

IsoRay, Inc.  
Form 10-Q  
November 14, 2008

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

FORM 10-Q

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

For the quarterly period ended September 30, 2008

or

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

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 x

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

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

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<u>Class</u>	<u>Outstanding as of November 3, 2008</u>
Common stock, \$0.001 par value	22,942,088

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**ISORAY, INC.**

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**PART I - FINANCIAL INFORMATION****IsoRay, Inc. and Subsidiaries****Consolidated Balance Sheets**

	<b>September 30, 2008 (Unaudited)</b>	<b>June 30, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,775,691	\$ 4,820,033
Short-term investments	3,566,800	3,726,000
Accounts receivable, net of allowance for doubtful accounts of \$54,588 and \$33,031, respectively	911,275	1,016,495
Inventory	851,051	899,964
Prepaid expenses and other current assets	256,783	267,001
<b>Total current assets</b>	<b>9,361,600</b>	<b>10,729,493</b>
Fixed assets, net of accumulated depreciation and amortization	5,754,259	6,040,641
Deferred financing costs, net of accumulated amortization	57,595	65,221
Licenses, net of accumulated amortization	443,728	455,646
Restricted cash	176,539	175,852
Other assets, net of accumulated amortization	350,549	345,040
<b>Total assets</b>	<b>\$ 16,144,270</b>	<b>\$ 17,811,893</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 791,746	\$ 751,402
Accrued payroll and related taxes	340,132	344,612
Notes payable, due within one year	66,201	64,486
Capital lease obligations, due within one year	14,951	25,560
<b>Total current liabilities</b>	<b>1,213,030</b>	<b>1,186,060</b>
Notes payable, due after one year	328,452	344,898
Asset retirement obligation	517,475	506,005
<b>Total liabilities</b>	<b>2,058,957</b>	<b>2,036,963</b>
Shareholders' equity:		
Preferred stock, \$.001 par value; 6,000,000 shares authorized: Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-

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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		47,573,221		47,464,507
Accumulated deficit		(33,502,519)		(31,708,923)
Total shareholders' equity		14,085,313		15,774,930
Total liabilities and shareholders' equity	\$	16,144,270	\$	17,811,893

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

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

	<b>Three months ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
Product sales	\$ 1,519,582	\$ 1,855,719
Cost of product sales	1,448,436	2,005,502
Gross margin (loss)	71,146	(149,783)
Operating expenses:		
Research and development expenses	218,550	256,370
Sales and marketing expenses	730,774	1,059,816
General and administrative expenses	780,157	902,025
Total operating expenses	1,729,481	2,218,211
Operating loss	(1,658,335)	(2,367,994)
Non-operating income (expense):		
Interest income	44,786	238,696
Loss on impairment of short-term investments	(159,200)	-
Financing and interest expense	(20,847)	(30,103)
Non-operating (expense) income, net	(135,261)	208,593
Net loss	\$ (1,793,596)	\$ (2,159,401)
Basic and diluted loss per share	\$ (0.08)	\$ (0.09)
Weighted average shares used in computing net loss per share:		
Basic and diluted	22,942,088	23,001,041

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

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

	<b>Three months ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,793,596)	\$ (2,159,401)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	303,489	206,937
Amortization of deferred financing costs and other assets	21,493	68,733
Amortization of discount on short-term investments	-	(67,593)
Loss on impairment of short-term investments	159,200	-
Accretion of asset retirement obligation	11,470	2,973
Share-based compensation	108,714	187,607
Changes in operating assets and liabilities:		
Accounts receivable, net	105,220	84,909
Inventory	48,913	(32,842)
Prepaid expenses and other current assets	10,218	(172,093)
Accounts payable and accrued liabilities	40,344	(592,673)
Accrued payroll and related taxes	(4,480)	168,460
Deferred revenue	-	(23,874)
Net cash used by operating activities	(989,015)	(2,328,857)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(17,107)	(2,484,363)
Additions to licenses and other assets	(7,458)	(51,707)
Change in restricted cash	(687)	-
Purchases of short-term investments	-	(5,947,407)
Proceeds from the sale or maturity of short-term investments	-	6,985,410
Net cash used by investing activities	(25,252)	(1,498,067)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Principal payments on notes payable	(14,731)	(13,588)
Principal payments on capital lease obligations	(10,609)	(50,160)
Proceeds from cash sales of common stock, pursuant to exercise of warrants	-	971,100
Proceeds from cash sales of common stock, pursuant to exercise of options	-	11,900
Repurchase of Company common stock	(4,735)	-
Net cash (used) provided by financing activities	(30,075)	919,252
Net decrease in cash and cash equivalents	(1,044,342)	(2,907,672)
Cash and cash equivalents, beginning of period	4,820,033	9,355,730

<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	\$	3,775,691	\$	6,448,058
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.**  
**Notes to the Unaudited Consolidated Financial Statements**  
**For the three-month periods ended September 30, 2008 and 2007**

**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 the Company's short-term securities (auction rate securities or ARS) have failed since February 2008 and no longer have an active market. These short term securities are valued by our broker using various assumptions including current interest rates, credit ratings, the issuer's financial health, etc. These are classified as Level 2.

The fair value hierarchy for our financial assets accounted for at fair value on a recurring basis at September 30, 2008 was:

	Level 1	Level 2	Level 3
Short-term investments	\$ –	\$ 3,566,800	\$ –

### SFAS 159

Effective July 1, 2008, the Company adopted SFAS 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.

### **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 September 30, 2008 and 2007, the calculation of diluted weighted average shares did not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2008 and 2007 were as follows:

	September 30,	
	2008	2007
Preferred stock	59,065	59,065
Common stock warrants	3,245,082	3,350,150
Common stock options	2,469,376	3,320,906
<b>Total potential dilutive securities</b>	<b>5,773,523</b>	<b>6,730,121</b>

### **4. Short-Term Investments**

The Company's short-term investments are classified as available-for-sale and recorded at fair market value. The Company's short-term investments consisted entirely of auction rate securities (ARS) of various student loan portfolios as of September 30, 2008 and June 30, 2008.

Beginning in February 2008, the uncertainties in the credit markets have prevented the Company from liquidating these investments. The securities continue to pay interest according to their stated terms and are all AAA/Aaa rated investments. The Company has recognized the decline in the fair value of these securities (which has been caused by the market uncertainties) as other than temporary and has recorded the impairment loss in the statement of operations.



In August 2008, the Company's broker for its ARS entered into a settlement with various government entities (including the New York Attorney General and the Securities and Exchange Commission) relating to the sale and marketing of ARS. Due to this settlement the Company will receive rights that will become effective in January 2009 which entitle the Company to sell its ARS to the Company's broker at par value. The Company intends to exercise its rights during the third quarter of fiscal year 2009 which should allow the Company to liquidate these securities. However, the ability to exercise these rights is dependent on the broker's financial resources and condition during this exercise period. Due to these uncertainties, the Company has continued to recognize the declines in the fair value of its ARS as other than temporary.

## 5. Inventory

Inventory consisted of the following at September 30, 2008 and June 30, 2008:

	September 30, 2008	June 30, 2008
Raw materials	\$ 687,147	\$ 696,958
Work in process	150,869	191,684
Finished goods	13,035	11,322
	\$ 851,051	\$ 899,964

## 6. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three months ended September 30, 2008 and 2007:

	Three months ended September 30,	
	2008	2007
Cost of product sales	\$ 9,130	\$ 37,003
Research and development	9,921	11,550
Sales and marketing expenses	58,692	59,557
General and administrative expenses	30,971	79,497
Total share-based compensation	\$ 108,714	\$ 187,607

As of September 30, 2008, total unrecognized compensation expense related to stock-based options was \$403,209 and the related weighted-average period over which it is expected to be recognized is approximately 0.70 years.

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

A summary of stock options within the Company's share-based compensation plans as of September 30, 2008 were as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2008	2,469,376	\$ 2.69	7.5	\$ 0.00
Vested and expected to vest at				
September 30, 2008	2,447,722	\$ 2.68	7.5	\$ 0.00
Vested and exercisable at				
September 30, 2008	2,141,002	\$ 2.55	7.4	\$ 0.00

The aggregate intrinsic value of options exercised during the three months ended September 30, 2008 and 2007 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 September 30,	
	2008(a)	2007 (b)
Weighted average fair value of options granted	\$ 0.51	\$ -
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	3.34%	-%
Weighted average life of the option (in years)	5.33	-
Weighted average historical stock price volatility	122.28%	-%
Expected dividend yield	0.00%	-%

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

(b) During the quarter ended September 30, 2007, the Company did not grant any stock options.

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

## 7. Extension of Warrants

On August 20, 2008, the Board of Directors extended the expiration dates of warrants issued pursuant to the Company's private placement memorandums dated October 17, 2005 and February 1, 2006 for an additional one-year period. These warrants originally began expiring in October 2007 but were retroactively extended for a one-year term on January 8, 2008 and extended again on August 20, 2008. Based on this additional extension, the warrants will now

expire between October 2009 and February 2010. No other terms or conditions of the warrants were changed. The change in expiration dates affected outstanding warrants to purchase 2,102,142 shares of common stock. Of these outstanding warrants there were warrants to purchase 12,500 shares held by the Chairman and Interim CEO of the Company.

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The change in expiration date was a modification of the original warrant based on market conditions and was accounted for as a financing transaction similar to an extension of time in the offering of shares in a stock sale. Therefore there was no effect on the statement of operations as the Company had previously determined that under SFAS 133 and EITF 00-19 these warrants were equity instruments rather than derivatives.

## **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.

### License Agreement with IBt

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 Cs-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 intend 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. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

## 9. New Accounting Pronouncements

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*. 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 of 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. The Company is currently evaluating the impact that the implementation of SFAS 160 will have with respect to the Company's interest in UralDial, LLC.

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.



## 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, 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 September 30, 2008, 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. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption.

### **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 September 30, 2008 compared to three months ended September 30, 2007**

**Revenues.** The Company generated revenue of \$1,519,582 during the three months ended September 30, 2008 compared to sales of \$1,855,719 during the three months ended September 30, 2007. The decrease of \$336,137 or 18% is due to decreased sales of the Company's Proxcelan Cs-131 brachytherapy seed. During the three months ended September 30, 2008, the Company sold its Proxcelan seeds to 47 different medical centers as compared to 49 medical centers during the corresponding period of 2007. The Company noted that the doctors at its major accounts took more vacations during the three months ended September 30, 2008 than during the three months ended September 30, 2007 which resulted in decreased orders. Also, the Company's sales force had significant turnover during the three months ended September 30, 2008. The Company did hire replacements for the sales force but the replacements did not start until the end of August and then participated in training which reduced their time in the field during the three months ended September 30, 2008. Also, the Company has noted increased competition from differing treatment modalities including IMRT which it believes has negatively affected revenues.

**Cost of product sales.** Cost of product sales was \$1,448,436 for the three months ended September 30, 2008 compared to cost of product sales of \$2,005,502 during the three months ended September 30, 2007. The decrease of \$557,066 or 28% was mainly due to more efficient production operations as the Company has worked to streamline its manufacturing process during the past six months. The major components of the decrease were materials, wages, benefits and related taxes, preload expenses, and small tools expense. Material costs decreased approximately \$275,000 due to the decreased sales volume, more efficient use of isotope, and a decrease in the overall cost of isotope. Part of the materials cost decrease is also due to an additional \$38,000 of isotope that was ordered in September 2007 to ensure that no orders were missed during the transition from the Company's old production facility to the new facility. Wages, benefits, and related taxes decreased approximately \$167,000 and are directly attributable to a reduced headcount as the Company has worked to more efficiently manage its manufacturing staff. Preload expenses decreased approximately \$107,000 due to decreased sales volumes and more in-house loading. Small tools expense decreased approximately \$69,000 as the prior year quarter contained items that were expensed as part of equipping the new facility that became operational in September 2007. These increases were partially offset by an increase in depreciation of approximately \$87,000 as a result of moving operations into a new production facility and purchasing new equipment.



**Gross margin (loss).** Gross margin was \$71,146 for the three month period ended September 30, 2008 compared to a gross loss of \$149,783 for the three month period ended September 30, 2007. The increase of \$220,929 or 147% was due to reductions in production costs and a more efficient use of manufacturing resources despite the decrease in revenues.

**Research and development.** Research and development expenses for the three month period ended September 30, 2008 were \$218,550 which represents a decrease of \$37,820 or 15% over the research and development expenses of \$256,370 for the corresponding period of 2007. The decrease is mainly due to a decrease in consulting and payroll, benefits and related taxes. Consulting decreased approximately \$40,000 as the Company's project to increase the efficiency of isotope production had lower spending as the consultant prepared for a demonstration. Payroll, benefits and related taxes decreased approximately \$41,000 due to a lower headcount. These decreases were partially offset by an increase in protocol expenses of approximately \$51,000 related to the Company's dual therapy protocol and data collection for other protocols.

**Sales and marketing expenses.** Sales and marketing expenses were \$730,774 for the three months ended September 30, 2008. This represents a decrease of \$329,042 or 31% compared to expenditures in the three months ended September 30, 2007 of \$1,059,816 for sales and marketing. The decrease is mainly due to wages, benefits and related taxes and marketing and advertising. Wages, benefits and related taxes decreased approximately \$241,000 due to a lower headcount and lower base salaries for sales people due to a new compensation plan that was originally introduced in April 2008 and subsequently changed in October 2008. Marketing and advertising expenses decreased approximately \$99,000 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.

**General and administrative expenses.** General and administrative expenses for the three months ended September 30, 2008 were \$780,157 compared to general and administrative expenses of \$902,025 for the corresponding period of 2007. The decrease of \$121,868 or 14% is primarily due to decreases in wages, benefits and related taxes, public company expenses, and share-based compensation partially offset by an increase in consulting expenses. Wages, benefits and related taxes decreased approximately \$66,000 mainly due to the resignation of the Company's CEO in February 2008. Public company expenses decreased approximately \$54,000 due to reduced investor relations activities partially offset by higher board compensation. Share-based compensation decreased approximately \$49,000 due to reduced option awards and due to the forfeiture of unvested options by the Company's former CEO. Consulting expenses increased approximately \$47,000 due to the Company's ISO 13458 audit that was conducted in July 2008 and compensation paid to the Company's interim CEO.

**Operating loss.** The Company continues to focus its resources on sales and retaining the administrative infrastructure to increase the level of demand for the Company's product. These objectives and resulting costs have resulted in the Company not being profitable and generating operating losses since its inception. In the three months ended September 30, 2008, the Company had an operating loss of \$1,658,335 which is a decrease of \$709,659 or 30% over the operating loss of \$2,367,994 for the three months ended September 30, 2007. The three months ended September 30, 2008 were negatively impacted by vacations taken by some of the Company's larger accounts and by turnover in our sales force as discussed above.

**Interest income.** Interest income was \$44,786 for the three months ended September 30, 2008. This represents a decrease of \$193,910 or 81% compared to interest income of \$238,696 for the three months ended September 30, 2007. The decrease is due to the Company's lower short-term investment balances and lower interest rates during the quarter ended September 30, 2008 as compared to the quarter ended September 30, 2007. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

**Loss on short-term investments.** The loss of \$159,200 for the quarter ended September 30, 2008 is due to uncertainties in the credit markets that have affected the liquidity of the Company's auction rate securities. The loss represents the amount to write-down these securities to their estimated fair market value. The Company's broker has entered into a settlement agreement that will grant the Company rights to redeem its auction rate securities at par value beginning in January 2009 and the Company intends to exercise these rights once they become effective. However, it cannot be certain that the broker's financial resources and condition will allow it to honor these rights. Therefore, the Company has recognized these losses as other than temporary and recorded them in the statement of operations rather than in other comprehensive income.

**Financing and interest expense.** Financing and interest expense for the three months ended September 30, 2008 was \$20,847 or a decrease of \$9,256 or 31% from financing and interest expense of \$30,103 for the corresponding period in 2007. Interest expense was approximately \$13,000 and \$22,000 for the three months ended September 30, 2008 and 2007, respectively. The remaining balance of financing and interest expense represents the amortization of deferred financing costs.

**Liquidity and capital resources.** The Company has historically financed its operations through cash investments from shareholders. During the quarter ended September 30, 2008, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

*Cash flows from operating activities*

Cash used in operating activities was approximately \$1.0 million for the three months ended September 30, 2008 compared to approximately \$2.3 million for the three months ended September 30, 2007. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities.

*Cash flows from investing activities*

Cash used in investing activities was approximately \$25,000 and \$1.5 million for the three months ended September 30, 2008 and 2007, respectively. Cash expenditures for fixed assets were approximately \$17,000 and \$2.5 million during the three months ended September 30, 2008 and 2007, respectively. The expenditures for fixed assets during the three months ended September 30, 2007 were related to the construction of the Company's new production facility.

*Cash flows from financing activities*

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

*Projected 2008 Liquidity and Capital Resources*

At September 30, 2008, cash and cash equivalents amounted to \$3,775,691 and short-term investments amounted to \$3,566,800 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 \$3.4 million of cash and cash equivalents and \$3.6 million of short-term investments as of November 7, 2008. 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.

The Company had revised its sales force compensation in April 2008 with a minor revision again in July 2008. The April and July 2008 revisions were done to deemphasize base salaries and increase commissions in the hope of reinvigorating the sales force and increasing sales. In October 2008, the Company further revised its sales force compensation by increasing base salaries up to a level commensurate with others in the industry. Management has proactively discussed these changes with its sales force to ensure that its base salary is now viewed as competitive but that its commission structure continues to provide the incentives necessary to reward good performance. Based on these discussions, the sales force appears motivated by this new compensation plan and management anticipates having lower turnover while preserving motivation in the sales team. The Company had a moderate increase in sales from September 2008 to October 2008 and management will continue to monitor the sales force to further implement the new compensation structure.

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 has two loan facilities in place as of September 30, 2008. 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. As of September 30, 2008, the principal balance owed was \$140,413. This loan is secured by certain equipment, materials and inventory of the Company, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was

originated in June 2006. The loan originally had a total facility of \$1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of \$418,670. The loan bears interest at nine percent and the principal balance owed as of September 30, 2008 was \$254,240. 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 September 30, 2008 was \$14,951.

*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 Cs-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 intend 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. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

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 scheduled for January 2009. The Company's demonstration was originally planned for October 2008 but was postponed until January 2009 due to technical difficulties encountered by the contractor.

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 of 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. The Company is currently evaluating the impact that the implementation of SFAS 160 will have with respect to the Company's interest in UralDial, LLC.

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 September 30, 2008. 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 other than as follows:

*Liquidation of Auction Rate Securities.* Although the broker which sold the Company auction rate securities has granted the Company the right to liquidate them during the fiscal third quarter ending March 31, 2009, this liquidation right is not secured by any assets of the broker. This liquidation right has been granted to many other companies which hold auction rate securities as well. There is no assurance funds will be available to pay the Company when liquidation occurs or the amount of proceeds which will ultimately be available.

### **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: November 13, 2008

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock  
Dwight Babcock, Interim Chief Executive  
Officer

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