

IsoRay, Inc.  
Form 10-Q  
February 11, 2008

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

FORM 10-Q

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

For the quarterly period ended December 31, 2007

or

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

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

Commission File No. 001-33407

**ISORAY, INC.**

(Exact name of registrant as specified in its charter)

Minnesota

(State or other jurisdiction of incorporation

or

organization)

41-1458152

(I.R.S. Employer  
Identification No.)

350 Hills St., Suite 106, Richland,

Washington

(Address of principal executive offices)

99354

(Zip Code)

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

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

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

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

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

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

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Class  
Common stock, \$0.001 par value

Outstanding as of February 4, 2007  
23,090,200

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**ISORAY, INC.**

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**PART I - FINANCIAL INFORMATION****IsoRay, Inc. and Subsidiary  
Consolidated Balance Sheets**

	<b>December 31, 2007 (Unaudited)</b>	<b>June 30, 2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,476,679	\$ 9,355,730
Short-term investments	8,680,137	9,942,840
Accounts receivable, net of allowance for doubtful accounts of \$48,479 and \$99,789, respectively	829,918	1,092,925
Inventory	995,233	880,834
Prepaid expenses	442,993	458,123
<b>Total current assets</b>	<b>14,424,960</b>	<b>21,730,452</b>
Fixed assets, net of accumulated depreciation		
Deferred financing costs, net of accumulated amortization	6,521,545	3,665,551
Licenses, net of accumulated amortization	80,473	95,725
Restricted cash	467,457	262,074
Other assets, net of accumulated amortization	172,500	-
	328,421	322,360
<b>Total assets</b>	<b>\$ 21,995,356</b>	<b>\$ 26,076,162</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,183,082	\$ 1,946,042
Accrued payroll and related taxes	508,960	459,068
Accrued interest payable	1,695	1,938
Deferred revenue	-	23,874
Notes payable, due within one year	47,189	49,212
Capital lease obligations, due within one year	109,484	194,855
Asset retirement obligation, current portion	-	131,142
<b>Total current liabilities</b>	<b>1,850,410</b>	<b>2,806,131</b>
Notes payable, due after one year	504,444	528,246
Capital lease obligations, due after one year	8,774	25,560
Asset retirement obligation	483,821	-
<b>Total liabilities</b>	<b>2,847,449</b>	<b>3,359,937</b>
Commitments and contingencies (see Note 9)		
Shareholders' equity:		

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Preferred stock, \$.001 par value; 6,000,000 shares authorized:			
Series A: 1,000,000 shares allocated; no shares issued and outstanding		-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding		59	59
Common stock, \$.001 par value; 194,000,000 shares authorized; 23,090,200 and 22,789,324 shares issued and outstanding			
		23,090	22,789
Additional paid-in capital		47,221,918	45,844,793
Accumulated deficit		(28,097,160)	(23,151,416)
Total shareholders' equity			
		19,147,907	22,716,225
Total liabilities and shareholders' equity			
	\$	21,995,356	\$ 26,076,162

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

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

	Three months ended December 31,		Six months ended December 31,	
	2007	2006	2007	2006
Product sales	\$ 1,758,344	\$ 1,414,155	\$ 3,614,063	\$ 2,439,599
Cost of product sales	2,241,795	1,387,394	4,247,297	2,675,539
Gross loss	(483,451)	26,761	(633,234)	(235,940)
Operating expenses:				
Research and development	395,545	216,254	651,915	461,852
Sales and marketing expenses	1,142,827	890,018	2,202,643	1,562,948
General and administrative expenses	919,164	821,529	1,821,189	2,554,661
Total operating expenses	2,457,536	1,927,801	4,675,747	4,579,461
Operating loss	(2,940,987)	(1,901,040)	(5,308,981)	(4,815,401)
Non-operating income (expense):				
Interest income	179,855	50,004	418,551	90,187
Financing expense	(25,211)	(67,413)	(55,314)	(120,670)
Non-operating income (expense), net	154,644	(17,409)	363,237	(30,483)
Net loss	\$ (2,786,343)	\$ (1,918,449)	\$ (4,945,744)	\$ (4,845,884)
Basic and diluted loss per share	\$ (0.12)	\$ (0.12)	\$ (0.21)	\$ (0.31)
Weighted average shares used in computing net loss per share:				
Basic and diluted	23,072,272	15,919,236	23,036,657	15,609,992

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

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

	<b>Six months ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,945,744)	\$ (4,845,884)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation and amortization of fixed assets	586,866	184,510
Amortization of deferred financing costs and other assets	90,541	69,580
Amortization of discount on short-term investments	(119,149)	-
Loss on settlement of ARO liability (Note 7)	(135,120)	-
Accretion of asset retirement obligation	14,703	3,091
Noncash share-based compensation	354,613	897,887
Changes in operating assets and liabilities:		
Accounts receivable, net	263,007	(385,554)
Inventory	(114,399)	(68,518)
Prepaid expenses	15,130	(51,060)
Accounts payable and accrued expenses	(762,960)	258,288
Accrued payroll and related taxes	49,892	154,338
Accrued interest payable	(243)	(780)
Deferred revenue	(23,874)	-
Net cash used by operating activities	(4,726,737)	(3,784,102)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(2,969,764)	(487,456)
Additions to licenses and other assets	(286,733)	(27,657)
Change in restricted cash	(172,500)	-
Purchases of short-term investments	(10,593,828)	-
Proceeds from the sale or maturity of short-term investments	11,975,680	-
Net cash used by investing activities	(2,047,145)	(515,113)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Principal payments on notes payable	(25,825)	(33,745)
Principal payments on capital lease obligations	(102,157)	(88,484)
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	1,010,913	611,997
Proceeds from cash sales of common stock, pursuant to exercise of options	11,900	590,463
Net cash provided by financing activities	894,831	5,791,871
Net (decrease) increase in cash and cash equivalents	(5,879,051)	1,492,656
Cash and cash equivalents, beginning of period	9,355,730	2,207,452
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 3,476,679</b>	<b>\$ 3,700,108</b>

Non-cash investing and financing activities:

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Increase in fixed assets related to asset retirement obligation	\$	473,096	\$	-
Cashless exercise of common stock options		-		50,000

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

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

**1. Basis of Presentation**

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

The accompanying interim consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, consistent in all material respects with those applied in the Company's Annual Report on Form 10-KSB for the fiscal year ended June 30, 2007. The financial information is unaudited but reflects all adjustments, consisting only of normal recurring accruals, which are, in the opinion of the Company's management, necessary for a fair statement of the results for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-KSB for the fiscal year ended June 30, 2007.

**2. Accounting for Uncertainty in Income Taxes**

On July 1, 2007, the Company adopted Financial Accounting Standards Board Interpretation No. 48 (FIN No. 48) *Accounting for Uncertainty in Income Taxes*. FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in accordance with SFAS No. 109 "Accounting for Income Taxes," prescribing a recognition threshold and measurement attribute for the recognition and measurement of a tax position taken or expected to be taken in a tax return. In the course of its assessment, management has determined that the Company, its subsidiary, and its predecessors is subject to examination of its income tax filings in the United States and state jurisdictions for the 2003 through 2006 tax years. In the event that the Company is assessed penalties and or interest; penalties will be charged to other operating expense and interest will be charged to interest expense.

The Company adopted FIN No. 48 using the modified prospective transition method, which requires the application of the accounting standard as of July 1, 2007. There was no impact on the financial statements as of and for the three and six months ended December 31, 2007 as a result of the adoption of FIN No. 48. In accordance with the modified prospective transition method, the financial statements for prior periods have not been restated to reflect, and do not include, the impact of FIN No. 48.

**3. Loss per Share**

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

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

	December 31,	
	2007	2006
Preferred stock	59,065	77,080
Preferred stock warrants	-	28,614
Common stock warrants	3,255,774	4,707,131
Common stock options	3,210,981	3,184,639
Convertible debentures	-	109,639
<b>Total potential dilutive securities</b>	<b>6,525,820</b>	<b>8,107,103</b>

#### 4. Short-Term Investments

The Company's short-term investments are classified as available-for-sale and recorded at fair market value. As of December 31, 2007 and June 30, 2007, the amortized cost of the Company's short-term investments equaled their fair market value. Accordingly, there were no unrealized gains or losses as of December 31, 2007 or June 30, 2007.

The Company's short-term investments consisted of the following at December 31, 2007 and June 30, 2007:

	December 31,		June 30,	
	2007		2007	
Municipal debt securities	\$	4,000,000	\$	3,000,000
Corporate debt securities		4,680,137		6,942,840
	\$	8,680,137	\$	9,942,840

#### 5. Inventory

Inventory consists of the following at December 31, 2007 and June 30, 2007:

	December 31,		June 30,	
	2007		2007	
Raw materials	\$	732,516	\$	682,327
Work in process		214,757		120,242
Finished goods		47,960		78,265
	\$	995,233	\$	880,834

#### 6. Restricted Cash

The Washington Department of Health, effective October 2007, has required the Company to provide collateral for the decommissioning of its facility. To satisfy this requirement, the Company established two CDs totaling \$172,500 in separate banks. The CDs both have original maturities of three months but are classified as long-term as the Company does not anticipate decommissioning the facility until the end of the current lease plus the lease option periods. These funds are to be used to settle the Company's remaining asset retirement obligations (Note 7).

## 7. Asset Retirement Obligations

SFAS No. 143, *Asset Retirement Obligations*, establishes standards for the recognition, measurement and disclosure of legal obligations associated with the costs to retire long-lived assets. Accordingly, under SFAS No. 143, the fair value of the future retirement costs of the Company's leased assets are recorded as a liability on a discounted basis when they are incurred and an equivalent amount is capitalized to property and equipment. The initial recorded obligation, which was discounted using the Company's credit-adjusted risk-free rate, is reviewed periodically to reflect the passage of time and changes in the estimated future costs underlying the obligation. The Company amortizes the initial amount capitalized to property and equipment and recognizes accretion expense in connection with the discounted liability over the estimated remaining useful life of the leased assets.

In fiscal year 2006, the Company established an initial asset retirement obligation of \$63,040 which represented the discounted cost of cleanup that the Company anticipated it would have to incur at the end of its equipment and property leases in its old production facility. This amount was determined based on discussions with qualified production personnel and on historical evidence. During fiscal year 2007, the Company reevaluated its obligations based on discussions with the Washington Department of Health and determined that the initial asset retirement obligation should be increased by an additional \$56,120. During the second quarter of fiscal year 2008, the Company removed all radioactive residuals and tenant improvements from its old production facility and returned the facility to the lessor. The Company had an asset retirement obligation of \$135,120 accrued for this facility but total costs incurred to decommission the facility were \$274,163 resulting in an additional expense of \$139,043 that is included in cost of products sold. The additional expense is mainly due to unanticipated construction costs to return the facility to its previous state. The Company originally believed that the lessor would retain many of the leasehold improvements in the building, but the lessor instead required their removal.

In September 2007, a new asset retirement obligation of \$473,096 was established representing the discounted cost of the Company's obligations to remove any residual radioactive materials and any unwanted leasehold improvements at the end of the lease term at its new production facility. The estimate was developed by qualified production personnel and the general contractor of the new facility. The Company has reviewed the estimate again based on its experience with decommissioning its old facility and believes that the original estimate continues to be applicable.

During the six month periods ended December 31, 2007 and 2006, the asset retirement obligation changed as follows:

	Six months ended December 31,	
	2007	2006
Beginning balance	\$ 131,142	\$ 67,425
New obligations	473,096	-
Settlement of existing obligation	(135,120)	-
Accretion of discount	14,703	3,091
Ending balance	\$ 483,821	\$ 70,516

## 8. Share-Based Compensation

Effective July 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment*, using the modified prospective method. The following table presents the share-based compensation expense recognized in accordance with SFAS No. 123R during the three and six months ended December 31, 2007 and 2006:

Three months ended December 31,		Six months ended December 31,	
2007	2006	2007	2006

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Cost of product sales	\$	36,827	\$	20,492	\$	73,830	\$	71,325
Research and development		11,550		7,879		23,100		19,714
Sales and marketing expenses		59,557		52,456		119,114		99,237
General and administrative expenses		59,072		35,617		138,569		707,611
Total share-based compensation	\$	167,006	\$	116,444	\$	354,613	\$	897,887

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As of December 31, 2007, total unrecognized compensation expense related to stock-based options was \$1,229,517 and the related weighted-average period over which it is expected to be recognized is approximately 1.02 years.

The Company currently provides stock-based compensation under three equity incentive plans approved by the Board of Directors. Options granted under each of the plans have a ten year maximum term, an exercise price equal to at least the fair market value of the Company's common stock on the date of the grant, and varying vesting periods as determined by the Board. For stock options that vest over time, the Company recognizes compensation cost on a straight-line basis over the requisite service period for the entire award.

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2007	3,210,981	\$ 2.68	8.04	\$ 863,361
Vested and expected to vest at December 31, 2007	3,171,547	\$ 2.66	8.04	\$ 863,361
Vested and exercisable at December 31, 2007	2,463,800	\$ 2.28	7.77	\$ 863,361

The aggregate intrinsic value of options exercised during the six months ended December 31, 2007 and 2006 was \$25,300 and \$1,557,600, respectively. The Company's current policy is to issue new shares to satisfy option exercises.

During the three and six months ended December 31, 2007, the Company did not grant any stock options. The weighted average fair value of stock option awards granted and the key assumptions used in the Black-Scholes valuation model to calculate the fair value are as follows:

	Three months ended December 31,		Six months ended December 31,	
	2007	2006	2007	2006
Weighted average fair value of options granted	\$ -	\$ 2.14	\$ -	\$ 2.11
Key assumptions used in determining fair value:				
Weighted average risk-free interest rate	-%	4.74%	-%	4.88%
Weighted average life of the option (in years)	-	6.00	-	5.58
Weighted average historical stock price volatility	-%	75.00%	-%	75.00%
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 stock price volatility are based on historical data of the Company.

## **9. Commitments and Contingencies**

### Patent and Know-How Royalty License Agreement

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

The licensor of the "know-how" has disputed management's contention that it is not using this "know-how". On September 25, 2007 and again on October 31, 2007, the Company participated in nonbinding mediation regarding this matter; however, no settlement was reached with the Lawrence Family Trust. As of February 11, 2008, the parties remain in negotiations to reach a mutually agreeable settlement. If no settlement is reached, the parties may demand binding arbitration.

### License Agreement with IBt

In February 2006, the Company signed a license agreement with International Brachytherapy SA (IBt), a Belgian company, covering North America and providing the Company with access to IBt's Ink Jet production process and its proprietary polymer seed technology for use in brachytherapy procedures using Cs-131. Under the original agreement royalty payments were to be paid on net sales revenue incorporating the technology.

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The Company paid license fees of \$275,000 (under the original agreement) and \$225,000 (under the Amendment) during fiscal years 2006 and 2007, respectively. The Amendment eliminates the previously required royalty payments based on net sales revenue, and the parties intend to negotiate terms for future payments by the Company for polymer seed components to be purchased at IBt's cost plus a to-be-determined profit percentage. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

### Perma-Fix Lease

On October 10, 2007, the Company executed a Lease Agreement with Perma-Fix Northwest Richland, Inc. (Perma-Fix). The Lease Agreement had an effective date of September 1, 2007, and provided for the continuation of the Company's lease of its PIRL facility located at 2025 Battelle Boulevard, Richland, Washington. The Company originally leased this facility from Nuvotec USA, Inc. under a Lease Agreement dated February 9, 2005, but Nuvotec USA, Inc. subsequently sold the facility to Perma-Fix. The new lease term was through January 31, 2008, with early termination permitted upon 45 days prior written notice. The Company terminated this lease in mid-December 2007.



## 10. Subsequent Events

### Extension of Warrants

On January 8, 2008, the Board of Directors retroactively extended the expiration dates of warrants issued pursuant to its private placement memoranda dated October 17, 2005 and February 1, 2006 for an additional one year period. These warrants began expiring in October 2007. Based on the extension, the warrants will now expire between October 2008 and February 2009. No other terms or conditions of the warrants were changed. The change in expiration dates affected outstanding warrants to purchase 2,102,142 shares of common stock. Of these outstanding warrants there were warrants to purchase 18,000 shares held by two directors of the Company. Prior to the extension, warrants to purchase 1,186,219 shares of common stock had passed their original expiration dates.

For the non-director warrants, the change in expiration date was a modification of the original warrant based on market conditions and was accounted for as a financing transaction similar to an extension of time in the offering of shares in a stock sale. Therefore there was no effect on the statement of operations as the Company had previously determined that under SFAS 133 and EITF 00-19 these warrants were equity instruments rather than derivatives.

The Company viewed the change in the director warrants as a modification of an existing warrant in accordance with SFAS 123R. The fair value of the modified warrant was calculated using the Black-Scholes valuation model as \$0.30 per warrant. The fair value of the original warrant immediately before the modification was calculated as zero as all of their warrants had previously expired. Total compensation cost of \$5,400 was recorded in January 2008 relating to the modification of the warrants held by the two directors.

### Director Not Standing for Re-Election

On January 8, 2008, Stephen Boatwright, one of the Company's directors, informed the Company that he would not stand for re-election at the Company's 2008 Annual Meeting of Shareholders, to be held on February 20, 2008, and that he will cease serving as a director of the Company on that date. There was no disagreement, as defined in 17 CFR 240.3b-7, between the Company and Mr. Boatwright that resulted in Mr. Boatwright's decision not to stand for re-election.

### By-Law Amendments

On January 8, 2008, the Board of Directors of the Company adopted Amended and Restated By-Laws, which were effective immediately. The Board of Directors amended and restated Section 1 of Article III of the By-Laws to give the Board of Directors the right to determine the number of directors, within a range of 1 to 10, that will serve on the Board at any given time, and to remove the term limit for directors. Prior to the amendment, shareholders had the ability to determine the number of directors, within a range of 1 to 10, that would serve on the Board at any given time, and directors were subject to a five year term limit.



The Board of Directors also amended and restated Section 3.B. of Article III of the By-Laws to shorten the required notice of Board meetings to five days. Prior to the amendment, fourteen days notice was required for Board meetings.

Shareholders have the right to change or repeal any of the By-Laws as described in Section 4 of Article VII.

#### 2008 Employee Stock Option Plan

On January 8, 2008, the Board of Directors unanimously adopted, subject to shareholder approval, the 2008 Employee Stock Option Plan (2008 Option Plan). The 2008 Option Plan allows the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to selected employees, consultants, and advisors of the Company. The 2008 Option Plan is on the Company's proxy ballot to be voted on by shareholders at the annual meeting to be held on February 20, 2008.

#### Russian Agreement

On January 23, 2008, the Company announced that it had become a 30% owner in a Russian limited liability company, UralDial, LLC, a new medical isotope manufacturing and distribution company based in Yekaterinburg, Russia. Under the terms of the UralDial Charter, the Company will own a 30% share in the new company, through its newly formed subsidiary, IsoRay International LLC. UNONA Holdings, a private holding company, will have a 40% ownership interest and a 30% ownership interest will be held by Russian engineers and scientists involved in the new company. All capital investments for the new manufacturing plant and the development of centers of excellence are expected to be provided by UNONA Holdings in support of the Russian government's new men's health initiatives.

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

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

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

*All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under "Risk Factors" beginning on page 19 below and in the "Risk Factors" section of our Form 10-KSB for the fiscal year ended June 30, 2007 that may cause actual results to differ materially.*

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

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

The discussion and analysis of the Company's financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-KSB for the fiscal year ended June 30, 2007, as filed with the Securities and Exchange Commission on September 28, 2007 are those that depend most heavily on these judgments and estimates. As of December 31, 2007, there have been no material changes to any of the critical accounting policies contained therein.

## **Results of Operations**

### **Three months ended December 31, 2007 compared to three months ended December 31, 2006**

**Product sales.** The Company generated sales of \$1,758,344 during the three months ended December 31, 2007, compared to sales of \$1,414,155 for the three months ended December 31, 2006. The increase of \$344,189 or 24% is due to increased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds. During the three months ended December 31, 2007, the Company sold its Proxcelan seeds to 53 different medical centers as compared to 33 medical centers during the corresponding period of 2006.

**Cost of product sales.** Cost of product sales was \$2,241,795 for the three months ended December 31, 2007 compared to cost of product sales of \$1,387,394 during the three months ended December 31, 2006. The major components of the increase of \$854,401 or 62% were depreciation, materials, occupancy costs, personnel costs, and preload expenses. Depreciation expenses increased approximately \$287,000 due to the depreciation on the new production facility and new equipment. Materials increased approximately \$229,000 mainly due to ordering and using more isotope in the three months ended December 31, 2007 compared to the corresponding period of 2006 and a higher unit price from our primary isotope supplier in 2007 compared to 2006. The increase in pricing came as a result of a price increase effective in February 2007 coupled with the Company's failure to order sufficient volume of isotope to obtain more favorable pricing. Occupancy costs increased approximately \$52,000 due to the higher rent on our new production facility and due to continued rent payments on the old facility through the middle of December 2007 as the Company completed its decommissioning. Personnel costs, including payroll, benefits, and related taxes, increased approximately \$58,000 as the number of production personnel increased. Preload expenses increased by approximately \$50,000 due to the higher volume of sales and due to continued start-up costs of the Company's internal preload facility. In January 2008, the Company's internal preload facility began shipping preloaded strands on a limited basis.

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

**Gross loss / margin.** Gross loss was \$483,451 for the three month period ended December 31, 2007. This represents a decrease in the Company's gross profit margin of \$510,212 or 1,907% over the corresponding period of 2006's gross margin of \$26,761. The increase in gross loss is due to the Company's higher revenues being more than offset by higher production costs and the costs of decommissioning the old production facility.

**Research and development expenses.** Research and development expenses for the three month period ended December 31, 2007 were \$395,545 which represents an increase of \$179,291 or 83% over research and development expenses of \$216,254 for the three month period ended December 31, 2006. The increase is due to higher personnel, protocol, consulting, and other miscellaneous expenses. Personnel costs, including payroll, benefits, and related taxes, increased approximately \$29,000 due to higher salaries to research and development personnel. Protocol expenses increased approximately \$76,000 mainly due to payments for the Company's randomized prospective clinical study, its dual-therapy study, and its continued monitoring and updating of the mono-therapy study. Consulting expenses increased approximately \$58,000 which is mainly due to the Company's ongoing project to increase the efficiency of isotope production. Various miscellaneous expenses increased by approximately \$29,000.



**Sales and marketing expenses.** Sales and marketing expenses were \$1,142,827 for the three months ended December 31, 2006. This represents an increase of \$252,809 or 28% compared to expenditures in the three months ended December 31, 2006 of \$890,018 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, increased approximately \$209,000 due to higher commissions paid due to higher revenues and an increase in sales force. Travel expenses increased approximately \$38,000 due to the increase in sales force. Consulting expenses increased approximately \$37,000 mainly due to payments to consultants to develop technical publications and other materials, to represent the Company at professional society meetings, and to serve as members of the Company's Cesium Advisory Group. The latter is a new advisory group comprised of radiation oncologists and physicists that met for the first time in December 2007. The purchase of market research reports and the purchase of subscriptions for US medical residents and development of new brochures and other marketing aids increased expenses by approximately \$49,000. These increases were partially offset by decreases of approximately \$49,000 in convention and tradeshow expenses and \$31,000 in hiring costs.

**General and administrative expenses.** General and administrative expenses for the three months ended December 31, 2007 were \$919,164 compared to general and administrative expenses of \$821,529 for the corresponding period of 2006. The increase of \$97,635 or 12% is mainly due to increased legal, share-based compensation, and personnel expenses partially offset by decreased travel expenses. Legal expenses increased by approximately \$79,000 due to costs incurred for contract drafting and review of the Company's interest in the new Russian entity and the IBt strategic global alliance agreements and for mediation costs with the Lawrence Family Trust. Without these fees, legal expenses would have decreased by approximately \$42,000. Share-based compensation increased approximately \$23,000 as a result of additional grants of stock options that occurred in March and June 2007. Personnel expenses, including payroll, benefits, and related taxes, increased approximately \$20,000 owing to a slight increase in headcount and salary increases. These increases were partially offset by a decrease in travel and related expenses of approximately \$34,000.

**Operating loss.** Due to the Company's rapid structural growth and related marketing costs and sales force needed to capture additional market share, an increase in production costs, and significant research and development expenditures, the Company has not been profitable and has generated operating losses since its inception. In the three months ended December 31, 2007, the Company had an operating loss of \$2,940,987 which is an increase of 1,039,947 or 55% over the operating loss of \$1,901,040 for the three months ended December 31, 2006.

**Interest income.** Interest income was \$179,856 for the three months ended December 31, 2007. This represents an increase of \$129,852 or 260% compared to interest income of \$50,004 for the three months ended December 31, 2006. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

**Financing expense.** Financing expense for the three months ended December 31, 2007 was \$25,211 or a decrease of \$42,202 or 63% from financing expense of \$67,413 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$18,000 and \$46,000 for the three months ended December 31, 2007 and 2006, respectively. The decrease in interest expense is due to the maturity and payoff of the convertible debentures during the fiscal year ended June 30, 2007. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2007 of the deferred financing costs relating to the Columbia River Bank line of credit.

**Six months ended December 31, 2007 compared to six months ended December 31, 2006**

**Product sales.** Sales for the six months ended December 31, 2007 were \$3,614,063 compared to sales of \$2,439,599 for the six months ended December 31, 2006. The increase of \$1,174,464 or 48% was due to increased sales volume of the Company's Proxcelan Cs-131 brachytherapy seeds. During the six months ended December 31, 2007 the Company sold its Cs-131 seeds to 65 different medical centers as compared to 35 centers during the corresponding period of 2006.

**Cost of product sales.** Cost of product sales was \$4,247,297 for the six months ended December 31, 2007 which represents an increase of \$1,571,758 or 59% compared to cost of product sales of \$2,675,539 during the six months ended December 31, 2006. Materials expense increased approximately \$523,000 mainly due to ordering and using more isotope in the six months ended December 31, 2007 compared to the corresponding period of 2006 and a higher unit price from our main supplier in 2007 compared to 2006. Depreciation expense increased approximately \$405,000 owing to the new production facility and new production equipment that was added in the past six months. Preload expenses increased approximately \$188,000 due to higher sales volumes and due to continued start-up costs of the Company's internal preload facility. Personnel expenses, including payroll, benefits, and related taxes, increased approximately \$177,000 due to hiring of additional production personnel to support higher production levels. Occupancy costs increased approximately \$95,000 as the Company entered into a lease for a new production facility in March 2007 and continued to pay rent on its old production facility through mid-December 2007.

The Company also had the following increases in cost of product sales expenditures that are directly related to the new facility that was opened in September 2007. The Company ordered isotope for the old facility to ensure adequate supply based on sales forecasts while it prepared to transition into the new production facility. To ensure a smooth transition with no missed order shipments, the Company ordered an additional \$38,000 of isotope in September 2007 that was not utilized as the removal and transportation of the isotope from the old facility to the new facility presented logistical challenges that made it cost prohibitive. As part of opening the new facility, the Company incurred approximately \$20,000 of wages and related taxes for personnel to perform equipment set-up and validation. The Company also expensed approximately \$82,000 of production materials and small tools for the new facility, none of which individually exceeded the \$2,500 threshold the Company uses in determining whether to capitalize production equipment.

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

**Gross loss.** Gross loss was \$633,234 for the six month period ended December 31, 2007. This represents an increase of \$397,294 or 168% over the corresponding period of 2006's gross loss of \$235,940. The increase is due to the increase in production costs more than offsetting the increase in revenues.

**Research and development expenses.** Research and development expenses for the six months ended December 31, 2007 were \$651,915 which represents an increase of \$190,063 or 41% over the research and development expenses of \$461,852 for the corresponding period of 2006. The major components of the increase were personnel, protocol, consulting, and travel expenses. Personnel expenses, including payroll, benefits, and related taxes, increased approximately \$43,000 due to higher salaries for research and development personnel. Protocol expenses increased approximately \$34,000 mainly due to payments for the Company's randomized prospective clinical study, its dual-therapy study, and its continued monitoring and updating of the mono-therapy study. Consulting expenses increased approximately \$67,000 which is mainly due to the Company's ongoing project to increase the efficiency of isotope production. Travel expenses increased approximately \$31,000 due to increased trips to Russia for the Company's interest in the new Russian entity that was announced in January 2008 and to Belgium to review work on the polymer technology licensed from IBt.

**Sales and marketing expenses.** Sales and marketing expenses were \$2,202,643 for the six months ended December 31, 2007. This represents an increase of \$639,695 or 41% compared to expenditures in the six months ended December 31, 2006 of \$1,562,948 for sales and marketing. Personnel expenses, including payroll, benefits, and related taxes, increased approximately \$454,000 due to higher commissions paid due to higher revenues and an increase in average headcount. Travel expenses increased approximately \$70,000 due to the increase in average headcount. Consulting expenses increased approximately \$84,000, mainly due to payments to consultants to develop technical publications and other materials, to represent the Company at professional society meetings, to serve as members of the Company's Cesium Advisory Group (a new advisory group comprised of radiation oncologists and physicists that met for the first time in December 2007), and increased expenses for a lobbying group. Dues and subscriptions increased approximately \$30,000 mainly due to the purchase of market research reports and the purchase of subscriptions for US medical residents. Marketing and advertising increased approximately \$88,000 as the Company created new brochures and other marketing aids. These increases were partially offset by a decrease of approximately \$95,000 in convention and tradeshow expenses as the Company reduced its overall budget for ASTRO and the smaller tradeshows.

**General and administrative expenses.** General and administrative expenses for the six months ended December 31, 2007 were \$1,821,189 compared to general and administrative expenses of \$2,554,661 for the corresponding period of 2006. The decrease of \$733,472 or 29% is primarily due to a decrease in share-based compensation of approximately \$569,000 and a one-time severance accrual of \$288,000 in the corresponding period of 2006. Travel expenses also decreased approximately \$66,000. These decreases were partially offset by increases in legal expenses and public company expenses. Legal expenses increased by approximately \$64,000 due to costs incurred for contract drafting and review of the Company's interest in the new Russian entity, the IBt strategic global alliance agreements and mediation costs with the Lawrence Family Trust. Without these fees, legal expenses would have decreased by approximately \$146,000. Public company expenses increased approximately \$89,000 owing to the new director compensation plan instituted in fiscal year 2008.

**Operating loss.** Due to the Company's rapid structural growth and related need to capture additional market share, the hiring of additional sales and marketing personnel, product revenues not covering production costs, and significant research and development expenditures, the Company has not been profitable and has generated operating losses since its inception. In the six months ended December 31, 2007, the Company had an operating loss of \$5,308,981 which is an increase of \$493,580 or 10% over the operating loss of \$4,815,401 for the six months ended December 31, 2006.

**Interest income.** Interest income was \$418,551 for the six months ended December 31, 2007. This represents an increase of \$328,364 or 364% compared to interest income of \$90,187 for the three months ended December 31, 2007. Interest income is mainly derived from excess funds held in money market accounts and invested in short-term investments.

**Financing expense.** Financing expense for the six months ended December 31, 2007 was \$55,314 or a decrease of \$65,356 or 54% from financing expense of \$120,670 for the corresponding period in 2006. Included in financing expense is interest expense of approximately \$40,000 and \$77,000 for the six months ended December 31, 2007 and 2006, respectively. The decrease in interest expense is due to the maturity and payment of the convertible debentures during the fiscal year ended June 30, 2007. The remaining balance of financing expense represents the amortization of deferred financing costs which decreased due to the write-off in fiscal year 2007 of the deferred financing costs relating to the Columbia River Bank line of credit.

**Liquidity and capital resources.** The Company has historically financed its operations through cash investments from shareholders. During the six months ended December 31, 2007, the Company's primary source of cash was the exercise of common stock warrants and options for \$983,000 and the Company primarily used existing cash reserves to fund its operations and capital expenditures.

#### *Cash flows from operating activities*

Cash used in operating activities was \$4.7 million for the six months ended December 31, 2007 compared to \$3.8 million for the six months ended December 31, 2006. Cash used by operating activities is net loss adjusted for non-cash items and changes in operating assets and liabilities. The increase in cash usage is mainly due to an increase in operating assets and liabilities related to a large decrease in accounts payable and accrued expenses. This is due to a payment in July 2007 for enriched barium that was included in the Company's June 2007 accounts payable balance.

#### *Cash flows from investing activities*

Cash used in investing activities was approximately \$1.9 million and \$515,000 for the six months ended December 31, 2007 and 2006, respectively. Cash expenditures for fixed assets were approximately \$3.0 million and \$487,000 during the six months ended December 31, 2007 and 2006, respectively. The large increase is mainly due to construction of our new facility and equipment purchases for the new facility. This was partially offset by net proceeds of approximately \$1.4 million from the sale of short-term securities.

#### *Cash flows from financing activities*

During the six months ended December 31, 2007, the Company issued 290,876 shares of common stock pursuant to the exercise of common stock options and warrants. The Company received \$1,022,813 in cash pursuant to these exercises.

#### *Projected 2008 Liquidity and Capital Resources*

At December 31, 2007, cash and cash equivalents amounted to \$3,649,179 and short-term investments amounted to \$8,680,137 compared to \$9,355,730 of cash and cash equivalents and \$9,942,840 of short-term investments at June 30, 2007.

The Company had approximately \$3.6 million of cash and \$7.6 million of short-term investments as of February 4, 2008. As of that date management believed that the Company's monthly required cash operating expenditures were approximately \$600,000 excluding capital expenditure requirements. The Company's cash operating expenditures were higher than this level during the six months ended December 31, 2007 but this was mainly due to the additional



expenditures necessary to make the new facility operational while maintaining operations at the previous facility.

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Assuming operating costs expand proportionately with revenue increases, other applications are pursued for seed usage outside the prostate market, protocols are expanded supporting the integrity of the Company's product and sales and marketing expenses continue to increase, management believes the Company will reach breakeven with revenues of approximately \$2 million per month. Management's plans to attain breakeven and generate additional cash flows include increasing revenues from both new and existing customers, developing additional therapies, and maintaining cost control. However, there can be no assurance that the Company will attain profitability or that the Company will be able to attain its aggressive revenue targets. If the Company does not experience the necessary increases in sales or if it experiences unforeseen manufacturing constraints, the Company may need to obtain additional funding. As the sales for the quarter ended December 31, 2007 declined, the Company is now focusing on reducing its production costs and making its sales force more efficient.

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 continue to market its products as planned or continue development and obtain regulatory approval of its future products. If the Company raises additional funds through equity sales, these sales may be dilutive to existing investors.

#### *Long-Term Debt and Capital Lease Agreements*

IsoRay had two loan facilities in place as of December 31, 2007. The first loan is from the Benton-Franklin Economic Development District (BFEDD) in an original principal amount of \$230,000 and was funded in December 2004. It bears interest at eight percent and has a sixty month term with a final balloon payment. As of December 31, 2007, the principal balance owed was \$174,491. This loan is secured by certain equipment, materials and inventory of the Company, and also required personal guarantees, for which the guarantors were issued approximately 70,455 shares of common stock. The second loan is from the Hanford Area Economic Investment Fund Committee (HAEIFC) and was originated in June 2006. The loan originally had a total facility of \$1,400,000 which was reduced in September 2007 to the amount of the Company's initial draw of \$418,670 (see Note 9). The loan bears interest at nine percent and the principal balance owed as of December 31, 2007 was \$377,142. This loan is secured by receivables, equipment, materials and inventory, and certain life insurance policies and also required personal guarantees.

The Company has certain capital leases for production and office equipment that expire at various times from March 2008 to April 2009. These leases currently call for total monthly payments of \$19,361. The total of all capital lease obligations at December 31, 2007 was \$118,258.

#### *Other Commitments and Contingencies*

On October 12, 2007, the Company entered into Amendment No. 1 (the Amendment) to its License Agreement dated February 2, 2006 with IBt. The original License Agreement provided the Company with access to IBt's proprietary polymer based seed encapsulation technology for use in brachytherapy procedures using Cesium-131 in the United States for a fifteen year term. A payment of \$225,000 was made on October 12, 2007 pursuant to the Amendment. As the parties agreed that the ink jet technology was not viable for Cesium-131 seeds, the Amendment eliminated the previously required royalty payments based on net sales revenue, and the parties intend to negotiate terms for future payments by the Company for polymer seed components to be purchased from IBt at IBt's cost plus a to-be-determined profit percentage. No agreement has been reached on these terms and there is no assurance that the parties will consummate an agreement pursuant to such terms.

The Company is subject to various local, state, and federal environmental regulations and laws due to the isotopes used to produce the Company's product. As part of normal operations, amounts are expended to ensure that the Company is in compliance with these laws and regulations. While there have been no reportable incidents or compliance issues, the Company incurred certain decommissioning expenses as part of vacating its old production facility. The Company has asset retirement obligations which represent the discounted cost of cleanup that the Company anticipates it will incur at the end of its equipment and property leases. This amount was determined based on discussions with qualified production personnel and on historical evidence. During the quarter ended December 31, 2007, the Company incurred \$274,163 of expenses to complete the decommissioning of its old production facility. These expenses were offset by the asset retirement obligation of \$135,120 resulting in a net expense of \$139,043 that was recorded in cost of products sales. Another asset retirement obligation of \$473,096 was established in the first quarter of fiscal year 2008 representing obligations at its new production facility. This new asset retirement obligation is for obligations to remove any residual radioactive materials and to remove any unwanted leasehold improvements at the end of the lease term.

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

The Company has no off-balance sheet arrangements.

#### **New Accounting Standards**

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

In February 2007, the FASB issued statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS 159). The statement allows entities to value financial instruments and certain other items at fair value. The statement provides guidance over the election of the fair value option, including the timing of the election and specific items eligible for the fair value accounting. Changes in fair values would be recorded in earnings. The statement is effective for fiscal years beginning after November 15, 2007. The Company does not believe the adoption of SFAS 159 will have a material effect on its consolidated financial statements.

#### **ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

## **ITEM 4 - CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2007. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective in timely alerting them to material information required to be included in the Company's periodic reports filed with the SEC under the Exchange Act. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures is designed to provide a reasonable level of assurance that the objectives of the system will be met.

### **Changes in Internal Control over Financial Reporting**

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

## **PART II - OTHER INFORMATION**

### **ITEM 1A - RISK FACTORS**

There have been no material changes to the risk factors disclosed in the "Risk Factors" section of our Annual Report on Form 10-KSB for the year ended June 30, 2007.

### **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

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#### (b) Reports on Form 8-K:

On October 16, 2007, the Company filed a Current Report on Form 8-K announcing its entry into a Lease Agreement for its prior production facility.

On October 17, 2007, the Company filed a Current Report on Form 8-K announcing its subsidiary's entry into Amendment No. 1 to its License Agreement with International Brachytherapy, SA.

On November 8, 2007, the Company filed a Current Report on Form 8-K announcing its financial results for the first quarter of fiscal 2008.

On January 14, 2008, the Company filed a Current Report on Form 8-K announcing certain amendments to its Bylaws and the decision by a director not to stand for re-election at the February 20, 2008 annual meeting of shareholders.

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