

IsoRay, Inc.  
Form 10QSB  
November 21, 2005

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, 2005

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

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 that the registrant was required to file such reports), and (2) been subject to such filing requirements for the past 90 days.

The registrant is not a shell company (as defined in Rule 12b-2 of the Exchange Act).

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

<u>Class</u>	<u>Outstanding as of November 14, 2005</u>
Common stock, \$0.001 par value	9,767,026

The issuer is not using the Transitional Small Business Disclosure format.

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**ISORAY, INC.**

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**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements (Unaudited)****IsoRay, Inc. and Subsidiary  
Consolidated Balance Sheet (Unaudited)  
September 30, 2005****ASSETS**

<b>Current assets:</b>	
Cash and cash equivalents	\$ 211,642
Accounts receivable, net of allowance for doubtful accounts of \$17,075	136,025
Inventory	120,152
Prepaid expenses	242,724
	<b>Total current assets</b>
	710,543
Fixed assets, net of accumulated depreciation and amortization	1,050,195
Other assets, net of accumulated amortization	792,622
	<b>Total assets</b>
	\$ 2,553,360

**LIABILITIES AND SHAREHOLDERS' (DEFICIT)**

<b>Current liabilities:</b>	
Accounts payable	\$ 468,712
Accrued payroll and related taxes	248,101
Accrued interest payable	93,818
Notes payable, due within one year	43,748
Capital lease obligations, due within one year	8,820
	<b>Total current liabilities</b>
	863,199
Notes payable, due after one year	542,156
Capital lease obligations, due after one year	15,960
Convertible debentures payable, due after one year	4,137,875
	<b>Total liabilities</b>
	5,559,190
<b>Shareholders' (deficit):</b>	
Preferred stock, \$.001 par value, 6,000,000 shares authorized:	
1,000,000 shares allocated to Series A: No shares issued and outstanding	
5,000,000 shares allocated to Series B: 1,260,732 shares issued and outstanding	1,261
IsoRay, Inc. common stock, \$.001 par value; 194,000,000 shares authorized;	
9,060,221 shares issued and outstanding	9,060
Additional paid-in capital	4,271,671
Accumulated deficit	(7,287,821)

Total shareholders' (deficit) (3,005,829)

Total liabilities and shareholders' (deficit) \$ 2,553,360

*The accompanying notes are an integral part of the financial statements.*

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**IsoRay, Inc, and Subsidiary**  
**Consolidated Statements of Operations**  
**Three Months Ended September 30, 2005 and 2004 (Unaudited)**

	2005	2004
Product sales	\$ 210,915	\$ -
Cost of product sales	720,166	-
Gross profit (loss)	(509,251)	-
Operating expenses:		
Research and development	25,782	-
Sales and marketing expenses	315,039	-
General and administrative expenses	960,949	4,169
Total operating expenses	1,301,770	4,169
Operating loss	(1,811,021)	(4,169)
Non-operating income (expense):		
Interest income	6,959	-
Financing expense	(155,628)	-
Non-operating income (expense), net	(148,669)	-
Net loss	\$ (1,959,690)	\$ (4,169)
Net loss per weighted-average share of common stock	\$ (0.22)	\$ Nil
Basic weighted average shares outstanding	8,830,965	2,415,215

*The accompanying notes are an integral part of the financial statements.*

**IsoRay, Inc. and Subsidiary**  
**Consolidated Statements of Cash Flows**  
**Three Months Ended September 30, 2005 and 2004 (Unaudited)**

	2005	2004
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (1,959,690)	\$ (4,169)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	45,961	-
Amortization of deferred financing costs and other assets	55,592	-
Compensation recorded in connection with issuance of common stock	330,000	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(86,056)	-
Inventory	(38,226)	-
Prepaid expenses	(61,458)	-
Accounts payable	(248,232)	395
Accrued payroll and related taxes	90,177	-
Accrued interest payable	52,493	-
Net cash used by operating activities	(1,819,439)	(3,774)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(253,833)	-
Additions to other assets	(54,458)	-
Net cash used by investing activities	(308,291)	-
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Funds advanced by officer/shareholder		3,774
Proceeds from sales of convertible debentures payable	550,000	-
Principal payments on notes payable	(19,436)	-
Principal payments on capital lease obligations	(4,408)	-
Proceeds from cash received on exercise of warrants	56,937	-
Proceeds from cash received on exercise of options	70,548	-
Net cash provided by financing activities	653,641	3,774
Net increase (decrease) in cash and cash equivalents	(1,474,089)	-
Cash and cash equivalents, beginning of period	1,685,731	-
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 211,642</b>	<b>\$ -</b>

*The accompanying notes are an integral part of the financial statements.*

**NOTE 1— ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

*Organization:*

The accompanying consolidated financial statements are those of IsoRay, Inc. ("the Company"), formerly known as Century Park Pictures Corporation, and its subsidiary operating company, IsoRay Medical, Inc. ("IsoRay Medical" or the "Subsidiary"). Both companies are headquartered in Richland, Washington.

The accompanying consolidated financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto as of June 30, 2005, and for the nine months then ended, as contained in the Company's transition report on Form 10-KSB, and with the audited financial statements of IsoRay Medical as of June 30, 2005 and 2004, and for the years then ended, as filed with the Company's Form 8-K on November 3, 2005.

The Company was incorporated in Minnesota on July 13, 1983. Since 1998, and until the completion of the recent merger with IsoRay Medical, which became effective July 28, 2005 (July 1, 2005 for accounting purposes), the Company did not conduct any business operations and had minimal assets and liabilities. Although the Company formerly had a September 30 fiscal year end, pursuant to the merger, the Company's year end was changed to June 30 to coincide with that of IsoRay Medical.

*Segment Reporting and Major Customers:*

IsoRay Medical operates in a single segment: isotope-based medical devices. IsoRay Medical began production and sales of its initial FDA approved product, the IsoRay <sup>131</sup>Cs brachytherapy seed, in October 2004 for the treatment of prostate cancer. Sales of the <sup>131</sup>Cs brachytherapy seed comprise all operating revenues of both companies. Three customers individually comprised more than 10% of product sales for the three month period ended September 30, 2005: Chicago Prostate Cancer Center, Texas Cancer Clinic, and Warren General Hospital.

*Summary of Significant Accounting Policies:*

*Basis of Presentation* - The accompanying unaudited consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America and reflect all normal recurring adjustments which, in the opinion of management of the Company, are necessary for a fair presentation of the results for the periods presented. The results of operations for such periods are not necessarily indicative of the results expected for the full fiscal year or for any future period.

*Basis of Consolidation* - The accompanying unaudited consolidated financial statements reflect the balance sheets of IsoRay, Inc. and its Subsidiary as of September 30, 2005, and the results of operations and statements of cash flows for the three months then ended net of all adjustments for inter-company transactions.

*Use of Estimates* - The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates and assumptions.

*Cash and Cash Equivalents* - Such assets consist of demand deposits, including interest-bearing money market accounts, held in one financial institution. These amounts are potentially subject to concentration of credit risk. The accounts are guaranteed by the Federal Deposit Insurance Corporation (FDIC) up to \$100,000. At September 30, 2005, uninsured cash balances totaled \$166,973.

*Inventory* - Inventory is reported at the lower of cost, determined using the weighted average method, or net realizable value.

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*Revenue Recognition* - Revenue for the three months ended September 30, 2005 was derived solely from sales of the <sup>131</sup>Cs brachytherapy seed. This product is shipped FOB shipping point, and is invoiced and the sale recorded in accounts receivable at the time of shipment.

*Stock-Based Compensation* - SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, requires companies to recognize stock-based expense based on the estimated fair value of employee stock options. Alternatively, SFAS No. 123 allows companies to retain the current approach set forth in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), provided that expanded footnote disclosure is presented. The Company has not adopted the fair value method of accounting for stock-based compensation under SFAS No. 123, but provides the pro forma disclosure required when appropriate.

*Income Tax* - Deferred taxes are provided, when material, on a liability method whereby deferred tax assets are recognized for deductible temporary differences and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. There were no material temporary differences for the periods presented. Deferred tax assets, subject to a valuation allowance, are recognized for future benefits of net operating losses being carried forward.

*Earnings Per Share* - Statement of Financial Accounting Standards No. 128, "Earnings per Share," requires dual presentation of basic earnings per share ("EPS") and diluted EPS on the face of all income statements issued after December 15, 1997 for all entities with complex capital structures. Basic EPS is computed as net income divided by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that could occur from common shares issuable through stock options, warrants, and other convertible securities. For the periods ended September 30, 2005 and 2004, the effect of the Company's outstanding options and common stock equivalents would have been anti-dilutive. Accordingly, only basic EPS is presented, and is computed on the basis of the weighted-average number of common shares outstanding during the period presented. At September 30, 2005, the Company had 1,260,732 shares of preferred stock which are exchangeable, on a one-to-one basis, with common stock, debentures which could be converted into 995,882 shares of common stock, options and warrants to purchase 2,939,682 shares of common stock, and warrants to purchase 224,305 shares of preferred stock (which could be exchanged to common stock) issued and outstanding. If the Company had been profitable as of the end of the period, these 5,420,601 derivatives that are convertible, exercisable or exchangeable into common stock would have been included in a separate calculation for diluted EPS.

**NOTE 2 — RELATED PARTY TRANSACTIONS:**

On July 28, 2005, the Board of Directors granted 100,000 options to purchase common stock to each of three independent Directors: Thomas Lavoy, Stephen Boatwright, and Robert Kauffman. The requisite Form 4 has been filed with the SEC for each grantee. Additionally, the Board voted to compensate each of the independent Directors \$1,000 per meeting for their attendance at the Board meetings. Directors who are also serving as management of the Company were not granted stock options for Director service, and will not be paid for attendance at Board meetings.

Mr. Boatwright is a member of Keller Rohrback, PLC, which provides legal services to the Company and IsoRay Medical. During the three-month period ended September 30, 2005, IsoRay Medical paid Keller Rohrback, PLC approximately \$140,000 for legal services.

**NOTE 3 - INCOME TAX:**

As of September 30, 2005, the deferred tax asset related to the Company's net operating loss carryforward is fully reserved. Due to the provisions of Internal Revenue Code Section 338, the Company may have limited net operating loss carryforwards available to offset financial statement or tax return taxable income in future periods as a result of the July 28, 2005 merger which involved a change in control of more than 50 percentage points of the issued and outstanding securities of the Company.

**NOTE 4 - GOING CONCERN:**

The financial statements have been prepared assuming that the Company will continue as a going concern. Certain conditions indicate that the Company may be unable to continue as a going concern. These conditions include the Company's cash balance of \$211,642 at September 30, 2005, coupled to the cash expenditure rate of approximately \$500,000 per month. Management has implemented plans to obtain additional cash for the Company (see Note 5). However, there is no assurance these plans will be successful in providing the Company the cash it needs on a timely basis through the end of the current fiscal year. The accompanying financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

**NOTE 5 - SUBSEQUENT EVENTS:**

On October 14, 2005, a shareholder provided the Company a short-term loan in the amount of \$250,000. This loan bears interest at ten percent and matures on December 1, 2005. In connection with the loan, the Company granted a warrant to purchase 12,500 shares of common stock at an aggregate exercise price of \$10.00.

On October 17, 2005, the Company commenced an offering of Investment Units ("Units") for sale pursuant to a Private Placement Offering (the "Offering"). The Offering consists of a maximum of 200 Units, each Unit consisting of 5,000 shares of Common Stock and a Warrant to purchase 5,000 shares of Common Stock at an exercise price of \$6.00 per share. This maximum can be increased, at the sole discretion of the Company, to a maximum of 300 Units. The Units are being sold for \$20,000 per Unit, and as of November 11, 2005, a total of 51.1 Units had been sold for \$1,022,000.

## **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

IsoRay, Inc. (formerly known as Century Park Pictures Corporation) was incorporated on July 13, 1983 in accordance with the laws of the State of Minnesota.

**Prior operations.** In prior periods, the Company developed, produced and marketed various intellectual products of entities engaged in the motion picture, television, and theatrical stage industries, such as creative writers, producers and directors, for the motion picture, pay/cable and commercial television markets.

The Company had no operations, and minimal assets and liabilities since its fiscal year ended September 30, 1999 through May 27, 2005.

**Merger with IsoRay Medical, Inc.** On May 27, 2005, the Company; a newly-formed, wholly-owned subsidiary, Century Park Transitory Subsidiary, Inc., a Delaware corporation; Thomas Scallen and Anthony Silverman, shareholders of the Company; and IsoRay Medical, Inc. entered into a Merger Agreement.

On July 28, 2005, the Merger contemplated by the Merger Agreement dated May 27, 2005 was completed with the filing of a Certificate of Merger with the Secretary of State of Delaware, merging Century Park Transitory Subsidiary, Inc. into IsoRay Medical, Inc. As a result of the Merger and pursuant to the Merger Agreement, IsoRay Medical became a wholly-owned subsidiary of the Company.

Following the Merger, the Company had approximately 10,237,797 shares of common and preferred stock outstanding. The total amount of shares outstanding, on a fully-diluted basis, at the time of the merger was 13,880,822, which includes not only shares of common stock, but also shares of preferred stock, warrants, options and convertible debentures that could be exercised or converted into shares of common stock. Following the Merger, on a fully diluted basis, the shareholders of IsoRay Medical owned approximately 82% of the Company's outstanding securities.

The acquisition of IsoRay Medical by the Company on July 28, 2005 effected a change in control and was accounted for as a "reverse acquisition" whereby IsoRay Medical is the accounting acquirer for financial statement purposes. From an accounting perspective, the merger was treated as a recapitalization rather than a purchase. Accordingly, assets acquired were minimal and non-material, no liabilities were assumed, no goodwill was recognized, no research and development assets were acquired and written off, and there are no contingent payments to be made. As permitted by Statement of Financial Accounting Standards (SFAS) No. 141, the effective date of the merger for accounting purposes has been established as July 1, 2005. In accordance with SFAS No. 141, the following proforma consolidated statement of operations of the Company and IsoRay Medical is presented as though the merger had occurred at the beginning of the three month period ended September 30, 2004.

IsoRay, Inc. and Subsidiary  
 Proforma Consolidated Statement of Operations  
 Three Months Ended September 30, 2004 (Unaudited)

Product sales	\$	-
Cost of product sales		-
Gross profit (loss)		-
Operating expenses:		
Research and development		15,515
Sales and Marketing expenses		9,313
General and administrative expenses		669,665
	Total operating expenses	694,493
	Operating loss	(694,493)
Non-operating income (expense):		
Interest income		225
Financing expens		(8,825)
	Net-operating income (expense), net	(8,600)
	Net loss	\$ (703,093)
Net loss per share of common stock	\$	(0.10)
Basic weighted average shares outstanding		7,145,883

Due to the fact the Company had no operations and minimal assets or liabilities prior to its merger with IsoRay Medical, Inc., management believes that comparisons to prior period financial statements do not provide meaningful information to users of the Company's financial statements. Accordingly no comparisons to prior period financial statements are discussed.

**Current and Planned Operations.** IsoRay Medical intends to utilize its patented radioisotope technology, chemists, engineers and management team to create a major therapeutic medical isotope and medical device company with the goal of providing improved patient outcomes in the treatment of prostate cancer and other solid cancer tumors. IsoRay Medical began production and sales of its initial FDA approved product, the IsoRay <sup>131</sup>Cs brachytherapy seed, in October 2004 for the treatment of prostate cancer. Management believes its technology will allow it to capture a leadership position in an expanded brachytherapy market. The physical characteristics of the Cesium-131 (Cs-131 or <sup>131</sup>Cs) isotope are expected to decrease radiation exposure to the patient and reduce the severity and duration of side effects, while treating cancer cells as effectively, if not more so than, other isotopes used in seed brachytherapy. Cesium-131 could also enable meaningful penetration in other solid tumor applications such as breast, lung, liver, brain and pancreatic cancer, expanding the total available market opportunity. The second radioisotope, Yttrium-90 (Y-90 or <sup>90</sup>Y), is currently being used in the treatment of non-Hodgkin's lymphoma and is in clinical trials for other applications. Other manufacturers have received FDA approval for <sup>90</sup>Y and IsoRay Medical believes production will not require clinical trials or an extensive FDA application process. Production is expected to begin in 2006.

Brachytherapy seeds are small devices used in an internal radiation therapy procedure. In recent years the procedure has become one of the primary treatments for prostate cancer and is now used more often than surgical removal of the prostate. The seed brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancer tumor (the word "brachytherapy" means close therapy). The seeds deliver therapeutic radiation by killing the tumor

cells and cells located in the immediate vicinity of the tumor while minimizing exposure to adjacent healthy tissue. This allows doctors to administer a higher dose of radiation at one time than is possible with external beam radiation. Each seed contains a radioisotope sealed within a welded titanium capsule. Approximately 85 to 135 seeds are permanently implanted in the prostate in a 45-minute outpatient procedure. The isotope decays over time and the seeds become inert. The seeds may be used as a primary treatment or in conjunction with other treatment modalities such as external beam radiation therapy, chemotherapy, or as treatment for residual disease after excision of primary tumors.

Management believes that the IsoRay <sup>131</sup>Cs seed represents the first major advancement in brachytherapy technology in over 18 years with attributes that could make it the long term "seed of choice" for internal radiation procedures. The <sup>131</sup>Cs seed has FDA approval for treatment of malignant disease (e.g. cancers of the head and neck, brain, liver, lung, breast, prostate, etc.) and may be used in surface, interstitial, and intracavity applications for tumors with known radiosensitivity.

## **Results of Operations.**

### **Three month period ended September 30, 2005.**

**Revenues.** During the three months ended September 30, 2005, the company generated \$210,915 in sales of its <sup>131</sup>Cs seed. IsoRay Medical, Inc. began sales of its <sup>131</sup>Cs seed on October 26, 2004 with one medical center customer. We began the three month period ended September 30, 2005 with seven customers who had ordered the <sup>131</sup>Cs seed from us. At November 11, 2005 the number of medical center customers who have ordered the <sup>131</sup>Cs seed has grown to thirteen. We believe revenue in the subsequent period should reflect this growth in customers.

**Gross profit (loss).** Gross profit (loss) was (\$509,251) for the three months ended September 30, 2005. Of the cost of product sales of \$720,166, approximately \$235,000 was paid to Pacific Northwest National Laboratory (PNNL) for use of their facilities and personnel, which are provided under contract in support of our current production. In the three-month period, we also recorded approximately \$28,000 in depreciation expense of tenant improvements we made to the production facilities at PNNL prior to inception of production. The tenant improvements will be fully depreciated in the three-month period ending December 31, 2005, and no further PNNL tenant improvement depreciation will be recorded after that time. Additionally, in the three month period ended September 30, 2005, we spent in excess of \$100,000 for production materials and small tools, none of which individually exceeded the \$2,500 threshold we use in determining whether to capitalize production equipment. These materials and small tools are needed to commence production in our new facility, the PEcoS-IsoRay Radiological Laboratory (PIRL). Most are long-lived items, and should not need replacing in the current fiscal year. The \$720,166 cost of product sales for the period also includes an estimate of \$7,750 for accrued vacation expense for production personnel. We anticipate moving production operations to our independent production facility PIRL in the three-month period ending December 31, 2005, and once production operations are transitioned from PNNL to PIRL we will no longer have expenses for use of PNNL facilities and personnel.

**Research and Development.** Research and development expenses for the three month period ended September 30, 2005 were approximately \$25,782. Of this amount, \$3,200 was paid in conjunction with development of a protocol study on the results of the 100 patients included in this protocol. The balance was paid for ongoing research and development of our Y-90 product.

**Sales and Marketing Expenses.** Sales and marketing expenses were \$315,039 for the three-month period ended September 30, 2005. Of this amount, approximately \$219,000 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 includes approximately \$4,750 for accrued vacation expense for sales and marketing and customer service personnel. The balance was spent on advertising, market research, trade shows and conferences.

**General and Administrative Expenses.** General and administrative expenses for the three months ended September 30, 2005 amounted to \$960,949. During this period, and in conjunction with the merger of the Company and IsoRay Medical, we recognized a one-time compensation expense of \$330,000, representing the value of 200,000 shares of IsoRay Medical common stock issued to an individual as a finder's fee. The valuation was based on the most recent sales of IsoRay Medical common stock in conjunction with a Private Placement Memorandum which commenced in October 2004. In the three month period ended September 30, 2005, these 200,000 shares of IsoRay Medical stock were canceled and exchanged as part of the recent merger with 168,472 shares of IsoRay, Inc. common stock. Approximately \$255,000 was paid in wages and related benefits and taxes during the period. Legal expenses were approximately \$161,000 for the period, and included approximately \$56,000 spent in conjunction with an out-of-court settlement of an employment dispute. General and administrative expenses for the period also included approximately \$12,500 for accrued vacation expense.

**Operating (Loss).** In the quarter ended September 30, 2005, the Company had an operating loss of \$(1,811,021).

**Non-Operating Income (Expense).** During the three-month period ended September 30, 2004, the Company earned \$6,959 interest income on funds held in certain near-liquid accounts. During this period, financing expense was \$155,628. Of this amount, approximately \$104,000 was paid as interest on loans, notes and convertible debentures outstanding. The balance of the financing expense was amortization of pre-paid financing cost, consisting primarily of the January 2005 issuance of common stock to guarantors of certain loans made to the company, and commissions and legal costs paid in conjunction with the issuance of convertible debentures.

**Liquidity and Capital Resources.** Due to our significant research and development expenditures and nominal product revenues, we have not been profitable and have generated operating losses since our inception. The Company had approximately \$500,000 cash on hand as of November 14, 2005. At the Company's current monthly required operating cash expenditures of approximately \$500,000 per month, cash on hand would fund the Company's operations through December 15, 2005, not including \$1.9 million in approved loans to fund operations for a longer period of time. In addition, we are raising funds through our Private Placement Memorandum dated October 17, 2005. As of November 11, 2005, we had received cash proceeds of \$1,022,000 from the issuance of units, consisting of common stock and warrants to purchase common stock, pursuant to this Private Placement Memorandum.

Our growth plan for 2006 includes expanding sales to existing customers, continuing a trend that has improved in the last half of 2005; discontinuing production efforts at Pacific Northwest National Laboratory, which should decrease operating costs; enhancing efforts to reduce the internal cost of goods; and expanding the base of suppliers of direct materials and value added services to direct materials.

IsoRay Medical has five outstanding loans. The first, from Tri-City Industrial Development Council, with an original principal amount of \$40,000, was funded in 2001 and requires a final principal only payment of \$10,000 in August 2006. It is non-interest bearing and unsecured. The second loan is from the Benton-Franklin Economic Development District 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 November 7, 2005, the principal balance owed was \$215,795. This loan is secured by certain equipment, materials and inventory of IsoRay Medical, and also required personal guarantees, for which the guarantors have been issued approximately 70,455 shares of our common stock. The third loan is a line of credit from Columbia River Bank, which provides credit in the amount of \$395,000. 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 have been issued approximately 107,401 shares of our common stock. As of November 7, 2005, \$200,000 was owed on the line of credit. The fourth loan is with Columbia River Bank in the amount of \$150,000, of which \$50,000 was funded as of October 31, 2005. This loan is to be used for equipment purchases only and is secured by the equipment purchased with the borrowed funds. It bears interest at seven percent for thirty-six months. As of November 7, 2005, the principal balance owed was approximately \$35,925. The fifth loan is with Albert Smith in the amount of \$250,000, and was funded on October 14, 2005. This loan bears

interest at ten percent and matures on December 1, 2005. In connection with the loan by Mr. Smith, IsoRay, Inc. granted a warrant to purchase 12,500 shares of common stock at an aggregate exercise price of \$10.00 to Mr. Smith. IsoRay Medical applied to the Hanford Area Economic Investment Fund Committee (HAEIFC) for a \$1,400,000 loan to fund equipment for IsoRay's leased production facility. The HAEIFC Board has preliminarily approved this loan with an interest rate of prime plus 2% and a ten year amortization period. The loan will be secured in part by the equipment acquired as well as personal guarantees. These guarantors will be issued approximately one share of our common stock for every \$12.00 of the loan guaranteed.



IsoRay Medical also had \$4,132,948 in principal amount of convertible debentures outstanding as of November 7, 2005, which were issued between February and June 2005. These debentures could be converted into 995,891 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), and has a twenty-four month term with accrued interest paid quarterly.

On April 4, 2005 a capital lease agreement was executed by IsoRay Medical with Nationwide Funding LLC, whereby the lessor funded the \$75,000 acquisition of a glove box being built to the Company's specifications by Premier Technology, Inc. of Pocatello, ID. This is a 48 month agreement with minimum monthly lease payments of \$2,475.38.

On May 16, 2005 a capital lease agreement was executed by IsoRay Medical with Vencore Solutions LLC. This is a capital lease for a hot cell with a lease line in the amount of \$430,000. This is a 36 month lease, with a purchase option at fair market value, defined in the lease agreement as not more than 15% of the initial fair value purchase price. Based on this amount, for the first five months, the minimum monthly lease payment will be \$8,348.50. The minimum monthly lease payment increases to \$17,500 for the remaining 31 months, based on the entire value of the \$430,000 lease line. In connection with the lease agreement, IsoRay Medical granted warrants to purchase 6,757 shares of its common stock at \$3.50/share.

At September 30, 2005, cash and cash equivalents amounted to \$211,642. During the three months ended September 30, 2005, the Company issued 97,917 shares of common stock pursuant to the exercise of warrants to purchase common stock and warrants to purchase preferred stock, which were exchanged for common stock immediately upon exercise. This exercise of warrants provided the Company with approximately \$56,937. Also during the three months ended September 30, 2005, the Company issued 56,284 shares of common stock pursuant to the exercise of options to purchase common stock. This exercise of options provided the Company with approximately \$70,548.

Management believes the Company will also need to draw down on the \$1.4 million loan that has been preliminarily approved by the Hanford Area Economic Investment Fund Committee to provide cash for operations and acquisition of capital equipment needed for the balance of the fiscal year ending June 30, 2006.

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

We have no material commitments for capital expenditures and no off-balance sheet arrangements.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

*The Company's Form 10-KSB, any Form 10-QSB or any Form 8-K of the Company or any other written or oral statements made by or on behalf of the Company may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995, which reflect the Company's current views with respect to future events and financial performance. The words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions identify forward-looking statements. 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. Such "forward-looking statements" are subject to risks and uncertainties set forth from time to time in the Company's SEC reports and are generally set forth below and particularly discussed in the Company's Form 10-KSB for the transition period ended June 30, 2005 and in the Company's Registration Statement on Form SB-2 filed on November 10, 2005.*

*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.*

### **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.**

- 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 through 2006.
- 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.
  - Our quarterly operating results will be subject to significant fluctuations.
  - We rely heavily on a limited number of suppliers.
  - 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 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 and our significant internal control deficiencies have not been remediated.
  - 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, 2005. 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.

(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 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 one full-time and three part-time persons involved in processing of transactions. Therefore, 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 hiring of additional full time staff. We plan to seek, but cannot be assured that we will be able to find, a qualified person to perform month end accounting procedures. As a result, this significant internal control deficiency had 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 in the foreseeable future. However, we will continue to monitor and assess the costs and benefits of additional staffing.

*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 do not have formal month end close procedures. As a result, there is a lack of timely review of the financial statements and Form 10-QSB. This significant internal control deficiency has not been remediated as of the end of the period covered by this report.

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 2. UNREGISTERED SALES OF EQUITY SECURITIES

On July 28, 2005, the Company issued warrants to purchase 25,000 shares of its common stock to Patrick Lambert as a consulting fee, in reliance on the exemption from registration provided by § 4(2) of the Securities Act of 1933, as amended.

### ITEM 5. OTHER INFORMATION

The Company's Board of Directors engaged DeCoria, Maichel & Teague, P.S., the independent auditor for the Company's wholly-owned subsidiary, to be its new independent auditor effective November 15, 2005, which was also the effective date of S.W. Hatfield, CPA's dismissal as the Company's certifying accountant by the Board.

Except for an expression of doubt about our ability to continue as a going concern, S.W. Hatfield audit reports on the Company's financial statements as of June 30, 2005 and September 30, 2004 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the two fiscal years ended June 30, 2005 and September 30, 2004, and through November 15, 2005 there were no disagreements with S.W. Hatfield on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of S.W. Hatfield would have caused it to make a reference to the subject matter of the disagreements in connection with its report; and there were no reportable events as described in Item 304(a)(1)(iv)(B) of Regulation S-B promulgated by the Securities and Exchange Commission (the "SEC") pursuant to the Securities Exchange Act of 1934, as amended.

The Company provided S.W. Hatfield with a copy of this disclosure and requested that S.W. Hatfield furnish the Company with a letter addressed to the SEC stating whether it agrees with the foregoing statements by the Company and, if not, stating the respects in which it does not agree. A copy of the letter from S.W. Hatfield is filed herewith as Exhibit 16.1.

During the Company's two most recent fiscal years and through November 15, 2005, the Company did not consult DeCoria, Maichel & Teague with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or any other matters or reportable events listed in Item 304(a)(2) of Regulation S-B. However, IsoRay Medical, the Company's wholly-owned subsidiary, has consulted with DeCoria, Maichel & Teague, its independent auditor, during these time periods solely in connection with IsoRay Medical's financial statements.

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

(a) Exhibits:

10.19 Express Pricing Agreement, dated October 5, 2005 between Federal Express Corp. and IsoRay Medical, Inc.

10.20 Girard Employment Agreement, dated October 6, 2005, between Roger E. Girard and IsoRay, Inc.

10.21 Contract Modification Quality Class G, dated October 25, 2005, to Contract Number X40224 between Energy Northwest and IsoRay, Inc.

16.1

Letter from S.W. Hatfield, CPA to the SEC dated November 21, 2005.





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

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Section 1350 Certifications

(b) Reports on Form 8-K:

On August 3, 2005, the Company filed a Current Report on Form 8-K announcing its acquisition of IsoRay Medical, Inc. as its wholly-owned subsidiary and the accompanying change in the Company's name to IsoRay, Inc.

On August 15, 2005, the Company filed an amendment to its Current Report on Form 8-K filed on August 3, 2005, in which the Company provided audited financial statements and pro forma financial information for IsoRay Medical, Inc.

On August 17, 2005, the Company filed a Current Report on Form 8-K announcing the new trading symbol, "ISRY.PK", for its common stock.

On November 3, 2005, the Company filed a Current Report on Form 8-K providing audited financial statements for IsoRay Medical, Inc. for the years ended June 30, 2005 and 2004.

On November 3, 2005, the Company filed a Current Report on Form 8-K announcing the commencement of quotations of its common stock on the OTC Bulletin Board under the symbol "ISRY.OB" and IsoRay Medical, Inc.'s nomination for a FLC Award for Excellence in Technology Transfer.

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 21, 2005

ISORAY, INC., a Minnesota corporation

By: /s/ Roger E. Girard

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Roger E. Girard, Chief Executive Officer

By: /s/ Michael K. Dunlop

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Michael K. Dunlop, Chief Financial Officer