

IsoRay, Inc.  
Form 10-Q  
May 12, 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 March 31, 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

(State or other jurisdiction of incorporation or  
organization)

41-1458152

(I.R.S. Employer  
Identification No.)

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

99354  
(Zip Code)

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

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

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

Yes ☒ No ☐

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐  
Smaller reporting company ☒

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

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

Class	Outstanding as of May 6, 2010
Common stock, \$0.001 par value	23,048,754

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ISORAY, INC.

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## PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries  
Consolidated Balance Sheets

	(Unaudited) March 31, 2010	June 30, 2009
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 2,425,844	\$ 2,990,744
Short-term investments	-	1,679,820
Accounts receivable, net of allowance for doubtful accounts of \$69,057 and \$86,931, respectively	872,561	746,568
Inventory	695,069	789,246
Prepaid expenses and other current assets	159,961	151,077
Total current assets	4,153,435	6,357,455
Fixed assets, net of accumulated depreciation and amortization	4,194,194	4,891,484
Deferred financing costs, net of accumulated amortization	13,830	28,186
Restricted cash	180,031	178,615
Other assets, net of accumulated amortization	266,788	285,826
Total assets	\$ 8,808,278	\$ 11,741,566
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued liabilities	\$ 700,949	\$ 698,882
Accrued payroll and related taxes	231,759	188,703
Notes payable, due within one year	48,340	161,437
Total current liabilities	981,048	1,049,022
Notes payable, due after one year	143,305	176,023
Asset retirement obligation	591,971	553,471
Total liabilities	1,716,324	1,778,516
<b>Shareholders' equity:</b>		
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; 22,945,421 and 22,942,088 shares issued and outstanding, respectively	22,945	22,942
Treasury stock, at cost, 13,200 shares	(8,390)	(8,390)

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Additional paid-in capital	47,898,972	47,818,203
Accumulated deficit	(40,821,632)	(37,869,764)
Total shareholders' equity	7,091,954	9,963,050
Total liabilities and shareholders' equity	\$ 8,808,278	\$ 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 March 31,		Nine months ended March 31,	
	2010	2009	2010	2009
Product sales	\$ 1,203,216	\$ 1,366,289	\$ 3,950,650	\$ 4,212,574
Cost of product sales	1,150,730	1,351,044	3,411,012	4,523,705
Gross income / (loss)	52,486	15,245	539,638	(311,131)
Operating expenses:				
Research and development expenses	98,964	301,907	226,924	826,513
Sales and marketing expenses	447,693	529,349	1,494,572	1,880,823
General and administrative expenses	596,224	666,637	1,748,664	2,205,616
Total operating expenses	1,142,881	1,497,893	3,470,160	4,912,952
Operating loss	(1,090,395)	(1,482,648)	(2,930,522)	(5,224,083)
Non-operating income (expense):				
Interest income	1,547	18,722	10,358	101,070
Gain on fair value of short-term investments	-	-	-	274,000
Financing and interest expense	(6,445)	(16,278)	(31,704)	(57,894)
Non-operating income (expense), net	(4,898)	2,444	(21,346)	317,176
Net loss	(1,095,293)	(1,480,204)	(2,951,868)	(4,906,907)
Preferred stock dividends	-	-	(36,679)	-
Net loss applicable to common shareholders	\$ (1,095,293)	\$ (1,480,204)	\$ (2,988,547)	\$ (4,906,907)
Basic and diluted loss per share	\$ (0.05)	\$ (0.06)	\$ (0.13)	\$ (0.21)
Weighted average shares used in computing net loss per share:				
Basic and diluted	22,942,458	22,942,088	22,942,458	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)

	Nine months ended March 31,	
	2010	2009
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,951,868)	\$ (4,906,907)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	719,032	905,678
Impairment of IBt license (see Note 4)	-	425,434
Write-off of certain foreign patents and trademarks		84,671
Amortization of deferred financing costs and other assets	36,368	60,448
Gain on fair value of short-term investments		(274,000)
Realized (gains) / losses on short-term investments		-
Accretion of asset retirement obligation	38,500	35,198
Share-based compensation	115,285	255,450
Changes in operating assets and liabilities:		
Accounts receivable, net	(125,993)	152,399
Inventory	94,177	78,162
Prepaid expenses and other current assets	(11,858)	94,068
Accounts payable and accrued expenses	22,067	132,403
Accrued payroll and related taxes	43,056	(75,616)
Net cash used by operating activities	(2,021,234)	(3,032,612)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(21,742)	(41,961)
Additions to licenses and other assets	-	(22,245)
Change in restricted cash	(1,416)	(2,243)
Purchases of short-term investments	-	(479,820)
Proceeds from the sale or maturity of short-term investments	1,679,820	4,000,000
Net cash provided by investing activities	1,656,662	3,453,731
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Principal payments on notes payable	(145,815)	(49,185)
Principal payments on capital lease obligations	-	(23,312)
Preferred dividends paid	(36,679)	-
Proceeds from cash sales of common stock, pursuant to exercise of options	2,166	-
Repurchase of Company common stock	-	(4,735)
Net cash used by financing activities	(180,328)	(77,232)
Net increase (decrease) in cash and cash equivalents	(544,900)	343,887
Cash and cash equivalents, beginning of period	2,990,744	4,820,033
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 2,445,844	\$ 5,163,920

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



IsoRay, Inc. and Subsidiaries

Notes to the Consolidated Unaudited Financial Statements

For the three and nine-month periods ended March 31, 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, 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.

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

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 non-controlling 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 non-controlling 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 anti-dilutive. At March 31, 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 March 31, 2010 and 2009 were as follows:

	March 31,	
	2010	2009
Preferred stock	59,065	59,065
Common stock warrants	3,216,644	3,216,644
Common stock options	2,317,237	2,430,839
Total potentially dilutive securities	5,592,946	5,706,548

### 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 ASC 360. 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 was impaired. Therefore, the Company recorded an impairment charge of \$425,434 that is included in cost of product sales for the nine months ended March 31, 2009.

### 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 March 31, 2010 the Company had no short-term investments and as of June 30, 2009, the Company had \$1,679,820 in short-term investments. 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 March 31, 2010 and June 30, 2009:

	March 31, 2010	June 30, 2009
Raw materials	\$ 559,946	\$ 609,932
Work in process	135,123	155,827
Finished goods	–	23,487
	<b>\$ 695,069</b>	<b>\$ 789,246</b>

## 7. Share-Based Compensation

The following table presents the share-based compensation expense recognized in the statement of operations during the three and nine months ended March 31, 2010 and 2009:

	Three months ended March 31,		Nine months ended March 31,	
	2010	2009	2010	2009
Cost of product sales	\$ 5,506	\$ 3,100	\$ 16,778	\$ 17,010
Research and development expenses	1,840	4,001	2,176	23,490
Sales and marketing expenses	19,599	18,869	70,684	123,852
General and administrative expenses	7,863	29,698	25,647	91,098
Total share-based compensation	\$ 34,808	\$ 55,668	\$ 115,285	\$ 255,450

As of March 31, 2010, total unrecognized compensation expense related to share-based options was \$92,251 and the related weighted-average period over which it is expected to be recognized is approximately 1.09 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 March 31, 2010 was as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at March 31, 2010	2,317,237	\$ 1.91	7.08	\$ 976,633
Vested and expected to vest at March 31, 2010	2,235,647	\$ 1.97	7.02	\$ 893,448
Vested and exercisable at March 31, 2010	1,854,603	\$ 2.29	6.72	\$ 536,375



The aggregate intrinsic value of options exercised during the nine months ended March 31, 2010 and 2009 was \$2,233 and \$0, 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 March 31,		Nine months ended March 31,	
	2010(a)	2009(b)	2010(c)	2009(d)
Weighted average fair value of options granted	\$ 0.56	\$ —	\$ 0.68	\$ 0.37
Key assumptions used in determining fair value:				
Weighted average risk-free interest rate	1.93%	—%	2.55%	2.63%
Weighted average life of the option (in years)	3.75	—	4.75	5.68
Weighted average historical stock price volatility	101.84%	—%	134.89%	191.04%
Expected dividend yield	0.00%	—%	0.00%	0.00%

- (a) During the three months ended March 31, 2010, the Company granted 30,000 stock options.
- (b) During the three months ended March 31, 2009, the Company did not grant any stock options.
- (c) During the nine months ended March 31, 2010, the Company granted 40,000 stock options.
- (d) During the nine months ended March 31, 2009, 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 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.

## 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. 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.

10. Subsequent Event

Management executed a sales agreement with C.K.Cooper & Company, Inc on April 22, 2010 to sell shares as the Company's sales agent at market prices. The sales agreement expires on June 30, 2010. If the shares are sold, the shares will be issued pursuant to the Form S-3 (File No. 333-162694) which became effective on November 13, 2009 and the prospectus supplement dated April 23, 2010. Sales cannot exceed \$4 million under the prospectus supplement and must be sold "at the market" price of the common stock as of the day the sales are made.



## 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 March 31, 2010, there have been no material changes to any of the critical accounting policies contained therein.

## Results of Operations

Three months ended March 31, 2010 compared to three months ended March 31, 2009

**Product sales.** The Company generated revenue of \$1,203,216 during the three months ended March 31, 2010 compared to revenue of \$1,366,289 during the three months ended March 31, 2009. The decrease of \$163,073 or 12% in revenue directly correlates with a reduction in the quantity of seeds sold. While no marketing program has been implemented for the treatment of sites other than prostate, these new treatment sites including lung, head and neck, colorectal and others contributed 5 new cases in the three months ended March 31, 2010 and approximately \$31,000 in additional revenue to the revenue generated by prostate related treatments. Management believes that the overall market for prostate brachytherapy has received increased pressure from other treatment modalities with higher reimbursement rates such as Intensity-Modulated Radiation Therapy (IMRT) and Robotics. While these new treatment sites for the quarter ended March 31, 2010 comprised 3% of Company revenue, management believes these sites present opportunities for growth with market acceptance that is not available at this time in the highly competitive prostate market.

**Cost of product sales.** Cost of product sales was \$1,150,730 for the three months ended March 31, 2010 compared to cost of product sales of \$1,351,044 during the three months ended March 31, 2009. The decrease in cost of \$200,314 or 15% correlates with the reduced sales. The major components of the decrease were personnel costs, materials, preload expenses, occupancy costs and depreciation and amortization expense. Personnel costs, including payroll, benefits, and related taxes, decreased approximately \$31,000 as the number of production personnel decreased for the three months ended March 31, 2010 compared to March 31, 2009. Materials decreased approximately \$66,000 mainly due to decreased rate of consumption of inventory materials as a result of changes in sales in the three months ended March 31, 2010 compared to March 31, 2009. Preload expenses decreased by approximately \$14,000 mainly due to the lower volume of sales and increased in-house loading for the three months ended March 31, 2010 compared to March 31, 2009. Occupancy costs were reduced by approximate \$17,000 for the three months ended March 31, 2010 compared to March 31, 2009 as a result of reduced rent and related utility consumption. Depreciation and amortization was reduced by approximately \$53,000 for the three months ended March 31, 2010 compared to March 31, 2009.

**Gross margin.** Gross margin was \$52,486 for the three month period ended March 31, 2010 as compared to \$15,245 for the three months ended March 31, 2009. This represents an increase in the Company's gross margin of \$37,241 or 244%. The increase in the gross margin is due to the Company's continuing efforts in managing production during decreased periods of sales.

**Research and development expenses.** Research and development expenses for the three month period ended March 31, 2010 were \$98,964 which represents a decrease of \$202,943 or 67% less than the research and development expenses of \$301,907 for the three month period ended March 31, 2009. The decrease in cost is primarily due to lower consulting, personnel expenses and protocol expense. Consulting expenses decreased approximately \$49,000 as the Company completed several projects related to production automation and bringing delivery methods to treat head and neck, lung and colorectal cancer to market. Protocol expenses decreased approximately \$61,000 as the major cost for the monotherapy protocol has been completed. Legal costs were reduced by approximately \$90,000 because in the three months ended March 31, 2009, the Company finalized its on-going strategy regarding foreign patents and trademarks and wrote-off \$84,671 of previously capitalized costs. The Company had pursued patents and trademarks in various foreign countries including Australia, Japan, and China; however, the Company no longer believes that pursuing patents and trademarks in these foreign countries is fundamental to its current business strategy.



**Sales and marketing expenses.** Sales and marketing expenses were \$447,693 for the three months ended March 31, 2010. This represents a decrease of \$81,656 or 15% compared to expenditures in the three months ended March 31, 2009 of \$529,349 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$46,000 due to a lower sales headcount. Training for physicians was reduced by approximately \$18,000 for the three months ended March 31, 2010 as the training that occurred in the three months ended March 31, 2009 did not occur in the three months ended March 31, 2010.

**General and administrative expenses.** General and administrative expenses for the three months ended March 31, 2010 were \$596,224 compared to general and administrative expenses of \$666,637 for the three months ended March 31, 2009. The decrease of \$70,413 or 11% is mainly due to decreased personnel, and consulting expenses that were partially offset by an increase in other costs. Personnel expenses, including payroll, benefits, related taxes, and share-based compensation decreased approximately \$77,000 due primarily to the resignation of the Company's CFO in October 2009. Public company and consulting expenses were reduced by approximately \$40,000 due primarily to the conversion of the interim CEO to a full-time employee. These reductions were partially offset by an increase in other costs of approximately \$46,000 that include franchise taxes, licenses and permits, credit card discount expense and allowance for bad debt.

**Operating loss.** The Company continues to focus its resources on improving sales while retaining the necessary administrative infrastructure to increase the level of demand for the Company's product. 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 March 31, 2010, the Company had an operating loss of \$1,090,395 which is a decrease of \$392,253 or 26% less than the operating loss of \$1,482,648 for the three months ended March 31, 2009.

**Interest income.** Interest income was \$1,547 for the three months ended March 31, 2010. This represents a decrease of \$17,175 or 92% compared to interest income of \$18,722 for the three months ended March 31, 2009. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments. The decrease is due to lower interest rates and lower balances in the Company's money market and short-term investment accounts.

**Financing and interest expense.** Financing and interest expense for the three months ended March 31, 2010 was \$6,445 or a decrease of \$9,833 or 60% from financing and interest expense of \$16,278 for the three months ended March 31, 2009. Included in financing expense is interest expense of approximately \$6,000 for each of the three months ended March 31, 2010 and 2009, respectively. The remaining balance of financing expense represents the amortization of deferred financing costs.

Nine months ended March 31, 2010 compared to nine months ended March 31, 2009

**Product sales.** Sales for the nine months ended March 31, 2010 were \$3,950,650 compared to sales of \$4,212,574 for the nine months ended March 31, 2009. The decrease of \$261,924 or 6% directly correlates with a reduction in the quantity of seeds sold. New treatment sites including lung, head and neck, colorectal and other applications contributed 19 new cases in the nine months ended March 31, 2010 and approximately \$108,000 in additional revenue to the revenue generated by prostate related treatments. Management believes that the overall market for prostate brachytherapy has received increased pressure from other treatment modalities with higher reimbursement rates such as Intensity-Modulated Radiation Therapy (IMRT) and Robotics. While these new treatment sites year to date only comprise 3% of Company revenue, management believes these sites present opportunities for growth with market acceptance that is not available at this time in the highly competitive prostate market.



Cost of product sales. Cost of product sales was \$3,411,012 for the nine months ended March 31, 2010 compared to cost of product sales of \$4,523,705 during the nine months ended March 31, 2009. The cost reduction of \$1,112,693 or 25% for the nine months ended March 31, 2010 were the result of both the reduction in sales and continued production efficiency improvements. Depreciation and amortization cost was reduced by approximately \$164,000. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$170,000 due to a reduction in the average production headcount levels. Preload expenses decreased approximately \$183,000 due to lower sales volumes and increased in-house loading. Occupancy costs were reduced by approximately \$64,000 as the Company continues to evaluate and reconfigure leased space that has resulted in a reduced facility rent. In addition, the Company continues to monitor its utility consumption and more efficient consumption of utilities in combination with a very mild winter has created a significant savings of approximately \$43,000 in utility costs that is included in occupancy cost for the nine months ended March 31, 2010 as compared to the nine months ended March 31, 2009. Other expenses were reduced by approximately \$435,000, primarily resulting from the impairment charge for the IBt license of approximately \$425,000 that was recorded in the nine months ended March 31, 2009.

Gross margin / (loss). Gross margin was \$539,638 for the nine month period ended March 31, 2010. This represents an improvement of \$850,769 compared to a gross loss of \$311,131 during the nine month period ended March 31, 2009. Included in the gross loss of \$311,131 for the nine months ended March 31, 2009 is the one-time IBt license impairment charge of \$425,434. Without this one-time expense, the Company would have recognized a gross margin of \$114,303 for the nine months ended March 31, 2009.

Research and development expenses. Research and development expenses for the nine months ended March 31, 2010 were \$226,924 which represents a decrease of \$599,589 or 73% less than the research and development expenses of \$826,513 for the nine months ended March 31, 2009. Consulting expenses decreased approximately \$88,000 as several production projects were completed related to both production automation and delivery methods to treat head and neck, lung, and colorectal cancers. These decreases were partially offset by the transition of a former R&D employee to a consulting role. Legal expenses were reduced by approximately \$125,000 in the nine months ended March 31, 2010 due to the Company finalizing its on-going strategy regarding foreign patents and trademarks and wrote-off \$84,671 of previously capitalized costs and the resulting reduction in continuing activities as a result during the nine months ended March 31, 2009. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$72,000 due to lower headcount. Protocol expense was reduced by approximately \$255,000 for the nine month period ended March 31, 2010 as the major cost for the monotherapy protocol has been completed.

Sales and marketing expenses. Sales and marketing expenses were \$1,494,572 for the nine months ended March 31, 2010. This represents a decrease of \$386,251 or 21% compared to expenditures in the nine months ended March 31, 2009 of \$1,880,823 for sales and marketing. Personnel expenses, including payroll, benefits, related taxes, and share-based compensation decreased approximately \$209,000 due to a lower sales headcount. Travel expenses also decreased approximately \$85,000 due to the decrease in average headcount

General and administrative expenses. General and administrative expenses for the nine months ended March 31, 2010 were \$1,748,664 compared to general and administrative expenses of \$2,205,616 for the nine months ended March 31, 2009. This represents a decrease of \$456,952 or 21%. Personnel costs including payroll, benefits, related taxes, and share-based compensation decreased approximately \$222,000 as a result of the CEO becoming an employee, the resignation of the CFO, an overall reduction in headcount and the related forfeiture of option grants and option grants that have been fully amortized. Public company expenses decreased approximately \$59,000 due to the CEO no longer being paid fees for service on the Board of Directors upon becoming an employee. Legal expenses decreased by approximately \$126,000 in the nine months ended March 31, 2010 as the Company incurred legal fees related to settling a lawsuit with a former employee during the nine months ended March 31, 2009.

Operating loss. The Company continues to focus its resources on improving sales while retaining the necessary administrative infrastructure to increase the level of demand for the Company's product. These objectives and resulting costs have resulted in the Company not being profitable and generating operating losses since its inception. In the nine months ended March 31, 2010, the Company had an operating loss of \$2,930,522 which is an improvement of \$2,293,561 or 44% better than the operating loss of \$5,224,083 for the nine months ended March 31, 2009. Included in the operating loss for the nine months ended March 31, 2009 is the one-time IBt license impairment loss of \$425,434. Without this impairment loss, the Company's operating loss would have been \$4,798,649 for the nine months ended March 31, 2009.

Interest income. Interest income was \$10,358 for the nine months ended March 31, 2010. This represents a decrease of \$90,712 or 90% compared to interest income of \$101,070 for the nine months ended March 31, 2009. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments. The decrease is due to lower interest rates and lower balances in the Company's money market and short-term investment accounts.

Gain on fair value of short-term investments. There was no gain on short-term investments for the nine months ended March 31, 2010 as compared to a gain of \$274,000 for the nine months ended March 31, 2009. The gain of \$274,000 for the nine months ended March 31, 2009 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 auction rate securities.

Financing and interest expense. Financing and interest expense for the nine months ended March 31, 2010 was \$31,704 or a decrease of \$26,190 or 45% from financing and interest expense of \$57,894 for the nine months ended March 31, 2009. Included in financing expense is interest expense of approximately \$17,000 and \$31,000 for the nine months ended March 31, 2010 and 2009, respectively. The decrease in interest expense is due to the reduction of the principal balances of the Company's overall debt and capital lease balances. 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 nine months ended March 31, 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 was \$2.0 million for the nine months ended March 31, 2010 compared to \$3.0 million for the nine months ended March 31, 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 provided by investing activities was approximately \$1.7 million for the nine months March 31, 2010 as compared to cash provided by investing activities of \$3.5 million for the nine months ended March 31, 2009. Cash expenditures for fixed assets were approximately \$22,000 and \$42,000 during the nine months ended March 31, 2010 and 2009, respectively. The Company sold its remaining auction rate securities in January 2009 which generated \$4.0 million of cash proceeds in the nine months ended March 31, 2009. The Company reinvested most of these proceeds in money market funds and certificates of deposit with maturities of less than 3 months which are classified as cash equivalents on the balance sheet.

#### Cash flows from financing activities

Cash used in financing activities was approximately \$180,000 and \$77,000 for the nine months ended March 31, 2010 and 2009, respectively. \$146,000 and \$72,000 was used mainly for payments of debt and capital leases in the nine months ended March 31, 2010 and 2009 respectively. Approximately \$108,000 of the \$146,000 in cash that was used for payments of debt and capital leases in the nine months ended March 31, 2010 was to retire the loan facility with Benton-Franklin Council of Governments (BFEDD). Approximately \$37,000 of the remaining cash consumed in financing activities was related to the payment of preferred dividends which was partially offset by the exercise of stock options.

#### Projected 2010 Liquidity and Capital Resources

At March 31, 2010, cash and cash equivalents amounted to \$2,425,844 and the Company had no short-term investments, 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 \$2.1 million of cash and no short-term investments as of April 30, 2010. The Company's monthly required cash operating expenditures were approximately \$225,000 in the nine months ended March 31, 2010, which represents a 40% decrease of approximately \$150,000 from average monthly cash operating expenditures in fiscal year 2009 of approximately \$375,000. This reduction is primarily the result of improved operating performance in fiscal year 2010. Management believes that less than \$100,000 will be spent on capital expenditures for 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 nine months ended March 31, 2010 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 the Hanford Area Economic Investment Fund Committee (HAEIFC), with a principal balance of approximately \$192,000 of which approximately \$48,000 will be due in the next 12 months.

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 mono therapy prostate protocols is adequate. For the nine months ended March 31, 2010, approximately \$54,000 has been spent.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at March 31, 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 for approximately 11 months. 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 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 nine months ended March 31, 2010.

Management is now focused on expanding into head and neck, colorectal and lung application segments and our cash and cash equivalents are only sufficient to meet cash requirements for operations, debt service and capital expenditures at our current monthly average expenses for the next eleven months assuming no expansion of our operations. As a result, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it plans to enter new market applications for the Company's technologies.

Management executed a sales agreement with C.K.Cooper & Company, Inc (CKCC) on April 22, 2010 to sell shares as the Company's sales agent at market prices. The sales agreement expires on June 30, 2010. If the shares are sold, the shares will be issued pursuant to the Form S-3 (File No. 333-162694) which became effective on November 13, 2009 and the prospectus supplement dated April 23, 2010. Sales cannot exceed \$4 million under the prospectus supplement and must be sold "at the market" price of the common stock as of the day the sales are made.

The Company expects to finance its cash needs through the sale of equity securities and possibly strategic collaborations or debt financing or through other sources that may be dilutive to existing shareholders. Funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds when needed, it may not be able to market its products as planned or continue development and regulatory approval of its future products. If the Company raises additional funds through equity sales, these sales may be dilutive to existing investors.

#### Long-Term Debt and Capital Lease Agreements

IsoRay has a single loan facility in place as of March 31, 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 March 31, 2010 was \$191,645. 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 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 March 31, 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.

## 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, except for the addition of the following risk factors:

The Price Of Our Common Stock May Be Adversely Affected By The Future Issuance And Sale Of Shares Of Our Common Stock Or Other Equity Securities, Including Pursuant To The Sales Agreement, Or By Our Announcement That Such Issuances And Sales May Occur. We cannot predict the size of future issuances or sales of our common stock or other equity securities, including those made pursuant to the sales agreement with CKCC, future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. In addition, CKCC, as agent for sales under the sales agreement, will not engage in any transactions that stabilize the price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities, including the issuances and sales pursuant to the sales agreement, or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

Our Reduced Stock Price May Adversely Affect Our Liquidity. Our common stock has been trading at less than \$1.00 per share periodically in the past. Many market makers are reluctant to make a market in stock with a trading price of less than \$1.00 per share. To the extent that we have fewer market makers for our common stock, our volume and liquidity will likely decline, which could further depress our stock price.

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. There can be no assurance that we will be able to maintain our listing on the NYSE Amex indefinitely. 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, 2010, 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, 2010, 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. The offering of Shares pursuant to the Agreement will terminate upon the earliest of (i) June 30, 2010, (ii) the sale of all Shares subject to the Agreement and (iii) the termination of the Agreement by the Company or CKCC.

CKCC has not yet commenced the Offering as it has not yet been instructed to do so by the Company.

ITEM 6 – EXHIBITS

Exhibits:

- 10.58 Consulting and Severance Agreement dated January 12, 2010 between IsoRay, Inc. and Lori Woods
- 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: May 10, 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)