

## IsoRay, Inc. (ISR)

### UPDATE REPORT

October 6, 2011

Rating Target

Strong Speculative Buy \$3.00

### Analysts

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- ◆ IsoRay Reports Solid Financial Results for FY2011
- ◆ U.S. Launch of Gliasite® / Iotrex™ Expected This Quarter

1.) **Gliasite® Receives FDA Clearance to Market in U.S.:** On September 12, 2011 IsoRay announced they received FDA 501(k) clearance to market their Gliasite® radiation therapy system, a balloon catheter device used to deliver Iotrex™ (Iodine-125) to treat malignant brain cancer following resection surgery. IsoRay improved the product design and manufacturing techniques requiring a new FDA 501(k) clearance. Gliasite® already has established reimbursement for both in-patient and out-patient settings.

2.) **Preparing for U.S. Launch of Gliasite®/Iotrex™:** IsoRay has begun preparations for the U.S. launch in Q4. Investors should note that Gliasite® is the only FDA-approved balloon catheter for brachytherapy treatment of brain cancer. IsoRay is also negotiating distribution agreements with the previous European distributor of Gliasite®. While the Gliasite® device will initially be sold for use with Iotrex™, a liquid formulation of Iodine -125, IsoRay also plans to develop a liquid formulation of Cs-131 for use with Gliasite®.

3.) **Solid Fiscal Year-End 2011 Results:** Although top-line revenues were relatively flat with FY 2011 sales of \$5.2M versus from \$5.3M in FY 2010, to \$5.2 million in FY 2011, gross profit rose 59% to \$1.2M from \$726K in FY 2010 as well as decreased operating expenses due to IRS section 48D research grants. As a result, IsoRay was able to reduce their net loss by 30% from (\$4.0M) and (\$0.18) EPS loss in FY 2010 to (\$2.9M) and (\$0.11) EPS loss in FY 2011.

4.) **Maintaining Strong Speculative Buy rating and 12-18 month price target of \$3.00.** We believe that IsoRay remains “under the radar” on Wall Street as management begins executing on multiple growth strategies. Our valuation is based on a 35x multiple on projected fiscal year 2015 EPS and discounted 25% for cumulative risk.

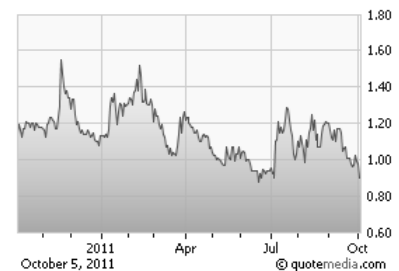


Symbol: ISR  
Exchange: AMEX

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CEO – Dwight Babcock

Market Data		Share Data		Most Recent Quarter	
Price	\$0.96	Outstanding	26.5M	Revenue	\$1.3M
52-Week	\$0.78-\$1.73	Cash/Share	\$0.08	Net Income	(\$0.7M)
Market Cap	\$25.4M	Book/Share	\$0.24	EPS	(\$0.03)
Avg. Daily Vol.	57,686	Price/Book	4.0x	Cash	\$2.1M
% Short	1.7%	Debt/Share	\$0.0	Debt	\$0.0M
Financial Results and Projections					
FYE June 30	2010	2011	2012E	2013E	2014E
Revenue	\$5.3M	\$5.2M	\$13.2M	\$15.9M	\$22.2M
Net Income	(\$4.0M)	(\$2.9M)	(\$0.6M)	\$0.6M	\$5.9M
EPS	(\$0.18)	(\$0.11)	(\$0.02)	\$0.02	\$0.17



Please See Last Two Pages For Important Disclosures And Analyst Certification

## Company Description

Richland, Washington-based IsoRay began production and sales of its initial FDA-cleared product, the IsoRay Proxcelan™ Cesium-131 brachytherapy seed in October 2004 for the treatment of prostate cancer. The more clinically beneficial characteristics of the Cesium-131 isotope are expected to decrease off-target 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 Iodine-125 or Palladium-103. Cesium-131 offers a combination of patient benefits that IsoRay believes are superior to other currently available brachytherapy isotopes.



In December 2007, IsoRay began selling its Proxcelan™ Cs-131 seeds for the treatment of ocular melanoma and in June 2009 began selling Proxcelan™ Cs-131 seeds for treatment of head and neck tumors. IsoRay continued to expand the number of areas of the body in which the Proxcelan™ Cs-131 seeds were being utilized by adding lung cancer in August 2009, colorectal cancer in October 2009, and chest wall cancer in December 2009.

IsoRay is also launching the GliaSite® radiation therapy system. It the only FDA-approved balloon catheter device used in the brachytherapy treatment of brain cancer. IsoRay has acquired an exclusive worldwide licence for Iotrex™ (liquid Iodine-125) which already has FDA approval for use in the GliaSite® therapy system and is developing liquid Cesium-131 also for use in the GliaSite® therapy system.

Calendar Quarter	MILESTONES & EVENTS					
	Prostate	Lung	Brain	Solid Tumors	Breast	Ocular
Q4 2010		✓ Initiate Post-Marketing Trial		Various Publications	✓ DATA Feasibility Trial	Various Publications
Q1 2011						
Q2 2011	✓ Initiate CS-131 + IMRT Post-Marketing Trial		✓ Obtain Iotrex Rights		Continued Development Accelerated Partial Breast Irradiation (APBI)	
Q3 2011			✓ GliaSite® FDAClearance			
ASTRO (Oct 2-6) Q4 2011			GliaSite/Iotrex Launch			
Q1 2012	DATA 5-Year Trial Publication	DATA Post-Marketing Trial	Continued Development of Liquid CS-131			

Source: IsoRay and LifeTech Capital Estimates

## Brachytherapy

Brachytherapy Dose Rate Comparison	
Dose Rate	Grays per Hour (Gy/hr)
Low Dose Rate (LDR)	≤ 2 Gy/hr
Medium Dose Rate (MDR)	2-12 Gy/hr
High Dose Rate (HDR)	≥ 12 Gy/hr

Source: Brachytherapy Physics

Brachytherapy is a medical procedure where radiation treatment is given to a patient by placing the radioactive source directly in, or near a target tissue. The name comes from the Greek root “brachy” meaning short, describing the small distance between the radiation source and the target tissue. This type of procedure has been in use for over a century and was implemented shortly after the discovery of radiation in the late 1800’s.<sup>1</sup> The most common application of this procedure is to treat malignant disease, though it has been proven effective in other applications such as the treatment of coronary in-stent restenosis.<sup>2</sup>

Brachytherapy can be characterized by a few different factors: placement of radiation source, radiation intensity, and radiation duration. The placement of the radiation source can be either contact or interstitial. When the radiation source is placed directly into the tissue to be irradiated it is referred to as interstitial brachytherapy. Contact brachytherapy involves placing the radiation source next to the tissue to be irradiated. This involves placing the radioactive material into a body cavity or body lumen, such as the cervix or oesophagus, respectively. The radiation source can also be placed externally to treat malignant skin lesions or in blood vessels to treat cardiovascular abnormalities. Radiation intensity, or dose rate, refers to the amount of radiation delivered to the surrounding tissue. The dose rates can vary from low to high dose (see table). Pulse Dose Rate (PDR) is another option in which the level of radiation is given in periodic pulses (usually one per hour) rather than continuously.<sup>3</sup> Radiation duration refers to the amount of time a target tissue is in contact with the radiation source. There is temporary and permanent brachytherapy. Temporary brachytherapy involves the placement of the radiation source for a set duration of time which can last from minutes to hours depending on many factors including type, size and location of the cancer, as well as the dose rate to be used.<sup>4</sup> Permanent brachytherapy involves placing small radioactive pellets or “seeds” into the tumor permanently. Each seed contains a radioisotope sealed within a welded titanium capsule. The seeds are only about the size of an uncooked grain of rice and emit radiation at a low dose rate for weeks to months until they eventually decay and cease to emit therapeutic levels of radiation. The seeds then remain in the body with no lasting effect.<sup>5</sup> Permanent brachytherapy has become one of the primary treatments for prostate cancer. When brachytherapy is the only treatment (monotherapy), approximately 70 to 120 seeds are permanently implanted in the prostate in an outpatient procedure lasting less than one hour. The number of seeds used varies based on the size of the prostate and the activity level specified by the physician. When brachytherapy is combined with external beam radiation or intensity modulated radiation therapy (dual therapy), then approximately 40 to 80 seeds are used in the procedure. Brachytherapy seeds can also be used in conjunction with other treatments for prostate cancer such as hormone therapy (neoadjuvant before implantation in prostate cancer) or chemotherapy. Another use for the seeds is for the treatment of potential residual disease after the resection of primary or secondary tumors, where seeds are placed in the surgical margin after surgery.



RESEARCH REFERENCES	
<sup>1</sup> A Brief History of Brachytherapy. “About Brachytherapy”. Web. <a href="http://www.aboutbrachytherapy.com/patients/brachytherapy/Pages/History.aspx">http://www.aboutbrachytherapy.com/patients/brachytherapy/Pages/History.aspx</a>	
<sup>2</sup> Members, A. /T. F.; Silber, S.; Albertsson, P.; Aviles, F. F.; Camici, P. G.; Colombo, A.; Hamm, C.; Jorgensen, E. et al. (2005). "Guidelines for Percutaneous Coronary Interventions: the Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology". European Heart Journal 26 (8): 804. doi:10.1093/eurheartj/ehi138. PMID 15769784. <a href="http://eurheartj.oxfordjournals.org/content/26/8/804.full.pdf+html">http://eurheartj.oxfordjournals.org/content/26/8/804.full.pdf+html</a>	
<sup>3</sup> "Brachytherapy." RadiologyInfo - The Radiology Information Resource for Patients. Radiological Society of North America, Inc. (RSNA). Web. <a href="http://www.radiologyinfo.org/en/info.cfm?pg=brachy">http://www.radiologyinfo.org/en/info.cfm?pg=brachy</a>	
<sup>4</sup> Gerbaulet A et al. (2005). "General aspects". In Gerbaulet A, Pötter R, Mazeron J, Limbergen EV. <i>The GEC ESTRO handbook of brachytherapy</i> . Belgium: ACCO. <a href="http://www.estro-education.org/publications/Documents/final%20introduction.pdf">http://www.estro-education.org/publications/Documents/final%20introduction.pdf</a>	
<sup>5</sup> Moule, R. N.; Hoskin, P. J. (2009). "Non-surgical treatment of localised prostate cancer". Surgical Oncology 18 (3): 255–267. doi:10.1016/j.suronc.2009.03.006. PMID 19442516. <a href="http://www.ncbi.nlm.nih.gov/pubmed/19442516">http://www.ncbi.nlm.nih.gov/pubmed/19442516</a>	

## Radiation Source in Brachytherapy

There are currently three main radioisotopes used in seed brachytherapy; Palladium-103 (Pd-103), Iodine-125 (I-125) and Cesium 131 (Cs-131). Iodine and Palladium have been on the market for a longer period of time than Cesium and currently hold the largest market share. Beginning in 1967, Iodine-125 became the first radioisotope manufactured in a titanium seed for use in LDR permanent brachytherapy. Its use continues today, but there has been a shift in recent years to Palladium-103 seeds due to a faster-acting, shorter half-life than Iodine-125. The shorter half-life advantages of Pd-103 comes with the drawback of less energy or tissue penetrating power emitted by the radioisotope in comparison to I-125. Proponents of Cs-131 had theorized that the physical properties of Cesium would be

Isotope Delivery Over Time					
Isotope	Half-Life	Energy	Anisotropy Factor	90% Dose	Total Dose
Cs-131	9.7 days	30.4 KeV	.969	33 days	115 Gy
Pd-103	17 days	20.8 KeV	.877 (TheraSeed® 200)	58 days	125 Gy
I-125	60 days	28.5 KeV	.930 (OncoSeed® 6711)	204 days	145 Gy

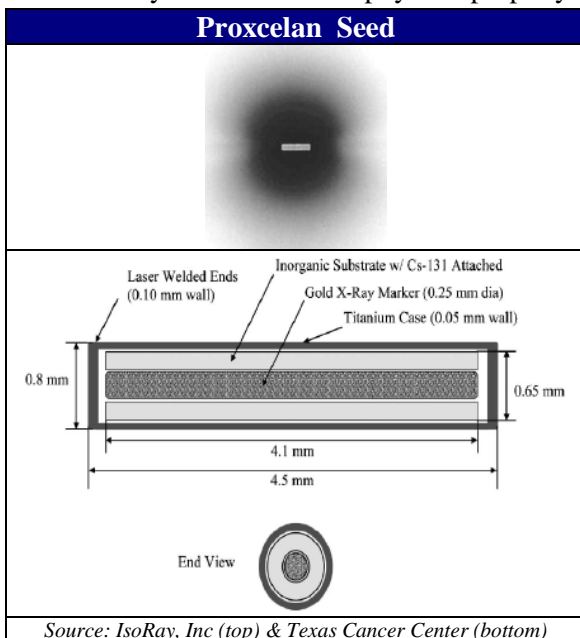
*Source: IsoRay*

the shorter half-life advantages of Pd-103 comes with the drawback of less energy or tissue penetrating power emitted by the radioisotope in comparison to I-125. Proponents of Cs-131 had theorized that the physical properties of Cesium would be

superior to those of the other two isotopes during their introduction into medical practice, but at the time economic and scientific limitations put a halt to Cesium’s development. These technology proponents included Donald C Lawrence, who in 1967 patented the titanium encapsulated “soft x-ray” brachytherapy seed and is referred to as one of the founding fathers of seed brachytherapy and Lane A Bray, current Chief Chemist for IsoRay. Lane Bray developed a patented process for economically separating and purifying Cesium-131, making the development of Cs-131 brachytherapy seeds viable. IsoRay received FDA 510(k) clearance in 2003 for treatment of malignant disease of the head and neck, brain, breast, prostate and other organs with their Proxcelan™ Cesium-131 brachytherapy seeds.

Cesium has physical properties that make it attractive as a radiation source for brachytherapy when compared to Iodine and Palladium. Cesium has a higher average energy than any other commonly used prostate brachytherapy isotope on the market. An average energy of 30.4 KeV which is 6.7% and 46.2% higher than the average energies of I-125 and Pd-103 (respectively) allows Cs-131 implants to dispense a uniform radiation dose across the target tissue. IsoRay’s Proxcelan™ Cs-131 seed also has an anisotropy factor that is very close to 1.0, meaning that its energy is very evenly distributed around the implant. These two factors allow for even energy distribution across the target tissue, also called good homogeneity. This helps improve patient outcomes by spreading the required radiation across the targeted area, while being able to spare critical structures, such as the urethra and rectum (in prostate cancer).<sup>1</sup> Cs-131 also has a shorter half-life than Pd-103 and I-125 of 9.7 days vs. 17 days and 60 days, respectively. The short half-life means that the radiation is delivered more quickly to the tissue with 90% of the prescribed dose being delivered in 33 days vs. 58 days for Pd-103 and 204 days for I-125. This physical property of Cesium also helps improve patient outcomes by reducing the side effect

profile of the brachytherapy procedure. In prostate cancer for example, the most common side effects arise from irritation of critical structures around the gland such as the urethra.<sup>2</sup> The shorter half-life of Cs-131 reduces the amount of time a patient would have to experience the irritating and potentially obstructive side effects of brachytherapy for the treatment of prostate cancer. A shorter half-life combined with the high energy of Cs-131 give the radioisotope a high biological effective dose (BED). The BED is an indicator of how well an isotope will perform against cancers exhibiting different characteristics; for example, slow or indolent types of cancer vs. fast growing tumors. Studies have shown Cs-131 is able to deliver a higher BED across a wide range of tumor types than either I-125 or Pd-103.<sup>3</sup> There have been a number of studies comparing the dosimetric parameters between Cs-131, Pd-103, and I-125 specifically in prostate cancer. These studies provide evidence of a clear advantage for Cesium-131 from a dosimetric point-of-view in terms of gland coverage. Gland coverage is determined by examining how well the gland is irradiated by at least 90% of the prescribed radiation dose, while keeping gland over-dosing (areas of the prostate receiving 150-200% of the prescribed radiation



Source: IsoRay, Inc (top) & Texas Cancer Center (bottom)

dose) to a minimum.<sup>4-7</sup>

IsoRay’s Proxcelan™ Cs-131 products have already received U.S. FDA 510(k) medical device clearance for the treatment of all solid tumor malignant disease (e.g., head and neck, brain, breast, prostate, etc.) found in the body, and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. In addition these devices 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. IsoRay also received FDA 510(k) approval for Proxcelan™ Cs-131 brachytherapy seeds that are preloaded into bioabsorbable braided strands. This clearance permits the product to be commercially distributed for treatment of lung, head and neck tumors as well as tumors in other organs. The 510(k) also clears the application of braided strands onto a bioabsorbable mesh matrix to further facilitate the implant procedure.

**RESEARCH REFERENCES**

<sup>1</sup>Prestidge B.R., Bice W.S., Jurkovic I., et al. Cesium-131 Permanent Prostate Brachytherapy: An Initial Report. Int. J. Radiation Oncology Biol. Phys. 2005; 63 (1) 5336-5337 [http://www.redjournal.org/article/S0360-3016\(05\)01764-5/pdf](http://www.redjournal.org/article/S0360-3016(05)01764-5/pdf)  
<sup>2</sup>Neill B, et al. The Nature and Extent of Urinary Morbidity in Relation to Prostate Brachytherapy Urethral Dosimetry. Brachytherapy 2007;6(3)173-9. [http://www.brachyjournal.com/article/S1538-4721\(07\)00210-3/abstract](http://www.brachyjournal.com/article/S1538-4721(07)00210-3/abstract)  
<sup>3</sup>Armpilia CI, et al. The Determination of Radiobiologically Optimized Half-lives for Radionuclides Used in Permanent Brachytherapy Implants. Int. J. Radiation Oncology Biol. Phys. 2003; 55 (2): 378-385.

<http://nssafame.com/community/isoraymedical/Document/10785/attachment/ArmpiliaIsotopes.pdf>

<sup>4</sup>Musmacher JS, et al, "Dosimetric Comparison of Cesium-131 and Palladium-103 for Permanent Prostate Brachytherapy" International Journal of Radiation Oncology Biology Physics, Volume 69, (Supplement 3), 2007, S730-1

<http://astro2007.abstractsnet.com/pdfs/07-2945.pdf>

<sup>5</sup>Yaparalvi R, et al, "Is Cs-131 or I-125 or Pd-103 the Ideal Isotope for Prostate Boost Brachytherapy? A Dosimetric View Point." International Journal of Radiation Oncology Biology Physics, Volume 69 (Supplement 3), 2007, S677-8

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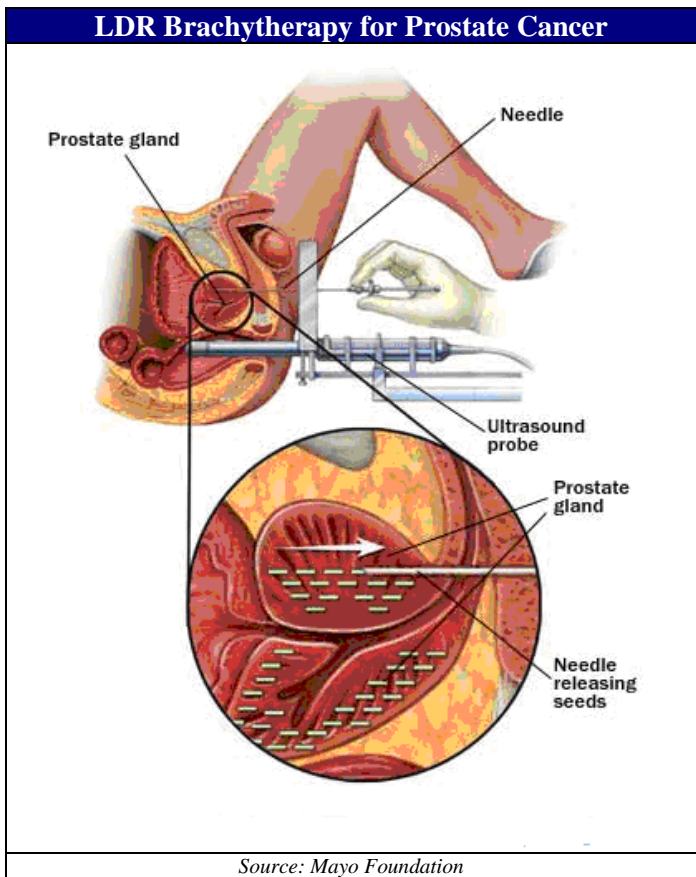
<sup>6</sup>Sutlief S and Wallner K, "Cs-131 Prostate Brachytherapy and Treatment Plan Parameters." Medical Physics, Volume 34, 2007, 2431

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<sup>7</sup>Kurtzman S, "Dosimetric Evaluation of Permanent Prostate Brachytherapy Using Cs-131 Sources" International Journal of Radiation Oncology Biology Physics, Volume 66 (Supplement 3), S395

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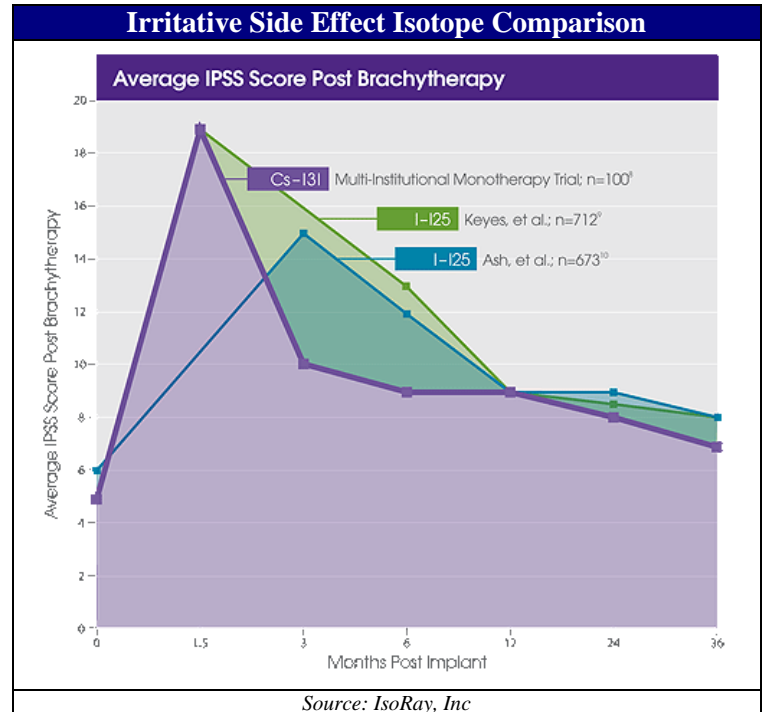
## Proxcelan™ Brachytherapy for Prostate Cancer



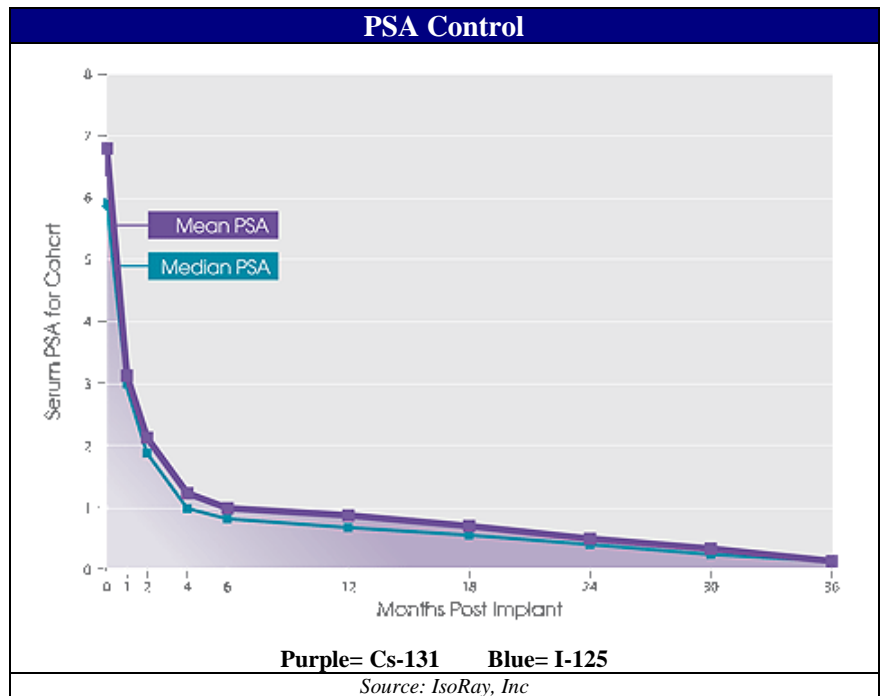
LDR permanent brachytherapy has been validated as an efficacious treatment for early stage prostate cancer with long term survival data now available from I-125 and Pd-103 seeds. There is clinical data to support that brachytherapy offers success rates for early-stage prostate cancer treatment that are equal to or better than those of radical prostatectomy or external beam radiation therapy.<sup>1</sup> A study of 2,963 prostate cancer patients who underwent brachytherapy monotherapy concluded that low-risk patients, who underwent adequate implants experienced rates of PSA relapse survival of greater than 90% between eight and ten years.<sup>2</sup> LDR permanent brachytherapy, as mentioned before, can be used in conjunction with other modalities to improve patient outcomes. Another published study demonstrated the combination of brachytherapy plus external-beam radiation therapy provides low rates of cancer recurrences at 15 years following treatment for early prostate cancer. The results showed biochemical relapse-free survival (BRFS: no two consecutive rises in PSA levels) was achieved in 74% of patients, BRFS was 88% among patients who were at a low-risk for developing a recurrence, 80% among patients who were at an intermediate-risk for developing a recurrence, and 53% among patients who were at a high risk for developing a recurrence.<sup>3</sup> Cesium, as mentioned before, is a newer radioisotope on the market and therefore long term survival data is not readily available yet. The shorter half-life, higher

energy and higher BED (along with other physical properties) associated with cesium suggest that it may be superior to the other isotopes due to a better uniform dose distribution within the prostate gland. Cs-131 could prove especially effective in treating fast repopulating tumor cells.<sup>4</sup> An independent study submitted 5 year data on Cs-131 for prostate cancer treatment in early 2011 for peer review. Positive long-term results will greatly strengthen the validity of Proxcelan™ therapy in comparison to the other currently used radioisotopes within the medical community and could help IsoRay steal market share from the competing radioisotopes.

In addition to having an efficacy profile for early stage prostate cancer that is as good, or better than the other competing procedures, brachytherapy also exhibits a preferable side effect profile as well. Two of the most concerning potential side effects that can arise from any of the commonly practiced prostate cancer interventional procedures are sexual impotence and urinary incontinence. Studies have shown that brachytherapy results in lower rates of impotence and incontinence than surgery.<sup>5</sup> The most significant side effect reported from LDR permanent interstitial brachytherapy are acute irritative bowel and especially urinary symptoms following implantation of the seeds. This is not unexpected considering the radiation from the seeds in the prostate gland can irritate the tissues of the urethra and bowl. These side effects are more common in brachytherapy procedures when compared to surgery or external beam radiation therapy.<sup>6</sup> Cs-131, as mentioned before, has a higher energy and shorter half-life, therefore the irritative side effects can be more pronounced with the use of the cesium radioisotope in the first few weeks after implantation. That said, it is very important to note that because of the much shorter half-life of cesium, patients can expect to experience a faster resolution of these side effects. Preliminary data drawn from a few clinical studies has supported such claims.<sup>7-9</sup>



Prostate Specific Antigen (PSA) control, long considered the gold standard in permanent prostate brachytherapy, has been promising thus far with Cs-131 treatment. A 100 patient, multi-institutional post marketing study of Cs-131 found similar tumor control rates to that of I-125 over 36 months as measured by PSA levels. The study has yet to have any PSA failures (rise in the blood level of PSA in prostate cancer patients after treatment) in patients treated with Cs-131.<sup>10</sup> The trial will continue to collect data moving forward to evaluate the long term efficacy of Cs-131 as a monotherapy.



IsoRay has commissioned a dual therapy protocol examining the dosimetric characteristics of Cs-131 and health related quality of life (HRQOL) results following combined Cs-131 permanent prostate brachytherapy and external beam radiotherapy

in patients with intermediate to high risk prostate cancer. The launch of the study began in early 2011 and is designed to confirm clinically what radiobiological data suggests regarding the effectiveness of this dual treatment modality. Positive results from this study could prove very significant for IsoRay. Intensity-Modulated Radiation Therapy (IMRT), an external radiation alternative to brachytherapy, has been taking an increasing role in radiotherapy and is expected to do so for the foreseeable future. Dual therapy efficacy could potentially open a new market for Proxcelan™ Cs-131 therapy in combination with IMRT.

**Recent Data:**

Recent data from studies at both Memorial Sloan-Kettering Cancer Center and Mount Sinai School of Medicine have found brachytherapy to be the current treatment of choice for the management of prostate cancer. A study from Sloan-Kettering followed 729 patients undergoing either brachytherapy or intensity-modulated radiotherapy to compare the long-term, prostate-specific antigen relapse-free survival outcome and incidence of toxicity for patients with low-risk prostate cancer. Conclusions from the study found among low-risk prostate cancer patients, the 7-year biochemical tumor control was superior for intraoperatively planned brachytherapy compared with high-dose intensity-modulated radiotherapy. Although significant toxicities were minimal for both groups, modest, but significant, increases in grade 2 urinary and rectal symptoms were noted for brachytherapy.<sup>11</sup>

A study from Mount Sinai School of Medicine followed 2,111 patients who underwent prostate brachytherapy to investigate biochemical freedom from failure, local control, freedom from metastasis and cause specific survival attributable to the procedure. Results demonstrated that permanent prostate brachytherapy yields excellent long-term oncologic outcomes with a 12-year biochemical freedom from failure rate of 78.6%, local failure rate of 7.3%, 12-year freedom from metastasis rate of 95.2%, and cause specific survival at 12 years of 94.5%. Conclusions from the trial found that a high biologically effective dose may need to be delivered to achieve successful biochemical freedom from failure, local control and cause specific survival.<sup>12</sup> One of the investigators of the trial, Dr. Nelson N. Stone from the Mount Sinai School of Medicine was quoted in an email to Reuters health elaborating on some of the findings from the trial:

*"When properly performed, where the delivered dose is high enough, brachytherapy compares favorably to all other prostate cancer treatments, including robotic prostatectomy, external beam irradiation (IMRT), and cryotherapy,"<sup>13</sup>*

**UPDATE:**

On June 20, 2011 IsoRay announced a new dual-therapy study using Cesium-131 brachytherapy (internal radiation therapy) and external beam radiation. Multiple sites have now received Institutional Review Board (IRB) approval for this study which will examine the efficacy of combining intensity modulated radiation (IMRT) with Cesium-131 brachytherapy to treat intermediate and high risk early stage prostate cancer. While Cesium-131 has been successful as a monotherapy for low and intermediate prostate cancers, physicians are also interested in its use in combination with external beam radiation therapy for cases that are at high risk of failure.

One of the co-principal investigators is Dr. John Sylvester, a nationally recognized expert who is one of the three clinicians who wrote the most recent American Brachytherapy Society guidelines for by prostate cancer brachytherapists worldwide, stated *"The Cesium-131 monotherapy trial we participated in has published a 98% success rate<sup>14</sup> in early stage cancer patients. We are excited about this new protocol for intermediate and high risk patients. We expect excellent cancer free survival rates and even less urinary side effects than past combination therapy protocols."*

**(SUBJECT TO TRIAL DESIGN CHANGES) POST-MARKETING CLINICAL TRIAL PROTOCOL**

<b>Title</b>	Dosimetric and Morbidity Outcomes of Cs-131 Brachytherapy in Combination With External Beam Radiation Therapy in Subjects With Intermediate to High Risk Adenocarcinoma of the Prostate: An Observational Study
<b># of Patients</b>	100 Male
<b>Population</b>	Diagnosed patients with intermediate to high risk cancer of the prostate. Patient will be in a Radiation Oncology setting.
<b>Ages</b>	18 and over
<b>Trial Design</b>	Observational Model:Cohort Time Perspective:Prospective
<b>Primary Endpoint</b>	The accumulation and analysis of dosimetric data resultant from Cs-131 permanent prostate brachytherapy in combination with external beam radiation therapy in the setting of intermediate to high risk cancer of the prostate
<b>Secondary Endpoint</b>	The accumulation and analysis of treatment related morbidities and PSA control rates following Cs-131 prostate brachytherapy in combination with external beam therapy for intermediate to high risk cancer of the prostate.
<b>Inclusion</b>	<ul style="list-style-type: none"> <li>•Histologically confirmed adenocarcinoma of the prostate</li> <li>•Clinical stage T1c - T2c (AJCC 6th Edition), NX/N0, M0</li> <li>•Karnofsky Performance Score of 90 to 100</li> <li>•Greater than or equal to 18 years of age</li> <li>•Prostate volumes by TRUS ≤ 60 cc</li> <li>•I-PSS score &lt; 15 (alpha blockers allowed)</li> <li>•Signed study-specific informed consent form prior to study entry</li> </ul> <p>Intermediate Risk prostate cancer as determined by the following:</p> <ul style="list-style-type: none"> <li>•Gleason sum of 7; PSA less than 10.1 ng/ml; Stage T2a or less</li> </ul>

	<ul style="list-style-type: none"> <li>•Gleason sum 6 or less; PSA &gt;10.0 and &lt; 20.1ng/ml; Stage T2a or less</li> <li>•Gleason sum 6 or less; PSA &lt; 10.1; Stage T2b</li> </ul>
	<p>High risk prostate cancer as determined by the following:</p> <ul style="list-style-type: none"> <li>•Any Gleason Sum; PSA greater than 20 ng/ml; Stage T2c or less</li> <li>•Gleason Sum &gt; 7; Any PSA; Stage T2c or less</li> <li>•Any Gleason Sum; Any PSA; Stage T2c</li> <li>•Any two or three intermediate risk factor</li> </ul>
<b>Exclusion</b>	<ul style="list-style-type: none"> <li>•Lymph node involvement (N1)</li> <li>•Evidence of distant metastases (M1)</li> <li>•Radical surgery for carcinoma of the prostate</li> <li>•Prior pelvic radiation</li> <li>•Previous or concurrent cancers other than basal, in situ, or squamous cell skin cancers unless disease-free for ≥ 5 years</li> <li>•Major medical or psychiatric illness, which in the investigator's opinion, would prevent completion of treatment and would interfere with follow-up</li> <li>•Hip prosthesis</li> <li>•Inability or refusal to provide informed consent</li> </ul> <p>Any hormonal blockade or therapy that:</p> <ul style="list-style-type: none"> <li>◦Has persisted for more than 6 months by time of protocol screening; OR</li> <li>◦Is ongoing within 3 months of study enrollment</li> </ul>
<b>Investigators</b>	<p>Co-Principal Investigator: Dr. John Sylvester, Lakewood Ranch Oncology Center Florida Co-Principal Investigator: Dr. Brian Moran, Director Chicago Prostate Center</p>

Source: ClinicalTrials.gov NCT00621413

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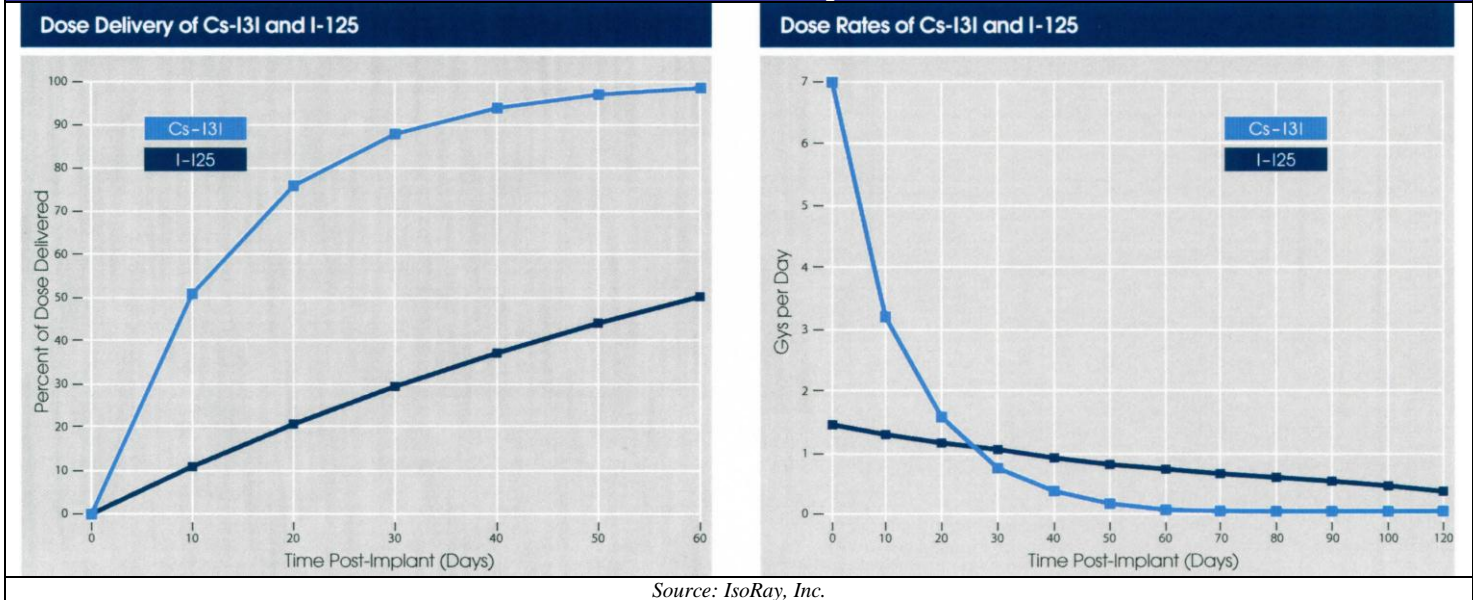
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## Cs-131 Brachytherapy for Lung Cancer

LDR permanent brachytherapy is often used in conjunction with surgery for the treatment of non small cell lung cancer (NSCLC). Often referred to as adjuvant lung brachytherapy, seeds are implanted in the tissue surrounding the resected tumor in an attempt to irradiate any cancerous cells that might have been left after surgery. Recurrent disease can often be attributed to missed diseased tissue during the surgery. After the removal of the tumor, the seeds are implanted into the remaining tissue via a polyglactin 910 bioabsorbable strand or mesh. The strand or mesh holds the seeds in place and generally takes about 45 days to dissolve. Cs-131 delivers 90% of its dose in the first 33 days, so the seeds have become fairly inert by the time the mesh is dissolved making it well suited for the system. The physical properties of Cs-131 in comparison to the other radioisotopes in use for this procedure allow for a much quicker and homogeneous distribution of prescribed radiation.

### Cs-131 vs. I-125 Comparison



The standard configuration of the mesh contains 4-6 strands per mesh with 10 seeds per strand, but the strands and mesh can be manufactured to each individual patient prescription.

IsoRay has initiated a post marketing trial investigating the use of Proxcelan™ Cs-131 therapy for patients diagnosed with early (Stage I) non-small cell lung cancer. The observational study will examine cancer re-growth in the area where it was surgically removed and quality of life in patients receiving sub-lobar resection in combination with Proxcelan™ Cs-131 seed implantation.

POST-MARKETING CLINICAL TRIAL PROTOCOL	
<b>Title</b>	Outcome Study of Cesium-131 Brachytherapy Following Sub-Lobar Resection for Early Stage NSCLC
<b># of Patients</b>	40 (male and female)
<b>Population</b>	Patients with clinical stage I non-small cell lung cancer who are not candidates for full lobectomy
<b>Ages</b>	Not Specified
<b>Trial Design</b>	Observational Model:Cohort Time Perspective:Prospective
<b>Endpoints</b>	Primary: Local Recurrence at 3 Years - Cancer regrowth in the area where it was surgically removed Secondary: Quality of Life at 2 years - Using questionnaires, data will be collected related to the sense of well-being experienced by the patient after treatment.
<b>Arm 1:</b>	All enrolled patients will undergo sub-lobar resection and brachytherapy implant with IsoRay Cesium-131 seed (85 Gray dose) in an effort to study and quantify recurrence/control patterns.
<b>Inclusion</b>	Patients must have suspicious lung nodule for clinical stage I/recurrent non-small cell Lung Cancer Mass Tumor size < 7 cm Patient must have a CT scan of the chest with upper abdomen within 90 days prior to date of pre-registration Patient must have ECOG/Zubrod performance status 0,1, or 2
<b>Exclusion</b>	Patient has already received high dose radiation to the area Cancerous nodule is very close to the esophagus or spinal cord, thereby increasing the risk of radiation treatment

	Pregnancy or unwillingness to practice a form of birth control (i.e. abstinence, oral contraceptives, etc.)
<b>Centers</b>	Weill Cornell Medical College, New York NY 10021
<b>Investigators</b>	Principal Investigator: Bhupesh Parashar, M.D. Weill Medical College of Cornell University

Source: ClinicalTrials.gov NCT01237171

Data from the trial is expected by the end of 2011 (calendar year). Investors should note that positive results from this trial would support the validity of Proxcelan™ seeds as a viable option adjuvant lung brachytherapy and that medical community adoption could increase top-line revenues for IsoRay as NSCLC currently does not account for a large portion of sales.

### **Cs-131 with da Vinci® Robotic Surgical System for Lung Cancer**

On July 12, 2011 IsoRay announced a milestone as their Cesium-131 brachytherapy seeds in mesh were implanted in an early stage lung cancer patient using Intuitive Surgical's (Nasdaq:ISRG) da Vinci® robotic surgical system. The procedure was performed by Dr. Deepak Khuntia (one of the nation's leading thought leaders in lung and brain tumors) and the surgical team at El Camino Hospital in California.

Stage 1 lung cancer patients are typically treated by performing extensive surgery to remove the entire lung or one of five lobes of the lung. For patients with restricted breathing conditions, this surgery is not an option and only a limited surgical procedure to remove the tumor mass from a lobe is possible. This leaves these patients with 20% to 40% cancer recurring along the surgical repair line.

Dr. Khuntia stated *"Mesh brachytherapy can dramatically reduce the recurrence rate for early-stage lung-cancer patients. With brachytherapy, recurrence is just one percent. That's a significant difference. At the same time, patients receive significantly less radiation exposure than traditional radiation."*

In addition, Dr. Edward Hall of the Archbold Medical Center in Georgia discussed the use of robotic surgery stating *"This is the first time we've had a viable surgical option to prevent staple/suture line (cancer) recurrence rates in patients with marginal lung and/or functional capacity. IsoRay's Cesium-131 & Robotic Surgery (da Vinci) allows us to offer these minimally invasive surgical and internal radiation advantages to patients with early stage tumors who would otherwise be inoperable because of limited pulmonary function or other health issues. In addition, the short half-life of Cs-131 minimizes exposure to radiation for surrounding tissues...I can foresee its use in many other minimally invasive techniques."* He went on to state that *"Ultimately, surgery offers the greatest potential for lung cancer cure. Due to the potential for serious complications, however, patients with compromised lung function or significant associated illnesses have been excluded from traditional surgical therapy. By increasing the accuracy of staging, significantly decreasing complication rates and reducing recurrence, the use of Cesium-131-based brachytherapy delivered via a robotic, minimally invasive approach, allows surgeons to extend to these patients this same potential for cure or disease control."*



Source: Intuitive Surgical Inc.

Intuitive Surgical's da Vinci® Surgical System enables surgeons to perform delicate and complex operations through a few tiny incisions with increased vision, precision, dexterity and control. The da Vinci Surgical System consists of several key components, including: an ergonomically designed console where the surgeon sits while operating, a patient-side cart

where the patient lays during surgery, four interactive robotic arms, a high-definition 3D vision system, and proprietary EndoWrist® instruments.

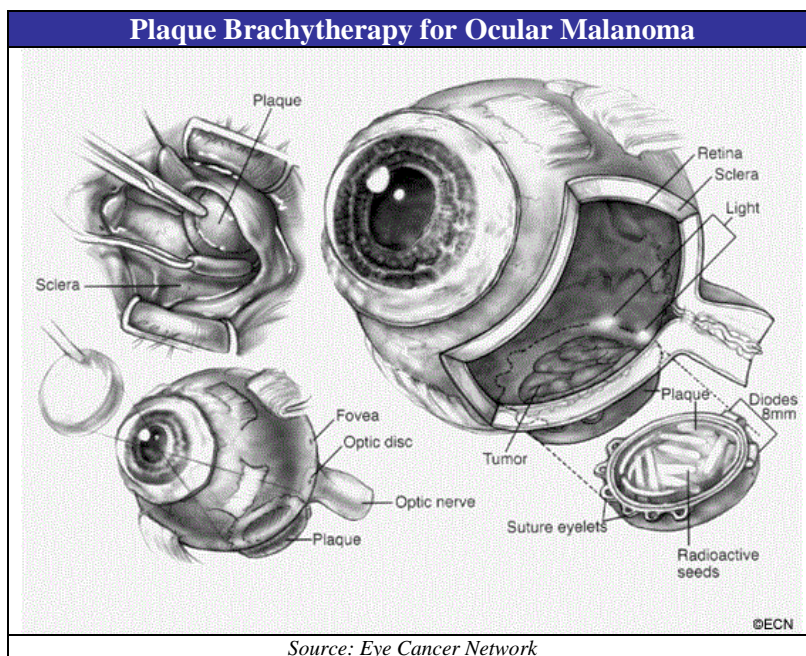
## Cs-131 Brachytherapy for Ocular Melanoma

Ocular melanoma (uveal melanoma) is the most common primary cancer of the eye in adults. It is diagnosed in about 2,500 adults every year in the United States and occurs most often in lightly pigmented individuals with a median age of 55 years. However, it can occur in all races and at any age. Ocular melanoma is caused by cancerous growth initiating from melanocytes in the eye. Ocular Melanoma is the second most common type of melanoma after cutaneous melanoma (skin cancer) and represents about 5% of all melanomas. Without treatment, ocular melanoma can cause blindness, around 50% of Ocular Melanoma cases lead to metastasis which can prove fatal.<sup>1</sup>

Treatment options for Ocular Melanoma include; surgery (could include removal of part of the iris, a portion of the outer eyeball, or entire eyeball), external beam radiation (including conformal proton beam radiation therapy and stereotactic radiosurgery), laser therapy, and plaque brachytherapy. Brachytherapy is the most commonly used radiation therapy for eye melanomas. The procedure is accomplished by placing the seeds in a plaque (shaped like a small cap) that is attached to the eyeball with stitches for 4 to 5 days. The patient generally stays in the hospital until the plaque is removed from the eye. Brachytherapy cures approximately 9 out of 10 small tumors and can preserve the vision of some patients.<sup>2</sup>

Cesium has advantages to palladium and Iodine in this application. Cs-131 provides better dose homogeneity and allows for greater penetration of therapeutic dose while maintaining a lower scleral dose.<sup>3,4</sup> This helps concentrate the radiation to the tumor site while minimizing exposure to other structures.

The first sale of Proxcelan Cs-131 for ocular melanoma was in late 2007. IsoRay is gathering data on the effectiveness of their isotope in this indication and publications are expected as the data matures. IsoRay's Cs-131 eye brachytherapy cases are manufactured to each individual patient dose. Standard configurations have up to 24 seeds with energy levels that are suitable for current plaque brachytherapy equipment and methodologies.

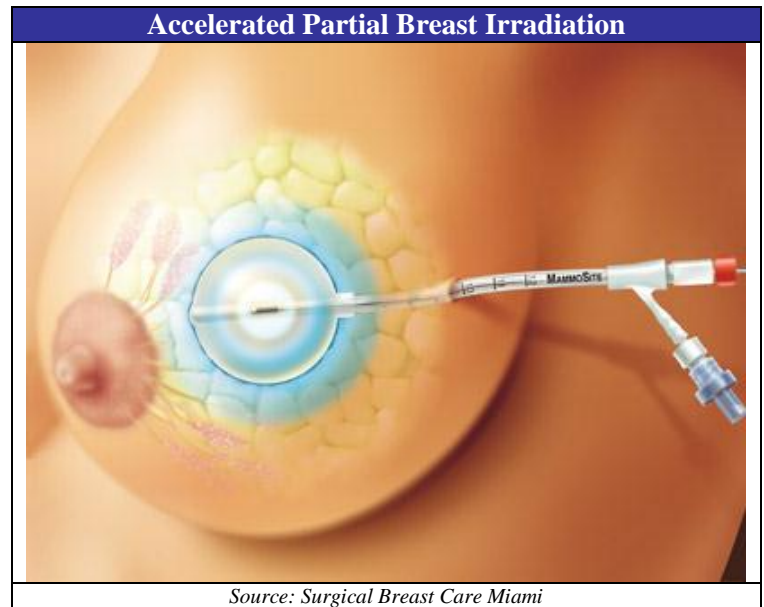


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## Cs-131 Brachytherapy for Breast Cancer

Accelerated partial breast irradiation (APBI) is an emerging, cutting-edge radiation treatment for early stage, localized breast cancer. It is used in tandem with breast-conserving surgery (lumpectomy) to obtain the highest possible rate of breast cancer control while offering minimal radiation exposure to healthy tissue and minimal cosmetic impact from the outcome of the breast cancer treatment. The procedure delivers high dose rate (HDR) radiation treatment directly around the lumpectomy site to treat any residual cancerous tissue that could have been left after the tumor resection. This area is where disease reoccurrence is most likely to take place. This targeted approach minimizes cosmetic deformities to the breast tissue and also reduces radiation to healthy tissues and organs, such as the heart and lungs, which can be in the field of treatment during whole breast irradiation. Without APBI, women who have a lumpectomy undergo up to six weeks of radiation treatment for the entire affected breast following surgery.



To date, APBI is only available in a limited number of facilities nationwide, because it requires HDR radiation. There are large capital expenditure costs involved for a hospital to construct and designate a highly secure, shielded environment where the treatments can take place. The HDR radiation procedure requires treatment to be delivered two times a day for five days.

In late 2010, IsoRay completed an initial feasibility study, which demonstrates the ability to use LDR Proxcelan™ Cs-131 brachytherapy seeds in APBI for breast cancer treatment. Using an FDA-cleared third party device, IsoRay conducted a series of internal studies to evaluate the prospect of using Cs-131 internal radiation therapy in APBI treatment. The studies included Monte Carlo simulations, used to determine radiation dose delivery to the proper site, which is considered the most accurate method of simulating radiation treatment. In addition, image-based brachytherapy treatment planning and physical dose measurements obtained from a specially designed phantom simulating a human breast were utilized. The initial studies support Cs-131 internal radiation therapy to be a viable alternative to HDR by successfully delivering the radiation dosage required for APBI.

LDR radiation therapies do not require the same special facilities and equipment associated with the current HDR treatments. The ability to use Cs-131 LDR internal radiation therapy for APBI would therefore dramatically increase the availability of the procedure. For the proposed Proxcelan™ APBI treatment, women would have a temporary device implanted at the time of their lumpectomy surgery. Patients would then be able to go home for four to five days until the Cs-131 internal radiation therapy was completed when they would return to the hospital for device removal. Therefore, in addition to increasing the availability of APBI procedure, the proposed Proxcelan™ treatment would also eliminate the need for multiple hospital visits for radiation treatment.

IsoRay is currently aggressively pursuing a plan to advance the adoption and usage of Cs-131 internal radiation therapy to treat cancers throughout the body, including early stage, localized breast cancer.

## New GliaSite® and Iotrex™ Brachytherapy for Brain Cancer

### Update:

On September 12, 2011 IsoRay announced they had received FDA 501(k) clearance to market their GliaSite® radiation therapy system, a balloon catheter device used to deliver Iotrex™ (Iodine-125) to treat malignant brain cancer following resection surgery. IsoRay had improved the product design and manufacturing techniques including a new balloon manufacturing system, which required a new FDA 501(k) clearance for use and the improved GliaSite® delivery system exceeded all prior product specifications during the reporting and testing phase. The GliaSite® system already has established reimbursement for both in-patient and out-patient settings. The new FDA 510(k) clearance can be accessed at:

[http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K111931.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111931.pdf)

The company believes sales of GliaSite® and Iotrex™ will begin in Q4 2011.

In June of 2010, IsoRay acquired exclusive worldwide distribution rights to the GliaSite® radiation therapy system, the only FDA-cleared balloon catheter device used in the treatment of brain cancer from Hologic, Inc (Nasdaq:HOLX). The GliaSite® device is used to perform intracavitary brachytherapy of the brain following resection of a tumor. A balloon catheter is introduced into the brain and inflated with a radioactive isotope solution. Radiation is delivered locally to the surrounding brain tissue treating primary, recurrent or metastatic tumors. The GliaSite® catheter is a dual balloon system. The inner balloon acts as a reservoir for the radioactive solution and the outer balloon is there to ensure that the radioactive solution is not released if the inner balloon is compromised.

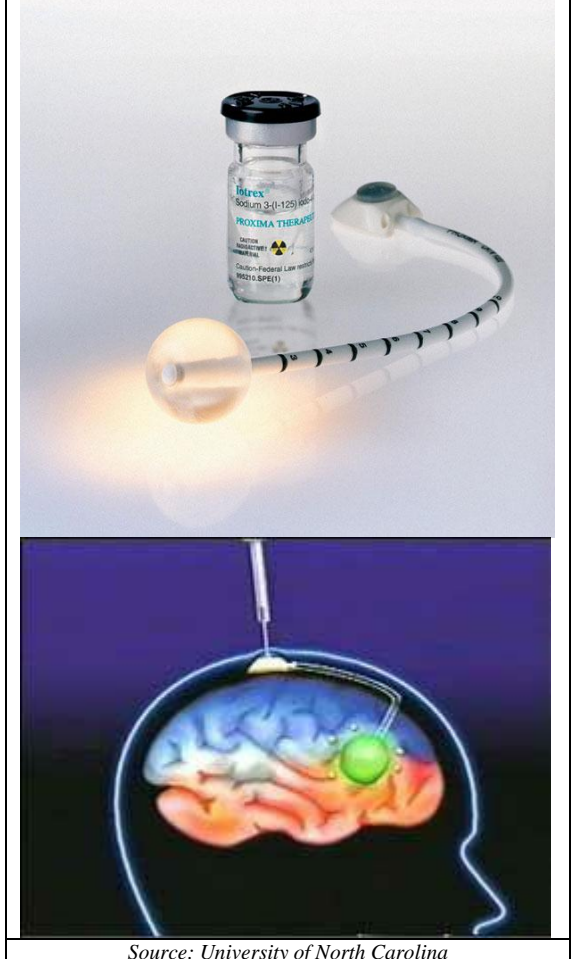
At the time of surgery, the GliaSite® device is placed by the Neurosurgeon within the resection cavity of the removed brain tumor. The injection port is affixed to the top of the skull and concealed under the skin. After the patient recovers from surgery, a pre-determined amount of radioactive solution is injected into the balloon. Treatment is delivered over 3-7 days as an outpatient procedure. At the end of treatment, the radioactive solution is removed, balloon deflated and the patient is discharged.<sup>1</sup> For a majority of patients, the device remains inside the brain permanently, but can be removed in a simple procedure performed under local anesthesia.<sup>2</sup>

Hologic discontinued sales of the GliaSite® device in 2008 due to small revenue share when compared to other company products. Investors should note that the GliaSite® device accounted for about \$8 million dollars in revenue annually before being discontinued, which could potentially represent a large addition to top line revenue for IsoRay.

IsoRay is currently seeking FDA 510(k) approval for a liquid form of Cs-131 for use in the GliaSite® system. While waiting for FDA clearance, the company has acquired an exclusive worldwide licence for Iotrex, a FDA approved liquid I-125 for use in the GliaSite® therapy system. The acquisition of Iotrex opens an immediate market opportunity to generate revenues from sales of GliaSite® in the brain cancer market. IsoRay is currently in negotiations for a distribution agreement with the previous European distributor of GliaSite® and expects launch of a sales initiative in early calendar Q4.

In addition to the progress with GliaSite®, Cesium-131 brachytherapy (internal radiation therapy) seeds were used for the first time to treat metastasized brain cancer. The seeds were implanted directly into a woman's brain following tumor resection to treat a cancer that had originated in the breast and she is now cancer-free. The procedure was performed by doctors at New York Presbyterian Hospital/ Weill Cornell Medical Center. Treatment of metastasized cancers, cancers

### GliaSite® Radiation Therapy System



Source: University of North Carolina

that originate in other organs, is the latest application of IsoRay's Cesium-131 brachytherapy treatment. The patient recently appeared for a television interview which can be seen at:

[http://www.wptv.com/dpp/news/health/medical\\_breakthroughs/brain-seeds%3A-planting-tumor-fighters](http://www.wptv.com/dpp/news/health/medical_breakthroughs/brain-seeds%3A-planting-tumor-fighters)

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## Cs-131 Brachytherapy Applications for Other Solid Tumors

Proxcelan™ Cesium-131 brachytherapy seeds have FDA 510(k) clearance for the treatment of all solid tumor malignant disease (e.g., head and neck, brain, breast, prostate, etc.) found in the body, and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. There are many different current solid tumor applications where Proxcelan™ could be efficacious and could gain market share.

### Head and Neck Cancer:

#### Current Treatment Options:

1) Surgery- including (not limited to): tumor resection, Mohs micrographic surgery, full or partial mandible resection, maxillectomy, laryngectomy, neck dissection, pedicle or free flap reconstruction, tracheostomy, gastrostomy tube or dental extraction and implants.

2) Chemotherapy- including (not limited to): Paclitaxel, Docetaxel, Carboplatin and Erbitux (cetuximab)

3) Radiation- including (not limited to): external beam radiation therapy (EBRT), accelerated and hyperfractionated radiation therapy, three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), and brachytherapy (both high-dose rate (HDR) and low-dose rate (LDR)).

Surgery, if viable, is the most common option in treating cases of head and neck cancer. Chemotherapy is often used in conjunction with surgery or radiation therapy depending on the type and stage of the cancer. Radiation therapy, both external beam therapy and brachytherapy, have been used together or in combination with surgery or chemotherapy

Proxcelan™ Cesium-131 brachytherapy could represent an improved approach to brachytherapy treatment of head and neck cancers.

On June 4, 2009, the world's first head and neck permanent seed Cesium-131 implantation procedure was performed by Dr. Karen Pitman of the Department of Otolaryngology and Communicative Sciences and Dr. Michael Baird of the Radiation Oncology Department of the University of Mississippi Medical Center. The implant was performed using Vicryl- embedded seeds in the tonsillar area in a patient who had locally failed IMRT external beam radiation and chemotherapy. The procedure was well tolerated by the patient. Investor should note while Proxcelan™ sales for the treatment of head and neck cancer are not a large part of IsoRay's current revenue stream, medical community adoption of the therapy could represent significant upside to the company.

### Colorectal Cancer:

#### Current Treatment Options:

Surgery- including (not limited to): open colectomy, laparoscopic-assisted colectomy, and polypectomy and local excision, polypectomy and local excision, local transanal resection, transanal endoscopic microsurgery (TEM), lower anterior resection, proctectomy with coloanal anastomosis, abdominoperineal resection, pelvic exenteration radiofrequency ablation, ethanol ablation, cryosurgery and hepatic artery embolization.

Chemotherapy- including (not limited to): Oxaliplatin, Leucovorin, Capecitabine, 5-fluorouracil, Irinotecan, Avastin, Erbitux, and Vectibix

Radiation- including (not limited to): external beam radiation, endocavitary radiation, brachytherapy, yttrium-90 microsphere radioembolization.

Colorectal cancer can be treated using surgery, radiation therapy, chemotherapy and other targeted therapies. Depending on the stage of the cancer, two or more of these types of treatment may be combined at the same time or used after one another. Low-dose rate (LDR) brachytherapy including Proxcelan Cs-131 is typically utilized in treating individuals with colorectal cancer who are not healthy enough to tolerate curative surgery. This is generally a one-time only procedure and does not require ongoing visits for several weeks as is common with other types of radiation therapy such as external-beam radiation therapy and endocavitary radiation therapy.

On October 10, 2009 the world's first colorectal permanent seed Cesium-131 implantation procedure was performed by Dr. Bhupesh Parashar, Dr. A Gabriella Wernicke and Dr. KS Clifford Chao from the Department of Radiation Oncology, and Dr. Jeffery Milsom from the Department of Gastrointestinal Surgery, at Weill Cornell Medical Center. This implant was performed on a 38 year old patient with locally recurrent colon cancer who underwent surgical resection of the tumor as a part of the treatment. The patient has a history of multiple prior surgeries and chemotherapy for colorectal cancer. The procedure was well tolerated and the patient had no evidence of cancer recurrence or any side effects that can be attributed to the Cesium-131 seed implant at the last follow-up visit. Investor should note while Proxcelan™ sales for the treatment of colorectal cancer are not a large part of IsoRay's current revenue stream, medical community adoption of the therapy could represent significant upside to the company.

**Update: Cs-131 Treatment of Gynecological Cancer**

On, August 15, 2011 IsoRay announced the world's first treatment using Cesium-131 brachytherapy seeds for gynecological cancer at the University of Kentucky's Markey Cancer Center on a patient whose cancer had reoccurred following previous radiation treatment. The procedure was performed by Dr. Marcus E. Randall who is the Markey Foundation Endowed Chair of the Department of Radiation Medicine. Treatment options for these patients have been historically limited to surgical removal of organs and tissue or palliative chemotherapy (non-cure), Dr. Randall stated that permanent seed implants *"are very safe and quite effective with good long term control and survival."*

While this currently does not represent a significant source of revenue for IsoRay, investors should note that the adoption of Cs-131 brachytherapy for the treatment of gynecological cancer could become a considerable contributor to top-line revenue if the practice gains favor in the medical community.

More on Dr. Randall can be found at: <http://www.mc.uky.edu/radiationmedicine/faculty/randall.asp>

**IsoRay FDA 510(k) Clearances**

IsoRay products have already received U.S. FDA 510(k) medical device clearance for use broad use by healthcare professionals. Specifically, the IsoRay Cesium-131 implant devices are indicated for the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.), and may be used in surface, interstitial, and intracavitary applications for tumors with known radiosensitivity. These devices 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. IsoRay has also received FDA 501(k) clearance for the GliaSite® radiation therapy balloon catheter delivery system for use with Iotrex™ Iodine-125.

Product	510(k) Ref #	Decision Date	References Documents for FDA 510(k) Clearance
GliaSite RTS	K111931	08/05/2011	<a href="http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111931.pdf">http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111931.pdf</a>
Proxcelan Cs-131 preloaded Strands, Model PI-1, Proxcelan Cs-131 Preloaded Strands In 18 Gauge Needles, Model PI-2	K092458	08/28/2009	<a href="http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092458.pdf">http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092458.pdf</a>
Proxcelan Cs-131 Preloaded Braided Strands, Model: PI-5	K092136	08/07/2009	<a href="http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092136.pdf">http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092136.pdf</a>
Cesium-131 Strand, Strand Preload, Preload, S-Cartridge	K062384	11/09/2006	<a href="http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062384.pdf">http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062384.pdf</a>
Lawrence CSERION, Model Cs-1	K030162	03/28/2003	<a href="http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030162.pdf">http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030162.pdf</a>

Source: United States Food & Drug Administration

## Market and Financial Assumptions

The radiotherapy market is fairly fragmented with many players and some in overlapping methodologies. Some players in the radiotherapy market are Theragenics (NYSE:TXG), Best Medical, Core Oncology, IsoAid, Oncura, C.R. Bard (NYSE:BCR), Hologic (Nasdaq:HOLX), Nucletron, Cianna Medical, Varian Medical (NYSE:VAR), Accuray (Nasdaq:ARAY) and Elekta (Nordic:EKTAB).

The overall radiotherapy market consists of several sub-markets. One is High-Dose Rate (HDR) brachytherapy which usually involves placing high-energy Iridium-192 directly on or within the tumor for a short period of time and then removed. It is performed on an outpatient basis over 2 to 10 sessions.

The next sub-market is Low-Dose Radiation (LDR) brachytherapy in which the radioisotopes (Palladium-103, Iodine-125 or Cesium-131) are implanted inside the patient for an extended period of time requiring only one patient visit for implant where upon the seeds are left in the patient to decay until they become inert.

While not widely used in the U.S., Pulsed-Dose Rate (PDR) brachytherapy is similar to HDR, however the radiation is given in short 'pulses' over several hours and requires the patient to be treated for the entire day.

A competing approach to brachytherapy is Intensity-Modulated Radiation Therapy (IMRT) which uses computer-controlled linear accelerators to shape the external radiation beam to approximate the shape of the tumor. Finally, radiotherapy in certain instances may compete against surgical resection, manual or robotic (Robotic Prostatectomy for example). Investors should note that IsoRay's Proxcelan™ can also be used in combination with IMRT.

The overall market can be considered mature but with intra-market shifts in methodologies and market share. In this respect, IMRT has been taking an increasing role in radiotherapy and is expected to do so for the foreseeable future and we believe one reason for this may be current economics of Medicare reimbursement for IMRT.<sup>1</sup>

Specifically, IsoRay's Proxcelan™ Cesium-131 brachytherapy seeds compete most directly with Palladium-103 and Iodine-125 seeds in the Low-Dose Radiation (LDR) market. Investors should note that IsoRay's Proxcelan™ can also be used in combination with IMRT. IsoRay's strategy is to gain a larger slice of a shrinking market in prostate cancer while launching in new cancer-types such as brain, lung, breast and the eye. Investors should note that IsoRay's Proxcelan™ is already FDA 510(k) cleared for all of these indications.

U.S. Peak Market Potential for IsoRay Proxcelan™ Cesium-131 Seeds by Indication							
Cancer Type	New Cases <sup>1</sup>	Deaths <sup>1</sup>	Survival Years <sup>2</sup>	IsoRay Potential Cases <sup>3</sup>	# of Seeds <sup>3</sup>	Price per Seed <sup>3</sup>	IsoRay Peak Sales <sup>3</sup>
Prostate	217,730	32,050	6.8	13,000 (6%)	85	\$72	\$79,560,000
Breast	209,060	40,230	5.2	10,000 (5%)	40	\$119	\$47,600,000
Lung	222,520	157,300	1.4	4,000 (2%)	40	\$119	\$19,040,000
Brain	22,020	13,140	1.7	2,000 (9%)	30	\$119	\$7,140,000
Head & Neck	49,260	11,480	4.3	2,000 (4%)	25	\$119	\$5,950,000
Ocular	2,480	230	10.8	200 (8%)	15	\$119	\$357,000
<b>IsoRay Potential Peak Sales</b>							<b>\$159,647,000</b>

<sup>1</sup> National Cancer Institute SEER 2010 Estimates

<sup>2</sup> Assumes Static Incidence

<sup>3</sup> IsoRay, Inc.

Our financial model assumes an increase in market share for prostate cancer with expected 5-year follow-up data publication. However, continued pricing pressures throughout the prostate sub-market are expected to offset some of these gains. A significant growth opportunity is expected from IsoRay's launch of GliaSite using Iotrex for treating brain cancer in calendar Q3 2011. We further expect IsoRay to leverage their existing Cesium-131 expertise to develop a liquid formulation of Cesium-135 for use with GliaSite. Looking farther ahead, IsoRay's development of Cesium-131 for Accelerated Partial Breast Irradiation (APBI) as well other in other solid tumors such as colon and head & neck cancers, provide additional growth opportunities. At this time, we are conservatively modeling 20% of IsoRay's potential peak sales by 2015.

Investors should note that IsoRay has minimum manufacturing batch-size requirements for which their sales levels have not yet fully consumed. The result is that gross margins are currently adversely impacted by unused manufactured quantities. As IsoRay's Proxcelan™ Cesium-131 brachytherapy sales increase, we expect to see margins improve significantly rising to approximately 50% by 2015.

We do not foresee additional operating expenses beyond those matched by sales growth as IsoRay already has FDA clearance for Proxcelan™ and their current and planned post-marketing study costs are typically shared with other institutions and investigators.

#### RESEARCH REFERENCES

<sup>1</sup> The Wall Street Journal "A Device to Kill Cancer, Lift Revenue." December 7, 2010

<http://online.wsj.com/article/SB10001424052748703904804575631222900534954.html>

## IsoRay Cs-131 Manufacturing

Cs-131 is a radioactive isotope produced by neutron bombardment of non-radioactive Barium-130 (Ba-130) which becomes radioactive Ba-131 and then decays by electron capture to the radioactive isotope Cs-131. To produce the Proxcelan™ seed, the purified Cs-131 isotope is adsorbed onto a ceramic core containing a gold X-ray marker. This internal core assembly is subsequently inserted into a titanium capsule that is then welded shut and becomes a sealed radioactive source and a biocompatible medical device.

IsoRay has identified key reactor facilities that are capable of meeting their production requirements. On December 1, 2010, IsoRay renewed their existing contract with Russia-based UralDial, LLC (a Russian LLC) to provide Cs-131 isotope from at least two Russian facilities to IsoRay's facility in Richland, Washington through December 31, 2011. IsoRay also receives irradiated barium from the MURR reactor (University of Missouri Research Reactor) in the U.S. Approximately 68% of IsoRay's Cs-131 is sourced from Russian with the remainder from the United States.

IsoRay's production facility is at Applied Process Engineering Laboratory (APEL) in Richland Washington and has over 15,000 square feet including space for isotope separation, seed production, order dispensing, a clean room for radiopharmacy work, and a dedicated shipping area.

### Seed Packaging

Most brachytherapy manufacturers offer their seed product to the end user packaged in five principal configurations provided in a sterile or non-sterile package depending on the customer's preference.

- Loose seeds
- Pre-loaded needles (loaded typically with three to five seeds and spacers)
- Pre-loaded Mick cartridges (fits the Mick® applicator)
- Strands of seeds (consists of seeds and spacers in a biocompatible "shrink wrap")
- Preloaded Strands (strands loaded into the needle)

Approximately 67% of IsoRay's Proxcelan™ seeds were configured in Mick® cartridges, 31% in stranded forms and the remaining 2% in a loose form. IsoRay loads approximately 96% of Mick® cartridges in our own facility which in fiscal year 2010 accounted for approximately 67% of seeds sold. The remaining approximately 33% of seeds sold are strand configurations including preloaded strands. Although IsoRay performs in-house analytical services to eliminate loss in isotope activity due to radioactive decay, they also utilize independent radiopharmacies to back up their own preloading operation, handle periodic increases in demand and cater to certain doctors' preferences.

IsoRay became the second company in the industry that has 510(k) clearance to preload both the strands and the mesh, which reduces loading costs by providing them directly to their customers.

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## Recent Financing Activity

On April 12, 2011 IsoRay announced an addition \$500,000 in institutional funding through the conversion of warrants in connection with the November 24, 2010 financing.

On November 24, 2010, IsoRay completed a Securities Purchase Agreement to sell 2,250,000 shares of common stock and four series of warrants for \$1.00 per share.

- (i) Series A Warrants in an amount equal to \$500,000 divided by the lower of \$1.50 and 90% of the average of the 3 lowest volume weighted average prices out of the 15 trading days preceding the exercise date (with a floor of \$0.75 for a maximum of 666,667 shares of common stock issuable upon exercise of the Series A Warrants)
- (ii) Series B Warrants in an amount equal to 25% of the number of shares of common stock issued at the closing, or Series B Warrants exercisable for 562,500 shares of common stock.
- (iii) Series C Warrants in an amount equal to 125% of the number of shares of common stock issued at the closing, or Series C Warrants exercisable for 2,812,500 shares of common stock.
- (iv) Series D Warrants in an amount equal to 125% of the number of shares of common stock issued at the closing, or Series D Warrants exercisable for 2,812,500 shares of common stock.

However, the Series D Warrants will only be exercisable to the extent that any of the Series C Warrants may not be exercised due to NYSE AMEX shareholder approval requirements limiting the number of overall below-market securities issuable to no greater than 4,418,026 shares of common stock. As a result of this limitation, the total number of Series A, B and C Warrants will not exceed Warrants exercisable for an aggregate of 2,168,026 shares of common stock, and Series D Warrants are expected to be issued to purchase 1,873,641 shares of common stock, assuming the Series A Warrants are exercisable for the maximum number of shares of common stock.

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

The Series A warrants will be eligible to be exercised at the option of the Company beginning on the 75th day after issuance and ending on the 90th day after issuance subject to the exercise price being above \$0.75 for the 15 day period prior to expiration and to meeting other equity conditions. All of the Series B warrants and 562,500 of the Series C warrants will be eligible to be exercised at the option of the Company at any time on or before 6 months after their issuance provided the common stock is trading at or above \$2.45 for 20 cumulative trading days and to meeting other equity conditions.

As of June 30, 2011, there were 3,819,185 warrants outstanding with a weighted average exercise price of \$3.69. In addition, there were 1,951,114 stock options outstanding and exercisable with a weighted average exercise price of \$2.01. As of September 20, 2011, IsoRay had 26,493,118 shares outstanding.

## Intellectual Property

IsoRay has a number of assigned patents and patent applications covering methodologies regarding isotope production, separation, and seed manufacturing as show below:

SELECTED ISORAY U.S. INTELLECTUAL PROPERTY FILINGS			
NUMBER	DESCRIPTION	FILED	ISSUED
7,531,150	Method of separating and purifying cesium-131 from barium carbonate	July 27, 2005	May 12, 2009
7,517,508	Method of separating and purifying Yttrium-90 from Strontium-90	July 25, 2005	April 14, 2009
7,510,691	Method for improving the recovery of cesium-131 from barium carbonate	February 27, 2007	March 31, 2009
7,479,261	Method of separating and purifying Cesium-131 from Barium nitrate	June 22, 2005	January 20, 2009
7,410,458	Brachytherapy implant seeds	November 12, 2003	August 12, 2008
7,316,644	Method for preparing particles of radioactive powder containing Cesium-131 for use in brachytherapy sources	August 5, 2005	January 8, 2008
6,066,302	Method of separation of Cesium-131 from Barium	April 28, 1999	May 23, 2000
20070212285	Method for improving the recovery of cesium-131 from barium carbonate	February 27, 2007	Pending
20060167332	Method for preparing particles of radioactive powder containing cesium-131 for use in brachytherapy sources	August 5, 2005	Pending
20060051269	Method of separating and purifying cesium-131 from barium nitrate	June 22, 2005	Pending
20060024223	Method of separating and purifying cesium-131 from barium carbonate	July 27, 2005	Pending
20060018813	Method of separating and purifying Yttrium-90 from Strontium-90	July 25, 2005	Pending

Source: U.S. Patent and Trademark Office

## Management/Directors

**Dwight Babcock, Chairman and Chief Executive Officer:** Mr. Babcock was appointed CEO of IsoRay on February 18, 2009. He was previously appointed Chairman and Interim CEO of the Company on February 26, 2008 and has served as a Director of the Company since 2006. Mr. Babcock has served as Chairman and Chief Executive Officer of Apex Data Systems, Inc., an information technology company, since 1975. Apex Data Systems automates the administration and claims adjudication needs of insurance companies both nationally and internationally. Mr. Babcock was formerly President and CEO of Babcock Insurance Corporation (BIC) from 1974 until 1985. BIC was a nationally recognized third party administrator operating within 35 states. Mr. Babcock has knowledge and experience in the equity arena and has participated in various activities within the venture capital, private and institutional capital markets. Mr. Babcock studied marketing and economics at the University of Arizona where he currently serves on the University of Arizona Astronomy Board. Mr. Babcock brings over 35 years of CEO-level experience to his service on the Company's Board.

**Brien Ragle, Controller, Principal Financial and Accounting Officer:** Mr. Ragle has over 14 years of finance and accounting experience, including financial reporting, and cost, project, and management accounting in addition to performing operational analysis. Mr. Ragle became IsoRay's Controller in October 2009. Before joining IsoRay in January 2007 as Cost Accounting Manager, Mr. Ragle was employed by BNG America, LLC, a wholly-owned subsidiary of Energy Solutions, LLC (ES) from 2005 to 2006 as a Project Accounting Manager and from 2000 to 2004 as a Business Unit Controller by SCM Consultants, Inc, a wholly-owned subsidiary of Tetra Tech, Inc (TTEK). Mr. Ragle holds Bachelor of Arts degrees in Business Administration, accounting emphasis, and Hospitality Management from Washington State University and is a Certified Public Accountant in the State of Washington.

**Fredric Swindler, Vice President--Quality Assurance/Regulatory Affairs:** Mr. Swindler joined IsoRay Medical in October 2006 and has over 40 years experience in manufacturing and regulatory compliance. Mr. Swindler also serves as Secretary for IsoRay, Inc., a position he has held since June 11, 2008. Mr. Swindler served as VP, Quality Assurance and Regulatory Affairs for Medisystems Corporation, a manufacturer and distributor of medical devices, from 1994 until joining the Company. During his tenure at Medisystems Corporation, Mr. Swindler developed a quality system to

accommodate vertically integrated manufacturing, developed regulatory strategies, policies and procedures, and submitted nine pre-market notifications (510(k)) to the FDA. Prior to this, Mr. Swindler held various positions with Marquest Medical Products from 1989 to 1994, Sherwood Medical Products from 1978 to 1989, Oak Park Pharmaceuticals in 1978, and Mead Johnson & Company from 1969 to 1978. Mr. Swindler holds a Bachelor of Science degree in Biomedical Engineering from Rose-Hulman Institute of Technology and a Masters of Business Administration from the University of Evansville.

**William Cavanagh III, Vice President, Research and Development:** Mr. Cavanagh joined IsoRay Medical in January 2010. Mr. Cavanagh has most recently been engaged in the research and development of dendritic cell therapies for cancer and infectious diseases. He served as Chief Scientific Officer for Sangretech Biomedical, LLC for the six years prior to joining IsoRay Medical. At Sangretech, he oversaw the design and implementation of a novel cancer therapy. Mr. Cavanagh began his extensive career in cancer treatment technologies in the early 1990s, when he helped lead research and development of a therapy involving the insertion of radioactive sources directly into the prostate for the treatment of prostate cancer (prostate brachytherapy). He has designed several cancer treatment-related studies, is listed as an author on 34 peer-reviewed publications, and is the listed inventor on a U.S. patent application detailing a novel treatment for cancer. Mr. Cavanagh has also served as Director of the Haakon Ragde Foundation for Advanced Cancer Studies in Seattle, Washington, where he led the research foundation in the selection of viable research projects directed at treating advanced cancers. Mr. Cavanagh holds a B.S. in Biology from the University of Portland (Oregon) and completed two years of medical school before beginning his career in research management.

**Lane Bray, Chief Chemist:** Mr. Bray is known nationally and internationally as a technical expert in separations, recovery, and purification of isotopes and is a noted authority in the use of cesium and strontium ion exchange for Department of Energy's West Valley and Hanford nuclear waste cleanup efforts. In 2000, Mr. Bray received the 'Radiation Science and Technology' award from the American Nuclear Society. Mr. Bray has authored or co-authored over 110 research publications, 12 articles for nine technical books, and holds 28 U.S. and foreign patents. Mr. Bray patented the USDOE/PNNL process for purifying medical grade Yttrium-90 that was successfully commercialized in 1999. Mr. Bray also invented and patented the proprietary isotope separation and purification process that is assigned to IsoRay. Mr. Bray was elected 'Tri-Citizen of the Year' in 1988, nominated for 'Engineer of the Year' by the American Nuclear Society in 1995, and was elected 'Chemist of the Year for 1997' by the American Chemical Society, Eastern Washington Section. Mr. Bray retired from the Pacific Northwest National Laboratory in 1998. Since retiring in 1998, Mr. Bray worked part time for PNNL on special projects until devoting all of his efforts to IsoRay in 2004. Mr. Bray has been a Washington State Legislator, a Richland City Councilman, and a Mayor of Richland. Mr. Bray has a B.A. in Chemistry from Lake Forest College.

### **Non-Management Directors**

**Robert Kauffman, Vice-Chairman:** Mr. Kauffman has been a Director of IsoRay since 2005 and was appointed Vice-Chairman of the Company on February 26, 2008. Mr. Kauffman has served as Chief Executive Officer and Chairman of the Board of Alanco Technologies, Inc. (NASDAQ: ALAN), an Arizona-based information technology company, since July 1, 1998. Mr. Kauffman was formerly President and Chief Executive Officer of NASDAQ-listed Photocomm, Inc., from 1988 until 1997 (since renamed Kyocera Solar, Inc.). Photocomm was the nation's largest publicly owned manufacturer and marketer of wireless solar electric power systems with annual revenues in excess of \$35 million. Prior to Photocomm, Mr. Kauffman was a senior executive of the Atlantic Richfield Company (ARCO) whose varied responsibilities included Senior Vice President of ARCO Solar, Inc., President of ARCO Plastics Company and Vice President of ARCO Chemical Company. Mr. Kauffman earned an M.B.A. in Finance at the Wharton School of the University of Pennsylvania, and holds a B.S. in Chemical Engineering from Lafayette College, Easton, Pennsylvania. Mr. Kauffman has substantial experience in serving as CEO for public companies, and brings these skills to his service on the Company's Board.

**Thomas LaVoy:** Mr. LaVoy has been a Director of IsoRay since 2005. Mr. LaVoy has served as Chief Financial Officer of SuperShuttle International, Inc., since July 1997 and as Secretary since March 1998. SuperShuttle is one of the largest providers of shuttle services in major cities throughout the West and Southwest regions of the United States. He has also served as a director of Alanco Technologies, Inc. (NASDAQ: ALAN) since 1998 and presently serves on its audit committee. From September 1987 to February 1997, Mr. LaVoy served as Chief Financial Officer of NASDAQ-listed Photocomm, Inc. Mr. LaVoy was a Certified Public Accountant with the firm of KPMG Peat Marwick from 1980 to

1983. Mr. LaVoy has a Bachelor of Science degree in Accounting from St. Cloud University, Minnesota, and is a Certified Public Accountant. Mr. LaVoy brings over 25 years of CFO experience for progressively growing companies in multiple industries to his service on the Company's Board.

**Albert Smith:** Mr. Smith has been a Director of IsoRay since 2006. Mr. Smith was the co-founder of and served as Vice Chairman of CSI Leasing, Inc., a private computer leasing company from 1972 until March 2005. He founded Extreme Video Solutions, LLC a privately held video conferencing company with headquarters in Scottsdale, Arizona in December 2005. In January 2008, he formed Face to Face Live, Inc. (successor to Extreme Video Solutions) where he presently serves as CEO. Mr. Smith presently serves as Chairman of the Board for Doulos Ministries, Inc. Mr. Smith has extensive experience in marketing and sales having managed a national sales force of over fifty people while at CSI Leasing, Inc. Mr. Smith holds a BS in Business Administration from Ferris State College. Mr. Smith brings his entrepreneurial skills in founding and growing multiple private companies, together with a strong sales and marketing background, to his service on the Company's Board.

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## Risks

Some of the operational and financial risks to IsoRay are:

- **FDA and Regulatory risks:** All of IsoRay's products are reliant on approvals by the U.S. FDA and other national regulatory bodies. While IsoRay's Cesium-131 implant devices have received FDA 510(k) clearance for the treatment of malignant disease, there can be no guarantee of timely or definite FDA or other national regulatory body approvals for any of their new products.
- **Need to Raise Additional Funds:** Although it is possible that IsoRay may raise sufficient operating funds for development through warrant conversions and potential partnerships, we believe that the company will be required to raise additional funds through the issuance of stock which would be dilutive to existing shareholders and could potentially affect the share price. We have included our estimate of future share issuance in our financial model but there can be no guarantee that our estimates are accurate.
- **Reimbursement:** IsoRay's business is dependent on government and private insurance for reimbursement with Centers for Medicare and Medicaid Services (CMS) providing coverage for approximately 65% of all prostate brachytherapy cases. Should the current or anticipated reimbursement rates be reduced, consolidated or eliminated, IsoRay's business would be adversely impacted.
- **Concentration:** Almost 50% of IsoRay's current brachytherapy business is dependent on five physicians. Any loss or event involving these physicians could negatively impact IsoRay revenues.
- **Limited Number of Suppliers:** Approximately 68% of IsoRay's CS-131 was supplied through UralDial from reactors located in Russia with the remainder from the U.S. Reliance on any single supplier increases the risks associated with concentrating isotope production at a single reactor facility which can be subject to unanticipated shutdowns and would adversely affect the company's financial position. In addition, virtually all titanium tubing used in IsoRay's brachytherapy seed manufacture comes from a single source, Accellent Corporation.
- **Environmental Risks:** IsoRay's business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Handling and disposing of such materials must comply with state and federal standards and there is a risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the respective manufacturing facility for an extended period of time. If IsoRay were to become liable for an accident or suffer an extended facility shutdown, they could incur significant costs, damages, and penalties.
- **Partnerships:** IsoRay may be dependent on partners for future development, clinical trials and regulatory filings of its products and may be reliant on future partners to successfully market its products. Failure of IsoRay's existing or future partners to perform satisfactorily or in a timely fashion could adversely impact the company's financial position.
- **Patent Litigation:** Third-party claims of infringement of intellectual property could require IsoRay to spend time and money on defending their intellectual property rights up to and including adverse judgments against IsoRay.
- **Sector Rotation:** IsoRay is a small medical device company often kept in a portfolio with similar companies. In such cases, a significant event for one company may have a material impact on the valuation of all similar companies regardless of their unique qualities.

**IsoRay, Inc.**  
**Consolidated Income Statement**

FYE Jun 30th

	Jun 30 2010	Sep 30 1Q11	Dec 31 2Q11	Mar 31 3Q11	Jun30 4Q11	Jun 30 2011	Sep 30 1Q12E	Dec 31 2Q12E	Mar 31 3Q12E	Jun30 4Q12E	Jun 30 2012E	Jun 30 2013E	Jun 30 2014E	Jun 30 2015E
Product Sales	5,286	1,327	1,245	1,410	1,257	5,239	1,560	2,560	3,560	5,559	13,239	15,887	22,242	30,026
Cost of Goods Sold	4,560	1,111	1,117	1,053	801	4,082	1,170	1,920	2,670	4,169	9,929	10,326	11,121	15,013
Gross Profit	726	216	128	357	456	1,157	390	640	890	1,390	3,310	5,560	11,121	15,013
Gross Margin	13.7%	16.3%	10.3%	25.3%	36.3%	22.1%	25.0%	25.0%	25.0%	25.0%	25.0%	35.0%	50.0%	50.0%
Research & Development	341	115	16	244	606	981	457	257	258	258	1,230	1,292	1,356	1,424
Research & Development Reimbursement [2]	0	0	(150)	(56)	(310)	(516)	(377)	0	0	0	(377)	0	0	0
Sales and Marketing	1,954	373	336	235	288	1,232	323	323	324	324	1,294	1,359	1,427	1,498
General and Administrative	2,440	596	561	628	638	2,423	636	636	636	636	2,544	2,671	2,805	2,945
Total Operating Expenses	4,735	1,084	763	1,051	1,222	4,120	1,039	1,216	1,218	1,218	4,691	5,321	5,587	5,867
Income from Operations	(4,009)	(868)	(635)	(694)	(766)	(2,963)	(649)	(576)	(328)	172	(1,381)	239	5,533	9,146
Interest Income	11	1	1	1	0	3	1	1	1	1	4	4	4	4
Loss on Impairment of Short Term Investments	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Financing and Interest Expense	(36)	(4)	(14)	(175)	(23)	(216)	(4)	(4)	(5)	(6)	(19)	(19)	(19)	(19)
Other Income	0	0	0	0	0	0	94	94	94	95	377	0	0	0
Gain (Loss) Fair Value of Warrant Liability	0	0	420	(163)	77	334	100	100	100	100	400	400	400	400
Total Other Income/Expense	(25)	(3)	407	(337)	54	121	191	191	190	190	762	385	385	385
Income Before Tax	(4,034)	(871)	(228)	(1,031)	(712)	(2,842)	(458)	(385)	(138)	362	(619)	624	5,918	9,531
Provision for Income Taxes [1]	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Net Income (Loss)	(4,034)	(871)	(228)	(1,031)	(712)	(2,842)	(458)	(385)	(138)	362	(619)	624	5,918	9,531
Preferred Stock Dividends	(11)	(3)	(3)	(2)	(3)	(11)	(3)	(3)	(2)	(3)	(11)	(11)	(11)	(11)
Net Income Applicable to Common	(4,045)	(874)	(231)	(1,033)	(715)	(2,853)	(461)	(388)	(140)	359	(630)	613	5,907	9,520
EPS - Diluted	(\$0.18)	(\$0.04)	(\$0.01)	(\$0.04)	(\$0.03)	(\$0.11)	(\$0.02)	(\$0.01)	(\$0.00)	\$0.01	(\$0.02)	\$0.02	\$0.17	\$0.26
Shares Outstanding - Diluted	22,960	23,049	25,071	26,009	26,399	25,132	26,450	27,773	28,050	28,331	27,651	33,181	34,840	36,582

**Balance Sheets**

(in Millions)

	6/30/09	6/30/10	6/30/11
<b>Assets:</b>			
Cash and Cash Equivalents	\$2,991	\$1,679	\$2,112
Short-Term Investments	1,680	0	0
Accounts Receivable	747	896	793
Inventories	789	682	750
Other Receivables	0	0	426
Prepaid Expenses & Other	151	260	141
Total Current Assets	\$6,358	\$3,517	\$4,222
Fixed Assets, Net	4,891	3,960	3,209
Deferred Financing Costs, Net	28	13	0
Licenses, Net	12	0	0
Restricted Cash	179	180	181
Other Assets	274	273	277
<b>TOTAL ASSETS</b>	<b>\$11,742</b>	<b>\$7,943</b>	<b>\$7,889</b>

**Liabilities:**

Accounts Payable	\$417	\$404	\$372
Accrued Protocol Expense	222	242	98
Accrued Radioactive Waste Disposal	60	60	108
Accrued Payroll and Related Taxes	104	187	125
Accrued Vacation	85	69	71
Notes Payable, ST	161	49	0
Total Current Liabilities	\$1,049	\$1,011	\$774
Notes Payable, LT	176	131	\$0
Asset Retirement Obligation, LT	554	605	662
Stockholders' Equity	9,963	6,196	6,453
<b>TOTAL LIAB. &amp; EQ</b>	<b>\$11,742</b>	<b>\$7,943</b>	<b>\$7,889</b>

**NOTES**

- [1] As of June 30, 2011, IsoRay, Inc had a net operating loss carryforwards of \$35.6 Million  
[2] Research Grants IRS Section 48D in 2Q11 plus \$377K Expected July 2011

**DISCLOSURES**



**Ratings and Price Target Changes over Past 3 Years**

Initiated February 16, 2011 – Strong Speculative Buy - Price Target \$3.00

**Analyst Certification:** We, Stephen M. Dunn and William D. Dawson, the authors of this research report certify that a.) All of the views expressed in this report accurately reflect our personal views about any and all of the subject securities or issuers discussed b.) No part of our compensation is directly or indirectly related to the specific recommendations or views expressed in this research report and c.) We may be eligible to receive other compensation based upon various factors, including total revenues of the Firm and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.

**DISCLOSURES**

Does the Analyst or any member of the Analyst's household have a financial interest in any securities of the Company?	NO
Does the Analyst or any member of the Analyst's household or Firm serve as an officer, director or advisory board member of the Company?	NO
Has the Analyst or any member of the Analyst's household received compensation directly or indirectly from the Company in the previous 12 months?	NO
Does the Firm or affiliates beneficially own ≥1% of the Company's common stock?	NO
Has the Firm or affiliates received investment banking services compensation in previous 12 months?	YES
Has the Firm or affiliates received non-investment banking securities-related services compensation in previous 12 months?	NO
Does the Firm or affiliates expect to receive or intend to seek investment banking compensation in next 3 months?	YES
Has the Firm or affiliates received non-securities services compensation in previous 12 months?	NO
Does the Firm or affiliates make a market in the Company's securities?	NO

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**Ratings Definitions:** 1) **Strong Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months; 2) **Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months; 3) **Strong Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 40% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Strong Buy" recommendation; 4) **Speculative Buy:** the stock is expected to appreciate and produce a total return of at least 20% over the next 12-18 months but **the volatility and investment risk is substantially higher** than our "Buy" recommendation; 5) **Neutral:** the stock is fairly valued for the next 12-18 months; 6) **Avoid/Sell:** the stock is expected to decline at least 20% over the next 12-18 months and should be avoided or sold if held; 7) **Under Review:** the previous rating and/or price target is suspended due to a significant event which now requires additional analysis and the previous rating and/or price target cannot be relied upon; 8) **Not Rated:** the stock has too much business or financial uncertainty to form an investment conclusion or is currently in the process of being acquired and 9) **Restricted:** coverage cannot be initiated or has been temporarily suspended to comply with applicable regulations and/or firm policies in certain circumstances such as investment banking or an advisory capacity involving the company.

LifeTech Capital Research	Research Coverage	Investment Banking	FINRA RULE 2711	Research Coverage	Investment Banking
Ratings Distribution	% of Total	% of Total	Ratings Distribution	% of Total	% of Total
Strong Buy	17%	50%	Buy	83%	60%
Strong Speculative Buy	67%	63%	Hold/Neutral	8%	100%
Buy	0%	0%	Sell	8%	0%
Speculative Buy	0%	0%	Total	100%	58%
Neutral	8%	100%			
Avoid/Sell	8%	0%			
Under Review	0%	0%			
Not Rated	0%	0%			
Restricted	0%	0%			
Total	100%	58%			

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