

IsoRay, Inc.
Form 10-Q
November 09, 2007

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 September 30, 2007

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 has (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐

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 November 3, 2007
23,090,200

ISORAY, INC.

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PART I – FINANCIAL INFORMATION**IsoRay, Inc. and Subsidiary
Consolidated Balance Sheets**

	September 30, 2007 (Unaudited)	June 30, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,448,058	\$ 9,355,730
Short-term investments	8,972,430	9,942,840
Accounts receivable, net of allowance for doubtful accounts of \$69,936 and \$99,789, respectively	1,008,016	1,092,925
Inventory	913,676	880,834
Prepaid expenses	630,216	458,123
Total current assets	17,972,396	21,730,452
Fixed assets, net of accumulated depreciation		
Deferred financing costs, net of accumulated amortization	6,416,073	3,665,551
Licenses, net of accumulated amortization	88,099	95,725
Other assets, net of accumulated amortization	254,375	262,074
Total assets	320,659	322,360
	\$ 25,051,602	\$ 26,076,162
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,352,991	\$ 1,946,042
Accrued payroll and related taxes	627,528	459,068
Accrued interest payable	2,316	1,938
Deferred revenue	-	23,874
Notes payable, due within one year	46,130	49,212
Capital lease obligations, due within one year	155,271	194,855
Asset retirement obligation, current portion	134,115	131,142
Total current liabilities	2,318,351	2,806,131
Notes payable, due after one year		
Capital lease obligations, due after one year	517,740	528,246
Asset retirement obligation	14,984	25,560
Total liabilities	473,096	-
Commitments and contingencies (see Note 8)		
Shareholders' equity:		
Preferred stock, \$.001 par value; 6,000,000 shares authorized:		

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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; 23,033,324 and 22,789,324 shares issued and outstanding	23,033	22,789
Additional paid-in capital	47,015,156	45,844,793
Accumulated deficit	(25,310,817)	(23,151,416)
Total shareholders' equity	21,727,431	22,716,225
Total liabilities and shareholders' equity	\$ 25,051,602	\$ 26,076,162

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

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

	Three months ended September 30,	
	2007	2006
Product sales	\$ 1,855,719	\$ 1,025,444
Cost of product sales	2,005,502	1,288,145
Gross loss	(149,783)	(262,701)
Operating expenses:		
Research and development	256,370	245,598
Sales and marketing expenses	1,059,816	672,930
General and administrative expenses	902,025	1,733,132
Total operating expenses	2,218,211	2,651,660
Operating loss	(2,367,994)	(2,914,361)
Non-operating income (expense):		
Interest income	238,696	40,183
Financing expense	(30,103)	(53,257)
Non-operating income (expense), net	208,593	(13,074)
Net loss	\$ (2,159,401)	\$ (2,927,435)
Basic and diluted loss per share	\$ (0.09)	\$ (0.19)
Weighted average shares used in computing net loss per share:		
Basic and diluted	23,001,041	15,300,747

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

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

	Three months ended September 30,	
	2007	2006
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (2,159,401)	\$ (2,927,435)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	206,937	89,426
Amortization of deferred financing costs and other assets	68,733	39,773
Amortization of discount on short-term investments	(67,593)	-
Accretion of asset retirement obligation	2,973	1,528
Noncash share-based compensation	187,607	781,443
Changes in operating assets and liabilities:		
Accounts receivable, net	84,909	(55,808)
Inventory	(32,842)	(56,407)
Prepaid expenses	(172,093)	(32,225)
Accounts payable and accrued expenses	(593,051)	69,766
Accrued payroll and related taxes	168,460	92,182
Accrued interest payable	378	1,713
Deferred revenue	(23,874)	-
Net cash used by operating activities	(2,328,857)	(1,996,044)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(2,484,363)	(55,390)
Additions to licenses and other assets	(51,707)	(21,256)
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	(1,498,067)	(76,646)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(13,588)	(17,269)
Principal payments on capital lease obligations	(50,160)	(51,061)
Proceeds from cash sales of common shares pursuant to private placement, net of offering costs	-	4,702,931
Proceeds from cash sales of preferred stock, pursuant to exercise of warrants	-	8,709
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	382,485
Net cash provided by financing activities	919,252	5,025,795
Net (decrease) increase in cash and cash equivalents	(2,907,672)	2,953,105

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Cash and cash equivalents, beginning of period	9,355,730	2,207,452
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 6,448,058	\$ 5,160,557
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, 2007 and 2006

1. Basis of Presentation

The accompanying consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiary (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-KSB for the fiscal year ended June 30, 2007. 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-KSB for the fiscal year ended June 30, 2007.

2. Accounting for Uncertainty in Income Taxes

On July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48 (FIN No. 48) *Accounting for Uncertainty in Income Taxes*. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109 "Accounting for Income Taxes," prescribing a recognition threshold and measurement attribute for the recognition and measurement of a tax position taken or expected to be taken in a tax return. In the course of its assessment, management has determined that the Company, its subsidiary, and its predecessors is subject to examination of its income tax filings in the United States and state jurisdictions for the 2003 through 2006 tax years. In the event that the Company is assessed penalties and or interest; penalties will be charged to other operating expense and interest will be charged to interest expense.

The Company adopted FIN No. 48 using the modified prospective transition method, which requires the application of the accounting standard as of July 1, 2007. There was no impact on the financial statements as of and for the three months ended September 30, 2007 as a result of the adoption of FIN No. 48. In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of FIN No. 48.

3. Loss per Share

The Company accounts for its income (loss) per common share according to Statement of Financial Accounting Standard (SFAS) No. 128, *Earnings Per Share*. Under the provisions of SFAS No. 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 to purchase the Company's common stock and common stock issuable upon the conversion of notes payable, are excluded from the calculations when their effect is antidilutive. At September 30, 2007 and 2006, the calculation of diluted weighted average shares does not include preferred stock, options, or warrants that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of September 30, 2007 and 2006 are as follows:

	September 30, 2007	September 30, 2006
Preferred stock	59,065	91,928
Preferred stock warrants	—	173,292
Common stock warrants	3,350,150	4,768,563
Common stock options	3,320,906	3,436,176
Convertible debentures	—	109,639
Total potential dilutive securities	6,730,121	8,579,598

4. Short-Term Investments

The Company short-term investments are classified as available-for-sale and recorded at fair market value. As of September 30, 2007 and June 30, 2007, the amortized cost of the Company's short-term investments equaled their fair market value. Accordingly, there were no unrealized gains and losses as of September 30, 2007 or June 30, 2007.

The Company's short-term investments consisted of the following at September 30, 2007 and June 30, 2007:

	September 30, 2007	June 30, 2007
Municipal debt securities	\$ 4,000,000	\$ 3,000,000
Corporate debt securities	4,972,430	6,942,840
	\$ 8,972,430	\$ 9,942,840

5. Inventory

Inventory consists of the following at September 30, 2007 and June 30, 2007:

	September 30, 2007	June 30, 2007
Raw materials	\$ 734,249	\$ 682,327
Work in process	147,637	120,242
Finished goods	31,790	78,265
	\$ 913,676	\$ 880,834

6. Asset Retirement Obligations

SFAS No. 143, *Asset Retirement Obligations*, establishes standards for the recognition, measurement and disclosure of legal obligations associated with the costs to retire long-lived assets. Accordingly, under SFAS No. 143, the fair value of the future retirement costs of the Company's leased assets are recorded as a liability on a discounted basis when they are incurred and an equivalent amount is capitalized to property and equipment. The initial recorded obligation, which was discounted using the Company's credit-adjusted risk-free rate, is reviewed periodically to reflect the passage of time and changes in the estimated future costs underlying the obligation. The Company amortizes the initial amount capitalized to property and equipment and recognizes accretion expense in connection with the discounted liability over the estimated remaining useful life of the leased assets.

In fiscal year 2006, the Company established an initial asset retirement obligation of \$63,040 which represented the discounted cost of cleanup that the Company anticipated it would have to incur at the end of its equipment and property leases in its old production facility. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. The Company anticipates spending most of the amounts represented by this accrual in fiscal year 2008.

In September 2007, a new asset retirement obligation of \$473,096 was established representing the discounted cost of the Company's obligations to remove any residual radioactive materials and any unwanted leasehold improvements at the end of the lease term at its new production facility. The estimate was developed by qualified production personnel and the general contractor of the new facility.

7. Share-Based Compensation

Effective July 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment*, using the modified prospective method. The following table presents the share-based compensation expense recognized in accordance with SFAS No. 123R during the three months ended September 30, 2007 and 2006:

	Three months ended September 30,	
	2007	2006
Cost of product sales	\$ 37,003	\$ 50,833
Research and development	11,550	11,835
Sales and marketing expenses	59,557	46,781
General and administrative expenses	79,497	671,994
Total share-based compensation	\$ 187,607	\$ 781,443

As of September 30, 2007, total unrecognized compensation expense related to stock-based options was \$1,470,023 and the related weighted-average period over which it is expected to be recognized is approximately 1.13 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 option activity within the Company's share-based compensation plans for the three months ended September 30, 2007 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at September 30, 2007	3,320,906	\$ 2.73	8.29	\$ 3,600,466
Vested and expected to vest at September 30, 2007	3,274,567	\$ 2.45	8.29	\$ 3,596,459
Vested and exercisable at September 30, 2007	2,438,817	\$ 2.18	8.01	\$ 3,502,713

The aggregate intrinsic value of options exercised during the three months ended September 30, 2007 and 2006 was \$25,300 and \$702,763, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

During the quarter ended September 30, 2007, the Company did not grant any stock options. 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,	
	2007	2006
Weighted average fair value of options granted	\$ —	\$ 2.10
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	—%	4.90%
Weighted average life of the option (in years)	—	5.51
Weighted average historical stock price volatility	—%	75.00%
Expected dividend yield	—%	0.00%

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. Because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee 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 lives of options and the stock price volatility are based on historical data of the Company.

8. Commitments and Contingencies

Patent and Know-How Royalty License Agreement

The Company is the holder of an exclusive license to use certain "know-how" developed by one of the founders of a predecessor to the Company and licensed to the Company by the Lawrence Family Trust, a Company shareholder. The terms of this license agreement require the payment of a royalty based on the Net Factory Sales Price, as defined in the agreement, of licensed product sales. Because the licensor's patent application was ultimately abandoned, only a 1% "know-how" royalty based on Net Factory Sales Price, as defined in the agreement, remains applicable. To date, management believes that there have been no product sales incorporating the "know-how" and that 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.

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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 and no settlement was reached with the Lawrence Family Trust. The parties have agreed to extend negotiations of a mutually agreeable settlement through December 1, 2007. If no settlement is reached, the parties may demand binding arbitration.

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. The Company paid license fees of \$275,000 during 2006 and another payment of \$225,000 was to be made in August 2006 pursuant to the license agreement. Royalty payments based on net sales revenue incorporating the technology are also required, with minimum quarterly royalties ranging from \$100,000 to \$200,000 and minimum annual royalties ranging from \$400,000 to \$800,000 over the term of the agreement.

On October 12, 2007, the Company entered into an amendment to the original license agreement as part of the global strategic alliance with IBt and paid the remaining \$225,000 license fee to IBt (see Note 9).

9. Subsequent Events

Perma-Fix Lease

On October 10, 2007, the Company executed a Lease Agreement with Perma-Fix Northwest Richland, Inc. (Perma-Fix). The Lease Agreement has an effective date of September 1, 2007, and provides for the continuation of the Company's lease of its PIRL facility located at 2025 Battelle Boulevard, Richland, Washington. The Company previously leased this facility from Nuvotec USA, Inc. under a Lease Agreement dated February 9, 2005, but Nuvotec USA, Inc. subsequently sold the facility to Perma-Fix. The new lease term is through January 31, 2008, with early termination permitted upon 45 days prior written notice. Monthly rent payments are \$5,000 and increase to \$50,000 per month if the Company has not vacated the premises by January 31, 2008, with an additional one-time payment due of \$100,000 if the Company continues to occupy the premises beyond February 1, 2008. The Company has already moved its production operations to its new facility at the Applied Process Engineering Laboratory, and is in the process of completing decommissioning work to vacate the PIRL facility, which management anticipates will occur by the end of December 2007.

Amended License Agreement with IBt

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The original License Agreement provided the Company with access to IBt’s proprietary ink jet technology and polymer based seed encapsulation technology for use in brachytherapy procedures using Cesium-131 in the United States for a fifteen year term.

The Company already paid a total of \$275,000 in license fees during fiscal year 2006. Another payment of \$225,000 was made on October 12, 2007 pursuant to the Amendment. 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 from IBt in the future at IBt's cost plus a to-be-determined profit percentage, although no agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

HAEIFC Loan Amendment

On October 30, 2007 the Company was notified by the Hanford Area Economic Investment Fund Committee (HAEIFC) that it had withdrawn the commitment of the Company's remaining undisbursed loan funds as of September 24, 2007. With the success of its capital raise completed in March 2007, management had no plans to use the undisbursed funds at an interest rate of 9% per annum.

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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 16 below and in the “Risk Factors” section of our Form 10-KSB for the fiscal year ended June 30, 2007 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-KSB as filed with the Securities and Exchange Commission on September 28, 2007 are those that depend most heavily on these judgments and estimates. As of September 30, 2007, there have been no material changes to any of the critical accounting policies contained therein.

Results of Operations

Three months ended September 30, 2007 compared to three months ended September 30, 2006

Revenues. The Company generated revenue of \$1,855,719 during the three months ended September 30, 2007 compared to sales of \$1,025,444 during the three months ended September 30, 2006. The increase of \$830,275 or 81% is due to increased sales of the Company's Proxcelan Cs-131 brachytherapy seed. During the three months ended September 30, 2007, the Company sold its Proxcelan seeds to 49 different medical centers as compared to 23 medical centers during the corresponding period of 2006.

Cost of product sales. Cost of product sales was \$2,005,502 for the three months ended September 30, 2007 compared to cost of product sales of \$1,288,145 during the three months ended September 30, 2006. The increase of \$717,357 or 56% was mainly due to higher production levels during the three months ended September 30, 2007 which were related to the increase in sales volume over the corresponding period from 2006 and increased isotope expenditures and small tools expense related to the start-up of the new facility. The major components of the increase attributable to higher production levels were wages, benefits, and related taxes, materials, depreciation, preload expenses, and occupancy costs. Wages, benefits, and related taxes increased approximately \$131,000 due to the hiring of additional production employees to support the higher production levels. Material costs increased approximately \$281,000 due to increased sales volume. Depreciation and amortization expense increased approximately \$118,000 due to the additional equipment placed in service in fiscal year 2007 and 2008. Preload expenses increased approximately \$88,000 due to higher sales volumes. Occupancy costs increased approximately \$42,000 due to higher rent expense on the Company's new, larger production facility and the continued rental payments on our old production facility. These increases were partially offset by a decrease in consulting expenses of approximately \$64,000 as the quarter ended September 30, 2006 contained consulting projects that were completed during fiscal year 2007 and less consulting projects were undertaken in the quarter ended September 30, 2007 due to the Company's focus on opening the new facility.

In addition to the increases noted above, the Company also had the following increases in cost of product sales expenditures that are directly related to the new facility that was opened in September 2007. The Company ordered isotope for the old facility to ensure adequate supply based on sales forecasts while it prepared to transition into the new production facility. To ensure a smooth transition with no missed order shipments, the Company ordered an additional \$38,000 of isotope in September 2007 that was not utilized as the removal and transportation of the isotope from the old facility to the new facility presented logistical challenges that made it cost prohibitive. As part of opening the new facility, the Company incurred approximately \$20,000 of wages and related taxes for personnel to perform equipment set-up and validation. The Company also expensed approximately \$82,000 of production materials and small tools for the new facility, none of which individually exceeded the \$2,500 threshold the Company uses in determining whether to capitalize production equipment.

Gross loss. Gross loss was \$149,783 for the three month period ended September 30, 2007 compared to a gross loss of \$262,701 for the three month period ended September 30, 2006. The decrease of \$112,918 or 43% was due to higher revenues offsetting fixed production costs partially offset by start-up costs of the new production facility.

Research and development. Research and development expenses for the three month period ended September 30, 2007 were \$256,370 which represents an increase of \$10,772 or 4% over the research and development expenses of \$245,598 for the corresponding period of 2006. The slight increase is due to wages, benefits, and related taxes increasing approximately \$13,000 due to higher salaries, consulting expenses increasing approximately \$9,000 as the Company continues its project to increase the efficiency of isotope production, legal fees increasing approximately \$17,000 relating to patents and trademarks, and other miscellaneous expenses increasing approximately \$15,000. These increases were partially offset by a decrease of approximately \$43,000 in clinical study protocol expenses as our mono therapy protocol is fully enrolled and our dual therapy protocol is just beginning to enroll patients.

Sales and marketing expenses. Sales and marketing expenses were \$1,059,816 for the three months ended September 30, 2007. This represents an increase of \$386,886 or 57% compared to expenditures in the three months ended September 30, 2006 of \$672,930 for sales and marketing. Wages, benefits, payroll taxes, travel and office and other support expenses relating to the Company's sales, marketing, and customer service personnel increased approximately \$304,000 due to the hiring of additional sales and marketing personnel. From September 30, 2006 to September 30, 2007, the Company increased its sales staff by eight persons. Marketing and advertising increased approximately \$40,000 as the Company's brochures, literature, and other marketing materials have been updated to reflect new clinical study protocol results and conclusions and the new Proxcelan brand name. Consulting expenses also increased about \$48,000 relating to consultants hired to assist with protocols, healthcare reimbursement, and business development.

General and administrative expenses. General and administrative expenses for the three months ended September 30, 2007 were \$902,025 compared to general and administrative expenses of \$1,733,132 for the corresponding period of 2006. The decrease of \$831,107 or 48% is primarily due to a decrease in share-based compensation expense of approximately \$592,000 and a one-time severance accrual of \$288,000 in the corresponding period of 2006. These were partially offset by an increase in investor relations and other public company expenses of approximately \$77,000 due to higher cash payments to directors and increased investor relations activities.

Operating loss. Due to the Company's rapid structural growth and related need to capture additional market share, through the hiring of additional sales and marketing personnel, product revenues not covering production costs, and significant research and development expenditures, the Company has not been profitable, and has generated operating losses since its inception. In the three months ended September 30, 2007, the Company had an operating loss of \$2,367,994 which is a decrease of \$546,367 or 19% over the operating loss of \$2,914,361 for the three months ended September 30, 2006.

Interest income. Interest income was \$238,696 for the three months ended September 30, 2007. This represents an increase of \$198,513 or 494% compared to interest income of \$40,183 for the three months ended September 30, 2006. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

Financing expense. Financing expense for the three months ended September 30, 2007 was \$30,103 or a decrease of \$23,154 or 43% from financing expense of \$53,257 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$22,000 and \$31,000 for the three months ended September 30, 2007 and 2006, respectively. The decrease in interest expense is due to the maturity and payment of the convertible debentures during the fiscal year ended June 30, 2007. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the final amortization of the deferred financing costs relating to the convertible debentures and the write-off in fiscal year 2007 of the deferred financing costs relating to the Columbia River line of credit.

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the quarter ended September 30, 2007, the Company's primary source of cash was the exercise of common stock warrants and options for \$983,000 and the Company primarily used existing cash reserves to fund its operations and capital expenditures.

Cash flows from operating activities

Cash used in operating activities was \$2.3 million for the three months ended September 30, 2007 compared to \$2.0 million for the three months ended September 30, 2006. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities. The increase in cash usage is mainly due to an increase in operating assets and liabilities related to a large decrease in accounts payable and accrued expenses. This is due to a payment in July 2007 for enriched barium that was included in the Company's June 2007 accounts payable balance.

Cash flows from investing activities

Cash used in investing activities was approximately \$1.5 million and \$77,000 for the three months ended September 30, 2007 and 2006, respectively. Cash expenditures for fixed assets were approximately \$2.5 million and \$55,000 during the three months ended September 30, 2007 and 2006, respectively. The large increase is mainly due to construction of our new facility and equipment purchases for the new facility. This was partially offset by net proceeds of approximately \$1.0 million from the sale of short-term securities.

Cash flows from financing activities

During the three months ended September 30, 2007, the Company issued 244,000 shares of common stock pursuant to the exercise of common stock options and warrants. The Company received \$983,000 in cash pursuant to these exercises.

Projected 2008 Liquidity and Capital Resources

At September 30, 2007, cash and cash equivalents amounted to \$6,448,058 and short-term investments amounted to \$8,972,430 compared to \$9,355,730 of cash and cash equivalents and \$9,942,840 of short-term investments at June 30, 2007.

The Company had approximately \$4.8 million of cash and \$9.0 million of short-term investments as of November 2, 2007. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$600,000 excluding capital expenditure requirements. The Company's cash operating expenditures were higher than this level during the quarter ended September 30, 2007 but this was mainly due to the additional expenditures necessary to make the new facility operational while maintaining operations at the previous facility.

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 \$2 million per month. Management's plans to attain breakeven and generate additional cash flows include increasing revenues from both new and existing customers, developing additional therapies, 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 expects to finance its future cash needs through the sale of equity securities, solicitation to warrant holders to exercise their warrants, 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, 2007. 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, 2007, the principal balance owed was \$179,412. 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 (see Note 9). The loan bears interest at nine percent and the principal balance owed as of September 30, 2007 was \$384,458. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

The Company has certain capital leases for production and office equipment that expire at various times from March 2008 to April 2009. These leases currently call for total monthly payments of \$19,361. The total of all capital lease obligations at September 30, 2007 was \$170,255.

Other Commitments and Contingencies

In February 2006, the Company signed a License Agreement with International Brachytherapy s.a. (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 (Cs-131). The Company paid license fees of \$275,000 during 2006 and another payment of \$225,000 was to be made in August 2006 pursuant to the License Agreement. Royalty payments based on net sales revenue are also required, with minimum quarterly royalties ranging from \$100,000 to \$200,000 and minimum annual royalties ranging from \$400,000 to \$800,000 over the term of the License Agreement.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The License Agreement provided the Company with access to IBt's proprietary polymer based seed encapsulation technology for use in brachytherapy procedures using Cesium-131 in the United States for a fifteen year term. A payment of \$225,000 was made on October 12, 2007 pursuant to the Amendment. As the parties agreed that the ink jet technology was not viable for Cesium-131 seeds, the Amendment eliminated 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 from IBt in the future at IBt's cost plus a to-be-determined profit percentage, although no agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

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 will incur certain decommissioning expenses as part of vacating its old production facility. Therefore, the Company established in fiscal year 2006 an initial asset retirement obligation of \$63,040 which represented the discounted cost of cleanup that the Company anticipated it will have to incur at the end of its equipment and property leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. The Company anticipates spending most of the amounts represented by this accrual in fiscal year 2008. In addition, another asset retirement obligation of \$473,096 was established in the first quarter of fiscal year 2008 representing obligations at its new production facility. This new asset retirement obligation is for obligations to remove any residual radioactive materials and to remove any unwanted leasehold improvements

at the end of the lease term.

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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 September 2006, the FASB issued statement No. 157, *Fair Value Measurements*, (SFAS 157). 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. SFAS 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. 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. The Company does not believe the adoption of SFAS 157 will have a material effect on its consolidated financial statements.

In February 2007, the FASB issued statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). 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 statement is effective for fiscal years beginning after November 15, 2007. The Company does not believe the adoption of SFAS 159 will have a material effect on its consolidated financial statements.

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As the Company has not yet filed an annual report including Regulation S-K Item 305 information, it is not required to provide Part I, Item 3 disclosure in this Quarterly Report.

ITEM 4 – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2007. 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-KSB for the year ended June 30, 2007.

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

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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 9, 2007

ISORAY, INC., a Minnesota corporation

By /s/ Roger E. Girard
 Roger E. Girard, Chief
 Executive Officer

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