

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, 2009

or

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

For the transition period from _____ to _____

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota

(State or other jurisdiction of incorporation or organization)

41-1458152

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

350 Hills St., Suite 106, Richland, Washington

(Address of principal executive offices)

99354

(Zip Code)

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

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

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

Yes No

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

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

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

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

Class
Common stock, \$0.001 par value

Outstanding as of May 6, 2009
22,942,088

ISORAY, INC.

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PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries Consolidated Balance Sheets

	March 31, 2009 (Unaudited)	June 30, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,163,920	\$ 4,820,033
Short-term investments	479,820	3,726,000
Accounts receivable, net of allowance for doubtful accounts of \$109,012 and \$33,031, respectively	864,096	1,016,495
Inventory	821,802	899,964
Prepaid expenses and other current assets	172,933	267,001
Total current assets	7,502,571	10,729,493
Fixed assets, net of accumulated depreciation and amortization	5,176,924	6,040,641
Deferred financing costs, net of accumulated amortization	38,261	65,221
Licenses, net of accumulated amortization	3,261	455,646
Restricted cash	178,095	175,852
Other assets, net of accumulated amortization	276,077	345,040
Total assets	<u>\$ 13,175,189</u>	<u>\$ 17,811,893</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 883,805	\$ 751,402
Accrued payroll and related taxes	268,996	344,612
Notes payable, due within one year	168,554	64,486
Capital lease obligations, due within one year	2,248	25,560
Total current liabilities	1,323,603	1,186,060
Notes payable, due after one year	191,645	344,898
Asset retirement obligation	541,203	506,005
Total liabilities	2,056,451	2,036,963
Shareholders' equity:		
Preferred stock, \$.001 par value; 6,000,000 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	59	59
Common stock, \$.001 par value; 194,000,000 shares authorized; 22,942,088 shares issued and outstanding	22,942	22,942
Treasury stock, at cost, 13,200 and 5,000 shares	(8,390)	(3,655)
Additional paid-in capital	47,719,957	47,464,507
Accumulated deficit	(36,615,830)	(31,708,923)
Total shareholders' equity	11,118,738	15,774,930
Total liabilities and shareholders' equity	<u>\$ 13,175,189</u>	<u>\$ 17,811,893</u>

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

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

	Three months ended March 31,		Nine months ended March 31,	
	2009	2008	2009	2008
Product sales	\$ 1,366,289	\$ 1,783,642	\$ 4,212,574	\$ 5,397,705
Cost of product sales	<u>1,351,044</u>	<u>1,682,981</u>	<u>4,523,705</u>	<u>5,930,278</u>
Gross margin (loss)	<u>15,245</u>	<u>100,661</u>	<u>(311,131)</u>	<u>(532,573)</u>
Operating expenses:				
Research and development expenses	301,907	434,418	826,513	1,086,333
Sales and marketing expenses	529,349	888,448	1,880,823	3,091,091
General and administrative expenses	<u>666,637</u>	<u>869,435</u>	<u>2,205,616</u>	<u>2,690,624</u>
Total operating expenses	<u>1,497,893</u>	<u>2,192,301</u>	<u>4,912,952</u>	<u>6,868,048</u>
Operating loss	<u>(1,482,648)</u>	<u>(2,091,640)</u>	<u>(5,224,083)</u>	<u>(7,400,621)</u>
Non-operating income (expense):				
Interest income	18,722	131,442	101,070	549,993
Gain (loss) on fair value of short-term investments	-	(187,300)	274,000	(187,300)
Financing and interest expense	<u>(16,278)</u>	<u>(22,826)</u>	<u>(57,894)</u>	<u>(78,140)</u>
Non-operating income (expense), net	<u>2,444</u>	<u>(78,684)</u>	<u>317,176</u>	<u>284,553</u>
Net loss	<u>\$ (1,480,204)</u>	<u>\$ (2,170,324)</u>	<u>\$ (4,906,907)</u>	<u>\$ (7,116,068)</u>
Basic and diluted loss per share	<u>\$ (0.06)</u>	<u>\$ (0.09)</u>	<u>\$ (0.21)</u>	<u>\$ (0.31)</u>
Weighted average shares used in computing net loss per share:				
Basic and diluted	<u>22,942,088</u>	<u>23,090,200</u>	<u>22,942,088</u>	<u>23,054,375</u>

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

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

	Nine months ended March 31,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,906,907)	\$ (7,116,068)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	905,678	849,716
Impairment of IBt license (see Note 4)	425,434	-
Write-off of certain foreign patents and trademarks (see Note 7)	84,671	-
Amortization of deferred financing costs and other assets	60,448	61,521
Amortization of discount on short-term investments	-	(145,165)
(Gain) loss on fair value of short-term investments	(274,000)	187,300
Settlement of asset retirement obligation	-	(135,120)
Accretion of asset retirement obligation	35,198	25,670
Share-based compensation	255,450	425,090
Changes in operating assets and liabilities:		
Accounts receivable, net	152,399	284,252
Inventory	78,162	18,395
Prepaid expenses and other current assets	94,068	58,095
Accounts payable and accrued liabilities	132,403	(880,599)
Accrued payroll and related taxes	(75,616)	(216,834)
Deferred revenue	-	(23,874)
Net cash used by operating activities	<u>(3,032,612)</u>	<u>(6,607,621)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(41,961)	(3,112,400)
Additions to licenses and other assets	(22,245)	(250,783)
Change in restricted cash	(2,243)	(174,273)
Purchases of short-term investments	(479,820)	(13,273,653)
Proceeds from the sale or maturity of short-term investments	<u>4,000,000</u>	<u>16,667,499</u>
Net cash provided (used) by investing activities	<u>3,453,731</u>	<u>(143,610)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(49,185)	(118,414)
Principal payments on capital lease obligations	(23,312)	(155,603)
Proceeds from cash sales of common stock, pursuant to exercise of warrants	-	1,010,913
Proceeds from cash sales of common stock, pursuant to exercise of options	-	11,900
Repurchase of Company common stock	<u>(4,735)</u>	<u>-</u>
Net cash (used) provided by financing activities	<u>(77,232)</u>	<u>748,796</u>
Net increase (decrease) in cash and cash equivalents	343,887	(6,002,435)
Cash and cash equivalents, beginning of period	<u>4,820,033</u>	<u>9,355,730</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 5,163,920</u>	<u>\$ 3,353,295</u>
Non-cash investing and financing activities:		
Increase in fixed assets related to asset retirement obligation	\$ -	\$ 473,096

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

IsoRay, Inc. and Subsidiaries
Notes to the Consolidated Unaudited Financial Statements
For the three and nine-month periods ended March 31, 2009 and 2008

1. Basis of Presentation

The accompanying consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries (IsoRay or the Company). All significant intercompany accounts and transactions have been eliminated in consolidation.

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2008. 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, 2008.

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

2. Changes in Accounting Policies

SFAS 157

Effective July 1, 2008, the Company implemented Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company elected to implement this Statement with the one-year deferral permitted by FASB Staff Position (FSP) 157-2 for nonfinancial assets and nonfinancial liabilities measured at fair value, except those that are recognized or disclosed on a recurring basis. This deferral applies to fixed assets and intangible asset impairment testing and initial recognition of asset retirement obligations for which fair value is used. The Company does not expect any significant impact to our consolidated financial statements when we implement SFAS 157 for these assets and liabilities.

SFAS 157 requires disclosures that categorize assets and liabilities measured at fair value into one of three different levels depending on the observability of the inputs employed in the measurement. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable inputs other than quoted prices included within Level 1 for the asset or liability, either directly or indirectly through market-corroborated inputs. Level 3 inputs are unobservable inputs for the asset or liability reflecting significant modifications to observable related market data or our assumptions about pricing by market participants.

Due to the uncertainties in the credit markets, the monthly auctions for auction rate securities (ARS) failed beginning in February 2008 and did not have an active market. These short term securities were valued by our broker using various assumptions including current interest rates, credit ratings, the issuer's financial health, etc. The Company's ARS were classified as Level 2 until their sale on January 5, 2009.

On October 16, 2008, the Company accepted an offer from UBS AG (UBS) providing the Company with Auction Rate Securities Rights Series B (Rights) pertaining to our ARS (see Note 5). These Rights were

a put option for the right to sell to UBS our ARS at par value. As the Rights were non-transferable and could not be attached to the ARS if they were sold to another entity, the Rights represented a free-standing instrument between the Company and UBS. The Rights were valued using a discounted cash flow model based on the Company's estimates and assumptions until they were exercised in January 2009.

At March 31, 2009, all of the Company's financial assets and liabilities are accounted and reported at fair value using Level 1 inputs.

SFAS 159

Effective July 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*. The statement allows entities to value many financial instruments and certain other items at fair value. SFAS 159 provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. If the fair value option is elected then unrealized gains and losses are reported in earnings at each subsequent reporting date. The Company elected not to measure any additional financial instruments or other items at fair value as of July 1, 2008 in accordance with SFAS 159. Accordingly, the adoption of SFAS 159 did not impact our consolidated financial statements. The Company did elect to fair value its ARS rights that were received in October 2008 and exercised in January 2009 in accordance with SFAS 159 (see Note 5).

3. Loss per Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, *Earnings Per Share*. Under the provisions of SFAS 128, primary and fully diluted earnings per share are replaced with basic and diluted earnings per share. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At March 31, 2009 and 2008, 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 antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of March 31, 2009 and 2008 were as follows:

	March 31,	
	<u>2009</u>	<u>2008</u>
Preferred stock	59,065	59,065
Common stock warrants	3,216,644	3,250,774
Common stock options	<u>2,430,839</u>	<u>2,831,728</u>
Total potentially dilutive securities	<u><u>5,706,548</u></u>	<u><u>6,141,567</u></u>

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 (see Note 11 for further details on the IBt license agreement). Management determined through this review that it does not currently intend to utilize the IBt license as part of its market strategy due to the cost of revamping its manufacturing process to incorporate the technology and as there can be no assurance that physicians would accept this new technology without extensive education and marketing costs. However, the Company does not intend to cancel the license agreement at this time; therefore, the license was reviewed in terms of an “abandoned asset” for purposes of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, it was determined that the entire value was impaired. Therefore, the Company recorded an impairment charge of \$425,434 in December 2008 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 consisted of the following at March 31, 2009 and June 30, 2008:

	March 31, 2009	June 30, 2008
Auction rate securities	\$ —	\$ 3,726,000
Certificates of deposit	479,820	—
	<u>\$ 479,820</u>	<u>\$ 3,726,000</u>

Beginning in February 2008, the uncertainties in the credit markets prevented the Company from liquidating its ARS (consisting of various student loan portfolios). The securities continued to pay interest according to their stated terms and were all AAA/Aaa rated investments. Through September 2008, the Company classified these securities as available-for-sale and recorded them at fair market value. The Company recognized a decline in the fair value of these securities (which has been caused by the market uncertainties) as other than temporary and recorded the loss in the statement of operations.

In October 2008, the Company accepted an offer from UBS to provide the Company with certain Rights pertaining to our ARS. The Rights were a put option allowing the Company to sell its ARS to UBS at par value at any time from January 2, 2009 to January 4, 2011. The Rights did not meet the definition of a derivative under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as there is no net settlement method. The Rights also did not meet the definition of a security under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. The Company elected to measure the Rights under the fair value option of SFAS 159 on the date they were received (see Note 2) and classified them as short-term investments.

Also in October 2008, the Company reclassified its ARS from available-for-sale to trading and recorded all changes in fair value to these securities in the statement of operations. The Company felt this reclassification was appropriate given that it accepted the offer of the Rights, it did not intend to hold these investments to maturity, and there was no longer an active market to permit their sale in the normal course of business.

On January 2, 2009, the Company exercised its put option with UBS to redeem its ARS at par value. The entire \$4 million of cash was deposited into the Company’s account on January 5, 2009.

6. Inventory

Inventory consisted of the following at March 31, 2009 and June 30, 2008:

	March 31, 2009	June 30, 2008
Raw materials	\$ 623,860	\$ 696,958
Work in process	189,132	191,684
Finished goods	<u>8,810</u>	<u>11,322</u>
	<u>\$ 821,802</u>	<u>\$ 899,964</u>

7. Other Assets

During the three months ended March 31, 2009, the Company performed a review of its prepaid legal fees for patents and trademarks that have not been obtained and are classified within other assets on the consolidated balance sheet. The focus of the review was patent and trademark applications that the Company had been pursuing in foreign countries. The Company decided to limit its foreign applications to Canada, Europe, and Russia, as well as the continued protection of the US patents and trademarks. This resulted in the write-off of \$84,671 of other patent and trademark application fees relating to other countries during the quarter ended March 2009.

8. 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, 2009 and 2008:

	Three months ended March 31,		Nine months ended March 31,	
	2009	2008	2009	2008
Cost of product sales	\$ 3,100	\$ 36,029	\$ 17,010	\$ 109,859
Research and development expenses	4,001	10,971	23,490	34,071
Sales and marketing expenses	18,869	59,557	123,852	178,671
General and administrative expenses	<u>29,698</u>	<u>(36,080)</u>	<u>91,098</u>	<u>102,489</u>
Total share-based compensation	<u>\$ 55,668</u>	<u>\$ 70,477</u>	<u>\$ 255,450</u>	<u>\$ 425,090</u>

Each quarter the Company reviews its forfeiture assumptions and adjusts its compensation expense when the actual pre-vesting forfeiture rate differs materially from the estimate. During the three months ended March 31, 2008, the Company recognized a credit to compensation expense in general and administrative expenses due to a significant variation between the estimated pre-vesting forfeiture rate and the actual pre-vesting forfeiture rate.

As of March 31, 2009, total unrecognized compensation expense related to share-based options was \$201,392 and the related weighted-average period over which it is expected to be recognized is approximately 0.60 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, 2009 were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at March 31, 2009	<u>2,430,839</u>	<u>\$ 2.61</u>	<u>7.03</u>	<u>\$ 0.00</u>
Vested and expected to vest at March 31, 2009	<u>2,419,937</u>	<u>\$ 2.61</u>	<u>7.02</u>	<u>\$ 0.00</u>
Vested and exercisable at March 31, 2009	<u>2,169,442</u>	<u>\$ 2.59</u>	<u>6.86</u>	<u>\$ 0.00</u>

The aggregate intrinsic value of options exercised during the nine months ended March 31, 2009 and 2008 was \$0 and \$25,300, 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,	
	<u>2009(a)</u>	<u>2008(b)</u>	<u>2009(c)</u>	<u>2008(b)</u>
Weighted average fair value of options granted	\$ -	\$ -	\$ 0.37	\$ -
Key assumptions used in determining fair value:				
Weighted average risk-free interest rate	-%	-%	2.63%	-%
Weighted average life of the option (in years)	-	-	5.68	-
Weighted average historical stock price volatility	-%	-%	191.04%	-%
Expected dividend yield	-%	-%	0.00%	-%

- (a) During the three months ended March 31, 2009, the Company did not grant any stock options.
- (b) During the three and nine months ended March 31, 2008, the Company did not grant any stock options.
- (c) 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.

9. UralDial

In December 2008, the Company entered into an agreement to sell its thirty percent (30%) interest in UralDial, LLC (UralDial) for a nominal amount. UralDial did not have any material assets or liabilities at the time of the Company's disposition of its ownership interest.

Also in December 2008, the Company finalized a contract to purchase cesium-131 from UralDial. Under the contract, the Company will purchase cesium-131 from UralDial rather than purchasing cesium-131 directly from its two existing suppliers in Russia. UralDial will provide cesium-131 from at least two Russian facilities subject to scheduled maintenance shutdowns of the facilities from time to time. The contract stabilizes supply arrangements for the 12 months beginning on December 15, 2008 and ending on December 31, 2009.

The Company has an existing distribution agreement with UralDial that allows UralDial to distribute Proxcelan Cs-131 brachytherapy seeds in Russia. The Company expects to begin shipping its brachytherapy seeds under this agreement once the regional healthcare budgets have been approved. The Company, through UralDial, has regulatory approval to sell cesium-131 seeds in Russia.

10. Distribution Agreement

On February 18, 2009, the Company entered into an exclusive distribution agreement with BrachySciences, a division of Biocompatibles International plc. The agreement allows BrachySciences to sell the Company's Proxcelan cesium-131 brachytherapy seeds throughout the United States. The Company did not have any sales under this agreement during the three months ended March 31, 2009.

11. 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.

License Agreement with IBt

In February 2006, the Company signed a license agreement with IBt covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using cesium-131. Under the original agreement, royalty payments were to be paid on net sales revenue incorporating the technology.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The Company paid license fees of \$275,000 (under the original agreement) and \$225,000 (under the Amendment) during fiscal years 2006 and 2008, respectively. The Amendment eliminates the previously required royalty payments based on net sales revenue, and the parties originally intended to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. In December 2008, the Company recorded an impairment charge to write down this license based on its current intentions to not utilize this technology (see Note 4).

12. New Accounting Pronouncements

In December 2007, FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141R), which replaces SFAS No. 141, *Business Combinations*. SFAS 141R applies to all transactions and other events in which one entity obtains control over one or more other businesses. The standard requires the fair value of the purchase price, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141R requires an acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interests in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the statement. SFAS 141R requires acquisition costs to be expensed as incurred and restructuring costs to be expensed in periods after the acquisition date. Earn-outs and other forms of contingent consideration are to be recorded at fair value on the acquisition date. Changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period will be recognized in earnings rather than as an adjustment to the cost of the acquisition. SFAS 141R generally applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 with early adoption prohibited.

In December 2007, the FASB issued statement SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51*. The statement requires noncontrolling interests or minority interests to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. Upon a loss of control, the interest sold, as well as any interest retained, is required to be measured at fair value, with any gain or loss recognized in earnings. Based on SFAS 160, assets and liabilities will not change for subsequent purchase or sales transactions with noncontrolling interests as long as control is maintained. Differences between the fair value of consideration paid or received and the carrying value of noncontrolling interests are to be recognized as an adjustment to the parent interest's equity. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. Due to the sale of its thirty percent interest in UralDial, the Company does not believe the implementation of SFAS 160 will have a material effect on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB No. 133*. SFAS 161 requires disclosures of the fair value of derivative instruments and their gains and losses in a tabular format, provides for enhanced disclosure of an entity's liquidity by requiring disclosure of derivative features that are credit-risk related, and requires cross-referencing within footnotes to enable financial statement users to locate information about derivative instruments. This statement is effective for fiscal years and interim periods beginning after November 15, 2008. The Company does not believe the adoption of SFAS 161 will have a material effect on its consolidated financial statements.

In May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to

be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. It was effective November 15, 2008, following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of this statement is not expected to have a material effect on the Company's financial statements.

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 21 below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2008 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 29, 2008 are those that depend most heavily on these judgments and estimates. As of March 31, 2009, there have been no material changes to any of the critical accounting policies contained therein, except for the adoption of SFAS 157 and 159 as noted below.

Fair Value Measurements

Effective July 1, 2008, the Company adopted statement No. 157, *Fair Value Measurements* (SFAS 157), which was issued by the FASB in September 2006. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements.

Fair Value Option for Financial Assets and Financial Liabilities

Effective July 1, 2008, the Company adopted statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159), which was issued by the FASB in February 2007. The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The Company elected not to measure any additional financial instruments or other items at fair value as of July 1, 2008 in accordance with SFAS 159. Accordingly, the adoption of SFAS 159 did not impact our consolidated financial statements.

Results of Operations

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

Product sales. The Company generated sales of \$1,366,289 during the three months ended March 31, 2009, compared to sales of \$1,783,642 for the three months ended March 31, 2008. The decrease of \$417,353 or 23% is mainly due to decreased sales volume of the Company's Proxcelan Cs-131 brachytherapy seed along with a lower average invoice price due to the expanded use of the Company's seeds in dual therapy cases which typically use fewer seeds. In addition, about 2% of the decrease is due to physicians ordering less seeds per implant as they have become more familiar with the isotope and its characteristics. The Company does not anticipate the number of seeds per implant declining any further but will need to increase the total number of implants to generate higher sales. Management also believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy seed sales. During the three months ended March 31, 2009, the Company sold its Proxcelan seeds to 50 different medical centers as compared to 57 medical centers during the corresponding period of 2008.

Cost of product sales. Cost of product sales was \$1,351,044 for the three months ended March 31, 2009 compared to cost of product sales of \$1,682,981 during the three months ended March 31, 2008. The decrease of \$331,937 or 20% is mainly due to reduced sales. The major components of the decrease were personnel costs, materials, preload expenses, and share-based compensation. Personnel costs, including payroll, benefits, and related taxes, decreased approximately \$154,000 as the number of production personnel decreased over the past year. Materials decreased approximately \$100,000 mainly due to ordering and using less isotope in the three months ended March 31, 2009 compared to the corresponding period of 2008. Preload expenses decreased by approximately \$73,000 mainly due to the lower volume of sales and increased in-house loading. Share-based compensation decreased approximately \$33,000 due to the forfeiture of unvested options by the Company's former EVP-Operations. These decreases were partially offset by an increase of approximately \$29,000 in depreciation expense.

Gross margin. Gross margin was \$15,245 for the three month period ended March 31, 2009. This represents a decrease in the Company's gross margin of \$85,416 or 85% over the corresponding

period of 2008's gross margin of \$100,661. The decrease in the gross margin is due to the Company's lower sales volume.

Research and development expenses. Research and development expenses for the three month period ended March 31, 2009 were \$301,907 which represents a decrease of \$132,511 or 31% less than the research and development expenses of \$434,418 for the three month period ended March 31, 2008. The decrease is due to lower consulting and personnel expenses partially offset by increased protocol expense and the write-off of certain foreign patent and trademark application fees. Consulting expenses, which are mainly due to an ongoing project to increase the efficiency of isotope production, decreased approximately \$189,000 as the Company has discontinued most funding until the final prototype testing trial. Personnel costs, including payroll, benefits, and related taxes, decreased approximately \$52,000 due to a reduced headcount in research and development. Protocol expenses increased approximately \$62,000 mainly due to the Company's dual-therapy study and its continued monitoring and updating of the mono-therapy study. Also 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 these 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 are fundamental to its current business strategy.

Sales and marketing expenses. Sales and marketing expenses were \$529,349 for the three months ended March 31, 2009. This represents a decrease of \$359,099 or 40% compared to expenditures in the three months ended March 31, 2008 of \$888,448 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$125,000 due to a lower sales headcount and a revised sales compensation plan. Consulting expenses decreased approximately \$95,000 as the Company reduced its reliance on third-parties as part of its expense reduction initiatives. Travel expenses decreased approximately \$65,000 mainly due to the decrease in sales force. Share-based compensation decreased approximately \$41,000 due to the forfeiture of unvested options. Marketing and advertising decreased approximately \$36,000 as the Company reduced advertising spending in some trade journals and reduced spending on the development of websites.

General and administrative expenses. General and administrative expenses for the three months ended March 31, 2009 were \$666,637 compared to general and administrative expenses of \$869,435 for the corresponding period of 2008. The decrease of \$202,798 or 23% is mainly due to decreased personnel and legal expenses that were partially offset by increased share-based compensation and consulting expenses. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$222,000 owing mainly to the resignation of the Company's CEO in February 2008 and the related severance payment. Legal expenses decreased by approximately \$79,000 from 2008 as in 2008 the Company incurred legal fees related to negotiation of severance upon the resignation of the CEO, the annual shareholder meeting, and legal advice related to various Board meetings. Share-based compensation increased by approximately \$66,000 as during the prior year period the Company reversed the expense for unvested and forfeited options of the former CEO. Consulting expenses increased by approximately \$31,000 due to payments to the Company's interim CEO and a computer infrastructure consultant that was not performing any services during the three months ended March 31, 2008. Effective March 1, 2009, the interim CEO was converted to employee status and his wages will no longer be shown in consulting expenses.

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, 2009, the

Company had an operating loss of \$1,482,648 which is a decrease of \$608,992 or 29% less than the operating loss of \$2,091,640 for the three months ended March 31, 2008.

Interest income. Interest income was \$18,722 for the three months ended March 31, 2009. This represents a decrease of \$112,720 or 86% compared to interest income of \$131,442 for the three months ended March 31, 2008. 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.

Loss on fair value of short-term investments. The loss of \$187,300 for the three months ended March 31, 2008 was due to the uncertainties in the credit markets particularly for certain auction rate securities. The loss represents the amount to write-down these securities to their estimated fair market value.

Financing and interest expense. Financing and interest expense for the three months ended March 31, 2009 was \$16,278 or a decrease of \$6,548 or 29% from financing and interest expense of \$22,826 for the corresponding period in 2008. Included in financing expense is interest expense of approximately \$6,000 and \$15,000 for the three months ended March 31, 2009 and 2008, respectively. The remaining balance of financing expense represents the amortization of deferred financing costs.

Nine months ended March 31, 2009 compared to nine months ended March 31, 2008

Product sales. Sales for the nine months ended March 31, 2009 were \$4,212,574 compared to sales of \$5,397,705 for the nine months ended March 31, 2008. The decrease of \$1,185,131 or 22% was mainly due to decreased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds along with a lower average invoice price due to the expanded use of the Company's seeds in dual therapy cases which typically use fewer seeds. In addition, about 4% of the decrease is due to physicians ordering less seeds per implant as they have become more familiar with the isotope and its characteristics. The Company will need to increase the number of total implants to increase sales. Management also believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy seed sales. During the nine months ended March 31, 2009 the Company sold its Cs-131 seeds to 68 different medical centers as compared to 79 centers during the corresponding period of 2008.

Cost of product sales. Cost of product sales was \$4,523,705 for the nine months ended March 31, 2009 which represents a decrease of \$1,406,573 or 24% compared to cost of product sales of \$5,930,278 during the nine months ended March 31, 2008. Materials expense decreased approximately \$738,000 mainly due to ordering and using less isotope in the nine months ended March 31, 2009 compared to the corresponding period of 2008. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$479,000 due to a reduction in the average production headcount levels. Preload expenses decreased approximately \$317,000 due to lower sales volumes and due to increased in-house loading. Small tools expenses decreased approximately \$83,000 mainly due to expensing items in the prior year that were part of equipping the new facility that became operational in September 2007. Share-based compensation decreased approximately \$92,000 mainly due to the forfeiture of unvested options by the Company's former EVP-Operations.

These decreases were offset by an impairment of the Company's IBt license for \$425,434 that was recorded in December 2008. Management completed its review of the license and associated technology related to this alternative seed encapsulation process in December 2008 and determined

that the adoption of this process would entail an overhaul of the Company's existing manufacturing procedures. In addition, there is no assurance that physicians would accept this new technology without extensive education and marketing. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, its entire value was written off in the accompanying financial statements.

During the nine months ended March 31, 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163 resulting in an additional expense of \$139,043 that is included in cost of products sold for the nine months ended March 31, 2008. This additional expense incurred in the nine months ended March 31, 2008 was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but instead required their removal.

Gross loss. Gross loss was \$311,131 for the nine month period ended March 31, 2009. This represents a decrease of \$221,442 or 42% over the corresponding period of 2008's gross loss of \$532,573. Included in the gross loss for the nine months ended March 31, 2009 is the one-time IBt license impairment loss 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, 2009 were \$826,513 which represents a decrease of \$259,820 or 24% less than the research and development expenses of \$1,086,333 for the corresponding period of 2008. The major components of the decrease were personnel, consulting, and travel expenses. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$163,000 due to lower headcount. Consulting expenses decreased approximately \$291,000 as the Company's project to improve the efficiency of isotope production is nearing its final prototype testing phase and the Company has discontinued most funding until the final prototype testing trial. Travel expenses decreased approximately \$41,000 due to decreased trips to Russia and Belgium than occurred in the prior year. These decreases were partially offset by an increase in protocol expenses of approximately \$179,000 mainly due to payments for the Company's dual-therapy study and its continued monitoring and updating of the mono-therapy study. Also in the nine 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 these 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 are fundamental to its current business strategy.

Sales and marketing expenses. Sales and marketing expenses were \$1,880,823 for the nine months ended March 31, 2009. This represents a decrease of \$1,210,268 or 39% compared to expenditures in the nine months ended March 31, 2008 of \$3,091,091 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$557,000 due to a lower sales headcount and a revised sales compensation plan that was originally introduced in April 2008 and subsequently amended in October 2008. Travel expenses also decreased approximately \$119,000 due to the decrease in average headcount. Consulting expenses decreased approximately \$228,000, mainly due to reduced reliance on third-parties as part of the Company's expense reduction initiatives. Marketing and advertising decreased approximately \$197,000 as during the prior year the Company updated its marketing literature to incorporate new data published from the protocols, developed additional websites for patients and doctors, and updated its sales booth. Dues and

subscriptions decreased approximately \$41,000 mainly due to the prior year purchases of market research reports and subscriptions for US medical residents. Share-based compensation decreased approximately \$55,000 due to the forfeiture of unvested options and fewer options being granted.

General and administrative expenses. General and administrative expenses for the nine months ended March 31, 2009 were \$2,205,616 compared to general and administrative expenses of \$2,690,624 for the corresponding period of 2008. The decrease of \$485,008 or 18% is primarily due to a decrease in personnel costs, public company expenses, share-based compensation, legal expenses, and travel expenses partially offset by increases in consulting and bad debt allowance. Personnel costs decreased approximately \$360,000 mainly due to the resignation of the Company's CEO in February 2008 and lower headcounts. Public company expenses decreased approximately \$113,000 due to lower investor relations costs partially offset by increased board compensation. Legal expenses decreased by approximately \$137,000 as in the nine months ended March 31, 2008 the Company incurred legal fees for contract drafting and review of the Company's interest in UralDial, the IBt strategic global alliance agreements, and settlement agreement and for mediation costs. These decreased legal costs were partially offset by legal fees incurred in settling a lawsuit with a former employee. Travel expenses also decreased approximately \$65,000. These decreases were partially offset by increased expense related to bad debt allowance of approximately \$76,000 and increased consulting expenses of approximately \$115,000 mainly due to compensation paid to the Company's interim CEO and the costs of the Company's ISO 13458 and CE mark audit that was conducted in July 2008.

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, 2009, the Company had an operating loss of \$5,224,083 which is a decrease of \$2,176,538 or 29% less than the operating loss of \$7,400,621 for the nine months ended March 31, 2008. 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.

Interest income. Interest income was \$101,070 for the nine months ended March 31, 2009. This represents a decrease of \$448,923 or 82% compared to interest income of \$549,993 for the nine months ended March 31, 2008. 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 (loss) on fair value of short-term investments. The gain of \$274,000 for the nine months ended March 31, 2009 is due to the receipt of the Company's rights related to its auction rate securities (ARS) issued by its broker in October 2008. The gain is calculated as the fair value amount of the put rights as estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's ARS.

Financing and interest expense. Financing and interest expense for the nine months ended March 31, 2009 was \$57,894 or a decrease of \$20,246 or 26% from financing and interest expense of \$78,140 for the corresponding period in 2008. Included in financing expense is interest expense of approximately \$31,000 and \$55,000 for the nine months ended March 31, 2009 and 2008, 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, 2009, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities was \$3.0 million for the nine months ended March 31, 2009 compared to \$6.6 million for the nine months ended March 31, 2008. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash flows from investing activities

Cash provided by investing activities was approximately \$3.5 million for the nine months March 31, 2009 as compared to cash used by investing activities of \$144,000 for the nine months ended March 31, 2008. Cash expenditures for fixed assets were approximately \$42,000 and \$3.1 million during the nine months ended March 31, 2009 and 2008, respectively. The expenditures for fixed assets during the nine months ended March 31, 2008 were related to the construction of the Company's new production facility. The Company sold its remaining auction rate securities in January 2009 which generated \$4.0 million of cash proceeds. 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 \$77,000 for the nine months ended March 31, 2009 and was used mainly for payments of debt and capital leases.

Projected 2008 Liquidity and Capital Resources

At March 31, 2009, cash and cash equivalents amounted to \$5,163,920 and short-term investments amounted to \$479,820, compared to \$4,820,033 of cash and cash equivalents and \$3,726,000 of short-term investments at June 30, 2008.

The Company had approximately \$3.5 million of cash and \$1.7 million of short-term investments as of May 6, 2009. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$400,000 excluding capital expenditure requirements.

Assuming operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, protocols are expanded supporting the integrity of the Company's product and sales and marketing expenses continue to increase, management believes the Company will reach breakeven with revenues of approximately \$1.5 million per month. Management's plans to attain breakeven and generate additional cash flows include increasing revenues from both new and existing customers and maintaining cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain its aggressive revenue targets. If the Company does not experience the necessary increases in sales or if it experiences unforeseen manufacturing constraints, the Company may need to obtain additional funding.

In February 2009, a controversial study was released and widely disseminated by the popular press claiming that PSA testing was not as important as previously believed. Heightened PSA levels did not necessarily correlate to a greater incidence of prostate cancer, according to this study. IsoRay has, as have all brachytherapy companies, relied extensively on PSA testing to show the patient that he needs treatment.

Management believes that the results of the study and the popularity of the alternative IMRT procedure, coupled with a very weak economy during the quarter ended March 31, 2009, resulted in fewer procedures than anticipated. Management continues to believe that Mr. Pasqualone's (Vice President of Business Development) credibility in the industry is important to improve sales but believes the macroeconomic factors impacting the industry as a whole continue to make it difficult to reverse negative sales trends.

The Company expects to finance its future 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. If the Company needs to raise additional money to fund its operations, 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 had two loan facilities in place as of March 31, 2009. The first loan is from the Benton-Franklin Economic Development District (BFEDD) in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment due in December 2009. As of March 31, 2009, the principal balance owed was \$124,360. This loan is secured by certain equipment, materials and inventory of the Company, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was originated in June 2006. The loan originally had a total facility of \$1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of \$418,670. The loan bears interest at nine percent and the principal balance owed as of March 31, 2009 was \$235,839. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

The Company has a capital lease for production equipment that expires in April 2009. The lease currently calls for total monthly payments of \$2,286. The total of all capital lease obligations at March 31, 2009 was \$2,248.

Other Commitments and Contingencies

In February 2006, the Company signed a license agreement with International Brachytherapy SA (IBt), a Belgian company, covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using cesium-131. Under the original agreement royalty payments were to be paid on net sales revenue incorporating the technology.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The Company paid license fees of \$275,000 (under the original agreement) and \$225,000 (under the Amendment) during fiscal years 2006 and 2008, respectively. The Amendment eliminates the previously required royalty payments based on net sales revenue, and the parties originally intended to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. Management no longer believes that introducing Cs-131 polymer seeds is a viable strategy due to concerns regarding physician acceptance and the costs to revamp the Company's existing manufacturing

procedures to incorporate this technology. In December 2008, the Company recorded an impairment charge to write down this license based on its current intentions to not utilize this technology.

In November 2008, a subsidiary of the Company entered into a written contract with a contractor based in the Ukraine to formalize a research and development project originally begun over two years ago to develop a proprietary separation process to manufacture enriched barium. There is no assurance that this process can be developed. The contract calls for an initial payment of \$17,800 and a payment of \$56,610 upon completion of a successful demonstration. The Company's initial demonstration has been postponed due to an electrical problem that damaged equipment and due to economic difficulties in the Ukraine that have protracted the contractor's efforts.

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.

New Accounting Standards

In December 2007, FASB issued SFAS No. 141(R), *Business Combinations* ("SFAS 141R"), which replaces SFAS No. 141, *Business Combinations* ("SFAS 141"). SFAS 141R applies to all transactions and other events in which one entity obtains control over one or more other businesses. The standard requires the fair value of the purchase price, including the issuance of equity securities, to be determined on the acquisition date. SFAS 141R requires an acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interests in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in the statement. SFAS 141R requires acquisition costs to be expensed as incurred and restructuring costs to be expensed in periods after the acquisition date. Earn-outs and other forms of contingent consideration are to be recorded at fair value on the acquisition date. Changes in accounting for deferred tax asset valuation allowances and acquired income tax uncertainties after the measurement period will be recognized in earnings rather than as an adjustment to the cost of the acquisition. SFAS 141R generally applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 with early adoption prohibited.

In December 2007, the FASB issued statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). The statement requires noncontrolling interests or minority interests to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. Upon a loss of control, the interest sold, as well as any interest retained, is required to be measured at fair value, with any gain or loss recognized in earnings. Based on SFAS 160, assets and liabilities will not change for subsequent purchase or sales transactions with noncontrolling interests as long as control is maintained. Differences between the fair value of

consideration paid or received and the carrying value of noncontrolling interests are to be recognized as an adjustment to the parent interest's equity. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. Due to the sale of its thirty percent interest in UralDial, LLC, the Company does not believe the implementation of SFAS 160 will have a material effect on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an amendment of FASB No. 133*. This Statement expands the annual and interim disclosure requirements of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, for derivative instruments within the scope of that Statement. The Company does not believe the adoption of SFAS No. 161 will have a material effect on its consolidated financial statements.

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 4T – 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, 2009. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

Changes in Internal Control over Financial Reporting

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

PART II - OTHER INFORMATION

ITEM 1A – RISK FACTORS

There have been no material changes for the risk factors disclosed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended June 30, 2008, except for the addition of the following risk factors:

The risk factor that immediately follows modifies the risk factors entitled "We Rely Heavily On A Limited Number Of Suppliers" and "Future Production Increases Will Depend On Our Ability To

Acquire Larger Quantities Of Cs-131 And Hire More Employees" contained in the Form 10-K for the year ended June 30, 2008.

We Have Entered Into An Agreement With A Single Distributor For Our Cesium-131 From Russia. We previously obtained the majority of our cesium from either the Institute of Nuclear Materials (INM) or the Russian Research Institute of Atomic Reactors (RIAR), both of which are located in Russia. In December 2008, we entered into an agreement with UralDial, LLC to purchase cesium-131 directly from UralDial instead of from INM and RIAR. As a result, we now rely on UralDial to obtain cesium-131 from Russian sources. UralDial has agreed to maintain at least two Russian sources of its cesium-131, and our agreement with UralDial has lower minimum purchase requirements than our prior agreements with INM and RIAR, and these lower minimum purchase requirements are being met at this time. Through the UralDial agreement, we have obtained set pricing for our Russian cesium-131 through the end of 2009. There can be no guarantee that UralDial will always be able to supply us with sufficient cesium-131, which could be due in part to risks associated with foreign operations and beyond our and UralDial's control, and if we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of cesium-131 would be reduced significantly unless we have a source of enriched barium for utilization in domestic reactors.

Our Reduced Stock Price May Adversely Affect Our Liquidity. Our common stock has been trading at less than \$1.00 a share in recent months. 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.

ITEM 4 – SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On February 18, 2009, the Company held its Annual Meeting of Shareholders at which our shareholders elected four Directors and ratified the appointment of our independent registered public accounting firm for the fiscal year ending June 30, 2009.

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

<u>Director</u>	<u>For</u>	<u>Withhold</u>
Dwight Babcock	14,916,234	1,905,529
Robert R. Kauffman	14,901,234	1,920,529
Thomas C. LaVoy	14,916,232	1,905,531
Albert Smith	14,901,234	1,920,529

- (b) *Appointment of our independent registered public accounting firm.* Proposal to ratify the appointment of DeCoria, Maichel & Teague, P.S. as independent registered public accounting firm of the Company for the fiscal year ending June 30, 2009 was approved as follows:

<u>For</u>	<u>Against</u>	<u>Abstain</u>
16,447,339	315,756	58,668

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

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: May 14, 2009

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock

Dwight Babcock, Chief Executive Officer

By /s/ Jonathan R. Hunt

Jonathan R. Hunt, Chief Financial Officer

CERTIFICATION

I, Dwight Babcock, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IsoRay, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2009

/s/ Dwight Babcock
Dwight Babcock
Chief Executive Officer

CERTIFICATION

I, Jonathan R. Hunt, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IsoRay, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2009

/s/ Jonathan R. Hunt
Jonathan R. Hunt
Chief Financial Officer

Section 1350 Certifications

Pursuant to 18 U.S.C. § 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of IsoRay, Inc., a Minnesota corporation (the "Company"), hereby certify that:

To my knowledge, the Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2009 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 14, 2009

/s/ Dwight Babcock

DWIGHT BABCOCK
CHIEF EXECUTIVE OFFICER

Dated: May 14, 2009

/s/ Jonathan R. Hunt

JONATHAN R. HUNT
CHIEF FINANCIAL OFFICER