

IsoRay, Inc.  
Form 10QSB  
May 15, 2007

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

FORM 10-QSB

Quarterly Report of Small Business Issuers under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2007

Commission File No. 000-14247

**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)

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

Check whether the issuer has (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Number of shares outstanding of each of the issuer's classes of common equity:

| <u>Class</u>                    | <u>Outstanding as of May 9, 2007</u> |
|---------------------------------|--------------------------------------|
| Common stock, \$0.001 par value | 22,732,108                           |

Transitional Small Business Disclosure Format : Yes  No

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**ISORAY, INC.**

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## PART I FINANCIAL INFORMATION

## Item 1. Consolidated Unaudited Financial Statements

**IsoRay, Inc. and Subsidiary  
Consolidated Balance Sheets**

|   | <b>March 31,<br/>2007<br/>(Unaudited)</b> | <b>June 30,<br/>2006</b> |
|---|---|--------------------------|
| <b>ASSETS</b>   |   |                          |
| <b>Current assets:</b>  |   |                          |
| Cash and cash equivalents   | \$ 22,214,256                             | \$ 2,207,452             |
| Accounts receivable, net of allowance for doubtful accounts of \$111,421 and \$85,183, respectively | 1,243,316                                 | 596,447                  |
| Inventory   | 270,782                                   | 161,381                  |
| Prepaid expenses  | 405,910                                   | 161,546                  |
| <b>Total current assets</b>   | <b>24,134,264</b>                         | <b>3,126,826</b>         |
| <b>Fixed assets, net of accumulated depreciation</b>  |   |                          |
| Deferred financing costs, net of accumulated amortization   | 208,789                                   | 274,358                  |
| Licenses, net of accumulated amortization   | 258,307                                   | 273,475                  |
| Other assets, net of accumulated amortization   | 347,994                                   | 338,987                  |
| <b>Total assets</b>   | <b>\$ 27,094,839</b>                      | <b>\$ 5,655,939</b>      |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>   |   |                          |
| <b>Current liabilities:</b>   |   |                          |
| Accounts payable and accrued expenses   | \$ 807,206                                | \$ 584,296               |
| Accrued payroll and related taxes   | 412,945                                   | 614,645                  |
| Accrued interest payable  | 13,456                                    | 11,986                   |
| Notes payable, due within one year  | 44,330                                    | 51,351                   |
| Capital lease obligations, due within one year  | 204,448                                   | 183,554                  |
| Convertible debentures payable, due within one year   | 355,000                                   | 455,000                  |
| <b>Total current liabilities</b>  | <b>1,837,385</b>                          | <b>1,900,832</b>         |
| Notes payable, due after one year   | 543,278                                   | 581,557                  |
| Capital lease obligations, due after one year   | 64,356                                    | 220,415                  |
| Asset retirement obligation   | 72,115                                    | 67,425                   |
| <b>Total liabilities</b>  | <b>2,517,134</b>                          | <b>2,770,229</b>         |
| <b>Shareholders' equity:</b>  |   |                          |
| <b>Preferred stock, \$.001 par value; 6,000,000 shares authorized:</b>                              |   |                          |
| Series A: 1,000,000 shares allocated; no shares issued and outstanding                              | -   | -                        |

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|  |                      |                     |
|--|----------------------|---------------------|
| Series B: 5,000,000 shares allocated; 59,065 and 144,759 shares issued and outstanding                                 | 59                   | 145                 |
| Common stock, \$.001 par value; 100,000,000 shares authorized; 22,732,108 and 15,157,901 shares issued and outstanding | 22,732               | 15,158              |
| Subscriptions receivable   | -                    | (6,122,007)         |
| Additional paid-in capital   | 44,971,147           | 22,538,675          |
| Accumulated deficit  | (20,416,233)         | (13,546,261)        |
| <b>Total shareholders' equity</b>  | <b>24,577,705</b>    | <b>2,885,710</b>    |
| <b>Total liabilities and shareholders' equity</b>  | <b>\$ 27,094,839</b> | <b>\$ 5,655,939</b> |

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

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

|  | Three months ended March 31, |                | Nine months ended March 31, |                |
|--|------------------------------|----------------|-----------------------------|----------------|
|  | 2007                         | 2006           | 2007                        | 2006           |
| Product sales                                | \$ 1,645,694                 | \$ 479,225     | \$ 4,085,293                | \$ 1,176,387   |
| Cost of product sales                        | 1,456,978                    | 791,457        | 4,132,518                   | 2,427,897      |
| Gross margin (loss)                          | 188,716                      | (312,232)      | (47,225)                    | (1,251,510)    |
| Operating expenses:                          |                              |                |                             |                |
| Research and development expenses            | 437,143                      | 86,194         | 898,995                     | 208,813        |
| Sales and marketing expenses                 | 849,744                      | 325,858        | 2,412,691                   | 981,429        |
| General and administrative expenses          | 937,905                      | 738,494        | 3,492,565                   | 2,374,887      |
| Total operating expenses                     | 2,224,792                    | 1,150,546      | 6,804,251                   | 3,565,129      |
| Operating loss                               | (2,036,076)                  | (1,462,778)    | (6,851,476)                 | (4,816,639)    |
| Non-operating income (expense):              |                              |                |                             |                |
| Interest income                              | 68,760                       | 25,472         | 158,947                     | 35,624         |
| Financing expense                            | (56,772)                     | (81,149)       | (177,443)                   | (432,257)      |
| Debt conversion expense                      | -                            | (141,414)      | -                           | (385,511)      |
| Non-operating income (expense), net          | 11,988                       | (197,091)      | (18,496)                    | (782,144)      |
| Net loss                                     | \$ (2,024,088)               | \$ (1,659,869) | \$ (6,869,972)              | \$ (5,598,783) |
| Basic and Diluted loss per share             | \$ (0.12)                    | \$ (0.11)      | \$ (0.42)                   | \$ (0.49)      |
| Shares used in computing net loss per share: |                              |                |                             |                |
| Basic and Diluted                            | 17,400,355                   | 14,567,672     | 16,198,067                  | 11,502,400     |

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

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

|   | <b>Nine months ended March 31,</b> |                |
|---|------------------------------------|----------------|
|   | <b>2007</b>                        | <b>2006</b>    |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                  |                                    |                |
| Net loss  | \$ (6,869,972)                     | \$ (5,598,783) |
| Adjustments to reconcile net loss to net cash used by operating activities:   |                                    |                |
| Depreciation and amortization of fixed assets                                 | 283,422                            | 174,751        |
| Amortization of deferred financing costs and other assets                     | 99,387                             | 185,634        |
| Accretion of asset retirement obligation                                      | 4,690                              | -              |
| Noncash share-based compensation  | 1,022,241                          | -              |
| Merger consulting fees paid by issuance of common stock                       | -                                  | 330,000        |
| Consulting and repair fees paid by issuance of common stock                   | -                                  | 39,752         |
| Rent expense paid by issuance of common stock                                 | -                                  | 60,018         |
| Debt conversion expense   | -                                  | 385,511        |
| Changes in operating assets and liabilities:                                  |                                    |                |
| Accounts receivable, net  | (646,869)                          | (543,341)      |
| Inventory   | (109,401)                          | (229,414)      |
| Prepaid expenses  | (244,364)                          | 66,285         |
| Accounts payable and accrued expenses   | 222,910                            | (324,560)      |
| Accrued payroll and related taxes   | (56,700)                           | 128,768        |
| Accrued interest payable  | 1,470                              | (41,325)       |
| Net cash used by operating activities   | (6,293,186)                        | (5,366,704)    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                  |                                    |                |
| Purchases of fixed assets   | (786,614)                          | (374,273)      |
| Additions to licenses and other assets  | (27,657)                           | (352,815)      |
| Cash acquired in reverse acquisition  | -                                  | 32,587         |
| Net cash used by investing activities   | (814,271)                          | (694,501)      |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                  |                                    |                |
| Borrowings on bank line of credit   | -                                  | 200,000        |
| Repayments on bank line of credit   | -                                  | (200,000)      |
| Proceeds from issuance of notes payable                                       | -                                  | 250,000        |
| Proceeds from sales of convertible debentures payable                         | -                                  | 550,000        |
| Principal payments on notes payable   | (95,301)                           | (486,700)      |
| Principal payments on capital lease obligations                               | (135,165)                          | (115,693)      |
| Proceeds from cash sales of common stock, net of offering costs               | 19,819,962                         | 6,516,413      |
| Proceeds from cash sales of preferred stock, pursuant to exercise of warrants | 8,709                              | 6,985          |
| Proceeds from cash sales of common stock, pursuant to exercise of warrants    | 6,448,181                          | 49,950         |
| Proceeds from cash sales of common stock, pursuant to exercise of options     | 1,106,333                          | 110,058        |

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|   |                      |                     |
|---|----------------------|---------------------|
| Payment of dividend to preferred shareholders                         | (38,458)             | -                   |
| Payments to common shareholders in lieu of issuing fractional shares  | -                    | (734)               |
| Net cash provided by financing activities                             | 27,114,261           | 6,880,279           |
| Net increase in cash and cash equivalents                             | 20,006,804           | 819,074             |
| Cash and cash equivalents, beginning of period                        | 2,207,452            | 1,653,144           |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>                       | <b>\$ 22,214,256</b> | <b>\$ 2,472,218</b> |
| <b>Non-cash investing and financing activities:</b>                   |                      |                     |
| Cashless exercise of common stock options                             | \$ 145,000           | \$ -                |
| Exchange of convertible debentures payable for shares of common stock | 49,999               | 3,682,875           |
| Fixed assets acquired by capital lease obligations                    | -                    | 507,947             |
| Issuance of common shares as partial payment for production equipment | -                    | 25,248              |
| Issuance of common shares as partial payment of notes payable         | -                    | 48,313              |
| Liabilities acquired in acquisition                                   | -                    | 21,355              |
| Prepaid rent paid by issuance of common stock                         | -                    | 120,036             |
| Issuance of warrants as an inducement for a note payable              | -                    | 60,000              |

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

**IsoRay, Inc.**  
**Notes to the Unaudited Consolidated Financial Statements**  
**For the three and nine month periods ended March 31, 2007 and 2006**

**1. Basis of Presentation**

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

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company’s Annual Report on Form 10-KSB for the fiscal year ended June 30, 2006, except for the July 1, 2006 adoption of Statement of Financial Accounting Standards No. 123R, “Share-Based Payment” (“SFAS No. 123R”) — See Note 2. 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-QSB should be read in conjunction with the Company’s Annual Report on Form 10-KSB for the fiscal year ended June 30, 2006.

**2. Share-Based Compensation**

Effective July 1, 2006, the Company adopted SFAS No. 123R using the modified-prospective method. Prior to July 1, 2006, the Company accounted for share-based employee compensation, including stock options, using the method prescribed in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations (“APB 25”). No share-based employee compensation cost was reflected in the statement of operations prior to the adoption of SFAS No. 123R. Results for prior periods have not been restated.

The following table presents the share-based compensation expense recognized in accordance with SFAS No. 123R during the three and nine months ended March 31, 2007 and in accordance with APB 25 during the three and nine months ended March 31, 2006:

|                                       | Three months<br>ended March 31, |              | Nine months<br>ended March 31, |              |
|---------------------------------------|---------------------------------|--------------|--------------------------------|--------------|
|                                       | 2007                            | 2006         | 2007                           | 2006         |
| Cost of product sales                 | \$ 21,076                       | \$ --        | \$ 92,401                      | \$ --        |
| Research and development              | 8,418                           | --           | 28,132                         | --           |
| Sales and marketing                   | 54,737                          | --           | 153,974                        | --           |
| General and administrative            | 40,123                          | --           | 747,734                        | --           |
| <b>Total share-based compensation</b> | <b>\$ 124,354</b>               | <b>\$ --</b> | <b>\$ 1,022,241</b>            | <b>\$ --</b> |

The adoption of SFAS No. 123R increased net loss for the three and nine months ended March 31, 2007 by \$124,354 and \$1,022,241, respectively. Basic loss per common share for the three and nine months ended March 31, 2007 would have been \$0.11 and \$0.36, respectively, if the Company had not adopted SFAS No. 123R, compared to reported basic loss per common share of \$0.12 and \$0.42, respectively. The total value of the stock option awards is expensed ratably over the service period of the employees receiving the awards. As of March 31, 2007, total unrecognized compensation cost related to stock-based options and awards was \$1,201,747 and the related weighted-average period over which it is expected to be recognized is approximately 1.05 years.





The Company currently provides stock-based compensation under three equity incentive plans approved by the Board of Directors: the Amended and Restated 2005 Employee Stock Option Plan, the Amended and Restated 2005 Stock Option Plan, and the Amended and Restated 2006 Director Stock Option Plan. Stock option awards granted from these plans are granted at the fair market value on the date of grant, and vest over a period determined at the time the options are granted, generally ranging from zero to three years, and generally have a maximum term of ten years. For stock options with graded vesting terms, the Company recognizes compensation cost on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards.

A summary of stock option activity within the Company's share-based compensation plans and charges for the nine months ended March 31, 2007 is as follows:

|  | Shares    | Price (a) | Life (b) | Value (c)    |
|--|-----------|-----------|----------|--------------|
| Outstanding at June 30, 2006             | 3,129,692 | \$ 2.05   |          |              |
| Granted (d)                              | 836,700   | 3.31      |          |              |
| Cancelled                                | (179,454) | 2.68      |          |              |
| Exercised                                | (698,499) | 1.16      |          |              |
| Outstanding at March 31, 2007            | 3,088,439 | \$ 2.56   | 8.37     | \$ 4,849,883 |
| Expected to vest at March 31, 2007       | 3,029,841 | \$ 2.55   | 8.64     | \$ 4,785,200 |
| Vested and exercisable at March 31, 2007 | 2,264,761 | \$ 2.19   | 8.48     | \$ 4,308,198 |

(a) Weighted average price per share.

(b) Weighted average remaining contractual life.

(c) Aggregate intrinsic value.

(d) All options granted had exercise prices equal to the ending market price of the Company's common stock on the grant date.

The aggregate intrinsic value of options exercised during the nine months ended March 31, 2007 was \$2,065,450.

The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows for the three and nine months ended March 31, 2007 and 2006:

|   | Three months ended March 31, |         | Nine months ended March 31, |         |
|---|------------------------------|---------|-----------------------------|---------|
|   | 2007                         | 2006    | 2007                        | 2006    |
| Weighted average fair value of options granted  | \$ 2.68                      | \$ 2.94 | \$ 2.18                     | \$ 1.31 |
| Key assumptions used in determining fair value: |                              |         |                             |         |
| Weighted average risk-free interest rate        | 4.45%                        | 4.78%   | 4.82%                       | 4.58%   |
| Expected life of the option (in years)          | 4.97                         | 7.25    | 5.50                        | 7.53    |
| Expected stock price volatility                 | 80.00%                       | 33.50%  | 75.65%                      | 30.84%  |

|                         |       |       |       |       |
|-------------------------|-------|-------|-------|-------|
| Expected dividend yield | 0.00% | 0.00% | 0.00% | 0.00% |
|-------------------------|-------|-------|-------|-------|

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

The following table illustrates the effect on net loss and net loss per common share for the three and nine months ended March 31, 2006 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all outstanding stock option awards for periods presented prior to the Company's adoption of SFAS No. 123R:

|  | Three months<br>ended<br>March 31,<br>2006 | Nine months<br>ended<br>March 31,<br>2006 |
|--|--|---|
| Net loss, as reported  | \$ 1,659,869                               | \$ 5,598,783                              |
| Stock-based compensation expense determined under fair value methods for all stock options | 180,000                                    | 336,000                                   |
| Proforma net loss  | \$ 1,839,869                               | \$ 5,934,783                              |
| Net loss per share:  |  |   |
| Basic, as reported   | \$ 0.11                                    | \$ 0.49                                   |
| Basic, pro forma   | \$ 0.13                                    | \$ 0.52                                   |

### 3. Loss per Share

The Company accounts for its income (loss) per common share according to SFAS No. 128, *Earnings Per Share*. Under the provisions of SFAS No. 128, primary and fully diluted earnings per share are replaced with basic and diluted earnings per share. Basic earnings per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. Common stock equivalents, including warrants to purchase the Company's common stock and common stock issuable upon the conversion of notes payable, are excluded from the calculations when their effect is antidilutive. At March 31, 2007 and 2006, the calculation of diluted weighted average shares does not include preferred stock, options, or warrants that are potentially convertible into common stock as those would be antidilutive due to the Company's net loss position.

Securities that could be dilutive in the future as of March 31, 2007 and 2006 are as follows:

|                                     | 2007      | March 31,<br>2006 |
|-------------------------------------|-----------|-------------------|
| Preferred stock                     | 59,065    | 199,264           |
| Preferred stock warrants            | -         | 179,512           |
| Common stock warrants               | 3,627,767 | 2,907,533         |
| Common stock options                | 3,088,439 | 2,815,768         |
| Convertible debentures              | 85,542    | 109,638           |
| Total potential dilutive securities | 6,860,813 | 6,211,715         |

#### **4. Risks and Uncertainties**

Our independent auditors have noted in their reports on our financial statements as of June 30, 2006 and 2005 and for the years then ended, that there is substantial doubt regarding our ability to continue as a going concern. Our large operating losses and accumulated deficit, among other things, have raised substantial doubt about our ability to continue as a going concern. However, in March 2007, we completed a public equity offering (see Note 7) and a warrant call (see Note 8) that raised gross proceeds of approximately \$20 million.

#### **5. Preferred Dividends**

On February 1, 2007, the Board of Directors declared a dividend on the Series B Preferred Stock of all outstanding and cumulative dividends through December 31, 2006. The total dividends of \$38,458 were paid on February 15, 2007.

#### **6. Share Rights Plan**

On February 1, 2007, the Board of Directors adopted a share rights plan. The plan grants to the Company's common shareholders a right to purchase a fractional share of preferred stock for each outstanding common share held of record at the close of business on February 16, 2007, subject to adjustment. This purchase right generally cannot be exercised by the Company's common shareholders to purchase stock until after a person or group acquires beneficial ownership of 15% or more of the Company's voting stock. However, the purchase rights held by the person or group that acquires 15% voting power will automatically become void and they will be unable to exercise their rights to purchase any shares of stock of the Company.

In addition, upon a merger or similar transaction resulting in an acquisition of the Company, each exercisable purchase right can be exercised by its holder to purchase common stock of the acquiring company with a market value of twice the right's exercise price. The purchase rights will expire on February 16, 2017.

Until a person or group acquires 15% or more of the Company's voting stock, the Board of Directors may redeem the rights for \$.001 per right (subject to adjustment). In certain events, the Board of Directors may also exchange the rights for shares of the Company's common stock, delay or temporarily suspend the exercisability of the rights or reduce the 15 percent stock ownership threshold to not less than 10 percent.

#### **7. Public Equity Offering**

On March 20, 2007, the Company entered into definitive securities purchase agreements (the "Purchase Agreements") with certain institutional investors pursuant to which the Company agreed to issue and sell an aggregate of 4,130,500 shares of its common stock at \$4.00 per share, through a registered direct offering, for aggregate gross proceeds of approximately \$16,522,000, before deducting estimated fees and expenses associated with the offering (the "Offering"). As part of the Offering, each purchaser of five shares of common stock received a warrant to purchase one share of common stock at an exercise price of \$5.00 per share with a 4-year term. A total of 826,100 warrants were issued under these terms. The closing took place on March 22, 2007. The shares of common stock offered by the Company in this transaction were registered under the Company's existing shelf registration statement (File No. 333-140246) on Form S-3, which was declared effective by the Securities and Exchange Commission on February 15, 2007, and the prospectus supplement dated March 21, 2007.

Punk, Ziegel & Company, L.P. and Maxim Group LLC (the "Placement Agents") acted as the placement agents for the Offering. On March 14, 2007 and February 2, 2006, the Company executed placement agent agreements (the "Placement Agent Agreements") by and between the Company and Punk, Ziegel & Company, L.P. and Maxim Group LLC, respectively. The Company paid the Placement Agents an aggregate fee equal to 6% of the gross proceeds of the Offering or approximately \$991,000. In addition, the Placement Agents also received 206,526 warrants with an exercise price of \$4.40 per share and a 5-year term as part of their overall fee.

## **8. Warrant Call**

As part of the August 2006 Stock Purchase Agreement, the Company issued warrants with an exercise price of \$3.00 per share. The warrants were callable by the Company for 45 days after a period of 60 trading days in which the closing price of the underlying stock was at or above \$4.50 per share for 30 of the 60 days.

As of February 16, 2007, the Company's common stock had traded at or above \$4.50 for 30 of the previous 60 days. On February 21, 2007, the Company sent out notices to the warrant holders establishing a call date of March 26, 2007. The warrant holders had the option to either exercise their warrants or permit the Company to repurchase the warrants for \$.01 per share on the call date. All of the remaining warrants were exercised prior to the call date.

## **9. Subsequent Events**

### Listing on the American Stock Exchange

On April 19, 2007, the Company's common stock was listed on the American Stock Exchange under the ticker symbol ISR.

### New Facility Lease

On May 2, 2007, IsoRay Medical, Inc. ("Medical"), the wholly owned operating subsidiary of the Company, entered into a lease for its new production facility with Energy Northwest, the owner of the Applied Process Engineering Laboratory. The new lease provides Medical with 19,328 square feet of manufacturing and office space and the Company intends to move all manufacturing operations to this new leased space and vacate its leased space at the PEcoS-IsoRay Radioisotope Laboratory ("PIRL") when the PIRL lease expires in October of 2007. The APEL lease has a three year term expiring on April 30, 2010, an option to renew for two additional three-year terms, and monthly rent of approximately \$26,700, subject to annual increases based on the Consumer Price Index. It is anticipated that it will take the Company approximately six to nine months to finish the necessary improvements and install the required equipment before operations can begin in the facility.

## **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-QSB 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-QSB, 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 revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under "Risk Factors" beginning on page 17 below and in the "Risk Factors" sections of our Form 10-KSB for the fiscal year ended June 30, 2006 and our Prospectus Supplement filed on March 23, 2007, that may cause actual results to differ materially.*

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

### **Critical Accounting Policies and Estimates**

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-KSB as filed with the Securities and Exchange Commission on September 28, 2006 are those that depend most heavily on these judgments and estimates. As of March 31, 2007, there have been no material changes to any of the critical accounting policies contained therein except for the adoption of SFAS No. 123R as noted below.

**Share-Based Compensation**

As part of our adoption of SFAS No. 123R as of July 1, 2006, we were required to recognize the fair value of share-based compensation awards as an expense. We apply the Black-Scholes option-pricing model in order to determine the fair value of stock options on the date of grant, and we apply judgment in estimating key assumptions that are important elements in the model such as the expected stock-price volatility, expected stock option life and expected forfeiture ratios. Our estimates of these important assumptions are based on historical data and judgment regarding market trends and factors. If actual results are not consistent with our assumptions and judgments used in estimating these factors, we may be required to record additional share-based compensation expense, which could be material to our results of operations.

**Adoption of SFAS No. 123R**

During December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 123R, which requires companies to measure and recognize compensation expense for all share-based payments at fair value. Share-based payments include stock option and nonvested share grants. We grant options to purchase common stock to some of our employees and directors under various plans at prices equal to the market value of the stock on the dates the options were granted. We historically have accounted for stock options using the method prescribed in APB 25 whereby if stock options are granted at the current market price then no compensation cost is recognized, and disclosed the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with SFAS No. 123. SFAS No. 123R, which was effective for us beginning on July 1, 2006, eliminates the ability to account for share-based compensation transactions using APB 25, and generally requires that such transactions be accounted for using prescribed fair-value-based methods. SFAS No. 123R permits public companies to adopt its requirements using one of two methods: (a) a “modified prospective” method in which compensation costs are recognized beginning with the effective date based on the requirements of SFAS No. 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123R that remain unvested on the effective date or (b) a “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits companies to restate based on the amounts previously recognized under SFAS No. 123 for purposes of pro forma disclosures either for all periods presented or for prior interim periods of the year of adoption. We have decided to adopt SFAS No. 123R using the modified prospective method.

The following table presents the share-based compensation expense recognized in accordance with SFAS No. 123R during the three and nine months ended March 31, 2007 and in accordance with APB 25 during the three and nine months ended March 31, 2006:

|                                | Three months<br>ended March 31, |       | Nine months<br>ended March 31, |       |
|--------------------------------|---------------------------------|-------|--------------------------------|-------|
|                                | 2007                            | 2006  | 2007                           | 2006  |
| Cost of product sales          | \$ 21,076                       | \$ -- | \$ 92,401                      | \$ -- |
| Research and development       | 8,418                           | --    | 28,132                         | --    |
| Sales and marketing            | 54,737                          | --    | 153,974                        | --    |
| General and administrative     | 40,123                          | --    | 747,734                        | --    |
| Total share-based compensation | \$ 124,354                      | \$ -- | \$ 1,022,241                   | \$ -- |





As of March 31, 2007, total unrecognized compensation cost related to stock-based options and awards was \$1,201,747 and the related weighted-average period over which it is expected to be recognized is approximately 1.05 years.

## **Results of Operations**

### **Three months ended March 31, 2007 and 2006**

**Revenues.** The Company generated sales of \$1,645,694 during the three months ended March 31, 2007, compared to sales of \$479,225 during the three months ended March 31, 2006. The increase of \$1,166,469 or 243% is due to increased sales volume of the Company's <sup>131</sup>Cs seed. During the three months ended March 31, 2007, the Company sold its <sup>131</sup>Cs seed to 36 different medical centers as compared to 18 centers during the corresponding period of 2006.

**Cost of product sales.** Cost of product sales was \$1,456,978 for the three months ended March 31, 2007 compared to cost of product sales of \$791,457 during the three months ended March 31, 2006. The increase of \$665,521 or 84% was due to the higher production levels during the three months ended March 31, 2007 which were related to the increase in sales volume over the corresponding period from 2006. The major components of the increase were wages, benefits and related taxes, materials, depreciation, preload expenses, and share-based compensation. Wages, benefits, and related taxes increased about \$211,000 for the three months ended March 31, 2007 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$335,000 in 2007, due to increased sales volumes. Depreciation expense increased about \$22,000 in 2007 due to the addition of equipment that was placed in service during the second half of the fiscal year ended June 30, 2006 and during fiscal year 2007. Preload expenses also increased by about \$107,000 for the three months ended March 31, 2007 due to the higher volume of sales. Share-based compensation expense was approximately \$21,000 and \$0 for the three months ended March 31, 2007 and 2006, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. These increases were partially offset by a decrease in payments to Pacific Northwest National Laboratory ("PNNL"). For the three months ended March 31, 2006, the Company used PNNL for manufacturing and other ancillary services. The Company stopped using PNNL to produce the seeds during fiscal year 2006 but continues to use PNNL for certain analytical support functions.

**Gross margin (loss).** Gross margin was \$188,716 for the three month period ended March 31, 2007. This represents an improvement of \$500,948 or 160% over the corresponding period of 2006's gross loss of \$312,232. The improvement in gross margin is due to higher revenues offsetting fixed production costs and increased production efficiency.

**Research and development.** Research and development expenses for the three month period ended March 31, 2007 were \$437,143 which represents an increase of \$350,949 or 407% over the research and development expenses of \$86,194 for the corresponding period of 2006. The major components of the increase were wages, benefits and related taxes, patent legal expenses, consulting, share-based compensation, and protocols expense. Wages, benefits and related taxes increased by about \$68,000 for the three months ended March 31, 2007 as the Company employed more research personnel than in the corresponding period of 2006. During the three months ended March 31, 2007, the Company incurred about \$111,000 of legal expenses related to patents and trademarks that were expensed. Consulting expenses were approximately \$129,000 and \$0 for the three months ended March 31, 2007 and 2006, respectively. The Company's consulting expenses increase in the three month period ended March 31, 2007 relates to its on-going project to increase the efficiency of production. Share-based compensation expense was approximately \$8,000 and \$0 for the three months ended March 31, 2007 and 2006, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. Clinical study protocol expenses increased about \$31,000 for the three months ended March 31, 2007 due to additional payments to clinics for participation in the Company's protocols.



**Sales and marketing expenses.** Sales and marketing expenses were \$849,744 for the three months ended March 31, 2007. This represents an increase of \$523,886 or 161% compared to the three months ended March 31, 2006's expenditures of \$325,858 for sales and marketing. Wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and customer service staff increased in 2007 as the Company has expanded its sales and marketing force to better service the various doctors and clinics throughout the United States and to increase usage of its products. Conventions, tradeshow, and consulting expenses for 2007 increased due to the Company's continued efforts to expand its market share and increase brand and market awareness. Also included in sales and marketing expenses for 2007 is share-based compensation expense of approximately \$55,000 due to the Company's implementation of SFAS No. 123R on July 1, 2006.

**General and administrative expenses.** General and administrative expenses for the three months ended March 31, 2007 were \$937,905 compared to general and administrative expenses of \$738,494 for the corresponding period of 2006. The increase of \$199,411 or 27% is primarily due to approximately \$40,000 of share-based compensation expense related to the implementation of SFAS No. 123R on July 1, 2006, approximately \$118,000 of increased payroll costs due to a higher headcount, and approximately \$81,000 relating to investor relations and other public company expenses, and an increase in the bad debt expense of \$62,000 as the Company increased its allowance for doubtful accounts during the three months ended March 31, 2007. These increased expenses were partially offset by a reduction in consulting fees as the prior year included consulting costs related to the 2006 private placement offerings, and a decrease in audit and legal fees as the Company had more regulatory and other filings in 2006 relating to various private placements and stock registration statements.

**Operating loss.** Due to our rapid structural growth and the related need to capture additional market share, and significant research and development expenditures, we have not been profitable, and have generated operating losses since our inception. In the three months ended March 31, 2007, the Company had an operating loss of \$2,036,076 which is an increase of \$573,298 or 39% over the operating loss of \$1,462,778 for the three months ended March 31, 2006.

**Interest income.** Interest income increased by \$43,288 or 170% to \$68,760 for the three months ended March 31, 2007. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

**Financing expense.** Financing expense for the three months ended March 31, 2007 was \$56,772 or a decrease of \$24,377 or 30% from financing expense of \$81,149 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$35,000 and \$29,000 for the three months ended March 31, 2007 and 2006, respectively. The increase in interest expense is due to the interest expense related to the Hanford Area Economic Investment Fund Committee (HAEIFC) loan that was entered into in June 2006. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2006 of the deferred financing costs relating to the debentures that were converted to common stock, partially offset by the amortization of the HAEIFC deferred financing costs.

**Debt conversion expense.** Debt conversion expense for the three months ended March 31, 2006 relates to the one-time recognition of \$141,414 expense in short-term inducement to convert debentures.

### **Nine months ended March 31, 2007 and 2006**

**Revenues.** Sales for the nine months ended March 31, 2007 were \$4,085,293 compared to sales of \$1,176,387 for the nine months ended March 31, 2006. The increase of \$2,908,906 or 247% is due to increased sales volume of the Company's <sup>131</sup>Cs seed. During the nine months ended March 31, 2007 the Company sold its <sup>131</sup>Cs seed to 44 different medical centers as compared to 22 centers during the corresponding period of 2006.

**Cost of product sales.** Cost of product sales was \$4,132,518 for the nine months ended March 31, 2007 compared to cost of product sales of \$2,427,897 during the nine months ended March 31, 2006. The increase of \$1,704,621 or 70% was due to the higher production levels during the nine months ended March 31, 2007 which were related to the increase in sales volume over the corresponding period from 2006. The major components of the increase were wages, benefits and related taxes, materials, depreciation, preload expenses, and share-based compensation. Wages, benefits, and related taxes increased about \$623,000 for the nine months ended March 31, 2007 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$331,000 in 2007, due to increased sales volumes. Depreciation and amortization expense increased about \$132,000 in 2007 due to the addition of equipment that was placed in service during the second half of the fiscal year ended June 30, 2006 and during fiscal year 2007. Preload expenses also increased by about \$236,000 for the nine months ended March 31, 2007 due to the higher volume of sales. Share-based compensation expense was approximately \$92,000 and \$0 for the nine months ended March 31, 2007 and 2006, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. These increases were partially offset by a decrease in payments to Pacific Northwest National Laboratory ("PNNL"). For the nine months ended March 31, 2006, the Company used PNNL for manufacturing and other ancillary services. The Company stopped using PNNL to produce the seeds during fiscal year 2006 but continues during fiscal year 2007 to use PNNL for certain analytical support functions.

**Gross margin (loss).** Gross loss was \$47,225 for the nine month period ended March 31, 2007. This represents an improvement of \$1,204,285 or 96% over the corresponding period of 2006's gross loss of \$1,251,510. The improvement in gross loss is due to higher revenues offsetting fixed production costs and increased production efficiency.

**Research and development.** Research and development expenses for the nine months ended March 31, 2007 were \$898,995 which represents an increase of \$690,182 or 331% over the research and development expenses of \$208,813 for the corresponding period of 2006. The major components of the increase were wages, benefits and related taxes, consulting, legal expenses, share-based compensation, and protocol expenses. Wages, benefits and related taxes were approximately \$249,000 and \$37,000 for the nine months ended March 31, 2007 and 2006, respectively, as the Company hired research scientists. Consulting expenses increased during 2007 due to a fiscal year 2007 project to increase the efficiency of production. During the nine months ended March 31, 2007, the Company incurred about \$130,000 of legal expenses related to patents and trademarks that were expensed. Share-based compensation expense was approximately \$28,000 and \$0 for the nine months ended March 31, 2007 and 2006, respectively, as the Company implemented SFAS No. 123R on July 1, 2006. Clinical study protocol expenses were higher for the nine months ended March 31, 2007 than in the corresponding period of 2006 due to additional payments to clinics for participation in the Company's protocols.

**Sales and marketing expenses.** Sales and marketing expenses were \$2,412,691 for the nine months ended March 31, 2007. This represents an increase of \$1,431,262 or 146% compared to the nine months ended March 31, 2006's expenditures of \$981,429 for sales and marketing. Wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and customer service staff increased about \$779,000 due to the hiring of additional sales and marketing personnel as the Company has more sales and marketing personnel than in the corresponding period of 2006. Conventions and tradeshow increased by about \$196,000 due to the Company's continued presence at these events in order to expand its market share. Marketing and advertising expenses increased

about \$111,000 as the Company has created and distributed brochures, videos, and other promotional literature designed to promote the benefits of our product. Consulting expenses increased due to consultants hired to increase brand and market awareness. Also included in sales and marketing expenses for the period ended March 31, 2007 is share-based compensation expense of about \$154,000 due to the implementation of SFAS No. 123R on July 1, 2006.

**General and administrative expenses.** General and administrative expenses for the nine months ended March 31, 2007 were \$3,492,565 compared to general and administrative expenses of \$2,374,887 for the corresponding period of 2006. The increase of \$1,117,678 or 47% is primarily due to approximately \$748,000 of share-based compensation expense related to the implementation of SFAS No. 123R on July 1, 2006, a one-time severance accrual of \$288,000, approximately \$355,000 of increased payroll costs due to a higher headcount, and approximately \$193,000 relating to investor relations and other public company expenses. These increased expenses were partially offset by a reduction in consulting fees of approximately \$330,000 which represented merger consulting fees incurred in the three months ended September 30, 2005. Other consulting expenses also decreased approximately \$144,000 as the Company hired more internal resources. In addition, audit related fees and legal expenses decreased approximately \$65,000 as the Company had more regulatory and other filings in fiscal year 2006 due to the merger, private placements, and registration statement filings.

**Operating loss.** Due to our rapid structural growth and related need to capture additional market share, product revenues not covering production costs, and significant research and development expenditures, we have not been profitable, and have generated operating losses since our inception. In the nine months ended March 31, 2007, the Company had an operating loss of \$6,851,476 which is an increase of \$2,034,837 or 42% over the operating loss of \$4,816,639 for the nine months ended March 31, 2006. Included in the operating loss for the nine months ended March 31, 2007 is share-based compensation expense of \$1,022,241 due to the implementation of SFAS No. 123R during the period and a one-time severance accrual of \$288,000. Without these two expense items, our operating loss would have only increased by \$724,596 or 15%.

**Interest income.** Interest income increased by \$123,323 or 346% to \$158,947 for the nine months ended March 31, 2007. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

**Financing expense.** Financing expense for the nine months ended March 31, 2007 was \$177,443 or a decrease of \$254,814 or 59% from financing expense of \$432,257 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$112,000 and \$277,000 for the nine months ended March 31, 2007 and 2006, respectively. The decrease in interest expense is due to the conversion of debentures to common stock during the fiscal year ended June 30, 2006 partially offset by interest expense related to the Hanford Area Economic Investment Fund Committee (HAEIFC) loan that was entered into in June 2006. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2006 of the deferred financing costs relating to the debentures that were converted to common stock, partially offset by the amortization of the HAEIFC deferred financing costs.

**Debt conversion expense.** Debt conversion expense for the nine months ended March 31, 2006 relates to the one-time recognition of \$385,511 expense in short-term inducement to convert debentures.

**Liquidity and capital resources.** At March 31, 2007, cash and cash equivalents amounted to \$22,214,256. During the nine months ended March 31, 2007, the Company closed an institutional round of financing (August 2006) and a public direct equity offering (March 2007). Pursuant to the round of institutional funding the Company issued 2,063,000 shares of common stock at a price of \$2.50 per share and 2,269,300 common stock warrants (including broker warrant commissions) with an exercise price of \$3.00 per share. Pursuant to the public equity offering the Company issued 4,130,500 shares of common stock at a price of \$4.00 per share, 826,100 common stock warrants with an exercise price of \$5.00 per share, and 206,526 common stock warrants representing placement agent warrants with an exercise price of \$4.40 per share. The institutional funding provided approximately \$4.7 million, net of offering costs and the public equity offering provided approximately \$15.1 million, net of offering costs. Additionally, the Company issued 3,031,327 shares of common stock pursuant to the exercise of common stock options and warrants and preferred stock warrants, which were exchanged for common stock immediately upon exercise. The Company received approximately \$7.5 million in cash pursuant to these exercises.

The Company had approximately \$21.4 million cash on hand as of May 4, 2007. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$700,000. Management believes that approximately \$5 million will be spent on improvements and equipment for the Company's new production facility. Management presently anticipates to reach break even within the latter half of calendar 2008 and believes cash and cash equivalents currently on hand will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements. Management believes the Company will reach break even with revenues of approximately \$2 million per month, subject to continuing to efficiently manufacture our product. If we should not experience an increase in sales or experience unforeseen manufacturing constraints, we may need to obtain additional funding.

Our growth plans for the remainder of fiscal 2007 include expanding sales to new customers, growing sales volume with existing customers, and developing additional therapies. Additional production capability, including new facilities and equipment and additional employees, will be needed to meet our anticipated growth. The Company completed a review of its current facilities, lease agreements and future needs based on current forecasts. The current production facility lease ends in October 2007 and the landlord has indicated it will not renew the lease. Management has also determined that a larger facility is necessary to handle the anticipated sales growth as the current production facility has limited space.

On May 2, 2007, the Company entered into a lease for a new production facility with 19,328 square feet of manufacturing and office space. The Company has already obtained the necessary permits and has begun to make the necessary leasehold improvements. The Company has applied for a radioactive material license amendment for this new facility and management believes the Company will be able to obtain the license in a timely manner. This new facility is expected to be operational before the end of calendar year 2007. It is possible that the Company will not be able to vacate its existing production facility by the end of its lease due to its new facility not being completed in time. In addition, there will likely be residual radioactive materials in the Company's equipment that will need to be remediated prior to removing the equipment from the facility. The Company is in negotiations with the landlord to extend the current lease for several months to enable a smooth transition to the new facility and allow for removal of the residual radioactive materials.

Management believes that the new production facility will be able to accommodate the Company's anticipated future growth during the lease term. The Company continues to use the Pacific Northwest National Laboratory ("PNNL") to provide third-party assay of its products, but has otherwise vacated PNNL facilities. Management is also currently



setting up facilities to move the third party assay of its products in house which will reduce isotope depletion and also minimize assay expenditures. Management believes that if the Company is unable to complete the leasehold improvements or obtain the radioactive material license amendment before having to vacate the present manufacturing facility that a temporary manufacturing facility is available and could be used, although production capacity and scheduling flexibility would be limited.

IsoRay has two loan facilities in place as of March 31, 2007. The first loan is from the Benton-Franklin Economic Development District ("BFEDD") in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment. As of March 31, 2007, the principal balance owed was \$189,004. This loan is secured by certain equipment, materials and inventory of IsoRay, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee and was originated in June 2006. The loan has a total facility of \$1,400,000 and bears interest at nine percent. As of March 31, 2007, the Company has taken only a partial draw of \$418,670 on the facility and the remaining facility of \$981,330 is available to use to purchase equipment. The principal balance owed on the loan as of March 31, 2007 was \$398,604. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies.

The Company had a line of credit from Columbia River Bank, which provided credit in the amount of \$375,000. This line expired on March 1, 2007 and the Company is currently working to renew this line.

The Company has certain capital leases for production and office equipment that expire at various times from March 2008 to April 2009. These leases currently call for total monthly payments of \$19,361. The total of all capital lease obligations at March 31, 2007 was \$268,804.

At March 31, 2007, the Company had outstanding \$355,000 of convertible debentures. These debentures could be converted into 85,542 shares of common stock at a conversion rate of \$4.15 per share. Each debenture bears interest at an annual rate of eight percent (not compounded) with accrued interest paid quarterly. The debentures mature at various times from April 2007 to June 2007.

In February 2006, the Company signed a license agreement with International Brachytherapy s.a. ("IBt") covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cesium-131. The Company paid license fees of \$275,000 during 2006 but did not make another payment of \$225,000 that was due in August 2006 or the minimum royalty payments in 2007 of \$100,000 per quarter as stated in the agreement. The Company has been in negotiations with IBt to modify this agreement to allow further evaluation of the polymer seed technology before deciding to implement it with Cesium-131.

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

The Company has no off-balance sheet arrangements.

### **Going Concern Issues**

Our independent auditors have noted in their reports on our financial statements as of June 30, 2006 and 2005 and for the years then ended, that there is substantial doubt regarding our ability to continue as a going concern. We had net losses of \$8,218,130 and \$4,269,188 for the years ended June 30, 2006 and 2005 and an accumulated deficit of \$13,546,261 at June 30, 2006. Our accumulated deficit at March 31, 2007 was \$20,416,233.

In March 2007, we completed a public equity offering (see Note 7) and a warrant call (see Note 8) that raised gross proceeds of approximately \$20 million. Due to raising this additional capital, management believes cash and cash equivalents on hand at March 31, 2007 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements assuming our revenues increase to permit us to break even in the latter half of 2008 and we continue to efficiently manufacture our product..

### **Recent Accounting Pronouncements**

In July 2006, the FASB issued Financial Accounting Standard Interpretation No. 48, Accounting for Uncertainty in Income Taxes ("FIN 48"). FIN 48 is an interpretation of SFAS 109 and it seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. In addition, FIN 48 requires expanded disclosure with respect to uncertainties in income taxes. The Company does not believe the adoption of FIN 48 on July 1, 2007 will have a material effect on its consolidated financial statements.

In September 2006, the FASB issued statement No. 157, Fair Value Measurements, ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007, with earlier application encouraged. Any amounts recognized upon adoption as a cumulative effect adjustment will be recorded to the opening balance of retained earnings in the year of adoption. The Company has not yet determined the impact of this Statement on its financial condition and results of operations.

In February 2007, the FASB issued statement No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115 ("SFAS 159"). The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The statement is effective for fiscal years beginning after November 15, 2007. The Company has not yet determined the impact of this Statement on its financial condition and results of operations.

### **Risk Factors**

**You should consider the following discussion of risks as well as other information regarding our operations. The risks and uncertainties described below are not the only ones. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. For a more detailed discussion of the risks facing us, you should review the "Risk Factors" sections contained in our Form 10-KSB for the fiscal year ended June 30, 2006, and our Prospectus Supplement filed with the SEC on March 23, 2007.**

- Our independent accountants have expressed uncertainty about our ability to continue as a going concern. However, in March 2007, we completed a public equity offering (see Note 7) and a warrant call (see Note 8) that raised gross proceeds of approximately \$20 million. Due to raising this additional capital, management believes cash and cash equivalents on hand at March 31, 2007 will be sufficient to meet our anticipated cash requirements for operations, debt service, and capital expenditure requirements assuming our revenues increase to permit us to break-even in the latter half of 2008 and we continue to efficiently manufacture our product.

- Our revenues depend upon one product, our <sup>131</sup>Cs brachytherapy seed, which is used to treat only one type of cancer as of the date of this report, although it is approved to treat any malignant disease.

- The lease on our production facility ends in October 2007 and although we have obtained a lease for a new production facility, there can be no assurance that this new facility will be licensed and the necessary leasehold improvements completed by the time our current lease expires.

  - We have limited data on the clinical performance of the <sup>131</sup>Cs seed.

- The passage of Initiative 297, which may in the future impose restrictions on sites generating certain types of radioactive wastes in Washington, may result in the relocation of our manufacturing operations.

- We may not be able to meet future demand without increasing our supply of the isotopes used to manufacture our product and also increasing our level of staffing.

  - We are subject to the risk that certain third parties may mishandle our product.

  - Our quarterly operating results will be subject to significant fluctuations.

  - We rely heavily on a limited number of suppliers, particularly on our Russian suppliers of <sup>131</sup>Cs which amount to well over 60% of the raw materials needed for our production.

- Future production increases will depend on our ability to acquire larger quantities of <sup>131</sup>Cs and hire more employees.

  - We are subject to uncertainties regarding reimbursement for use of our product.

- It is possible that other treatments may be deemed superior to brachytherapy for the treatment of cancer and if this were to occur, demand for our product could decline.

- Our industry is intensely competitive, and many of our competitors are larger than we are and possess greater resources.

- We may be unable to adequately protect or enforce our intellectual property rights or secure rights to third-party patents, the value of our granted patent and our patents pending is uncertain, and one of our licensed patents may be terminated under certain conditions.

  - Failure to comply with government regulations, which are quite complex, could harm our business.

  - Our business exposes us to product liability claims and also involves environmental risks.

  - We rely heavily upon the expertise of our executive officers and key scientific personnel.

    - Our ability to expand into foreign markets is uncertain.

    - Our ability to expand operations and manage growth is uncertain.

    - Our reporting obligations as a public company are costly.

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·Historically, there has been a limited market for our common stock, and while our volume is still limited, the Company was recently listed on the American Stock Exchange. Our stock price is subject to volatility.

· Our common stock may be subject to penny stock regulation.

·Future sales by shareholders of the shares available for sale in the public market, or the perception that such sales may occur, may depress the price of our common stock.

· We do not expect to pay dividends for the foreseeable future.

· Certain provisions of Minnesota law and our charter documents have an anti-takeover effect.

### ITEM 3. 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 the end of the period covered by this report. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

#### *Management's Remediation Initiatives*

As previously reported, our independent registered public accounting firm, in connection with the review of our consolidated financial statements for the period ended September 30, 2005, advised the Board of Directors and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness. In particular, our independent registered public accounting firm identified the following weaknesses in our internal control system: (1) a lack of segregation of duties and (2) a lack of formal procedures relating to all areas of financial reporting. The independent registered public accounting firm indicated that they considered these weaknesses to be significant deficiencies as that term is defined under standards established by the American Institute of Certified Public Accountants. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes our internal controls from reducing to an appropriately low level of risk that material misstatements in our financial statements will not be prevented or detected on a timely basis. The Company considered these matters in connection with the period end closing of accounts and preparation of the related consolidated financial statements and determined that no prior period financial statements were materially affected by such matters.

During the second quarter of fiscal year 2007, the Company completed the implementation of the following control improvements to remediate the two material weaknesses:

#### *Lack of segregation of duties*

- § Reviewed the duties of all accounting personnel and reassigned any conflicting duties to other personnel;
- § Established daily management reviews of cash and accounts receivable activities and positions;
- § Distributed monthly operating results for review by management in an appropriate time frame; and
- § Established monthly reconciliation procedures including review by the appropriate supervisor.

#### *Financial reporting procedures*

- § Established monthly reconciliation procedures including review by the appropriate supervisor;
- § Established and implemented various accounting policies and procedures; and
- § Distributed monthly operating results for review by management in an appropriate time frame.

Based on the evaluation completed in the third quarter of fiscal year 2007, the Company has concluded that these control improvements are properly designed and operating effectively as of March 31, 2007, and the two significant deficiencies that previously existed have been substantially remediated.

## PART II - OTHER INFORMATION

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES

On March 22, 2007, the Company issued 206,526 warrants with an exercise price of \$4.40 per share to Punk, Ziegel & Company, L.P. and Maxim Group LLC as part of their placement agent fee for the Company's March 2007 public offering, in reliance on the exemption from registration provided by § 4(2) of the Securities Act of 1933, as amended.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

(a) On February 20, 2007, the Company held its Annual Meeting of Stockholders at which our stockholders elected seven Directors and ratified the appointment of our independent registered public accounting firm for the fiscal year ending June 30, 2007.

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

| Director              | For        | Withhold  |
|-----------------------|------------|-----------|
| Dwight Babcock        | 8,762,544  | 1,664,681 |
| Stephen R. Boatwright | 8,697,853  | 1,729,372 |
| Roger E. Girard       | 10,381,744 | 45,481    |
| Robert R. Kauffman    | 8,762,544  | 1,664,681 |
| Thomas C. LaVoy       | 8,707,853  | 1,719,372 |
| Albert Smith          | 8,710,353  | 1,716,872 |
| David J. Swanberg     | 10,214,569 | 212,656   |

(c) *Appointment of our independent registered public accounting firm.* Proposal to ratify the appointment of DeCoria, Maichel & Teague, P.S. as independent registered public accounting firm of the Company for the fiscal year ending June 30, 2007 was approved as follows:

| For        | Against | Abstain |
|------------|---------|---------|
| 10,363,680 | 24,224  | 79,321  |

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

| (a)  | 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   |

(b) Reports on Form 8-K:

On February 7, 2007, the Company filed a Current Report on Form 8-K announcing the approval of a share rights plan and the adoption of certain bylaw amendments.

On March 23, 2007, the Company filed a Current Report on Form 8-K announcing the sale of common stock and warrants to certain institutional investors pursuant to a securities purchase agreement.

On April 4, 2007, the Company filed a Current Report on Form 8-K announcing that as a result of its warrant call on March 26, 2007, the Company received \$4,989,000 of capital from warrant exercises.

On May 8, 2007, the Company filed a Current Report on Form 8-K announcing its subsidiary, IsoRay Medical, Inc., entered into a new lease for 19,328 square feet to be used for its new production facility.



SIGNATURES

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

Dated: May 15, 2007

ISORAY, INC., a Minnesota corporation

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

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