)
Net loss applicable to common shareholders	$ (874,540)	$ (909,366)
Basic and diluted loss per share	$ (0.04)	$ (0.04)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,048,754	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,	
	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (871,882)	$ (906,708)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	224,528	242,904
Amortization of deferred financing costs and other assets	7,262	18,191
Amortization of discount on short-term investments	-	9
Accretion of asset retirement obligation	13,724	12,547
Share-based compensation	24,592	57,927
Changes in operating assets and liabilities:		
Accounts receivable, net	62,923	(52,868)
Inventory	3,089	68,260
Prepaid expenses, other current assets and other assets	(49,632)	(25,183)
Accounts payable and accrued liabilities	22,560	10,875
Accrued protocol expense	(29,698)	
Accrued radioactive waste disposal	12,000	
Accrued payroll and related taxes	(61,497)	58,449
Accrued vacation	1,756	
Net cash used by operating activities	(640,275)	(515,597)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(1,892)	(8,000)
Change in restricted cash	(214)	(536)
Proceeds from the sale or maturity of short-term investments	-	720,000
Net cash provided (used) by investing activities	(2,106)	711,464
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(11,919)	(17,235)
Net cash used by financing activities	(11,919)	(17,235)
Net increase (decrease) in cash and cash equivalents	(654,300)	178,632
Cash and cash equivalents, beginning of period	1,678,869	2,990,744
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 1,024,569	$ 3,169,376

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

IsoRay, Inc. and Subsidiaries

Notes to the Unaudited Consolidated Financial Statements
For the three month periods ended September 30, 2010 and 2009

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, 2010. 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, 2010.

Certain amounts in the prior-year financial statements have been reclassified to conform to the current year presentation.

2. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standards setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position, results of operations and cash flows upon adoption.

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 anti-dilutive. At September 30, 2010 and 2009, the calculation of diluted weighted average shares does not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be anti-dilutive 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, 2010 and 2009 were as follows:

	September 30,	
	2010	2009
Preferred stock	59,065	59,065
Common stock warrants	3,165,768	3,216,644
Common stock options	2,151,372	2,606,769
Total potentially dilutive securities	5,376,205	5,882,478

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4. Inventory

Inventory consisted of the following at September 30, 2010 and June 30, 2010:

	September 30, 2010	June 30, 2010
Raw materials	$ 514,913	$ 546,080
Work in process	129,903	130,840
Finished goods	6,772	4,757
	$ 678,588	$ 681,677

5. Share-Based Compensation

The following table presents the share-based compensation expense recognized in the statement of operations during the three months ended September 30, 2010 and 2009:

	Three months ended September 30,	
	2010	2009
Cost of product sales	$ 8,470	$ 5,897
Research and development expenses	5,410	162
Sales and marketing expenses	3,847	23,625
General and administrative expenses	6,865	28,243
Total share-based compensation	$ 24,592	$ 57,927

As of September 30, 2010, total unrecognized compensation expense related to share-based options was $223,901 and the related weighted-average period over which it is expected to be recognized is approximately 1.24 years.

The Company currently provides share-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, 2010 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2010	2,151,372	$ 1.87	7.01	$ 754,362
Vested and expected to vest at September 30, 2010	2,064,046	$ 1.93	6.94	$ 687,668
Vested and exercisable at September 30, 2010	1,614,293	$ 2.27	6.54	$ 477,588

There were no options exercised during the three months ended September 30, 2010 and 2009, 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,	
	2010(a)	2009(b)
Weighted average fair value of options granted	$ –	$ 0.51
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	–%	2.50%
Weighted average life of the option (in years)	–	4.00
Weighted average historical stock price volatility	–%	132.21%
Expected dividend yield	–%	–%

(a) During the three months ended September 30, 2010, the Company granted no stock options.

(b) During the three months ended September 30, 2009, the Company granted 10,000 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 with an equivalent term in effect as of the date of grant. The expected option lives, volatility, and forfeiture assumptions are based on historical data of the Company.

6. 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.

7. Preferred Dividends

Cumulative preferred dividends outstanding through December 31, 2009 of $36,679 were paid as of that date. As of September 30, 2010, there are cumulative preferred dividends outstanding of $7,974.

8. Subsequent Events

On October 1, 2010, the Company issued a placement notice with C.K. Cooper & Company, Inc. to begin selling shares under the "at the market" sales agreement between the two parties dated April 22, 2010 and as amended on July 29, 2010. Under the placement notice additional cash of approximately $360,000 has been raised through sales of common stock at market prices through November 10, 2010.

Beginning on October 20, 2010, the Company revised the exercise price of certain outstanding warrants to $0.95 per share. The election to exercise the common stock warrants at the reduced strike price of $.95 per share of common stock was required to be postmarked on or before October 30, 2010, after which time the warrants reverted to their original exercise prices. Exercise of warrants at the reduced exercise price has generated approximately $200,000 in cash as of November 10, 2010.

On October 29, 2010 the Company received notification from the U.S. Department of Health and Human Services and the Internal Revenue Service regarding the receipt of grants for three qualifying therapeutic discovery projects in the total amount of $526,510. The initial grant award amount payable for the year ended June 30, 2010 to the Company in the amount of $109,316 is to be funded on or before November 16, 2010. The remaining grant award of $417,194 is to be paid to the Company after the completion of the fiscal year on June 30, 2011 and prior to July 30, 2011.

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 14 below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2010 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 28, 2010 are those that depend most heavily on these judgments and estimates. As of September 30, 2010, there have been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2010 compared to three months ended September 30, 2009

Product sales. The Company generated revenue of $1,327,127 during the three months ended September 30, 2010 compared to revenue of $1,379,087 during the three months ended September 30, 2009. The decrease of $51,960 or 4% in revenue is the result of an overall reduction in the quantity of seeds sold which was partially offset by a 4% increase in the average price per seed sold. Revenue from new modalities increased to approximately $95,064 in the three months ended September 30, 2010 as compared to approximately $32,500 in the three months ended September 30, 2009, or approximately 193%. Management believes that the overall market for prostate brachytherapy continues to receive increased pressure from other treatment modalities with higher reimbursement rates such as Intensity-Modulated Radiation Therapy (IMRT) and Robotics.

Cost of product sales. Cost of product sales was $1,111,527 for the three months ended September 30, 2010 compared to cost of product sales of $1,160,089 during the three months ended September 30, 2009. The decrease in cost of product sales of $48,562 or 4% directly relates to the reduction in product sales. The major components of the net decrease of cost of product sales in the amount of $48,562 were comprised of personnel costs of approximately $41,000, preload expenses of approximately $16,000, and depreciation and amortization expense of approximately $10,000, that were partially offset by an increase in materials cost of approximately $19,000.

The cost savings achieved in the three months ended September 30, 2010 compared to three months ended September 20, 2009 represent continued management achievement of cost reductions achieved in the prior fiscal year in line with current levels of revenue. The savings achieved in the prior year that have been maintained include improved production processes, improved utilization of labor, continuation of a reduced reliance on consultants along with an increase in utilizing the Company's in-house loading services.

Gross margin. Gross margin was $215,600 for the three month period ended September 30, 2010 as compared to $218,998 for the three months ended September 30, 2009. This represents a decrease in the Company's gross margin of $3,398 or approximately 2%. The decrease in the gross margin is the result of a decrease in product sales which exceeded the increase in cost savings for the three months ended September 30, 2010 when compared to the three months ended September 30, 2009 and resulted in an increase in the gross margin percentage from 15.9% for the three months ended September 30, 2009 to 16.2% for the three months ended September 30, 2010.

Research and development expenses. Research and development expenses for the three month period ended September 30, 2010 were $114,522 which represents an increase of $45,640 or 66% more than the research and development expenses of $68,882 for the three month period ended September 30, 2009. The major components of the net increase in Research and Development costs were comprised of a continued reduction in protocol expense of approximately $13,000 and consulting expense of approximately $12,000 that was offset by an increase in payroll and benefits of approximately $60,000 and travel expense of approximately $12,000.

The net increase in Research and Development expense is the result of an increase in payroll and benefits cost related to the addition of a Vice President of R&D and an increase in labor expenditures related to the development efforts for treatments of brain, breast and lung cancers along with additional travel costs. These increases were partially offset by a continued effort by Company management to reduce consulting costs and minimize protocol expenses.

Sales and marketing expenses. Sales and marketing expenses were $373,425 for the three months ended September 30, 2010. This represents a decrease of $69,474 or 16% compared to expenditures in the three months ended September 30, 2009 of $442,899 for sales and marketing.

The net cost savings of $69,474 was a direct result of a reduction in conventions and tradeshow expense of approximately $19,000, marketing and advertising of approximately $31,000, and approximately $20,000 in share-based compensation. These savings are the result of active management of convention and tradeshow activities, marketing and advertising expenses and a reduction of share-based compensation.

General and administrative expenses. General and administrative expenses for the three months ended September 30, 2010 were $596,133. This represents a decrease of $6,298 or approximately 1% compared to general and administrative expenses of $602,431 for the three months ended September 30, 2009.

The net cost savings of $6,298 were the result of reductions in share-based compensation of approximately $21,000 and legal expenses of approximately $18,000, that were offset partially by increases in Audit, SOX and tax expenses of approximately $13,000, office equipment and supplies of approximately $5,000 and other expenses of approximately $14,000.

Operating loss. The Company continues to focus its resources on improving sales while continuing to retain the necessary administrative and production infrastructure to meet the demands for the Company's products as sales levels change. These objectives and resulting costs have resulted in the Company not being profitable and generating operating losses since its inception. In the three months ended September 30, 2010, the Company had an operating loss of $868,480 which is a decrease of $26,734 or 3% less than the operating loss of $895,214 for the three months ended September 30, 2009.

Interest income. Interest income was $1,061 for the three months ended September 30, 2010. This represents a decrease of $4,806 or 82% compared to interest income of $5,867 for the three months ended September 30, 2009. Interest income is primarily derived from excess funds held in money market accounts. The decrease in interest income of $4,806 is due to lower interest rates and lower balances in the Company's money market account.

Financing and interest expense. Financing and interest expense for the three months ended September 30, 2010 was $4,463 or a decrease of $12,898 or 74% from financing and interest expense of $17,361 for the three months ended September 30, 2009. Included in financing expense is interest expense of approximately $4,000 for the three months ended September 30, 2010 and approximately $7,000 for the three months ended September 30, 2009. The remaining balance of financing 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, 2010, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities increased approximately $124,678 to approximately $640,275 for the three months ended September 30, 2010 compared to approximately $515,597 for the three months ended September 30, 2009. 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 used by investing activities increased approximately $713,570 to approximately $2,106 for the three months September 30, 2010 as compared to cash provided by investing activities of approximately $711,464 for the three months ended September 30, 2009. The primary influence in the change in cash used in financing activities in the three months ended September 30, 2010 to September 30, 2009 is the maturation of short-term investments in the three months ended September 30, 2009 in the amount of $720,000. Cash expenditures for fixed assets were approximately $2,000 and $8,000 during the three months ended September 30, 2010 and 2009, respectively.

Cash flows from financing activities

Cash used in financing activities was approximately $12,000 and $17,000 for the three months ended September 30, 2010 and 2009, respectively, and was used primarily for payment of debt during the three months ended September 30, 2010 and 2009, respectively.

Projected 2011 Liquidity and Capital Resources

At September 30, 2010, cash and cash equivalents amounted to $1,024,569 compared to $1,678,869 of cash and cash equivalents at September 30, 2009.

The Company had approximately $1,323,532 of cash and no short-term investments as of November 10, 2010. The Company’s monthly required cash operating expenditures were approximately $215,000 in the three months ended September 30, 2010, which represents a 5% decrease or approximately $10,000 from average monthly cash operating expenditures in fiscal year 2010 of approximately $225,000. This reduction is primarily the result of continued improvements in operating performance during fiscal year 2011. Management believes that less than $100,000 will be spent on capital expenditures for fiscal year 2011 outside of any research and development, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company has a single remaining loan facility outstanding with the Hanford Area Economic Investment Fund Committee (HAEIFC), with a principal balance of approximately $168,000 of which approximately $51,000 will be due in the next twelve months.

The Company intends to continue its existing protocol studies and to begin new protocol studies on lung cancer treatment using Cesium-131. The Company continues to believe that approximately $100,000 in expense will be incurred during fiscal year 2011 related to protocol expenses relating to lung cancer and 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, 2010 will not be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through the next twelve months but will fund operations through February 28, 2011.

Management 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, colorectal and lung implants while maintaining the Company's focus on cost control. Company management continues to believe that the Company will reach breakeven with revenues of approximately $750,000 per month with cash flow breakeven from operations being reached at approximately $700,000. 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 three fiscal years and did not improve during the three months ended September 30,

2010. As management is now focused on expanding into head and neck, colorectal, lung and brain 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. As the Company does not meet the minimum stockholder's equity listing requirement for NYSE AMEX, management plans to sell equity and/or debt at a possible discount to the market price to seek to raise $2 to $5 million on or before December 31, 2010, but we do not have any agreements in place to do so other than our existing "at the market" sales agreement. Through October 31, 2010, the Company has raised approximately $564,000 through "at the market" offerings and through the solicitation of warrants at a reduced exercise price.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders but as the Company now has insufficient capital to fund operations through the end of the current fiscal year, it may need to offer substantial discounts from the market price of our common stock. Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders. 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 will have to discontinue or significantly curtail operations.

Long-Term Debt and Capital Lease Agreements

IsoRay has a single loan facility in place as of September 30, 2010. This loan facility is from the 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, 2010 was $168,076. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees. This loan facility was modified effective October 1, 2010 by the lender to reflect a reduction in the interest rate from nine percent to five and one-half percent with all other terms remaining unchanged.

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 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, 2010. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

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

The Company is continuing the process of developing and implementing the remediation plan to address the material weakness and significant deficiency identified in its Form 10-K for the fiscal year ended June 30, 2010. This plan is as follows-

- The Company continues to assess opportunities to further segregate duties within a limited staff.
- The staff is utilizing continuing professional education opportunities to enhance their knowledge.
- Management is conducting ongoing reviews of all significant and non-routine transactions.

As a result of the ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge, believes that the consolidated financial statements for the quarter ended September 30, 2010 fairly present in all material respects the financial condition and results of operations for the Company in conformity with U.S. generally accepted accounting principles.

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, 2010, except for the changes to the following risk factor that was included in the Form 10-K:

Failure to Comply with NYSE Amex Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock. Our common stock is presently listed on the NYSE Amex. The NYSE Amex will consider delisting a company's securities if, among other things, the company fails to maintain minimum stockholder's equity or the company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. As of the quarter ended September 30, 2010, IsoRay fell below the minimum stockholder's equity requirement of $6 million needed to maintain its listing. Management is actively pursuing a capital raise to increase its stockholder's equity above $6 million. There can be no assurance that we will be able to raise sufficient capital to maintain our listing on the NYSE Amex. In the event that our common stock is delisted from the NYSE Amex, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock.

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

Use of Proceeds from Registered Securities

On October 27, 2009, we filed a registration statement on Form S-3 to register securities up to $15 million in value for future issuance in our capital raising activities. The registration statement became effective on November 13, 2009, and we filed a prospectus supplement relating to the Sales Agreement described below on April 23, 2010. The Commission file number assigned to the registration statement is 333-162694.

On April 22, 2010, we entered into a Sales Agreement (the "Agreement") with C. K. Cooper & Company, Inc. ("CKCC"). Pursuant to the terms of the Agreement, the Company may offer and sell (the "Offering") from time to time through CKCC, as the Company's sales agent, up to $4 million of shares of the Company's common stock, par value $0.001 per share (the "Shares"). CKCC is not required to sell any specific number or dollar amount of Shares but will use its commercially reasonable efforts, as the Company's agent and subject to the terms of the Agreement, to sell the Shares offered, as instructed by the Company. Sales of the Shares, if any, may be made by means of ordinary brokers' transactions on the NYSE AMEX at market prices and such other sales as agreed to by the Company and CKCC. CKCC will receive from us a commission of 2.0% based on the gross sales price per share for any Shares sold through it as agent under the Agreement. Net proceeds from the sale of the Shares will be used for general corporate purposes. The Company has also agreed to reimburse CKCC for certain expenses incurred in connection with entering into the Agreement and has provided CKCC with customary indemnification rights.

On July 29, 2010, we entered into an amendment (the "Amendment") to the Agreement. The purpose of the Amendment is to extend the term of the offering of Shares by CKCC as the Company's sales agent pursuant to the Agreement. The offering of Shares pursuant to the Agreement, as amended by the Amendment, will terminate upon the earliest of (i) December 31, 2010, (ii) the sale of all Shares subject to the Agreement or (iii) the termination of the Agreement by the Company or CKCC. The other terms of the Agreement remain in effect and have not been changed by the Amendment.

CKCC was instructed by the Company to commence the Offering on October 1, 2010 via a placement notice permitting "at the market" sales of common stock through October 31, 2010. As of October 31, 2010, CKCC had sold 304,227 shares of common stock for gross proceeds of $368,781. As sales occurred subsequent to the end of the most recent completed fiscal quarter, expense and use of proceeds information for these sales will be provided in the Company's Form 10-Q filing for the fiscal quarter ending December 31, 2010.

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.

ISORAY, INC., a Minnesota corporation

Dated: November 15, 2010 By /s/ Dwight Babcock
Dwight Babcock, Chief Executive Officer
(Principal Executive Officer)

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