

IsoRay, Inc.  
Form 10-Q  
February 14, 2011

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, 2010

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota  
(State or other jurisdiction of incorporation or organization)

41-1458152  
(I.R.S. Employer Identification No.)

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

99354  
(Zip Code)

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

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

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

Yes  No

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

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

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

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

| Class                           | Outstanding as of February 8, 2011 |
|---------------------------------|------------------------------------|
| Common stock, \$0.001 par value | 25,816,476                         |

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ISORAY, INC.

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## PART I – FINANCIAL INFORMATION

IsoRay, Inc. and Subsidiaries  
Consolidated Balance Sheets

|  | (Unaudited)<br>December 31,<br>2010 | June 30,<br>2010    |
|--|-------------------------------------|---------------------|
| <b>ASSETS</b>  |                                     |                     |
| Current assets:  |                                     |                     |
| Cash and cash equivalents  | \$ 2,770,366                        | \$ 1,678,869        |
| Accounts receivable, net of allowance for doubtful accounts of \$32,153 and \$36,390, respectively | 1,008,779                           | 896,266             |
| Inventory  | 775,167                             | 681,677             |
| Prepaid expenses and other current assets  | 245,613                             | 259,975             |
| <b>Total current assets</b>  | <b>4,799,925</b>                    | <b>3,516,787</b>    |
| Fixed assets, net of accumulated depreciation and amortization                                     | 3,546,219                           | 3,959,983           |
| Deferred financing costs, net of accumulated amortization  | 156,144                             | 13,277              |
| Restricted cash  | 180,556                             | 180,154             |
| Other assets, net of accumulated amortization  | 275,206                             | 272,594             |
| <b>Total assets</b>  | <b>\$ 8,958,050</b>                 | <b>\$ 7,942,795</b> |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>  |                                     |                     |
| Current liabilities:   |                                     |                     |
| Accounts payable and accrued liabilities   | \$ 454,715                          | \$ 404,401          |
| Accrued protocol expense   | 69,528                              | 242,029             |
| Accrued radioactive waste disposal   | 84,060                              | 60,060              |
| Accrued payroll and related taxes  | 135,675                             | 186,513             |
| Accrued vacation   | 71,172                              | 68,525              |
| Notes payable, due within one year   | 52,985                              | 49,445              |
| <b>Total current liabilities</b>   | <b>868,135</b>                      | <b>1,010,973</b>    |
| Notes payable, due after one year  | 101,677                             | 130,550             |
| Warrant liabilities  | 1,304,000                           | -                   |
| Asset retirement obligation  | 633,149                             | 605,391             |
| <b>Total liabilities</b>   | <b>2,906,961</b>                    | <b>1,746,914</b>    |
| Commitments and contingencies (Note 6)   |                                     |                     |
| 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;<br>25,829,325 and 23,048,754 shares issued and outstanding | 25,829              | 23,049              |
| Treasury stock, at cost, 13,200 shares  | (8,390)             | (8,390)             |
| Additional paid-in capital  | 49,037,162          | 48,084,783          |
| Accumulated deficit   | (43,003,571)        | (41,903,620)        |
| <b>Total shareholders' equity</b>   | <b>6,051,089</b>    | <b>6,195,881</b>    |
| <b>Total liabilities and shareholders' equity</b>   | <b>\$ 8,958,050</b> | <b>\$ 7,942,795</b> |

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

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

|   | Three months ended December 31, |              | Six months ended December 31, |                |
|---|---------------------------------|--------------|-------------------------------|----------------|
|   | 2010                            | 2009         | 2010                          | 2009           |
| Product sales   | \$ 1,244,922                    | \$ 1,368,347 | \$ 2,572,049                  | \$ 2,747,434   |
| Cost of product sales   | 1,117,005                       | 1,100,193    | 2,228,532                     | 2,260,282      |
| Gross income  | 127,917                         | 268,154      | 343,517                       | 487,152        |
| Operating expenses:   |                                 |              |                               |                |
| Research and development expenses                             | 15,612                          | 59,078       | 130,133                       | 127,960        |
| Sales and marketing expenses                                  | 335,612                         | 603,980      | 709,038                       | 1,046,879      |
| General and administrative expenses                           | 561,208                         | 550,009      | 1,157,341                     | 1,152,440      |
| Total operating expenses                                      | 912,432                         | 1,213,067    | 1,996,512                     | 2,327,279      |
| Operating loss  | (784,515)                       | (944,913)    | (1,652,995)                   | (1,840,127)    |
| Non-operating income (expense):                               |                                 |              |                               |                |
| Interest income   | 979                             | 2,944        | 2,040                         | 8,811          |
| Gain on fair value of warrant liability                       | 420,000                         | -            | 420,000                       | -              |
| Other income  | 149,879                         |              | 149,879                       |                |
| Financing and interest expense                                | (14,412)                        | (7,898)      | (18,875)                      | (25,259)       |
| Non-operating income (expense), net                           | 556,446                         | (4,954)      | 553,044                       | (16,448)       |
| Net loss  | (228,069)                       | (949,867)    | (1,099,951)                   | (1,856,575)    |
| Preferred stock dividends                                     | (2,658)                         | (36,679)     | (5,316)                       | (36,679)       |
| Net loss applicable to common shareholders                    | \$ (230,727)                    | \$ (986,546) | \$ (1,105,267)                | \$ (1,893,254) |
| Basic and diluted loss per share                              | \$ (0.01)                       | \$ (0.04)    | \$ (0.05)                     | \$ (0.08)      |
| Weighted average shares used in computing net loss per share: |                                 |              |                               |                |
| Basic and diluted   | 25,070,992                      | 22,942,088   | 24,059,873                    | 22,942,088     |

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

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

|  | Six months ended December 31, |                     |
|--|-------------------------------|---------------------|
|  | 2010                          | 2009                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>   |                               |                     |
| Net loss   | \$ (1,099,951)                | \$ (1,856,575)      |
| Adjustments to reconcile net loss to net cash used by operating activities:                                    |                               |                     |
| Depreciation and amortization of fixed assets  | 446,740                       | 484,572             |
| Amortization of deferred financing costs and other assets  | 26,702                        | 29,100              |
| Gain on fair value of warrant liabilities  | (420,000)                     | -                   |
| Accretion of asset retirement obligation   | 27,758                        | 25,378              |
| Share-based compensation   | 48,250                        | 80,477              |
| Changes in operating assets and liabilities:   |                               |                     |
| Accounts receivable, net   | (112,513)                     | (174,867)           |
| Inventory  | (93,490)                      | 35,361              |
| Prepaid expenses and other current assets  | 35,232                        | (3,972)             |
| Accounts payable and accrued expenses  | 50,314                        | 18,817              |
| Accrued protocol expense   | (172,501)                     | 11,878              |
| Accrued radioactive waste disposal   | 24,000                        | (23,940)            |
| Accrued payroll and related taxes  | (50,838)                      | 16,552              |
| Accrued vacation   | 2,647                         | (17,702)            |
| Net cash used by operating activities  | (1,287,650)                   | (1,374,921)         |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |                               |                     |
| Purchases of fixed assets  | (32,976)                      | (18,000)            |
| Change in restricted cash  | (402)                         | (1,049)             |
| Proceeds from the sale or maturity of short-term investments   | -                             | 1,679,820           |
| Net cash provided (used) by investing activities   | (33,378)                      | 1,660,771           |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |                               |                     |
| Principal payments on notes payable  | (25,333)                      | (134,331)           |
| Preferred dividends paid   | (10,632)                      | (36,679)            |
| Proceeds from sales of common stock and warrants, net of offering costs pursuant to registered public offering | 1,998,040                     | -                   |
| Proceeds from sales of common stock, net of offering costs pursuant to at the market offering                  | 250,632                       | -                   |
| Proceeds from sales of common stock, pursuant to exercise of warrants  | 199,818                       | -                   |
| Net cash used by financing activities  | 2,412,525                     | (171,010)           |
| Net increase (decrease) in cash and cash equivalents   | 1,091,497                     | 114,840             |
| Cash and cash equivalents, beginning of period   | 1,678,869                     | 2,990,744           |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>  | <b>\$ 2,770,366</b>           | <b>\$ 3,105,584</b> |

Supplemental disclosures of cash flow information:

Non-cash investing and financing activities:

|  |              |      |
|--|--------------|------|
| Initial measurement of warrant liabilities | \$ 1,724,000 | \$ - |
|--|--------------|------|

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



## IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements  
For the three and six months ended December 31, 2010 and 2009

## 1. Basis of Presentation

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

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010. 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, 2010.

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

## 2. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the "FASB") or other standards setting bodies that are adopted by us as of the specified effective dates. Unless otherwise discussed, we believe the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position, results of operations and cash flows upon adoption.

## 3. Loss per Share

Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants and options to purchase the Company's common stock, are excluded from the calculations when their effect is antidilutive. At December 31, 2010 and 2009, the calculation of diluted weighted average shares did not include preferred stock, common stock warrants, or options that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of December 31, 2010 and 2009, were as follows:

|  | December 31,     |                  |
|--|------------------|------------------|
|  | 2010             | 2009             |
| Preferred stock                            | 59,065           | 59,065           |
| Common stock warrants                      | 5,173,945        | 3,216,644        |
| Common stock options                       | 2,146,372        | 2,412,236        |
| <b>Total potential dilutive securities</b> | <b>7,379,382</b> | <b>5,687,945</b> |



## 4. Inventory

Inventory consisted of the following at December 31, 2010 and June 30, 2010:

|                 | December 31,<br>2010 | June 30,<br>2010 |
|-----------------|----------------------|------------------|
| Raw materials   | \$ 654,580           | \$ 546,080       |
| Work in process | 103,323              | 130,840          |
| Finished goods  | 17,264               | 4,757            |
|                 | \$ 775,167           | \$ 681,677       |

## 5. Share-Based Compensation

The following table presents the share-based compensation expense recognized during the three and six months ended December 31, 2010 and 2009:

|                                     | Three months<br>ended December 31, |           | Six months<br>ended December 31, |           |
|-------------------------------------|------------------------------------|-----------|----------------------------------|-----------|
|                                     | 2010                               | 2009      | 2010                             | 2009      |
| Cost of product sales               | \$ 8,470                           | \$ 5,375  | \$ 16,940                        | \$ 11,272 |
| Research and development expenses   | 5,410                              | 174       | 10,820                           | 336       |
| Sales and marketing expenses        | 3,847                              | 27,460    | 7,694                            | 51,085    |
| General and administrative expenses | 5,930                              | (10,459)  | 12,795                           | 17,784    |
| Total share-based compensation      | \$ 23,657                          | \$ 22,550 | \$ 48,249                        | \$ 80,477 |

As of December 31, 2010, total unrecognized compensation expense related to stock-based options was \$194,792 and the related weighted-average period over which it is expected to be recognized is approximately 1.12 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, 2010 was as follows:

|  | Number of<br>Options | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Aggregate<br>Intrinsic<br>Value |
|--|----------------------|--|---|---------------------------------|
| Outstanding at December 31, 2010                 | 2,146,372            | \$ 1.87                                  | 6.8   | \$ 645,522                      |
| Vested and expected to vest at December 31, 2010 | 2,059,546            | \$ 1.93                                  | 6.7   | \$ 587,179                      |
| Vested and exercisable at December 31, 2010      | 1,614,293            | \$ 2.27                                  | 6.3   | \$ 355,198                      |

There were no options exercised during the six months ended December 31, 2010 and 2009, 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 fair value model to calculate the fair value are as follows:

|  | Three months<br>ended December 31, |         | Six months<br>ended December 31, |         |
|--|------------------------------------|---------|----------------------------------|---------|
|  | 2010(a)                            | 2009(b) | 2010(c)                          | 2009(d) |
| Weighted average fair value of options granted     | \$ -                               | \$ -    | \$ -                             | \$ 0.51 |
| Key assumptions used in determining fair value:    |                                    |         |                                  |         |
| Weighted average risk-free interest rate           | -%                                 | -%      | -%                               | 2.50%   |
| Weighted average life of the option (in years)     | -                                  | -       | -                                | 4.00    |
| Weighted average historical stock price volatility | -%                                 | -%      | -%                               | 132.21% |
| Expected dividend yield                            | -%                                 | -%      | -%                               | 0.00%   |

- (a) During the three months ended December 31, 2010, the Company did not grant any stock options.
- (b) During the three months ended December 31, 2009, the Company did not grant any stock options.
- (c) During the six months ended December 31, 2010, the Company did not grant any stock options.
- (d) During the six months ended December 31, 2009, the Company granted 10,000 stock options.

The Black-Scholes fair value 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 fair value 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.



6. 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.

7. Fair Value Measurements

Effective July 1, 2008, for the financial assets and liabilities of the Company, and effective July 1, 2009, for the non-financial assets and liabilities of the Company, disclosure requirements were expanded to include the following information for each major category of assets and liabilities that are measured at fair value on a recurring basis: financial assets of the Company include cash and cash equivalents, short-term investments, accounts receivable, net of allowance and restricted cash - these are measured using level 1 inputs. Financial liabilities of the Company include accounts payable and accrued liabilities, accrued payroll and related taxes, notes payable, due within one year and notes payable, due after one year - these are measured using level 1 inputs. Non-financial assets of the Company include inventory, prepaid and other current assets, fixed assets, deferred financing costs, licenses and other assets which are measured using level 2 inputs. The Financial liabilities of the Company include the three warrant liabilities measured using level 2 inputs. The non-financial liability of the Company includes the asset retirement obligation measured using level 3 inputs.

8. Preferred Dividends

On December 8, 2010, the Board of Directors declared a dividend on the Series B Preferred Stock of all currently payable and accrued outstanding and cumulative dividends through December 31, 2010 in the amount of \$10,632. Dividends on the Series B Preferred Stock were last paid on December 31, 2009 as declared by the Board of Directors on December 11, 2009 in the amount of \$36,679. The dividends outstanding and cumulative through December 31, 2010 of \$10,632 and through December 31, 2009 of \$36,679 were paid as of those dates.

## 9. Shareholders' Equity

On November 22, 2010, the Company entered into a Securities Purchase Agreement (as amended on December 27, 2010) as part of the Company's registered offering with Hudson Bay Master Fund and closed the transaction on November 24, 2010 for the sale of 2,250,000 shares of common stock and four series of warrants. The total warrants exercisable in series A, series B and series C will be a maximum aggregate of 2,168,026 for a maximum number of below market securities issued, together with the shares of common stock sold in the offering, of no greater than 4,418,026 shares of common stock, which is the maximum issuable under the NYSE AMEX requirements without obtaining shareholder approval for the issuance. Series D Warrants, which are not below market securities, are expected to be issued to purchase 1,873,641 shares of common stock, assuming the Series A Warrants are exercisable for the maximum number of shares of common stock.

The exercise price of each of the Series A, B and C Warrants will be equal to the lower of (i) \$1.50 and (ii) 90% of the average of the 3 lowest volume weighted average prices out of the 15 trading days preceding the exercise date, but in no event will the exercise price of the Series A Warrants be less than \$0.75 per share. The Warrants will have terms varying from one hundred twenty days from the offering closing date for the Series A Warrants to six months from the offering closing date for the Series B Warrants to five years from the initial exercisability date for the Series C and D Warrants. The Series A, B and C Warrants were immediately exercisable following the closing of the offering. The Series D Warrants will not be exercisable until six months after the closing and will have an exercise price equal to \$1.56.

The Shares and warrants were issued pursuant to the Company's shelf registration statement (the "Registration Statement") on Form S-3 (File No. 333-162694), which became effective on November 13, 2009, and prospectus supplements filed on November 24, 2010 and on December 29, 2010.

By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in this offering. LifeTech received a cash fee of 5% of the gross proceeds received under the offering (excluding proceeds received on the exercise of C or D Warrants), and will also receive warrants to purchase 3% of the common stock sold in the offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech shall not be exercisable for six months following the closing, shall have a five year term, and an exercise price of \$1.56 per share.

The Series A warrants will be eligible to be exercised at the option of the Company on the expiration date subject to the exercise price being above \$0.75 for the 15 day period prior to expiration and to meeting other equity conditions.

All of the Series B warrants and 562,500 of the Series C warrants will be eligible to be exercised at the option of the Company at any time on or before 6 months after their issuance provided the common stock is trading at or above \$2.45 for 20 cumulative trading days and to meeting other equity conditions.

Based on the guidance contained in ASC 815 management has concluded that the warrants in Series A, Series B, and Series C should be classified a liability and has recorded a liability at fair value. The Company determined the fair value of the warrants using the Black-Scholes fair value model. The Company determined the fair value of the warrants to be \$1,724,000 on the date of the offering. The Company has recognized a gain on the change in fair value of \$420,000 in the three months ended December 31, 2010.

|                                 | Warrants  | Weighted average<br>exercise price |
|---------------------------------|-----------|------------------------------------|
| Outstanding as of June 30, 2010 | 3,165,768 | \$ 5.550                           |
| Series A warrants               | 508,130   | \$ 0.984                           |

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|                                     |           |    |       |
|-------------------------------------|-----------|----|-------|
| Series B warrants                   | 562,500   | \$ | 0.984 |
| Series C warrants                   | 1,096,391 | \$ | 0.984 |
| Warrants exercised                  | (226,344) | \$ | 0.950 |
| Outstanding as of December 31, 2010 | 5,173,945 | \$ | 3.610 |

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The November 2010 offering yielded \$1,998,040, net of offering costs of \$251,960 (\$112,500 of commission expense, \$137,142 of legal and accounting expense and \$2,318 of other costs). Warrant liabilities that total \$1,724,000 as established related to Series A, B, and C warrants. Deferred financing costs of \$193,051 were established related to the warrant liabilities for Series A, B, and C warrants.

The deferred offering costs of \$193,051 as discussed above will be amortized by the following schedule:

|                         |            |           |                    |
|-------------------------|------------|-----------|--------------------|
| Series A deferred costs | \$ 21,391  | 4 months  | \$ 5,348 per month |
| Series B deferred costs | \$ 26,431  | 6 months  | \$ 4,405 per month |
| Series C deferred costs | \$ 145,230 | 60 months | \$ 2,420 per month |

On April 22, 2010 we entered into a Sales Agreement (the “Agreement”) with C.K. Cooper & Company, Inc. (“CKCC”). Pursuant to the terms of the Agreement, the Company may offer and sell (the “Offering”) from time to time through CKCC, as the Company’s sales agent, up to \$4 million of shares of the Company’s common stock, par value \$0.001 per share (the “Shares”). CKCC is not required to sell any specific number or dollar amount of Shares but will use its commercially reasonable efforts, as the Company’s agent and subject to the terms of the Agreement, to sell the Shares offered, as instructed by the Company. Sales of the Shares, if any, may be made by means of ordinary brokers’ transactions on the NYSE AMEX at market prices and such other sales as agreed to by the Company and CKCC. CKCC will receive from us a commission of 2.0% based on the gross sales price per share for any Shares sold through it as agent under the Agreement. Net proceeds from the sale of the Shares were used for general corporate purposes. The Company has also agreed to reimburse CKCC for certain expenses incurred in connection with entering into the Agreement and has provided CKCC with customary indemnification rights. We filed a prospectus supplement relating to the Agreement described above on April 23, 2010.

On July 29, 2010, we entered into an amendment (the “Amendment”) to the Agreement to extend the term of the offering of Shares by CKCC as the Company’s sales agent through December 31, 2010. The offering of Shares pursuant to the Agreement, as amended by the Amendment, terminated on December 31, 2010.

On October 1, 2010 the Company instructed CKCC via placement notice permitting “at the market” sales of common stock through October 31, 2010. CKCC sold 304,227 shares of common stock on behalf of the Company, with the Company receiving \$250,632 in equity net of offering costs of \$118,149 (\$7,301 in commissions, \$110,276 in legal and accounting expenses, and \$571 in other costs).

In October 2010, the Company offered a temporary reduction in the exercise price of certain warrants to purchase shares of common stock previously issued, pursuant to §4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder, in 2005 and 2006.

On October 20, 2010 the Company commenced soliciting warrant exercises from existing holders at a reduced exercise price of \$0.95 per warrant exercised prior to October 31, 2010. Warrant holders exercised warrants to purchase 226,344 shares of common stock. This solicitation of warrants yielded \$199,818 net of offering costs.

10. Grant Award

On October 29, 2010, the Company received three grant awards totaling \$526,510 for qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The award covers tax years 2009 (ended 06-30-2010) and 2010 (ends 06-30-2011). The total award amount applicable to tax year 2009 was \$109,316 and the payment was received during the three months ended December 31, 2010 and was recorded in the non-operating income (expense) section of the consolidated statement of operations as other income. The remaining award amount applicable to tax year 2010 is \$417,194 of which \$40,513 had been earned in the six months ended December 31, 2010. The grant award income was recorded in the non-operating income (expense) section of the consolidated statement of operations as other income and on the balance sheet as an other receivable in the prepaid expenses and other current assets section. The remaining amount of the award granted to the Company during tax year 2010 is \$376,681.

Reimbursement from the Internal Revenue Service for expenses incurred during tax year 2010 (ends June 30, 2011) under this grant is anticipated to be received during the month of July 2011.

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 23 below and in the “Risk Factors” section of our Form 10-K for the fiscal year ended June 30, 2010 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 28, 2010 are those that depend most heavily on these judgments and estimates. As of December 31, 2010, there had been no material changes to any of the critical accounting policies contained therein.

## Results of Operations

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

Revenues. The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole, however, the strategy implemented by management in the prior year in diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to mitigate the lost revenue from the prostate segment.

### Key operating factors

| Description              | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Product Sales (Prostate) | \$ 1,139,530                   | \$ 1,323,047                   | \$ (183,517)  | (14)%        |
| Product Sales (Other)    | \$ 105,392                     | \$ 45,300                      | \$ 60,092     | 133%         |
| Total product sales      | \$ 1,244,922                   | \$ 1,368,347                   | \$ (123,425)  | (9)%         |

Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity –Modulated Radiation Therapy (IMRT) and Robotics but that combination treatments incorporating brachytherapy with other modalities in the prostate and treatment of other body sites with brachytherapy have the potential to continue to increase.

### Cost of product sales.

Cost of product sales was influenced to a large degree by three key operating factors while overall costs remain relatively unchanged for the three months ended December 31, 2010 compared to the three months ended December 31, 2009.

The first key operating factor that changed in the three months ended December 31, 2010 as compared to the three months ended December 31, 2009 is materials cost. Materials cost increased primarily as a result of the increased isotope cost as a result of contractual purchase requirements based on its contract with its Russian supplier and increased ordering in December to ensure that a sufficient supply of isotope was on hand to meet orders during periods of inclement weather in the US and abroad that caused disruptions of shipments to the Company.

The second key operating factor for cost of product sales was pre-loading services. This operational department continues to enable the Company to meet the requirements of our customers while providing added value to our shareholders through improved utilization of our staff and improved responsiveness to our customers as is evidenced by the increased number of physicians utilizing the pre-load services of the Company in the three months ended December 31, 2010. The department is able to load orders to physician specifications without the requirement of consuming additional isotope to allow for decay during the additional shipping and loading time at a third-party pre-loading facility, and is able to maintain better control over the entire manufacturing process and timing of the shipment to customers.

The third key operating factor for cost of product sales was payroll expense and benefits. This savings was primarily the result of utilizing production staff to support research and development efforts and transferring the associated cost to the developmental projects to allow for recovery of the costs through the qualifying therapeutic discovery project grants from the Internal Revenue Service.

#### Key operating factors

| Description                   | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Material                      | \$ 430,777                     | \$ 394,537                     | \$ 36,240     | 9%           |
| Pre-loading                   | \$ 97,153                      | \$ 85,967                      | \$ 11,186     | 13%          |
| Payroll and benefits          | \$ 204,629                     | \$ 235,533                     | \$ (30,904)   | (13)%        |
| Cost of product sales (Other) | \$ 384,447                     | \$ 384,156                     | \$ 290        | 0%           |
| Total cost of product sales   | \$ 1,117,005                   | \$ 1,100,193                   | \$ 16,812     | 2%           |

Gross margin. Gross margin for the three month period ended December 31, 2010 decreased compared to the three month period ended December 31, 2009 primarily as a result of the previously discussed reduction in sales related in the prostate market coupled with the inability to decrease fixed costs. Management continued to seek to control variable costs however at this time most remaining production costs are of a fixed nature and related to minimum personnel costs to meet peak demand orders.

#### Key operating factor

| Description             | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Gross margin            | \$ 127,917                     | \$ 268,154                     | \$ (140,237)  | (52)%        |
| Gross margin percentage | 10%                            | 20%                            |               |              |

Research and development. Research and development costs were influenced by four key operating factors for the three months ended December 31, 2010 compared to the three months ended December 31, 2009. The first key operating factor was other organ research expense which increased primarily due to material costs from projects related to three key research initiatives that have been identified by management for future growth and for which management sought out and received grant funds from the US government to assist with the development costs of the technologies. The second key operating factor was payroll and benefits which increased as a result of increased efforts undertaken on the three key research initiatives mentioned previously as well as the addition of a Vice-President of Research and Development in January 2010. The third key operating factor was protocol expense which decreased as several studies have fully enrolled and the Company has only started limited strategic efforts going forward into fiscal year 2011. The fourth key operating factor is travel expense which increased with the addition of the previously discussed addition of a Vice-President of Research and Development.

## Key operating factors

| Description                      | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|----------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Other organ research             | \$ 23,525                      | \$ 20                          | \$ 23,505     | 117,525%     |
| Payroll and benefits             | \$ 78,471                      | \$ 3,316                       | \$ 75,155     | 2,266%       |
| Protocol expense                 | \$ (134,031)                   | \$ 22,500                      | \$ (156,531)  | (696)%       |
| Travel expense                   | \$ 12,260                      | \$ -                           | \$ 12,260     | 100%         |
| Research and development (Other) | \$ 35,387                      | \$ 33,242                      | \$ 2,145      | 6%           |
| Total research and development   | \$ 15,612                      | \$ 59,078                      | \$ (43,466)   | (74)%        |

Sales and marketing expenses. Sales and marketing expenses decreased in the three months ended December 31, 2010 compared to the three months ended December 31, 2009 primarily as a result of five key operating factors.

The first key operating factor influencing the decreased sales and marketing expenses was a reduction in consulting expense as most of the functions of this consultant are now being performed by employees of the Company. The second key operating factor influencing the decrease in sales and marketing expenses was conventions and tradeshows as management has increasingly targeted activities at particular events to the results delivered by the Company's presence at the events. The third key operating factor influencing the decrease in sales and marketing expense is marketing and advertising expenses which decreased primarily through management developing resources in the Company to perform certain functions within the Company and that in the three months ended December 31, 2009 there were physician linecards, patient brochures and other marketing materials printed that did not recur during the three months ended December 31, 2010. The fourth key operating factor influencing the decrease in sales and marketing expenses was payroll benefits and share-based compensation which decreased primarily as a result of the compensation related to the resignation of the Chief Operating Officer (COO) in January 2010. The fifth key operating factor influencing the decrease in sales and marketing expenses was travel expense which decreased as a result of the non-recurring travel costs of the former COO in the three months ended December 31, 2009 and the targeted reduction in travel costs through more efficient trip planning by the sales force.

## Key operating factors

| Description                    | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Consulting                     | \$ 220                         | \$ 23,749                      | \$ (23,529)   | (99)%        |
| Conventions and tradeshows     | \$ 12,381                      | \$ 78,131                      | \$ (65,750)   | (84)%        |
| Marketing and advertising      | \$ 22,432                      | \$ 62,676                      | \$ (40,244)   | (64)%        |
| Payroll, benefits & share comp | \$ 231,623                     | \$ 322,452                     | \$ (90,829)   | (28)%        |
| Travel                         | \$ 52,526                      | \$ 74,833                      | \$ (22,307)   | (30)%        |
| Sales and marketing (Other)    | \$ 16,430                      | \$ 42,139                      | \$ (25,709)   | (61)%        |
| Total sales and marketing      | \$ 335,612                     | \$ 603,980                     | \$ (268,368)  | (44)%        |

General and administrative expenses. General and administrative expenses increased in the three months ended December 31, 2010 compared to the three months ended December 31, 2009 primarily as a result of five key operating factors. The first key operating factor was audit, SOX and tax expense that was reduced as the result of reduced audit costs in the three months ended December 31, 2010 as compared to the three months ended December 31, 2009. The second key operating factor was consulting expense that was increased as a result of costs related to working with the notified body regarding approval of certain products for sale in the European Union (EU) that have already been approved for sale in the markets of the US and Canada. The third key operating factor was legal expense that decreased in the three months ended December 31, 2010 compared to December 31, 2009 which was the result of

costs related to Securities and Exchange Commission filings, and the timing of the annual shareholder meeting. The fourth key operating factor was payroll, benefits and share-based compensation expense that was increased as a result of departments returning to normal staffing levels, annual increases in pay to staff in the three months ended December 31, 2010 and a non-recurring reversal of share-based compensation costs that occurred in the three months ended December 31, 2009. The fifth key operating factor was public company expense that increased as a result of the NYSE AMEX annual listing fee expense associated with new shares issued in the various capital raising efforts during the three months ended December 31, 2010.

## Key operating factors

| Description                        | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|------------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Audit, SOX and tax                 | \$ 5,710                       | \$ 23,456                      | \$ (17,746)   | (76)%        |
| Consulting                         | \$ 85,954                      | \$ 72,031                      | \$ 13,923     | 19%          |
| Legal                              | \$ 43,387                      | \$ 69,902                      | \$ (26,515)   | (38)%        |
| Payroll, benefits & share comp     | \$ 242,866                     | \$ 204,123                     | \$ 38,743     | 19%          |
| Public company                     | \$ 82,785                      | \$ 69,282                      | \$ 13,503     | 19%          |
| General and administrative (Other) | \$ 100,506                     | \$ 111,215                     | \$ (10,709)   | (10)%        |
| Total general and administrative   | \$ 561,208                     | \$ 550,009                     | \$ 11,199     | 2%           |

Operating loss. Operating loss for the three months ended December 31, 2010 was reduced compared to the three months ended December 31, 2009 despite reduced sales as management continued to focus on a targeted reduction or maintenance of costs in all production and overhead functions within the Company as have been discussed in previous sections.

## Key operating factor

| Description    | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|----------------|--------------------------------|--------------------------------|---------------|--------------|
| Operating loss | \$ (784,515)                   | \$ (944,913)                   | \$ 160,398    | 17%          |

Interest income. Interest income for the three months ended December 31, 2010 was reduced compared to the three months ended December 31, 2009 as a direct result of reduced cash and cash equivalent balances when coupled with reduced short-term interest rates.

## Key operating factor

| Description     | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-----------------|--------------------------------|--------------------------------|---------------|--------------|
| Interest income | \$ 979                         | \$ 2,944                       | \$ (1,965)    | (67)%        |

Gain on fair value of warrant liability. During the three months ended December 31, 2010, there was a warrant liability established upon issuance of warrants to the purchaser in a registered public offering during November 2010. Per ASC 820, the warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2010, the Company evaluated the fair value of the warrant liability using the Black-Scholes option pricing model on which the original warrant liability was based and applied updated inputs at December 31, 2010. The resulting change in fair value was recorded as of December 31, 2010.

## Key operating factor

| Description                             | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|---|--------------------------------|--------------------------------|---------------|--------------|
| Gain on fair value of warrant liability | \$ 420,000                     | \$ -                           | \$ 420,000    | 100%         |



Other income. Other income for the three months ended December 31, 2010 increased compared to the three months ended December 31, 2009 as a direct result of the receipt of three IRS Qualifying Therapeutic Device Program grants. The grant awards total approximately \$526,510. In the three months ended December 31, 2010, the Company recorded and received as other income reimbursement for half of the qualifying expenses incurred in fiscal year 2010 and awarded in October 2010. The Company has evaluated the expense associated with each grant effort on a monthly basis and recorded half of the expense incurred until the individual grant limits are reached as other income and in other receivables as part of prepaid expenses and other current assets. The Internal Revenue Service is expected to reimburse the Company in July 2011 for the amounts incurred in fiscal year 2011.

## Key operating factor

| Description                  | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Other grant income (FY 2010) | \$ 109,316                     | \$ -                           | \$ 109,316    | 100%         |
| Other grant income (FY2011)  | \$ 40,513                      | \$ -                           | \$ 40,513     | 100%         |
| Other income                 | \$ 50                          | \$ -                           | \$ 50         | 100%         |
| Total other income           | \$ 149,879                     | \$ -                           | \$ 149,879    | 100%         |

Financing and interest expense. Financing and interest expense for the three months ended December 31, 2010 increased when compared to the three months ended December 31, 2009 as a direct result of the November 2010 equity offering and the related amortization of deferred offering costs throughout the life of the warrant liability.

## Key operating factor

| Description                          | Three months<br>ended 12-31-10 | Three months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------------------|--------------------------------|--------------------------------|---------------|--------------|
| Interest expense                     | \$ 1,685                       | \$ 4,171                       | \$ (2,486)    | (60)%        |
| Deferred financing expense           | \$ 12,727                      | \$ 3,727                       | \$ 9,000      | 241%         |
| Total financing and interest expense | \$ 14,412                      | \$ 7,898                       | \$ 6,514      | 82%          |

Six months ended December 31, 2010 compared to six months ended December 31, 2009

Revenues. The overall decrease in revenue generated by prostate brachytherapy is consistent with revenue decreases experienced by this segment of the industry as a whole, however, the strategy implemented by management in the prior year in diversifying the number of body sites being actively treated with the Proxcelan Cs-131 brachytherapy seed has continued to mitigate the lost revenue from the prostate segment.

## Key operating factors

| Description              | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------|------------------------------|------------------------------|---------------|--------------|
| Product Sales (Prostate) | \$ 2,372,657                 | \$ 2,670,134                 | \$ (297,477)  | (11)%        |
| Product Sales (Other)    | \$ 199,392                   | \$ 77,300                    | \$ 122,092    | 158%         |
| Total product sales      | \$ 2,572,049                 | \$ 2,747,434                 | \$ (175,385)  | (6)%         |

Management believes that the overall market for prostate brachytherapy has continued to receive increased pressure from other treatment options with higher reimbursement rates such as Intensity –Modulated Radiation Therapy (IMRT) and Robotics but that combination treatments incorporating brachytherapy with other modalities in the prostate field and treatment of other body sites with brachytherapy have the potential to continue to increase.

Cost of product sales. Cost of product sales was decreased to a large degree by four key operating factors while overall costs remain relatively unchanged for the six months ended December 31, 2010 compared to the six months ended December 31, 2009. The first key operating factor that changed in the six months ended December 31, 2010 as compared to the six months ended December 31, 2009 is materials cost. Materials cost increased primarily as a result of an increased cost of isotope through meeting required contractual purchasing requirements for the Company's contract with its Russian supplier when combined with the ordering of additional isotope to ensure a sufficient inventory on hand to meet orders during periods of inclement weather in the US and abroad that caused disruptions and delays of shipments to the Company.

The second key operating factor for cost of product sales was depreciation and amortization expense. This operational expense has continued to decrease in fiscal year 2011 as equipment reached the end of its depreciable life and has not required replacement or significant repair as a result of the diligent maintenance process implemented by management and executed by the staff of the Company.

The third key operating factor for cost of product sales was occupancy expense. The increase in occupancy expense in the six months ended December 31, 2010 as compared to the six months ended December 31, 2009 was the result of a non-recurring reduction in electrical expense in the six months ended December 31, 2009 as the result of resolving a billing issue that was properly accrued for in the period incurred and relieved when resolved.

The fourth key operating factor for cost of product sales was payroll expense and benefits. The Company has utilized existing staff to support research and development efforts that have been undertaken and the related labor cost has been included in research and development expense as appropriate.

#### Key operating factors

| Description                   | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-------------------------------|------------------------------|------------------------------|---------------|--------------|
| Depreciation and amortization | \$ 444,075                   | \$ 467,081                   | \$ (23,006)   | (5)%         |
| Material                      | \$ 859,353                   | \$ 816,510                   | \$ 42,843     | 5%           |
| Occupancy                     | \$ 148,006                   | \$ 129,567                   | \$ 18,439     | 14%          |
| Payroll and benefits          | \$ 411,662                   | \$ 483,185                   | \$ (71,523)   | (15)%        |
| Cost of product sales (Other) | \$ 365,436                   | \$ 363,939                   | \$ 1,497      | 0%           |
| Total cost of product sales   | \$ 2,228,532                 | \$ 2,260,282                 | \$ (31,750)   | (1)%         |

Gross margin. Gross margin for the six month period ended December 31, 2010 decreased compared to the six month period ended December 31, 2009 primarily as a result of the previously discussed reduction in sales related in the prostate market and inability to decrease fixed costs required regardless of revenue levels. Management continued to seek to control variable costs as sales did not improve over the same period in the prior year, however at this time most remaining production costs are of a fixed nature and related to minimum personnel costs to meet peak demand orders.

## Key operating factor

| Description             | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-------------------------|------------------------------|------------------------------|---------------|--------------|
| Gross margin            | \$ 343,517                   | \$ 487,152                   | \$ (143,635)  | (29)%        |
| Gross margin percentage | 13%                          | 18%                          |               |              |

Research and development. Research and development costs were influenced by four key operating factors for the six months ended December 31, 2010 compared to the six months ended December 31, 2009. The first key operating factor was other organ research expense which increased primarily due to material costs from projects related to three key research initiatives that have been identified by management for future growth and for which management sought out and received grant funds from the US government to assist with the development costs of the technologies. The second key operating factor was payroll and benefits which increased as a result of the cost of production staff used in research and development on three qualifying therapeutic discovery project grants that were awarded to the Company as well as the addition of a Vice-President of Research and Development in January 2010. The third key operating factor was protocol expense which decreased as the result of the Company determining that several protocols were accrued beyond the now expected costs. Additionally, the Company has only started limited strategic protocol efforts going forward into fiscal year 2011. The fourth key operating factor is travel expense which increased with the addition of the previously discussed addition of a Vice-President of Research and Development.

## Key operating factors

| Description                      | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|----------------------------------|------------------------------|------------------------------|---------------|--------------|
| Other organ research             | \$ 25,850                    | \$ 3,171                     | \$ 22,679     | 715%         |
| Payroll and benefits             | \$ 138,414                   | \$ 5,134                     | \$ 133,280    | 2,596%       |
| Protocol expense                 | \$ (123,063)                 | \$ 46,700                    | \$ (24,762)   | (364)%       |
| Travel expense                   | \$ 24,637                    | \$ 13                        | \$ 24,624     | 189,415%     |
| Research and development (Other) | \$ 64,295                    | \$ 72,942                    | \$ (8,647)    | (12)%        |
| Total research and development   | \$ 130,133                   | \$ 127,960                   | \$ 2,173      | 2%           |

Sales and marketing expenses. Sales and marketing expenses decreased in the six months ended December 31, 2010 compared to the six months ended December 31, 2009 primarily as a result of five key operating factors. The first key operating factor influencing the decreased sales and marketing expenses was a reduction in consulting expense as most of the functions of this consultant are now being performed by employees of the Company. The second key operating factor influencing the decrease in sales and marketing expenses was conventions and tradeshow as management has increasingly targeted activities at particular events to the results delivered by the Company's presence at the events. The third key operating factor influencing the decrease in sales and marketing expense is marketing and advertising expenses which decreased primarily through management developing resources in the Company to perform certain functions within the Company and that in the six months ended December 31, 2009 there were physician linecards, patient brochures and other marketing materials printed that did not recur during the six months ended December 31, 2010. The fourth key operating factor influencing the decrease in sales and marketing expenses was payroll benefits and share-based compensation which decreased primarily as a result of the compensation related to the resignation of the Chief Operating Officer (COO) in January 2010. The fifth key operating factor influencing the decrease in sales and marketing expenses was travel expense which decreased as a result of the non-recurring travel costs of the former COO in the three months ended December 31, 2009 and the targeted reduction in travel costs through more efficient trip planning by the sales force.



## Key operating factors

| Description                    | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------------|------------------------------|------------------------------|---------------|--------------|
| Consulting                     | \$ 16,720                    | \$ 39,649                    | \$ (22,929)   | (58)%        |
| Conventions and tradeshow      | \$ 18,714                    | \$ 103,002                   | \$ (84,288)   | (82)%        |
| Marketing and advertising      | \$ 36,749                    | \$ 107,734                   | \$ (70,985)   | (66)%        |
| Payroll, benefits & share comp | \$ 492,288                   | \$ 582,682                   | \$ (90,394)   | (16)%        |
| Travel                         | \$ 114,955                   | \$ 132,783                   | \$ (17,828)   | (13)%        |
| Sales and marketing (Other)    | \$ 29,612                    | \$ 81,029                    | \$ (51,417)   | (63)%        |
| Total sales and marketing      | \$ 709,038                   | \$ 1,046,879                 | \$ (337,841)  | (32)%        |

General and administrative expenses. General and administrative expenses increased in the six months ended December 31, 2010 compared to the six months ended December 31, 2009 primarily as a result of five key operating factors. The first key operating factor was audit, SOX and tax expense that was reduced as the result of reduced audit costs in the six months ended December 31, 2010 as compared to the six months ended December 31, 2009. The second key operating factor was consulting expense that was increased as a result of increased consulting expense as a result of costs related to working with the notified body regarding approval of certain products for sale in the European Union (EU) that have already been approved for sale in the markets of the US and Canada. The third key operating factor was legal expense that decreased as a result of costs related to Securities and Exchange Commission filings, and the timing of the annual shareholder meeting which was held in the six months ended December 31, 2009 but not in the six months ended December 31, 2010. The fourth key operating factor was payroll, benefits and share-based compensation expense that was increased as a result of departments returning to normal staffing levels, annual increases in pay to staff in the three months ended December 31, 2010 and a non-recurring reversal of share-based compensation costs that occurred in the three months ended December 31, 2009. The fifth key operating factor was public company expense that increased as a result of the NYSE AMEX annual listing fee expense associated with new shares issued in the various capital raising efforts during the three months ended December 31, 2010.

## Key operating factors

| Description                        | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|------------------------------------|------------------------------|------------------------------|---------------|--------------|
| Audit, SOX and tax                 | \$ 58,582                    | \$ 63,463                    | \$ (4,881)    | (8)%         |
| Consulting                         | \$ 159,183                   | \$ 147,529                   | \$ 11,654     | 8%           |
| Legal                              | \$ 78,316                    | \$ 123,298                   | \$ (44,982)   | (36)%        |
| Payroll, benefits & share comp     | \$ 487,526                   | \$ 461,897                   | \$ 25,629     | 6%           |
| Public company                     | \$ 134,128                   | \$ 117,779                   | \$ 16,349     | 14%          |
| General and administrative (Other) | \$ 239,606                   | \$ 238,474                   | \$ 6,120      | 0%           |
| Total general and administrative   | \$ 1,157,341                 | \$ 1,152,440                 | \$ 4,901      | 0%           |

Operating loss. Operating loss for the six months ended December 31, 2010 was reduced compared to the six months ended December 31, 2009 despite reduced sales as management continued to focus on a targeted reduction or maintenance of costs in all production and overhead functions within the Company as have been discussed in previous sections.

## Key operating factor

Six months                  Six months

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| Description    | ended 12-31-10 | ended 12-31-09 | Variance (\$) | Variance (%) |
|----------------|----------------|----------------|---------------|--------------|
| Operating loss | \$ (1,652,995) | \$ (1,840,127) | \$ 187,132    | (10)%        |

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Interest income. Interest income for the six months ended December 31, 2010 was reduced compared to the six months ended December 31, 2009 as a direct result of reduced cash and cash equivalent balances when coupled with reduced short-term interest rates.

Key operating factor

| Description     | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|-----------------|------------------------------|------------------------------|---------------|--------------|
| Interest income | \$ 2,040                     | \$ 8,811                     | \$ (6,771)    | (77)%        |

Gain on fair value of warrant liability. During the six months ended December 31, 2010, there was a warrant liability established upon issuance of warrants to the purchaser in a registered public offering during November 2010. Per ASC 820, the warrant liability requires periodic evaluation for changes in fair value. As required at December 31, 2010, the Company evaluated the fair value of the warrant liability using the Black-Scholes fair value model on which the original warrant liability was based and applied updated inputs at December 31, 2010. The resulting change in fair value was recorded as of December 31, 2010.

Key operating factor

| Description                             | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|---|------------------------------|------------------------------|---------------|--------------|
| Gain on fair value of warrant liability | \$ 420,000                   | \$ -                         | \$ 420,000    | 100%         |

Other income. Other income for the six months ended December 31, 2010 increased compared to the six months ended December 31, 2009 as a direct result of the receipt of three IRS Qualifying Therapeutic Device Program grants. The grant awards total approximately \$526,510. In the six months ended December 31, 2010, the Company recorded and received as other income reimbursement for half of the qualifying expenses incurred in fiscal year 2010 and awarded in October 2010. The Company has evaluated the expense associated with each grant effort on a monthly basis and recorded half of the expense incurred until the individual grant limits are reached as other income and in other receivables as part of prepaid expenses and other current assets. The Internal Revenue Service is expected to reimburse the Company in July 2011 for the amounts incurred in fiscal year 2011.

Key operating factor

| Description                  | Six months<br>ended<br>12-31-10 | Six months<br>ended<br>12-31-09 | Variance (\$) | Variance (%) |
|------------------------------|---------------------------------|---------------------------------|---------------|--------------|
| Other grant income (FY 2010) | \$ 109,316                      | \$ -                            | \$ 109,316    | 100%         |
| Other grant income (FY2011)  | \$ 40,513                       | \$ -                            | \$ 40,513     | 100%         |
| Other income                 | \$ 50                           | \$ -                            | \$ 50         | 100%         |
| Total other income           | \$ 149,879                      | \$ -                            | \$ 149,879    | 100%         |

Financing and interest expense. Financing and interest expense for the six months ended December 31, 2010 increased when compared to the six months ended December 31, 2009 as a direct result of the November 2010 equity offering and the related amortization of deferred offering costs throughout the life of the warrant liability.

## Key operating factor

| Description                          | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--------------------------------------|------------------------------|------------------------------|---------------|--------------|
| Interest expense                     | \$ 5,596                     | \$ 11,457                    | \$ (5,861)    | (51)%        |
| Deferred financing expense           | \$ 13,279                    | \$ 13,802                    | \$ (523)      | (4)%         |
| Total financing and interest expense | \$ 18,875                    | \$ 25,259                    | \$ (6,384)    | (25)%        |

Liquidity and capital resources. The Company has historically financed its operations through cash investments from shareholders. During the six months ended December 31, 2010, the Company primarily used existing cash reserves to fund its operations and capital expenditures.

## Cash flows from operating activities

Cash used by operating activities is the net loss adjusted for non-cash items and changes in operating assets and liabilities. Management continued to reduce cash consumed in operating activities through a combination of cost reductions and operational efficiencies identified in the results of operations that resulted in a reduction in net loss which was then reduced by the non-cash items and changes in operating assets and liabilities for the six months ended December 31, 2010 when compared to the six months ended December 31, 2009.

## Key operating factor

| Description  | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|--|------------------------------|------------------------------|---------------|--------------|
| Net loss   | \$ (1,099,951)               | \$ (1,856,575)               | \$ 756,624    | (41)%        |
| Non-cash items                                       | \$ 129,450                   | \$ 619,527                   | \$ (490,077)  | (79)%        |
| Non-cash changes in operating assets and liabilities | \$ (317,149)                 | \$ (137,873)                 | \$ (179,276)  | 130%         |
| Net cash used by operating activities                | \$ (1,287,650)               | \$ (1,374,921)               | \$ 87,271     | (6)%         |

## Cash flows from investing activities

Cash used by investing activities during the six months ended December 31, 2010 was primarily the result of the investment in equipment related to research and development activities in support of the IRS Qualifying Therapeutic Device Program grant research. Cash provided in the six months ended December 31, 2009 was primarily the result of short-term investments maturing and being liquidated and offset by minor investments in fixed assets. The amounts recorded to restricted cash in both periods are the accrual of interest earned on certificates of deposit with two financial institutions that are a requirement of the Washington State Department of Health.

## Key operating factor

| Description  | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$)  | Variance (%) |
|--|------------------------------|------------------------------|----------------|--------------|
| Purchases of fixed assets                                    | \$ (32,976)                  | \$ (18,000)                  | \$ (14,976)    | 83%          |
| Change in restricted cash                                    | \$ (402)                     | \$ (1,049)                   | \$ 647         | (62)%        |
| Proceeds from the sale or maturity of short-term investments | \$ -                         | \$ 1,679,820                 | \$ 1,678,820   | 100%         |
| Net cash provided (used) by investing activities             | \$ (33,378)                  | \$ 1,660,771                 | \$ (1,694,149) | (102)%       |





## Cash flows from financing activities

Cash provided by financing activities in the six months ended December 31, 2010 was the result of sales of common stock in at-the-market transactions, through warrant exercises and in a registered public offering. Cash used during the six months ended December 31, 2009 was the result of dividend payments to the preferred shareholders and payments on the lone remaining debt facility with Hanford Area Economic Investment Fund (HAEIFC).

Cash used during the six months ended December 31, 2009 was the result of dividend payments to the preferred shareholders and payments on the debt facility with the HAEIFC, and the extinguishment of the debt facility with the Benton-Franklin Council of Governments (BFEDD).

## Key operating factor

| Description   | Six months<br>ended 12-31-10 | Six months<br>ended 12-31-09 | Variance (\$) | Variance (%) |
|---|------------------------------|------------------------------|---------------|--------------|
| Principal payments on notes payable                 |                              |                              |               |              |
| HAEIFC  | \$ (25,333)                  | \$ (18,433)                  | \$ 6,900      | 37%          |
| BFEDD   | \$ -                         | \$ (115,898)                 | \$ (115,898)  | (100)%       |
| Preferred dividend payments                         | \$ (10,632)                  | \$ (36,679)                  | \$ 26,047     | (71)%        |
| Proceeds from sale of common stock                  | \$ 2,448,490                 | \$ -                         | \$ 2,448,490  | 100%         |
| Net cash provided (used) by<br>financing activities | \$ 2,412,525                 | \$ (171,010)                 | \$ 2,583,535  | (1,511)%     |

## Projected Fiscal Year 2011 Liquidity and Capital Resources

At December 31, 2010, the Company held cash and cash equivalents of \$2,770,366 as compared to \$1,678,869 of cash and cash equivalents at June 30, 2010.

The Company had approximately \$2.53 million of cash and cash equivalents and no short-term investments as of February 8, 2011. The Company's monthly required cash operating expenditures were approximately \$215,000 in the six months ended December 31, 2010, which represents a 6% decrease of approximately \$15,000 from average monthly cash operating expenditures in fiscal year 2010, which is primarily a result of improved operating performance from fiscal year 2010 to fiscal year 2011. Management believes that less than \$100,000 will be spent on capital expenditures for the fiscal year 2011, but there is no assurance that unanticipated needs for capital equipment may not arise.

The Company has a single remaining loan facility outstanding with HAEIFC, with a principal balance of approximately \$155,000, of which approximately \$53,000 will be due in the next 12 months.

The Company intends to continue its existing protocol studies and to begin new protocol studies on lung cancer treatment using Cesium-131. The Company continues to believe that approximately \$100,000 in expense will be incurred during fiscal year 2011 related to protocol expenses relating to lung cancer and dual therapy and mono therapy prostate protocols.

Based on the foregoing assumptions, management believes cash, cash equivalents, and short-term investments on hand at December 31, 2010 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through at least the next twelve months.



Management plans to attain breakeven and generate additional cash flows by increasing revenues from both new and existing customers (through our direct sales channels and through our distributors), expanding into other market applications which initially will include head and neck, colorectal and lung implants while maintaining the Company's focus on cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain increases in its revenue. Sales in the prostate market have not shown the increases necessary to breakeven during the past three fiscal years and did not improve during the six months ended December 31, 2010. As management is now focused on expanding into head and neck, colorectal and lung applications, management believes the Company will need to raise additional capital for protocols, marketing staff, production staff and production equipment as it attempts to gain market share.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders. Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders. Of course, funding may not be available to it on acceptable terms, or at all. If the Company is unable to raise additional funds, it may be unable to expand into new applications and may need to curtail operations.

#### Long-Term Debt

IsoRay has a single loan facility in place as of December 31, 2010 from the Hanford Area Economic Investment Fund Committee (HAEIFC), which 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 five and one-half percent and the principal balance owed as of December 31, 2010 was \$154,662. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

#### Other Commitments and Contingencies

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company believes that if it relocates its current production facilities then certain decommissioning expenses will be incurred. An asset retirement obligation was established in the first quarter of fiscal year 2008 for the Company's obligations at its current production facility. This asset retirement obligation will be for obligations to remove any residual radioactive materials and to remove all leasehold improvements.

The industry that the Company operates in is subject to product liability litigation. Through its production and quality assurance procedures, the Company works to mitigate the risk of any lawsuits concerning its product. The Company also carries product liability insurance to help protect it from this risk.

The Company previously disclosed a contingency related to its research and development project underway in the Ukraine to develop a proprietary separation process to manufacture enriched barium. As the prototype has not been successfully demonstrated and is not expected to be, the Company does not intend to make the final payment to the contractor, as the final payment was only due following a successful demonstration of the prototype.

The Company has no off-balance sheet arrangements.

### ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

### ITEM 4 – CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2010. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

#### Changes in Internal Control over Financial Reporting

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

The Company is continuing the process of developing and implementing the remediation plan to address the material weakness and significant deficiency identified in its Form 10-K for the fiscal year ended June 30, 2010.

This plan is as follows:

- The Company continues to assess opportunities to further segregate duties within a limited staff.
- The staff is utilizing continuing professional education opportunities to enhance their knowledge.
- Management is conducting ongoing reviews of all significant and non-routine transactions.

As a result of ongoing reviews of all significant and non-routine transactions, management believes that there are no material inaccuracies or omissions of material fact and to the best of its knowledge believes that the consolidated financial statements for the quarter ended December 31, 2010 fairly present in all material respects the financial condition and results of operations for the Company in conformity with U.S generally accepted accounting principles.

## 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, 2010, except for the changes to the following risk factors that were included in the Form 10-K:

Failure to Comply with NYSE Amex Listing Standards And Any Resulting Delisting Could Adversely Affect The Market For Our Common Stock. Our common stock is presently listed on the NYSE Amex. The NYSE Amex will

consider delisting a company's securities if, among other things, the company fails to maintain minimum stockholder's equity or the company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the NYSE Amex, as to whether such issuer will be able to continue operations and/or meet its obligations as they mature. As of the quarter ended December 31, 2010, IsoRay met the minimum stockholder's equity requirement of \$6 million needed to maintain its listing, but will need to amend a provision in its outstanding amended and restated Series C warrant to meet the minimum equity requirement for the quarter ending March 31, 2011.

Management intends to negotiate a revision to the cash settlement terms of its outstanding amended and restated Series C warrant to classify this warrant as equity instead of a liability. Although management believes it can reach a satisfactory revision to its Series C warrant, there can be no assurance that we will be able to reach a satisfactory resolution of this negotiation to maintain our listing on the NYSE Amex or that additional concessions will not have to be granted to the holder of this warrant. In the event that our common stock is delisted from the NYSE Amex, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock.

The Price Of Our Common Stock May Be Adversely Affected By The Future Issuance And Sale Of Shares Of Our Common Stock Or Other Equity Securities, Or By Our Announcement That Such Issuances And Sales May Occur. We cannot predict the size of future issuances or sales of our common stock or other equity securities, including those made pursuant to the Company's November 2010 securities purchase agreement with an investor who purchased 2.25 million shares and warrants to purchase up to 4,041,667 shares of common stock, future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities, or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

Future Sales By Shareholders, Or The Perception That Such Sales May Occur, May Depress The Price Of Our Common Stock. The sale or availability for sale of substantial amounts of our shares in the public market, including shares issuable upon conversion of outstanding preferred stock or exercise of common stock warrants and options, or the perception that such sales could occur, could adversely affect the market price of our common stock and also could impair our ability to raise capital through future offerings of our shares. As of February 8, 2011, we had 25,816,476 outstanding shares of common stock, and the following additional shares were reserved for issuance: 2,146,372 shares upon exercise of outstanding options, 5,173,945 shares upon exercise of outstanding warrants, and 59,065 shares upon conversion of preferred stock. Any decline in the price of our common stock may encourage short sales, which could place further downward pressure on the price of our common stock and may impair our ability to raise additional capital through the sale of equity securities.

The Issuance Of Shares Upon Exercise Of Derivative Securities May Cause Immediate And Substantial Dilution To Our Existing Shareholders. The issuance of shares upon conversion of the preferred stock and the exercise of common stock warrants and options may result in substantial dilution to the interests of other shareholders since these selling shareholders may ultimately convert or exercise and sell all or a portion of the full amount issuable upon exercise. If all derivative securities were converted or exercised into shares of common stock, including the maximum number of warrants issuable in our November 2010 offering, there would be approximately 7,379,382 additional shares of common stock outstanding as a result. The issuance of these shares will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

We Have Ongoing Cash Requirements. IsoRay has generated material operating losses since inception. We expect to continue to experience significant net operating losses. Due to recent capital investments and substantial cost reductions, management believes cash and cash equivalents on hand will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements through December 31, 2011. Management now estimates that operational cashflow breakeven will be achieved at approximately \$700,000 in monthly revenue. However, there is no assurance as to when break-even will occur. If we are unable to generate profits and unable to obtain additional financing to meet our working capital requirements, we may have to curtail our business.

**We Rely Heavily On A Limited Number Of Suppliers.** Some materials used in our products are currently available only from a limited number of suppliers. In fiscal 2010, approximately sixty-eight percent (68%) of our Cs-131 was supplied through UralDial from reactors located in Russia. Unless the Company substantially increases its purchase requirements resulting from significant increases in demand for its product, the cost of Cs-131 in Russia could increase from current pricing.

If the development of barium enrichment capabilities is successful, the Company plans to expand Cs-131 manufacturing capability at the MURR reactor in the United States. Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which can be subject to unanticipated shutdowns. Failure to obtain deliveries of Cs-131 from multiple sources could have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers beyond the three currently used.

We may not be able to locate additional suppliers outside of Russia capable of producing the level of output of cesium at the quality standards we require. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our suppliers' control.

Virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from another single supplier. We do not have formal written agreements with Accellent Corporation. Any interruption or delay in the supply of materials required to produce our products could harm our business if we were unable to obtain an alternative supplier or substitute equivalent materials in a cost-effective and timely manner. To mitigate any potential interruptions, the Company continually evaluates its inventory levels and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

**We Have Entered Into An Agreement With A Single Distributor For Our Cesium-131 From Russia.** In December 2009, the Company entered into a new agreement with UralDial, which has been renewed through December 31, 2011, to purchase Cs-131 directly from UralDial instead of directly from Institute of Nuclear Materials (INM) and Research Institute of Atomic Reactors (RIAR) as the Company had done prior to the original agreement with UralDial in December 2008. As a result, the Company continues to rely on UralDial to obtain Cs-131 from Russian sources. UralDial has agreed to maintain at least two Russian sources of its Cs-131 and through the UralDial agreement we have obtained set pricing for our Russian Cs-131 through the end of 2011. There can be no guarantee that UralDial will always be able to supply us with sufficient Cs-131 or will renew our existing contract on favorable terms in December 2011, which could be due in part to risks associated with foreign operations and beyond our and UralDial's control. If we were unable to obtain supplies of isotopes from Russia in the future, our overall supply of Cs-131 would be reduced significantly unless we have a source of enriched barium for utilization in domestic reactors.

**We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Products.** Hospitals and freestanding clinics may be less likely to purchase our products if they cannot be assured of receiving favorable reimbursement for treatments using our products from third-party payers, such as Medicare and private health insurance plans. Currently, Medicare reimburses hospitals at fixed rates that cover the cost of stranded and loose seeds. Clinics and physicians performing procedures in a free standing center are reimbursed at the actual cost of the seeds. It is expected that CMS will continue to reimburse providers using this same methodology throughout 2011.



In 2003, IsoRay applied to the CMS and received a reimbursement code for our Cs-131 seed. On July 1, 2007, CMS revised the coding system for brachytherapy seeds and separated the single code into two codes – one code for loose seeds and a second code for stranded seeds. This methodology was applied to all companies manufacturing brachytherapy seeds. Reimbursement amounts are reviewed and revised annually based upon information submitted to CMS on claims by providers. Adjustments can be made to reimbursement amounts or coverage policies, which could result in changes to reimbursement for brachytherapy services. These changes can positively or negatively affect market demand for our products. We monitor these changes and provide comments, as permitted, when changes are proposed, prior to implementation.

There were improvements in CMS reimbursement for our product for 2011 but there is no assurance this will continue to occur and is subject to revision annually.

Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our products. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our products will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs, such as those passed by the federal government in 2010, could significantly affect the purchase of healthcare services and products in general and demand for our products in particular. Medicare is the payer in approximately 70% of all U.S. prostate brachytherapy cases and management anticipates this percentage to increase annually. We are unable to predict whether potential healthcare reforms will be enacted, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

If We Are Unable To Successfully Address The Material Weakness In Our Internal Controls, Our Ability To Report Our Financial Results On A Timely And Accurate Basis May Be Adversely Affected. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our reputation and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls that need improvement. In its assessment of the effectiveness in internal control over financial reporting as of June 30, 2010, the Company determined that there were deficiencies that constituted a material weakness. Specifically, the Company did not maintain a sufficient complement of personnel with the appropriate level of knowledge, experience and training to analyze, review and monitor the accounting of complex financial transactions. As a result, the Company did not prepare adequate contemporaneous documentation that would provide a sufficient basis for an effective evaluation and review of the accounting for complex transactions that are significant or non-routine. This material weakness resulted in errors in the preliminary June 30, 2010 consolidated financial statements and more than a remote likelihood that a material misstatement of the Company's annual or interim financial statements would not be prevented or detected. The Company is in the process of developing and implementing a remediation plan to address the material weakness described above, along with the deficiencies also identified in the assessment, which are described in our Annual Report on Form 10-K filed with the SEC on September 28, 2010. Specifically, the Company continues to assess opportunities to address issues with segregation of duties, staff has received additional professional education, management conducts ongoing reviews of all significant and non-routine transactions, and the Company is assessing additional steps that may be taken in the remainder of fiscal year 2011 to improve internal controls. We cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future and had not improved the process as of December 31, 2010. Any failure to implement

required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

Certain Provisions of Minnesota Law and Our Charter Documents Have an Anti-Takeover Effect. There exist certain mechanisms under Minnesota law and our charter documents that may delay, defer or prevent a change of control. Anti-takeover provisions of our articles of incorporation, bylaws and Minnesota law could diminish the opportunity for shareholders to participate in acquisition proposals at a price above the then-current market price of our common stock. For example, while we have no present plans to issue any preferred stock, our Board of Directors, without further shareholder approval, may issue shares of undesignated preferred stock and fix the powers, preferences, rights and limitations of such class or series, which could adversely affect the voting power of the common shares. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our Board of Directors that could have the effect of delaying, deterring or preventing a change in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act, or MBCA, regarding "business combinations," which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. We amended our shareholder rights plan to permit the issuance of the common stock and warrants to the investor in the November 2010 offering and therefore the investor may acquire up to 25% of our outstanding common stock. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all shareholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the Company not approved by our Board of Directors.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

### Use of Proceeds from Registered Securities

On October 27, 2009, we filed a registration statement on Form S-3 to register securities up to \$15 million in value for future issuance in our capital raising activities. The registration statement became effective on November 13, 2009, and the commission file number assigned to the registration statement is 333-162694.

On April 22, 2010 we entered into a Sales Agreement (the "Agreement") with C.K. Cooper & Company, Inc. ("CKCC"). Pursuant to the terms of the Agreement, the Company may offer and sell (the "Offering") from time to time through CKCC, as the Company's sales agent, up to \$4 million of shares of the Company's common stock, par value \$0.001 per share (the "Shares"). CKCC is not required to sell any specific number or dollar amount of Shares but will use its commercially reasonable efforts, as the Company's agent and subject to the terms of the Agreement, to sell the Shares offered, as instructed by the Company. Sales of the Shares, if any, may be made by means of ordinary brokers' transactions on the NYSE AMEX at market prices and such other sales as agreed to by the Company and CKCC. CKCC will receive from us a commission of 2.0% based on the gross sales price per share for any Shares sold through it as agent under the Agreement. Net proceeds from the sale of the Shares will be used for general corporate purposes. The Company has also agreed to reimburse CKCC for certain expenses incurred in connection with entering into the Agreement and has provided CKCC with customary indemnification rights. We filed a prospectus supplement relating to the Agreement described above on April 23, 2010.

On July 29, 2010, we entered into an amendment (the "Amendment") to the Agreement to extend the term of the offering of Shares by CKCC as the Company's sales agent through December 31, 2010. The offering of Shares pursuant to the Agreement, as amended by the Amendment, terminated on December 31, 2010.

On October 1, 2010 the Company instructed CKCC via placement notice permitting "at the market" sales of common stock through October 31, 2010. CKCC sold 304,227 shares of common stock on behalf of the Company, with the Company receiving \$250,632 in equity net of offering costs of \$118,149 (\$7,301 in commissions, \$110,276 in legal and accounting expenses, and \$571 in other costs).

There was no material change in the use of proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b). Through December 31, 2010 we have maintained the proceeds as cash and cash equivalents and did not use any of the proceeds.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

On November 22, 2010, a securities purchase agreement was executed between Hudson Bay Master Fund and the Company for 2,250,000 shares of common stock with Aurora Capital acting as the broker for the transaction. As part of the transaction, Hudson Bay Master Fund received four series of warrants (collectively, the "Warrants") - (i) Series A Warrants in an amount equal to \$500,000 divided by the lower of \$1.50 and 90% of the average of the 3 lowest volume weighted average prices out of the 15 trading days preceding the exercise date (with a floor of \$0.75 for a maximum of 666,667 shares of common stock issuable upon exercise of the Series A Warrants); (ii) Series B Warrants in an amount equal to 25% of the number of shares of common stock issued at the closing, or Series B Warrants exercisable for 562,500 shares of common stock; (iii) Series C Warrants in an amount equal to 125% of the number of shares of common stock issued at the closing, or Series C Warrants exercisable for 2,812,500 shares of common stock; and (iv) Series D Warrants in an amount equal to 125% of the number of shares of common stock issued at the closing, or Series D Warrants exercisable for 2,812,500 shares of common stock but the Series D Warrants will only be exercisable to the extent that any of the Series C Warrants may not be exercised due to NYSE AMEX shareholder approval requirements limiting the number of overall below-market securities issuable to no greater than 4,418,026 shares of common stock. As a result of this limitation, the total number of Series A, B and C Warrants that may be issued will not exceed Warrants exercisable for an aggregate of 2,168,026 shares of common stock, and Series D Warrants are expected to be issued to purchase 1,873,641 shares of common stock, assuming the Series A Warrants are exercisable for the maximum number of shares of common stock.

The exercise price of each of the Series A, B and C Warrants will be equal to the lower of (i) \$1.50 and (ii) 90% of the average of the 3 lowest volume weighted average prices out of the 15 trading days preceding the exercise date, but in no event will the exercise price of the Series A Warrants be less than \$0.75 per share. The Warrants will have terms varying from one hundred twenty days from the offering closing date for the Series A Warrants to six months from the offering closing date for the Series B Warrants to five years from the initial exercisability date for the Series C and D Warrants. The Series A, B and C Warrants will be immediately exercisable following the closing of the offering. The Series D Warrants will not be exercisable until six months after the closing and will have an exercise price equal to \$1.56. The Series A and Series C Warrants were amended and restated via an Amendment Agreement dated December 27, 2010.

The Shares and Warrants were issued pursuant to the Company's shelf registration statement (the "Registration Statement") on Form S-3 (File No. 333-162694), which became effective on November 13, 2009, and prospectus supplements filed on November 24, 2010 and on December 29, 2010.



By letter agreement dated October 27, 2010, LifeTech Capital, a division of Aurora Capital, LLC, acted as placement agent in connection with the placement of the securities in the November 2010 offering. LifeTech received a cash fee of 5% of the gross proceeds received under the offering (excluding proceeds received on the exercise of C or D Warrants), and also received warrants to purchase 3% of the common stock sold in the offering and 3% of the Series A, B and C Warrants exercised at any time, which warrants issued to LifeTech shall not be exercisable for six months following the closing, shall have a five year term, and an exercise price of \$1.56 per share.

The November 2010 offering yielded \$1,998,040, net of offering costs of \$251,960 (\$112,500 of commission expense, \$137,142 of legal and accounting expense and \$2,318 of other costs). Warrant liabilities that total \$1,724,000 as established related to Series A, B, and C warrants. Deferred financing costs of \$193,051 were established related to the warrant liabilities for Series A, B, and C warrants.

There was no material change in the use of proceeds from our public offering as described in our final prospectus filed with the SEC pursuant to Rule 424 (b). Through December 31, 2010 we had not used any of the net proceeds and invested the net proceeds in cash and cash equivalents.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

#### Unregistered Sales of Equity Securities

In October 2010, the Company offered a temporary reduction in the exercise price of certain warrants to purchase shares of common stock previously issued, pursuant to §4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder, in 2005 and 2006.

On October 20, 2010 the Company commenced soliciting warrant exercises from existing holders at a reduced exercise price of \$0.95 per warrant exercised prior to October 31, 2010. Warrant holders exercised warrants to purchase 226,344 shares of common stock. This solicitation of warrants yielded \$199,818 net of offering costs.

No placement or underwriting fees were paid in connection with the warrant solicitation. Proceeds from the exercise of the warrants were used for general working capital purposes.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: February 14, 2011

ISORAY, INC., a Minnesota corporation

By /s/ Dwight Babcock  
Dwight Babcock, Chief Executive Officer  
(Principal Executive Officer)

By /s/ Brien Ragle  
Brien Ragle, Controller  
(Principal Financial and Accounting Officer)