

IsoRay, Inc.  
Form 10QSB  
November 14, 2006

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 September 30, 2006

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 November 10, 2006</u>
Common stock, \$0.001 par value	15,853,852

Transitional Small Business Disclosure Format : Yes  No

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**ISORAY, INC.**

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****IsoRay, Inc. and Subsidiary  
Consolidated Balance Sheets**

	<b>September 30, 2006 (Unaudited)</b>	<b>June 30, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,160,557	\$ 2,207,452
Accounts receivable, net of allowance for doubtful accounts of \$63,237 and \$85,183, respectively	652,255	596,447
Inventory	217,788	161,381
Prepaid expenses	193,771	161,546
<b>Total current assets</b>	<b>6,224,371</b>	<b>3,126,826</b>
Fixed assets, net of accumulated depreciation	1,608,257	1,642,293
Deferred financing costs, net of accumulated amortization	252,501	274,358
Licenses, net of accumulated amortization	268,419	273,475
Other assets, net of accumulated amortization	347,383	338,987
<b>Total assets</b>	<b>\$ 8,700,931</b>	<b>\$ 5,655,939</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 654,062	\$ 584,296
Accrued payroll and related taxes	706,827	614,645
Accrued interest payable	13,699	11,986
Notes payable, due within one year	46,031	51,351
Capital lease obligations, due within one year	190,266	183,554
Convertible debentures payable, due within one year	455,000	455,000
<b>Total current liabilities</b>	<b>2,065,885</b>	<b>1,900,832</b>
Notes payable, due after one year	569,608	581,557
Capital lease obligations, due after one year	162,642	220,415
Asset retirement obligation	68,953	67,425
<b>Total liabilities</b>	<b>2,867,088</b>	<b>2,770,229</b>
Shareholders' equity:		
Preferred stock, \$.001 par value; 6,000,000 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-

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Series B: 5,000,000 shares allocated; 91,298 and 144,759 shares issued and outstanding	91	145
Common stock, \$.001 par value; 194,000,000 and 100,000,000 shares authorized; 15,853,852 and 15,157,901 shares issued and outstanding	15,854	15,158
Subscriptions receivable	-	(6,122,007)
Additional paid-in capital	22,291,594	22,538,675
Accumulated deficit	(16,473,696)	(13,546,261)
Total shareholders' equity	5,833,843	2,885,710
Total liabilities and shareholders' equity	\$ 8,700,931	\$ 5,655,939

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

**IsoRay, Inc. and Subsidiary**  
**Consolidated Statements of Operations**  
**Three Months Ended September 30, 2006 and 2005 (Unaudited)**

	<b>Three months ended</b>	
	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>
Product sales	\$ 1,025,444	\$ 210,915
Cost of product sales	1,288,145	720,166
Gross loss	(262,701)	(509,251)
Operating expenses:		
Research and development	245,598	25,782
Sales and marketing expenses	672,930	315,039
General and administrative expenses	1,733,132	960,949
Total operating expenses	2,651,660	1,301,770
Operating loss	(2,914,361)	(1,811,021)
Non-operating income (expense):		
Interest income	40,183	6,959
Financing expense	(53,257)	(155,628)
Non-operating income (expense), net	(13,074)	(148,669)
Net loss	\$ (2,927,435)	\$ (1,959,690)
Basic loss per share	\$ (0.19)	\$ (0.22)
Shares used in computing net loss per share:		
Basic	15,300,747	8,830,965

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

**IsoRay, Inc. and Subsidiary**  
**Consolidated Statements of Cash Flows**  
**Three Months Ended September 30, 2006 and 2005 (Unaudited)**

	<b>Three months ended</b>	
	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,927,435)	\$ (1,959,690)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	89,426	45,961
Amortization of deferred financing costs and other assets	39,773	55,592
Accretion of asset retirement obligation	1,528	-
Noncash share-based compensation	781,443	-
Merger consulting fees paid by issuance of common stock	-	330,000
Changes in operating assets and liabilities:		
Accounts receivable, net	(55,808)	(86,056)
Inventory	(56,407)	(38,226)
Prepaid expenses	(32,225)	(61,458)
Accounts payable and accrued expenses	69,766	(248,232)
Accrued payroll and related taxes	92,182	90,177
Accrued interest payable	1,713	52,493
Net cash used by operating activities	(1,996,044)	(1,819,439)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(55,390)	(253,833)
Additions to licenses and other assets	(21,256)	(54,458)
Net cash used by investing activities	(76,646)	(308,291)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sales of convertible debentures payable	-	550,000
Principal payments on notes payable	(17,269)	(19,436)
Principal payments on capital lease obligations	(51,061)	(4,408)
Proceeds from cash sales of common shares pursuant to private placement, net of offering costs	4,702,931	-
Proceeds from cash sales of preferred stock, pursuant to exercise of warrants	8,709	-
Proceeds from cash sales of common stock, pursuant to exercise of warrants	-	56,937
Proceeds from cash sales of common stock, pursuant to exercise of options	382,485	70,548
Net cash provided by financing activities	5,025,795	653,641
Net increase in cash and cash equivalents	2,953,105	(1,474,089)
Cash and cash equivalents, beginning of period	2,207,452	1,685,731

<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	\$	5,160,557	\$	211,642
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The accompanying notes are an integral part of these financial statements.

**IsoRay, Inc.**  
**Notes to the Unaudited Consolidated Financial Statements**  
**For the three-month periods ended September 30, 2006 and 2005**

**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 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**

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”). Under APB 25, if stock options are granted at market price then no compensation cost is recognized, and a disclosure is made regarding the pro forma effect on net earnings assuming compensation cost had been recognized in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (“SFAS 123”). During December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS 123R, *Share-Based Payment*, which requires companies to measure and recognize compensation expense for all share-based payments at fair value. SFAS 123R 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 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 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 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 123 for purposes of pro forma disclosures either for all periods presented or prior interim periods of the year of adoption. Effective July 1, 2006, the Company adopted SFAS 123R using the modified prospective method. No share-based employee compensation cost was reflected in the statement of operations prior to the adoption of SFAS 123R. Results for prior periods have not been restated.

The following table presents the share-based compensation expense recognized in accordance with SFAS 123R during the three months ended September 30, 2006 and in accordance with APB 25 during the three months ended September 30, 2005:



	Three months ended September 30,	
	2006	2005
Cost of product sales	\$ 50,833	\$ --
Research and development	11,835	--
Sales and marketing	46,781	--
General and administrative	671,994	--
Total share-based compensation	\$ 781,443	\$ --

The adoption of SFAS 123R reduced income before income tax expense and net income for the three months ended September 30, 2006 by \$781,443. Basic loss per common share for the three months ended September 30, 2006 would have been \$0.14 if the Company had not adopted SFAS 123R, compared to reported basic loss per common share of \$0.19. The total value of the stock options awards is expensed ratably over the service period of the employees receiving the awards. As of September 30, 2006, total unrecognized compensation cost related to stock-based options and awards was \$944,407 and the related weighted-average period over which it is expected to be recognized is approximately 1.23 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 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 three months ended September 30, 2006 is as follows:

	Shares	Price (a)	Life (b)	Value (c)
Outstanding at June 30, 2006	3,129,692	\$ 2.05		
Granted (d)	627,900	3.15		
Exercised	(321,416)	1.19		
Outstanding at September 30, 2006	3,436,176	\$ 2.33	9.04	\$ 3,667,141
Expected to vest at September 30, 2006	3,380,949	\$ 2.32	9.04	\$ 3,629,538
Vested and exercisable at September 30, 2006	2,789,770	\$ 2.04	8.98	\$ 3,510,462

(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 three months ended September 30, 2006 was \$702,763.

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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 months ended September 30, 2006 and 2005:

	Three months ended September 30,	
	2006	2005
Weighted average fair value of options granted	\$ 2.10	\$ 0.68
Key assumptions used in determining fair value:		
Weighted average risk-free interest rate	4.90%	4.60%
Expected life of the option (in years)	5.51	8.50
Expected stock price volatility	75.00%	30.00%
Expected dividend yield	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 months ended September 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to all outstanding stock option awards for periods presented prior to the Company's adoption of SFAS 123R:

	Three months Ended September 30, 2005
Net loss, as reported	\$ 1,959,690
Stock-based compensation expense determined Under fair value methods for all stock options	156,000
Proforma net loss	\$ 2,115,690
Net loss per share:	
Basic, as reported	\$ 0.22
Basic, pro forma	\$ 0.24

### 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. Basic weighted average shares outstanding for the year ended June 30, 2005 have been adjusted to reflect the exchange ratio contained in the merger transaction dated July 28, 2005. At June 30, 2006 and 2005, 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.

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Securities that could be dilutive in the future as of September 30, 2006 and 2005 are as follows:

	September 30,	
	2006	2005
Preferred stock	91,928	1,260,732
Preferred stock warrants	173,292	224,300
Common stock warrants	4,768,563	354,627
Common stock options	3,436,176	2,310,046
Convertible debentures	109,639	997,078
<b>Total potential dilutive securities</b>	<b>8,579,598</b>	<b>5,146,783</b>

#### 4. Risks and Uncertainties

The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business. However, our large operating losses and accumulated deficit, among other things, raise substantial doubt about our ability to continue as a going concern. Management plans to raise additional financing (including the sale of additional equity or borrowings) and grow the revenues of our core product while continually analyzing other market opportunities. However, no assurance can be given that such financing will be completed on terms acceptable to the Company or that the Company will be able to meet its revenue targets. If the Company is unable to obtain additional financing and grow revenues, we may have to curtail our business or cease operations. The financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

#### 5. Return of Subscription Receivable Shares

The Company had previously entered into Purchase Agreements with Mercatus & Partners, Limited, a United Kingdom private limited company ("Mercatus") in December 2005 that permitted Mercatus to purchase 1,748,146 shares of common stock subject to the receipt of funding. As no funding had been received, on May 18, 2006, the Company requested the return of the share certificates. After significant delay and the Company's attainment of a court order, the share certificates were returned. On August 8, 2006, the share certificates were cancelled and the Purchase Agreements were terminated. The Company then reversed the subscription receivable and the related entry to additional paid-in capital.

#### 6. August 2006 Stock Purchase Agreement

On August 17, 2006, the Company sold certain shares of its common stock and warrants to purchase common stock pursuant to a Common Stock and Warrant Purchase Agreement (the "Purchase Agreement") dated August 9, 2006. The securities were issued to 25 accredited investors pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. MicroCapital, LLC acted as the lead investor for the transaction. Net proceeds of \$4.7 million was received by the Company in exchange for the issuance of 2,063,000 shares of common stock and warrants to purchase 2,063,000 shares of common stock. In addition, brokers assisting the Company with the capital raise were issued warrants to purchase 206,300 shares of common stock on identical terms as the warrants issued to investors. If all warrants were exercised, the Company would receive \$6,808,500.

Pursuant to the Purchase Agreement, the purchase price per share of the Company's common stock was \$2.50, and the accompanying warrants were issued with an exercise price of \$3.00 per share. The warrants and the Purchase Agreement contain anti-dilution provisions, including one providing that, if the Company issues stock or rights to acquire stock at a price less than \$2.00 (excluding certain issuances such as options to employees, directors and certain consultants and shares issued in connection with licensing or leasing transactions), the Company is required to issue to each investor additional shares equal to 25% of what such investor purchased in the original transaction. The warrants are exercisable by the holder (subject to anti-dilution and adjustment provisions) for a period of five years from the date of issuance. The warrants are callable by the Company for 45 days after a period of 60 trading days in which the price of the underlying stock exceeds \$4.50 per share for 30 of the 60 days, and only if a registration statement covering the underlying shares is effective.

In connection with the Purchase Agreement, the Company also entered into a Registration Rights Agreement whereby the Company has agreed to file a registration statement to cover the re-sale of the shares of common stock sold and issuable upon exercise of the warrants. Under the Registration Rights Agreement, the Company has agreed to file the registration statement within 60 days of the closing, cure any defect causing the registration statement to fail to be effective within 10 business days, and cause suspension periods for the registration statement to not exceed 60 days in any 360 day period. If the Company fails to comply with these provisions, the Company will be required to pay as liquidated damages an amount equal to 2% of the aggregate purchase price paid by the investors for each 30 day period during which the failure continues, not to exceed 10% of the aggregate purchase price. A Form SB-2 Registration Statement to register these shares was filed with the SEC on October 16, 2006 and amended on October 19, 2006 and is currently pending SEC review.

#### **7. Settlement Agreements with Former Executives**

In September 2006, the Company entered into a settlement agreement with a former executive. As part of the settlement the Company agreed to pay the former executive \$100,000 in September 2006 and \$215,000 in January 2007.

Also in September 2006, the Company reached a preliminary settlement agreement, subject to approval of the Board of Directors, with its former Chief Financial Officer. The preliminary settlement calls for payments totaling \$288,000, with the timing of these payments under negotiation.

#### **8. Subsequent Event**

##### Supply Contract

On October 6, 2006, IsoRay Medical, Inc., the wholly owned subsidiary of the Registrant, entered into a Contract with FSUE "SSE - Research Institute of Atomic Reactors" ("RIAR") in Russia. The Contract provides for delivery to IsoRay Medical of purified Cs-131 isotope, which is used by IsoRay Medical to produce its proprietary Cs-131 brachytherapy seed used in the treatment of prostate cancer. The total value of the Contract over its term, which expires on May 1, 2014, is \$6,300,000. Delivery of the isotope is scheduled to commence in January 2007 and continue through December 2013, upon submission of written orders by IsoRay Medical forty-five days in advance of the planned date of delivery.

IsoRay Medical also entered into an Agreement for Exclusive Right to Buy on October 6, 2006 with RIAR. This Agreement gives IsoRay Medical the exclusive right to purchase the Cs-131 isotope produced by RIAR for a period of seven years, or through October 6, 2013.

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

### ***Caution Regarding Forward-Looking Information***

*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 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 14 below and in the "Risk Factors" sections of our Form 10-KSB for the fiscal year ended June 30, 2006 and our amended Registration Statement on Form SB-2 initially filed on November 10, 2005 and amended on October 24, 2006 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 September 30, 2006, there have been no material changes to any of the critical accounting policies contained therein except for the adoption of SFAS 123R as noted below.

### **Share-Based Compensation**

As part of our adoption of SFAS 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.

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### **Adoption of SFAS 123R**

During December 2004, the Financial Accounting Standards Board (“FASB”) issued SFAS 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 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 123. SFAS 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 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 123R for all share-based payments granted or modified after the effective date, and based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 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 123 for purposes of pro forma disclosures either for all periods presented or prior interim periods of the year of adoption. We have decided to adopt SFAS 123R using the modified prospective method.

During the three months ended September 30, 2006, we recognized \$781,443 of compensation expense related to the expensing of stock options in accordance with SFAS 123R. Approximately \$51,000, \$12,000, \$47,000, and \$672,000 of this amount is included in cost of products sales, research and development, sales and marketing, and general and administrative expenses, respectively, in the accompanying consolidated statements of operations. As of September 30, 2006, total unrecognized compensation cost related to stock-based options was \$944,407 and the related weighted-average period over which it is expected to be recognized is approximately 1.23 years.

### **Results of Operations**

#### **Three months ended September 30, 2006 compared to three months ended September 30, 2005**

**Revenues.** The Company generated sales of \$1,025,444 during the three months ended September 30, 2006, compared to sales of \$210,915 during the three months ended September 30, 2005. The increase of \$814,529 or 386% is due to increased sales volume of the Company’s <sup>131</sup>Cs seed. During the three months ended September 30, 2006, the Company sold its <sup>131</sup>Cs seed to 23 different medical centers as compared to 10 centers during the corresponding period of 2005.



**Cost of product sales.** Cost of product sales was \$1,288,145 for the three months ended September 30, 2006 compared to cost of product sales of \$720,166 during the three months ended September 30, 2005. The increase of \$567,979 or 79% was due to the higher production levels during the three months ended September 30, 2006 which were related to the increase in sales volume over the corresponding period from 2005. The major components of the increase were wages, benefits and related taxes, materials, depreciation, third-party preload services, share-based compensation, and rent and occupancy expenses. Wages, benefits, and related taxes increased about \$201,000 to approximately \$374,000 for the three months ended September 30, 2006 due to the hiring of additional production employees to support the higher production levels. Materials costs increased about \$297,000 to approximately \$421,000 in 2006, due to increased sales volumes. Depreciation expense increased about \$42,000 to approximately \$83,000 in 2006 due to the addition of equipment that was placed in service during the second half of the fiscal year ended June 30, 2006. Third-party preload services also increased by about \$58,000 to approximately \$74,000 for the three months ended September 30, 2006 due to the higher volume of sales. Share-based compensation expense was approximately \$51,000 and \$0 for the three months ended September 30, 2006 and 2005, respectively, as the Company implemented SFAS 123R on July 1, 2006. Rent and occupancy expenses were approximately \$39,000 and \$0 for the three months ended September 30, 2006 and 2005, respectively, as the Company moved into its independent production facility in the second half of fiscal year 2006. These increases were offset by lower payments to Pacific Northwest National Laboratory ("PNNL") as the Company discontinued using PNNL's facilities and personnel to manufacture its product during fiscal year 2006. For the three months ended September 30, 2005, the Company paid PNNL approximately \$235,000 under a production contract. The Company has continued to use PNNL for certain analytical support functions and paid PNNL approximately \$80,000 during the three months ended September 30, 2006.

**Gross loss.** Gross loss was \$262,701 for the three month period ended September 30, 2006. This represents an improvement of \$246,550 or 48% over the corresponding period of 2005's gross loss of \$509,251. The improvement in gross loss is due to higher revenues and greater production efficiency.

**Research and development.** Research and development expenses for the three month period ended September 30, 2006 were \$245,598 which represents an increase of \$219,816 or 853% over the research and development expenses of \$25,782 for the corresponding period of 2005. The major components of the increase were wages, benefits and related taxes, protocol studies, consulting, and share-based compensation. Wages, benefits and related taxes were approximately \$64,000 and \$0 for the three months ended September 30, 2006 and 2005, respectively, as the Company hired research scientists. Protocol studies expenses increased about \$73,000 to approximately \$76,000 for the three-months ended September 30, 2006 as more patients were enrolled in these studies. Consulting expenses increased about \$65,000 to approximately \$88,000 as the Company continues to refine the production of isotopes. Share-based compensation expense was approximately \$12,000 and \$0 for the three months ended September 30, 2006 and 2005, respectively, as the Company implemented SFAS 123R on July 1, 2006.

**Sales and marketing expenses.** Sales and marketing expenses were \$672,930 for the three months ended September 30, 2006. This represents an increase of \$357,891 or 114% compared to the three months ended September 30, 2005's expenditures of \$315,039 for sales and marketing. During the three months ended September 30, 2006, approximately \$392,000 was paid for wages, including payroll-related taxes, travel, office and other support expenses on behalf of our sales and marketing and customer service staff and approximately \$47,000 represents share-based compensation expense. The balance was spent on advertising, market research, and trade shows and conferences. The increase over the prior year is due to increased sales and marketing personnel and increased expenses to market the Company's <sup>131</sup>Cs seeds through promotional materials and conventions and tradeshow as the Company continues its efforts to expand its market share.

**General and administrative expenses.** General and administrative expenses for the three months ended September 30, 2006 were \$1,733,132 compared to general and administrative expenses of \$960,949 for the corresponding period of 2005. The increase of \$772,183 or 80% is primarily due to approximately \$672,000 of share-based compensation expense related to the implementation of SFAS 123R on July 1, 2006, a one-time severance accrual of \$288,000, approximately \$100,000 of increased payroll costs due to a higher headcount, approximately \$27,000 relating to investor relations expenses, and approximately \$12,000 relating to higher insurance premiums due to the growth of the Company. These increased expenses were partially offset by a reduction in consulting fees of approximately \$330,000 which represents merger consulting fees incurred in the three months ended September 30, 2005.

**Operating loss.** Due to our significant research and development expenditures, additional responsibilities as a reporting company, rapid structural growth, and product revenues not covering production costs, we have not been profitable, and have generated operating losses since our inception. In the three months ended September 30, 2006, the Company had an operating loss of \$2,914,361 which is an increase of \$1,103,340 or 61% over the operating loss of \$1,811,021 for the three months ended September 30, 2005. Included in the operating loss for the three months ended September 30, 2006 is share-based compensation expense of \$781,443 due to the implementation of SFAS 123R during the period and a one-time severance accrual of \$288,000. Without these two expense items, our operating loss would have had only a marginal increase.

**Interest income.** Interest income increased by \$33,224 or 477% to \$40,183 for the three months ended September 30, 2006. Interest income is mainly derived from excess funds held in certain near-liquid accounts.

**Financing expense.** Financing expense for the three months ended September 30, 2006 was \$53,257 or a decrease of \$102,371 or 66% from financing expense of \$155,628 for the corresponding period in 2005. Included in financing expense is interest expense of approximately \$31,000 and \$104,000 for the three months ended September 30, 2006 and 2005, 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.

**Liquidity and capital resources.** At September 30, 2006, cash and cash equivalents amounted to \$5,160,557. During the three months ended September 30, 2006, 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 a round of institutional funding. This funding provided approximately \$4.7 million, net of offering costs. Additionally, the Company issued 327,636 shares of common stock pursuant to the exercise of common stock options and preferred stock warrants, which were exchanged for common stock immediately upon exercise. The Company received \$391,194 in cash pursuant to these exercises.

The Company had approximately \$4.7 million cash on hand as of October 31, 2006. As of that date management believes that the Company's monthly required cash operating expenditures were approximately \$800,000. Management believes that assuming expenditures continue at approximately the same monthly rate and that it is able to fund a portion of its equipment purchases with the HAEIFC loan, that the Company's cash on hand will fund operating expenditures through the beginning of March 2007. This is based on the Company attaining its current revenue targets and the ability to efficiently manufacture our product. If we should experience disruptions in our revenues then our monthly cash requirements would increase and necessitate that we obtain additional funding prior to February 2007.

Our growth plans for fiscal 2007 include expanding sales to new customers, growing sales volume with existing customers, and expanding production capability through the purchase of additional equipment. The Company has also begun a review of its current facilities and future needs. The Company continues to use PNNL to provide third-party assay of its products, but has otherwise vacated PNNL facilities. This review includes evaluating the Company's need for space given its growth projections. It is anticipated that additional employees and production equipment will be needed to meet future growth. This will create the need for additional production and office space that would be leased through an operating lease.

IsoRay has three loans outstanding as of September 30, 2006. The first loan is from the Benton-Franklin Economic Development District ("BFEDD") in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment. As of September 30, 2006, the principal balance owed was \$201,312. 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 a line of credit from Columbia River Bank, which provides credit in the amount of \$375,000. It bears interest at a floating prime plus two percent rate, and is secured by certain accounts receivable and inventory and personal guarantees, for which the guarantors were issued approximately 107,401 shares of common stock. As of September 30, 2006, no balance was outstanding on the line of credit. The line of credit expires on March 1, 2007. The third 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 September 30, 2006, 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 September 30, 2006 was \$414,327. This loan is secured by receivables, equipment, materials and inventory of IsoRay, and certain life insurance policies.

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 capital lease obligations at September 30, 2006 was \$352,908.

At September 30, 2006, the Company had outstanding \$455,000 of convertible debentures. These debentures could be converted into 109,639 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 February 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 and another payment of \$225,000 was to be made in August 2006 pursuant to the license agreement. Royalty payments based on net sales revenue are also required, with minimum quarterly royalties ranging from \$100,000 to \$200,000 and minimum annual royalties ranging from \$400,000 to \$800,000 over the term of the agreement. Management is engaged in further negotiations with IBt and may ultimately terminate this agreement, although management has not yet decided on a course of action.

As of the date of this report, the payment due in August 2006 has not been made as the Company has been in continued negotiations with IBt concerning the amount and timing of future royalty payments due to the low market acceptance of the polymer seed technology.

In September 2006, the Company entered into a settlement agreement with a former executive. As part of the settlement the Company agreed to pay the former executive \$100,000 in September 2006 and \$215,000 in January 2007. As of September 30, 2006 the remaining payment of \$215,000 is accrued in accrued payroll.

Also in September 2006, the Company reached a preliminary settlement agreement, subject to approval of the Board of Directors, with its former Chief Financial Officer. The preliminary settlement calls for payments totaling \$288,000, with the timing of these payments under negotiation.

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

The Company has no off-balance sheet arrangements.

### **Going Concern Issues**

Our financial statements have been prepared assuming we will 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 September 30, 2006 was \$16,473,696. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustment that might result from the outcome of this uncertainty. Management plans to obtain the necessary financing and to continue to grow revenues in order to achieve profitability but no assurances can be given that management will be able to obtain additional financing or grow revenues to a profitable level.

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 or cease operations. Our continuation as a going concern is dependent upon our ability to generate sufficient cash flow to meet our obligations on a timely basis, to obtain additional financing, and, ultimately, to attain profitability. Should any of these events not occur, the accompanying financial statements will be adversely effected and we may have to cease 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 amended Registration Statement on Form SB-2 originally filed with the SEC on November 10, 2005 and amended on October 24, 2006.**

- Our independent accountants have expressed uncertainty about our ability to continue as a going concern.

- 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 tissue.
  - We have limited data on the clinical performance of the <sup>131</sup>Cs seed.
    - We will need to raise additional capital to fund our operations until we reach profitability.
- 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 have limited manufacturing experience and 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 have limited specific experience with the sales and marketing of the <sup>131</sup>Cs seed.
    - 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 Barium and Cesium which amount to well over 50% of the raw materials needed for our production.
  - 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 would 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 our executive officers and key scientific personnel.
        - Our ability to expand into foreign markets is uncertain.
      - Our ability to successfully commercialize our product is uncertain.
        - Our reporting obligations as a public company are costly.
  - There is a limited market for our common stock, and our stock price is likely to be volatile.
    - 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.

### ITEM 3. CONTROLS AND PROCEDURES

(a) Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of September 30, 2006. 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.

(b) In connection with the review of our consolidated financial statements for the period ended September 30, 2005, our independent registered public accounting firm 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 deficiencies to be reportable conditions 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. Notwithstanding the material weaknesses identified by our independent registered public accountants, we believe that the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operation and cash flows of the Company as of, and for, the periods represented in this report.

The size of the Company has previously prevented us from being able to employ sufficient resources at this time to enable us to have an adequate level of supervision and segregation of duties within our internal control system. Set forth below is a discussion of the significant internal control deficiencies that had not been remediated as of the end of the period covered by this report.

*Lack of segregation of duties.* Our size has prevented us from being able to employ sufficient resources to enable us to have an adequate level of segregation of duties within our internal control system. There are two dedicated employees and three employees that work in accounting and other departments who are involved in the processing of transactions. Due to the small employee base it is difficult to effectively segregate accounting duties. While we strive to segregate duties as much as practicable, budgetary considerations have not previously allowed the addition of full time staff. We are currently reorganizing the accounting department to more effectively segregate duties but we believe additional staff is still needed. We will continue in our attempt to add staff to allow for fuller segregation of duties, although there is no certainty additional staff can be successfully hired. As a result, this significant internal control deficiency has not been remediated as of the end of the period covered by this report, nor do we know if we will be able to remediate this weakness during the upcoming quarter.

*Lack of formal procedures relating to all areas of financial reporting including a lack of review by management.* Due to the size of our Company, and as a consequence of the lack segregation of duties, we historically have not previously had formal month-end close procedures. As a result, historically there has been a lack of timely review of the financial statements. However, near the end of fiscal year 2006 we began developing monthly close procedures. These procedures were partially implemented at September 30, 2006 and the Company is completing the documented monthly close process to ensure that monthly financial results are communicated to management in a timely manner. This significant internal control deficiency has not been fully remediated as of the end of the period covered by this report but we anticipate that it will be fully remediated by the end of the second quarter of fiscal year 2007 which ends on December 31, 2006.

If we are unable to remediate the identified material weaknesses, there is a more than remote likelihood that a material misstatement to our SEC reports will not be prevented or detected, in which case investors could lose confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our ability to raise additional capital and could also have an adverse effect on our stock price.

## **PART II - OTHER INFORMATION**

### **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 August 10, 2006, the Company filed a Current Report on Form 8-K announcing the return of the Mercatus shares and their cancellation.

On August 18, 2006, the Company filed a Current Report on Form 8-K announcing the sale of unregistered common stock and warrants pursuant to a Common Stock and Warrant Purchase Agreement.

On September 8, 2006, the Company filed a Current Report on Form 8-K announcing a press release of the Company's preliminary financial results for the year ended June 30, 2006 and anticipated first quarter of fiscal year 2007.

On September 11, 2006, the Company filed a Current Report on Form 8-K announcing the resignation of the Company's Chief Financial Officer, the appointment of a new Chief Financial Officer, and the transcript from the Company's presentation at the Roth Capital Conference.

On November 6, 2006, the Company filed a Current Report on Form 8-K announcing its subsidiary's entry into two contracts for the supply of Cesium-131 with RIAR in Russia.



SIGNATURES

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

Dated: November 13, 2006

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