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IsoRay, Inc.
Form 10-Q
February 17, 2009

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 December 31, 2008

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 Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

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

Class
Common stock, \$0.001 par value

Outstanding as of February 6, 2008
22,942,088

ISORAY, INC.

Table of Contents

| | | |
|----------------|---|----|
| PART I | FINANCIAL INFORMATION | |
| Item 1 | Consolidated Unaudited Financial Statements | 1 |
| | Consolidated Balance Sheets | 1 |
| | Consolidated Statements of Operations | 2 |
| | Consolidated Statements of Cash Flows | 3 |
| | Notes to Consolidated Unaudited Financial Statements | 4 |
| Item 2 | Management’s Discussion and Analysis of Financial Condition and Results of Operations | 11 |
| Item 3 | Quantitative and Qualitative Disclosures About Market Risk | 20 |
| Item 4T | Controls and Procedures | 21 |
| PART II | OTHER INFORMATION | |
| Item 1A | Risk Factors | 21 |
| Item 6 | Exhibits | 22 |
| Signatures | | 23 |

PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets

| | December 31, 2008 (Unaudited) | June 30, 2008 |
|--|-------------------------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 2,483,876 | \$ 4,820,033 |
| Short-term investments | 4,000,000 | 3,726,000 |
| Accounts receivable, net of allowance for doubtful accounts of \$79,110 and \$33,031, respectively | 830,108 | 1,016,495 |
| Inventory | 888,270 | 899,964 |
| Prepaid expenses and other current assets | 215,558 | 267,001 |
| Total current assets | 8,417,812 | 10,729,493 |
| Fixed assets, net of accumulated depreciation and amortization | 5,468,386 | 6,040,641 |
| Deferred financing costs, net of accumulated amortization | 48,336 | 65,221 |
| Licenses, net of accumulated amortization | 6,376 | 455,646 |
| Restricted cash | 177,438 | 175,852 |
| Other assets, net of accumulated amortization | 349,075 | 345,040 |
| Total assets | \$ 14,467,423 | \$ 17,811,893 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | \$ 735,873 | \$ 751,402 |
| Accrued payroll and related taxes | 269,011 | 344,612 |
| Notes payable, due within one year | 176,153 | 64,486 |
| Capital lease obligations, due within one year | 10,777 | 25,560 |
| Total current liabilities | 1,191,814 | 1,186,060 |
| Notes payable, due after one year | 203,129 | 344,898 |
| Asset retirement obligation | 529,206 | 506,005 |
| Total liabilities | 1,924,149 | 2,036,963 |
| Shareholders' equity: | | |
| Preferred stock, \$.001 par value; 6,000,000 shares authorized: | | |
| Series A: 1,000,000 shares allocated; no shares issued and outstanding | - | - |
| Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding | 59 | 59 |
| Common stock, \$.001 par value; 194,000,000 shares authorized; 22,942,088 shares issued and outstanding | 22,942 | 22,942 |

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| | | |
|--|---------------|---------------|
| Treasury stock, at cost, 13,200 and 5,000 shares | (8,390) | (3,655) |
| Additional paid-in capital | 47,664,289 | 47,464,507 |
| Accumulated deficit | (35,135,626) | (31,708,923) |
| Total shareholders' equity | 12,543,274 | 15,774,930 |
| Total liabilities and shareholders' equity | \$ 14,467,423 | \$ 17,811,893 |

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

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

| | Three months ended December 31, | | Six months ended December 31, | |
|---|---------------------------------|----------------|-------------------------------|----------------|
| | 2008 | 2007 | 2008 | 2007 |
| Product sales | \$ 1,326,703 | \$ 1,758,344 | \$ 2,846,285 | \$ 3,614,063 |
| Cost of product sales | 1,724,225 | 2,241,795 | 3,172,661 | 4,247,297 |
| Gross loss | (397,522) | (483,451) | (326,376) | (633,234) |
| Operating expenses: | | | | |
| Research and development expenses | 306,056 | 395,545 | 524,606 | 651,915 |
| Sales and marketing expenses | 620,700 | 1,142,827 | 1,351,474 | 2,202,643 |
| General and administrative expenses | 758,822 | 919,164 | 1,538,979 | 1,821,189 |
| Total operating expenses | 1,685,578 | 2,457,536 | 3,415,059 | 4,675,747 |
| Operating loss | (2,083,100) | (2,940,987) | (3,741,435) | (5,308,981) |
| Non-operating income (expense): | | | | |
| Interest income | 37,562 | 179,855 | 82,348 | 418,551 |
| Gain on fair value of short-term investments | 433,200 | - | 274,000 | - |
| Financing and interest expense | (20,769) | (25,211) | (41,616) | (55,314) |
| Non-operating income, net | 449,993 | 154,644 | 314,732 | 363,237 |
| Net loss | \$ (1,633,107) | \$ (2,786,343) | \$ (3,426,703) | \$ (4,945,744) |
| Basic and diluted loss per share | \$ (0.07) | \$ (0.12) | \$ (0.15) | \$ (0.21) |
| Weighted average shares used in computing net loss per share: | | | | |
| Basic and diluted | 22,942,088 | 23,072,272 | 22,942,088 | 23,036,657 |

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

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

| | Six months ended December 31, | |
|---|-------------------------------|----------------|
| | 2008 | 2007 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (3,426,703) | \$ (4,945,744) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | |
| Depreciation and amortization of fixed assets | 604,651 | 586,866 |
| Impairment of IBt license (see Note 4) | 425,434 | - |
| Amortization of deferred financing costs and other assets | 44,144 | 90,541 |
| Amortization of discount on short-term investments | - | (119,149) |
| Gain on fair value of short-term investments | (274,000) | - |
| Settlement of asset retirement obligation | - | (135,120) |
| Accretion of asset retirement obligation | 23,201 | 14,703 |
| Share-based compensation | 199,782 | 354,613 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 186,387 | 263,007 |
| Inventory | 11,694 | (114,399) |
| Prepaid expenses and other current assets | 51,443 | 15,130 |
| Accounts payable and accrued expenses | (15,529) | (763,203) |
| Accrued payroll and related taxes | (75,601) | 49,892 |
| Deferred revenue | - | (23,874) |
| Net cash used by operating activities | (2,245,097) | (4,726,737) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of fixed assets | (32,396) | (2,969,764) |
| Additions to licenses and other assets | (7,458) | (286,733) |
| Change in restricted cash | (1,586) | (172,500) |
| Purchases of short-term investments | - | (10,593,828) |
| Proceeds from the sale or maturity of short-term investments | - | 11,975,680 |
| Net cash used by investing activities | (41,440) | (2,047,145) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Principal payments on notes payable | (30,102) | (25,825) |
| Principal payments on capital lease obligations | (14,783) | (102,157) |
| Proceeds from cash sales of common stock, pursuant to exercise of warrants | - | 1,010,913 |
| Proceeds from cash sales of common stock, pursuant to exercise of options | - | 11,900 |
| Repurchase of Company common stock | (4,735) | - |
| Net cash (used) provided by financing activities | (49,620) | 894,831 |
| Net decrease in cash and cash equivalents | (2,336,157) | (5,879,051) |
| Cash and cash equivalents, beginning of period | 4,820,033 | 9,355,730 |

| | | |
|---|--------------|--------------|
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 2,483,876 | \$ 3,476,679 |
| Non-cash investing and financing activities: | | |
| Increase in fixed assets related to asset retirement obligation | \$ - | \$ 473,096 |

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

IsoRay, Inc. and Subsidiaries
Notes to the Consolidated Unaudited Financial Statements
For the three and six-month periods ended December 31, 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 auction rate securities (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.

On October 16, 2008, the Company accepted an offer from UBS AG (UBS) providing the Company with Auction Rate Securities Rights Series B (Rights) pertaining to our ARS (see Note 5). These Rights are a put option for the right to sell to UBS our ARS at par value. As the Rights are non-transferable and cannot be attached to the ARS if they are sold to another entity, the Rights represent a free-standing instrument between the Company and UBS. The Rights were valued using a discounted cash flow model based on the Company's estimates and assumptions.

The fair value hierarchy for our financial assets accounted for at fair value on a recurring basis at December 31, 2008 was:

| | Level 1 | Level 2 | Level 3 |
|---|---------|----------------|------------|
| Auction rate securities | \$ | – \$ 3,244,450 | \$ – |
| Auction rate securities rights – put option | | – | – 755,550 |
| | \$ | – \$ 3,244,450 | \$ 755,550 |

SFAS 159

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

3. Loss per Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, Earnings Per Share. Under the provisions of SFAS 128, primary and fully diluted earnings per share are replaced with basic and diluted earnings per share. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At December 31, 2008 and 2007, the calculation of diluted weighted average shares does not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2008 and 2007 were as follows:

| | December 31, | |
|-----------------------|--------------|-----------|
| | 2008 | 2007 |
| Preferred stock | 59,065 | 59,065 |
| Common stock warrants | 3,245,082 | 3,255,774 |
| Common stock options | 2,458,708 | 3,210,981 |

| | | |
|-------------------------------------|-----------|-----------|
| Total potential dilutive securities | 5,762,855 | 6,525,820 |
|-------------------------------------|-----------|-----------|

5

4. Impairment of IBt License

In December 2008, the Company reevaluated its license agreement with International Brachytherapy SA (IBt) in connection with an overall review of its present cost structure and projected market and manufacturing strategies (see Note 9 for further details on the IBt license agreement). Management determined through this review that it does not currently intend to utilize the IBt license as part of its market strategy due to the cost of revamping its manufacturing process to incorporate the technology and as there can be no assurance that physicians would accept this new technology without extensive education and marketing costs. However, the Company does not intend to cancel the license agreement at this time; therefore, the license was reviewed in terms of an “abandoned asset” for purposes of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, it was determined that the entire value should be written off. Therefore, the Company recorded an impairment charge of \$425,434 that is included in cost of product sales for the three and six months ended December 31, 2008.

5. Short-Term Investments

The Company’s short-term investments consisted of the following at December 31, 2008 and June 30, 2008:

| | December 31, 2008 | June 30, 2008 |
|---|----------------------|------------------|
| Auction rate securities | \$ 3,244,450 | \$ 3,726,000 |
| Auction rate securities rights – put option | 755,550 | – |
| | \$ 4,000,000 | \$ 3,726,000 |

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

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

Also in October 2008, the Company reclassified its ARS from available-for-sale to trading and has recorded all changes in fair value to these securities during the quarter ended December 31, 2008 in the statement of operations. The Company felt this reclassification was appropriate given that it accepted the offer of the Rights, it did not intend to hold these investments to maturity, and there is no longer an active market to permit their sale in the normal course of business.

6. Inventory

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

| | December 31, 2008 | June 30, 2008 |
|-----------------|----------------------|------------------|
| Raw materials | \$ 659,138 | \$ 696,958 |
| Work in process | 221,866 | 191,684 |
| Finished goods | 7,266 | 11,322 |
| | \$ 888,270 | \$ 899,964 |

7. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and six months ended December 31, 2008 and 2007:

| | Three months ended December 31, | | Six months ended December 31, | |
|-------------------------------------|------------------------------------|------------|----------------------------------|------------|
| | 2008 | 2007 | 2008 | 2007 |
| Cost of product sales | \$ 4,780 | \$ 36,827 | \$ 13,910 | \$ 73,830 |
| Research and development expenses | 9,568 | 11,550 | 19,489 | 23,100 |
| Sales and marketing expenses | 46,291 | 59,557 | 104,983 | 119,114 |
| General and administrative expenses | 30,429 | 59,072 | 61,400 | 138,569 |
| Total share-based compensation | \$ 91,068 | \$ 167,006 | \$ 199,782 | \$ 354,613 |

As of December 31, 2008, total unrecognized compensation expense related to stock-based options was \$332,181 and the related weighted-average period over which it is expected to be recognized is approximately 0.67 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 December 31, 2008 were as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|--|-------------------|---------------------------------|---|---------------------------|
| Outstanding at December 31, 2008 | 2,458,708 | \$ 2.63 | 7.28 | \$ 0.00 |
| Vested and expected to vest at December 31, 2008 | 2,448,164 | \$ 2.62 | 7.28 | \$ 0.00 |
| Vested and exercisable at December 31, 2008 | 2,175,819 | \$ 2.57 | 7.11 | \$ 0.00 |

The aggregate intrinsic value of options exercised during the six months ended December 31, 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 December 31, | | Six months ended December 31, | |
|--|---------------------------------|---------|-------------------------------|---------|
| | 2008(a) | 2007(b) | 2008(c) | 2007(b) |
| Weighted average fair value of options granted | \$ 0.25 | \$ - | \$ 0.37 | \$ - |
| Key assumptions used in determining fair value: | | | | |
| Weighted average risk-free interest rate | 1.99% | -% | 2.63% | -% |
| Weighted average life of the option (in years) | 6.00 | - | 5.68 | - |
| Weighted average historical stock price volatility | 252.93% | -% | 191.04% | -% |
| Expected dividend yield | 0.00% | -% | 0.00% | -% |

(a) During the three months ended December 31, 2008, the Company granted 50,000 stock options.

(b) During the three and six months ended December 31, 2007, the Company did not grant any stock options.

(c) During the six months ended December 31, 2008, the Company granted 95,000 stock options.

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

8. UralDial

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

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

The Company has an existing distribution agreement with UralDial that allows UralDial to distribute Proxcelan Cs-131 brachytherapy seeds in Russia. The Company expects to begin shipping its brachytherapy seeds under this agreement once regulatory approval has been obtained in Russia.

9. Commitments and Contingencies

Patent and Know-How Royalty License Agreement

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

The licensor of the "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

License Agreement with IBt

In February 2006, the Company signed a license agreement with IBt covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using 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 originally intended to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. In December 2008, the Company recorded an impairment charge to write down this license based on its current intentions to not utilize this technology (see Note 4).

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

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

11. Subsequent Events

Liquidation of ARS

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

ITEM 2 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-Q contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (“PSLRA”). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.

All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under “Risk Factors” beginning on page 21 below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2008 that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company's views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the Securities and Exchange Commission on September 29, 2008 are those that depend most heavily on these judgments and estimates. As of December 31, 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 December 31, 2008 compared to three months ended December 31, 2007

Product sales. The Company generated sales of \$1,326,703 during the three months ended December 31, 2008, compared to sales of \$1,758,344 for the three months ended December 31, 2007. The decrease of \$431,641 or 25% is mainly due to decreased sales volume of the Company's Proxcelan Cs-131 brachytherapy seed along with a lower average invoice price due to the expanded use of the Company's seeds in dual therapy cases which typically use fewer seeds. In addition, about 5% of the decrease is due to physicians ordering less seeds per implant as they have become more familiar with the isotope and its characteristics. The Company does not anticipate the number of seeds per implant declining any further but will need to increase the total number of implants to generate higher sales. Management also believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy seed sales. During the three months ended December 31, 2008, the Company sold its Proxcelan seeds to 47 different medical centers as compared to 53 medical centers during the corresponding period of 2007.

Cost of product sales. Cost of product sales was \$1,724,225 for the three months ended December 31, 2008 compared to cost of product sales of \$2,241,795 during the three months ended December 31, 2007. The decrease of \$517,570 or 23% is due to reduced sales and more efficient production operations as the Company has worked to streamline its manufacturing process during the past year, offset by a one-time impairment of \$425,434 related to the Company's IBt license. The major components of the decrease were depreciation, materials, personnel costs, preload expenses, share-based compensation, and small tools expense. Depreciation expenses decreased approximately \$83,000 as the prior year also contained depreciation of both the Company's new production facility and the old production facility. Materials decreased approximately \$362,000 mainly due to ordering and using less isotope in the three months ended December 31, 2008 compared to the corresponding period of 2007 and a lower unit price from our primary isotope suppliers in 2008 compared to 2007. The decrease in pricing came as a result of negotiations with our main suppliers for the calendar year 2008; however, these prices increased again in January 2009 although not to the same level as 2007. Personnel costs, including payroll, benefits, and related taxes, decreased approximately \$158,000 as the number of production personnel decreased. Preload expenses decreased by approximately \$137,000 mainly due to the lower volume of sales and increased in-house loading. Share-based compensation decreased approximately

\$32,000 due to the forfeiture of unvested options by the Company's former EVP-Operations. Small tools expenses decreased approximately \$25,000 as the prior year quarter contained items that were expensed as part of equipping the new facility that became operational in September 2007.

These decreases were offset by an impairment of the Company's IBt license for \$425,434 that was recorded in December 2008. Management completed its review of the license and associated technology related to this alternative seed encapsulation process in December 2008 and determined that the adoption of this process would entail an overhaul of the Company's existing manufacturing procedures. In addition, there is no assurance that physicians would accept this new technology without extensive education and marketing. As there are no anticipated future revenues from the IBt license and the Company cannot sell or transfer the license, its entire value was written off in the accompanying financial statements.

In addition to these changes, the Company also recorded a one-time charge of \$139,043 in the quarter ended December 31, 2007 relating to expenses to decommission its old production facility. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163. This additional expense incurred in the quarter ended December 31, 2007 was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but the lessor instead required their removal.

Gross loss. Gross loss was \$397,522 for the three month period ended December 31, 2008. This represents a decrease in the Company's gross loss of \$85,929 or 18% over the corresponding period of 2007's gross loss of \$483,451. Included in the gross loss for the three month period ended December 31, 2008 is the one-time IBt license impairment loss of \$425,434. Without this impairment loss, the Company's gross margin would have been \$27,912 or an increase in the gross profit margin of \$511,363 or 106% due to the Company's more efficient manufacturing process, lack of decommissioning costs in the 2008 period, and lower costs of supply.

Research and development expenses. Research and development expenses for the three month period ended December 31, 2008 were \$306,056 which represents a decrease of \$89,489 or 23% less than the research and development expenses of \$395,545 for the three month period ended December 31, 2007. The decrease is due to lower personnel, consulting, and travel expenses. Personnel costs, including payroll, benefits, and related taxes, decreased approximately \$70,000 due to a reduced headcount in research and development. Consulting expenses, which are mainly due to an ongoing project to increase the efficiency of isotope production, decreased approximately \$62,000 as the project is nearing its final prototype testing phase. Travel expenses decreased by approximately \$20,000. These decreases were partially offset by increased protocol expenses of approximately \$66,000 mainly due to the Company's dual-therapy study and its continued monitoring and updating of the mono-therapy study.

Sales and marketing expenses. Sales and marketing expenses were \$620,700 for the three months ended December 31, 2008. This represents a decrease of \$522,127 or 46% compared to expenditures in the three months ended December 31, 2007 of \$1,142,827 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$192,000 due to a lower sales headcount and a revised sales compensation plan that was originally introduced in April 2008 and subsequently amended in October 2008. Travel expenses decreased approximately \$92,000 mainly due to the decrease in sales force. Consulting expenses decreased approximately \$79,000 as the Company reduced its reliance on third-parties as part of its expense reduction initiatives. Marketing and advertising decreased approximately \$62,000 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. Conventions and tradeshows decreased approximately \$60,000 mainly due to ASTRO (a large tradeshow) being held in September in 2008 when it historically has been held in October or November. Dues and subscriptions also decreased approximately \$21,000 as the Company had purchased market research reports and subscriptions for US medical residents in the quarter ended December 31, 2007 but did not do so in the quarter ended December 31, 2008.

General and administrative expenses. General and administrative expenses for the three months ended December 31, 2008 were \$758,822 compared to general and administrative expenses of \$919,164 for the corresponding period of 2007. The decrease of \$160,342 or 17% is mainly due to decreased personnel expenses, legal, public company expenses, share-based compensation, and travel expenses partially offset by increased bad debt allowance and consulting expenses. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$72,000 owing mainly to the resignation of the Company's CEO in February 2008. Legal expenses decreased by approximately \$47,000 due to costs incurred during 2007 for contract drafting and review of the Company's interest in UralDial and the IBt strategic global alliance agreements and for mediation costs. These decreased legal costs were partially offset by legal fees incurred in settling a lawsuit with a former employee. Public company expenses, which are mainly comprised of board compensation, investor relations, and listing and transfer agent fees, decreased approximately \$41,000 due to lower investor relations costs partially offset by increased board compensation. Share-based compensation decreased approximately \$29,000 due to the forfeiture of unvested options by the Company's former CEO. Travel expenses also decreased approximately \$22,000. These decreases were partially offset by increased expense related to bad debt allowance of approximately \$46,000 and increased consulting expenses of approximately \$36,000 mainly due to compensation paid to the Company's interim CEO.

Operating loss. The Company continues to focus its resources on improving sales while retaining the necessary administrative infrastructure to increase the level of demand for the Company's product. These objectives and resulting costs have resulted in the Company not being profitable and generating operating losses since its inception. In the three months ended December 31, 2008, the Company had an operating loss of \$2,083,100 which is a decrease of \$857,887 or 29% less than the operating loss of \$2,940,987 for the three months ended December 31, 2007. Included in the operating loss for the three month period ended December 31, 2008 is the one-time IBt license impairment loss of \$425,434. Without this impairment loss, the Company's operating loss would have been \$1,657,666 or a decrease of \$1,283,321 or 44% compared to the three months ended December 31, 2007.

Interest income. Interest income was \$37,562 for the three months ended December 31, 2008. This represents a decrease of \$142,293 or 79% compared to interest income of \$179,855 for the three months ended December 31, 2007. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments. The decrease is due to lower interest rates and lower balances in the Company's money market and short-term investment accounts.

Gain on fair value of short-term investments. The gain of \$433,200 for the three months ended December 31, 2008 is due to the receipt of auction rate securities rights (Rights) issued by the Company's broker in October 2008. The gain is calculated as the fair value amount of the Rights as estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's auction rate securities (ARS).

Financing and interest expense. Financing and interest expense for the three months ended December 31, 2008 was \$20,769 or a decrease of \$4,442 or 18% from financing and interest expense of \$25,211 for the corresponding period in 2007. Included in financing expense is interest expense of approximately \$12,000 and \$18,000 for the three months ended December 31, 2008 and 2007, respectively. The remaining balance of financing expense represents the amortization of deferred financing costs.

Six months ended December 31, 2008 compared to six months ended December 31, 2007

Product sales. Sales for the six months ended December 31, 2008 were \$2,846,285 compared to sales of \$3,614,063 for the six months ended December 31, 2007. The decrease of \$767,778 or 21% was mainly due to decreased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds along with a lower average invoice price due to the expanded use of the Company's seeds in dual therapy cases which typically use fewer seeds. In addition, about 4% of the decrease is due to physicians ordering less seeds per implant as they have become more familiar with the isotope and its characteristics. The Company will need to increase the number of total implants to increase sales. Management also believes that other treatment options with higher reimbursement rates, such as IMRT, put pressure on Proxcelan Cs-131 seed sales as well as other brachytherapy seed sales. During the six months ended December 31, 2008 the Company sold its Cs-131 seeds to 60 different medical centers as compared to 65 centers during the corresponding period of 2007.

Cost of product sales. Cost of product sales was \$3,172,661 for the six months ended December 31, 2008 which represents a decrease of \$1,074,636 or 25% compared to cost of product sales of \$4,247,297 during the six months ended December 31, 2007. Materials expense decreased approximately \$637,000 mainly due to ordering and using less isotope in the six months ended December 31, 2008 compared to the corresponding period of 2007 and a lower unit price from our primary isotope suppliers. The decrease in pricing came as a result of negotiations with our main suppliers for the calendar year 2008; however, these prices increased again in January 2009 although not to the same level as 2007. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$325,000 due to a reduction in the average production headcount levels. Preload expenses decreased approximately \$244,000 due to lower sales volumes and due to increased in-house loading. Small tools expenses decreased approximately \$94,000 mainly due to expensing items in the prior year that were part of equipping the new facility that became operational in September 2007. Share-based compensation decreased approximately \$59,000 mainly due to the forfeiture of unvested options by the Company's former EVP-Operations.

These decreases were offset by an impairment of the Company's IBt license for \$425,434 that was recorded in December 2008. Management completed its review of the license and associated technology related to this alternative seed encapsulation process in December 2008 and determined that the adoption of this process would entail an overhaul of the Company's existing manufacturing procedures. In addition, there is no assurance that physicians would accept this new technology without extensive education and marketing. As there are no anticipated future revenues from the license and the Company cannot sell or transfer the license, its entire value was written off in the accompanying financial statements.

During the six months ended December 31, 2007, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163 resulting in an additional expense of \$139,043 that is included in cost of products sold for the six months ended December 31, 2007. This additional expense incurred in the six months ended December 31, 2007 was mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but instead required their removal.

Gross loss. Gross loss was \$326,376 for the six month period ended December 31, 2008. This represents a decrease of \$306,858 or 48% over the corresponding period of 2007's gross loss of \$633,234. Included in the gross loss for the six months ended December 31, 2008 is the one-time IBt license impairment loss of \$425,434. Without this impairment loss, the Company's gross margin would have been \$99,058 or an increase in the gross profit margin of \$732,292 or 116% due to the Company's more efficient manufacturing process, lack of corresponding decommissioning costs in the 2008 period, and lower costs of supply.

Research and development expenses. Research and development expenses for the six months ended December 31, 2008 were \$524,606 which represents a decrease of \$127,309 or 20% less than the research and development expenses of \$651,915 for the corresponding period of 2007. The major components of the decrease were personnel, consulting, and travel expenses. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$111,000 due to lower headcount. Consulting expenses decreased approximately \$102,000 as the Company's project to improve the efficiency of isotope production is nearing its final prototype testing phase. Travel expenses decreased approximately \$31,000 due to decreased trips to Russia and Belgium than occurred in the prior year. These decreases were partially offset by an increase in protocol expenses of approximately \$118,000 mainly due to payments for the Company's dual-therapy study and its continued monitoring and updating of the mono-therapy study.

Sales and marketing expenses. Sales and marketing expenses were \$1,351,474 for the six months ended December 31, 2008. This represents a decrease of \$851,169 or 39% compared to expenditures in the six months ended December 31, 2007 of \$2,202,643 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, decreased approximately \$433,000 due to a lower sales headcount and a revised sales compensation plan that was originally introduced in April 2008 and subsequently amended in October 2008. Travel expenses also decreased approximately \$54,000 due to the decrease in average headcount. Consulting expenses decreased approximately \$134,000, mainly due to reduced reliance on third-parties as part of the Company's expense reduction initiatives. Marketing and advertising decreased approximately \$162,000 as during the prior year the Company updated its marketing literature to incorporate new data published from the protocols, developed additional websites for patients and doctors, and updated its sales booth. Dues and subscriptions decreased approximately \$38,000 mainly due to the prior year purchases of market research reports and subscriptions for US medical residents. Hiring costs also decreased approximately \$34,000 as during the prior year the Company had paid third-parties to assist with recruiting new sales associates.

General and administrative expenses. General and administrative expenses for the six months ended December 31, 2008 were \$1,538,979 compared to general and administrative expenses of \$1,821,189 for the corresponding period of 2007. The decrease of \$282,210 or 15% is primarily due to a decrease in personnel costs, public company expenses, share-based compensation, legal expenses, and travel expenses partially offset by increases in consulting and bad debt allowance. Personnel costs decreased approximately \$139,000 mainly due to the resignation of the Company's CEO in February 2008. Public company expenses decreased approximately \$95,000 due to lower investor relations costs partially offset by increased board compensation. Share-based compensation decreased approximately \$77,000 due to the forfeiture of unvested options by the Company's former CEO. Legal expenses decreased by approximately \$58,000 as in the six months ended December 31, 2007 the Company incurred legal fees for contract drafting and review of the Company's interest in UralDial and the IBt strategic global alliance agreements and for mediation costs. These decreased legal costs were partially offset by legal fees incurred in settling a lawsuit with a former employee. Travel expenses also decreased approximately \$53,000. These decreases were partially offset by increased expense related to bad debt allowance of approximately \$97,000 and increased consulting expenses of approximately \$84,000 mainly due to compensation paid to the Company's interim CEO and the costs of the Company's ISO 13458 and CE mark audit that was conducted in July 2008.

Operating loss. The Company continues to focus its resources on improving sales while retaining the necessary administrative infrastructure to increase the level of demand for the Company's product. These objectives and resulting costs have resulted in the Company not being profitable and generating operating losses since its inception. In the six months ended December 31, 2008, the Company had an operating loss of \$3,741,435 which is a decrease of \$1,567,546 or 30% less than the operating loss of \$5,308,981 for the six months ended December 31, 2007. Included in the operating loss for the six months ended December 31, 2008 is the one-time IBt license impairment loss of \$425,434. Without this impairment loss, the Company's operating loss would have been \$3,316,001 or a decrease of \$1,992,980 or 38% compared to the six months ended December 31, 2007.

Interest income. Interest income was \$82,348 for the six months ended December 31, 2008. This represents a decrease of \$336,203 or 80% compared to interest income of \$418,551 for the six months ended December 31, 2007. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments. The decrease is due to lower interest rates and lower balances in the Company's money market and short-term investment accounts.

Gain on fair value of short-term investments. The gain of \$274,000 for the six months ended December 31, 2008 is due to the receipt of the Company's Rights issued by its broker in October 2008. The gain is calculated as the fair value amount of the Rights as estimated on the date of receipt plus the changes in their fair value offset by additional realized losses on the Company's ARS.

Financing and interest expense. Financing and interest expense for the six months ended December 31, 2008 was \$41,616 or a decrease of \$13,698 or 25% from financing and interest expense of \$55,314 for the corresponding period in 2007. Included in financing expense is interest expense of approximately \$25,000 and \$40,000 for the six months ended December 31, 2008 and 2007, respectively. The decrease in interest expense is due to the reduction of the principal balances of the Company's overall debt and capital lease balances. The remaining balance of financing expense represents the amortization of deferred financing costs.

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the six months ended December 31, 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 \$2.2 million for the six months ended December 31, 2008 compared to \$4.7 million for the six months ended December 31, 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 \$41,000 and \$2.0 million for the six months ended December 31, 2008 and 2007, respectively. Cash expenditures for fixed assets were approximately \$32,000 and \$3.0 million during the six months ended December 31, 2008 and 2007, respectively. The expenditures for fixed assets during the six months ended December 31, 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 \$50,000 for the six months ended December 31, 2008 and was used mainly for payments of debt and capital leases.

Projected 2008 Liquidity and Capital Resources

At December 31, 2008, cash and cash equivalents amounted to \$2,483,876 and short-term investments amounted to \$4,000,000, which includes the Company's Rights, 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 \$5.5 million of cash and \$0.5 million of short-term investments as of February 6, 2009. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$400,000 excluding capital expenditure requirements.

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

In late November 2008, the Company hired Anthony Pasqualone as Vice President of Business Development who is responsible for sales. Mr. Pasqualone has extensive experience in the brachytherapy industry and the Company believes his credibility in the industry and extensive sales experience should help management reverse the trend of sales decreases experienced by the Company during the past two fiscal quarters.

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

Long-Term Debt and Capital Lease Agreements

IsoRay had two loan facilities in place as of December 31, 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 December 31, 2008, the principal balance owed was \$132,925. 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 December 31, 2008 was \$246,357. 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 December 31, 2008 was \$10,777.

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 originally intended to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. Management no longer believes that introducing Cs-131 polymer seeds is a viable strategy due to concerns regarding physician acceptance and the costs to revamp the Company's existing manufacturing procedures to incorporate this technology. In December 2008, the Company recorded an impairment charge to write down this license based on its current intentions to not utilize this technology.

In November 2008, a subsidiary of the Company entered into a written contract with a contractor based in the Ukraine to formalize a research and development project originally begun over two years ago to develop a proprietary separation process to manufacture enriched barium. There is no assurance that this process can be developed. The contract calls for an initial payment of \$17,800 and a payment of \$56,610 upon completion of a successful demonstration. The Company's initial demonstration has been postponed until March 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 or sales transactions with noncontrolling interests as long as control is maintained. Differences between the fair value of consideration paid or received and the carrying value of noncontrolling interests are to be recognized as an adjustment to the parent interest’s equity. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and earlier adoption is prohibited. Due to the sale of its thirty percent interest in UralDial, LLC, the Company does not believe the implementation of SFAS 160 will have a material effect on its consolidated financial statements.

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

ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, the Company is not required to provide Part I, Item 3 disclosure in this Quarterly Report.

ITEM 4T – CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 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, except for the addition of the following risk factors:

The risk factor that immediately follows modifies the risk factors entitled "We Rely Heavily On A Limited Number Of Suppliers" and "Future Production Increases Will Depend On Our Ability To Acquire Larger Quantities Of Cs-131 And Hire More Employees" contained in the Form 10-K for the year ended June 30, 2008.

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

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

ITEM 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: February 17, 2009

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