IsoRay, Inc.
Form 10-K
September 28, 2017

United States Securities and Exchange Commission

Washington, D.C. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended June 30, 2017

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	41-1458152
(State of incorporation)	(I.R.S. Employer Identification No.)
350 Hills St., Suite 106 Richland, Washington	99354
(Address of principal executive offices)	(Zip code)

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

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Name of exchange on which registered
Common Stock, $0.001 par value	NYSE MKT

Securities registered pursuant to Section 12(g) of the Act:

Series C Preferred Share Purchase Rights

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x
Emerging growth company ¨	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter – $31,910,103 as of December 31, 2016.

The number of shares outstanding of the registrant’s common stock, $0.001 par value per share, as of September 25, 2017 was 55,017,419.

Documents incorporated by reference – none.

ISORAY, INC.

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Caution Regarding Forward-Looking Information

In addition to historical information, this Form 10-K 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-K, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under Item 1A – Risk Factors beginning on page 23 below that may cause actual results to differ materially.

Consequently, all of the forward-looking statements made in this Form 10-K 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.

PART I

As used in this Form 10-K, unless the context requires otherwise, "we" or "us" or "IsoRay" or the "Company" means IsoRay, Inc. and its subsidiaries.

As used in this Form 10-K, unless the context requires otherwise, "fiscal year" or "fiscal" means the Company's financial year that begins on July 1 and ends on June 30 of the following year (for example: fiscal year 2017 is equivalent to the year ended June 30, 2017).

ITEM 1 – BUSINESS

General

IsoRay, Inc. (formerly known as Century Park Pictures Corporation) was incorporated in Minnesota in 1983. On July 28, 2005, IsoRay Medical, Inc. (Medical) became a wholly-owned subsidiary of IsoRay, Inc. pursuant to a merger. Medical was formed under Delaware law on June 15, 2004 and on October 1, 2004 acquired two affiliated predecessor companies that began operations in 1998. Medical, a Delaware corporation, develops, manufactures and sells isotope-based medical products and devices for the treatment of cancer and other malignant diseases. Medical is headquartered in Richland, Washington.

IsoRay International LLC (International), a Washington limited liability company, was formed on November 27, 2007 and is a wholly-owned subsidiary of the Company. International has entered into various international distribution agreements.

Available Information

Our website address is www.IsoRay.com. Information on this website is not a part of this Form 10-K (this "Report"). We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4, and 5 filed on behalf of directors and executive officers, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (Exchange Act) available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). You can also read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You can obtain additional information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

Information regarding our corporate governance, including the charters of our audit committee, our nominations and corporate governance committee and our compensation committee, and our Codes of Conduct and Ethics is available on our website (www.IsoRay.com). We will provide copies of any of the foregoing information without charge upon request to Mark Austin, Controller, 350 Hills Street, Suite 106, Richland, WA, 99354.

Business Operations

Overview

In 2003, IsoRay obtained clearance from the Food and Drug Administration (FDA) for the use of Cesium-131 (Cs-131) radioisotope in the treatment of all malignant tumors. As of the date of this Report, such applications include prostate cancer, brain cancer, breast cancer, colorectal cancer, gynecological cancer, lung cancer, liver cancer, ocular melanoma and pancreatic cancer. The brachytherapy seed form (a sealed source) of Cs-131 may be used in surface, interstitial and intra-cavity applications for tumors with known radio-sensitivity. Management believes the combination of a short half-life and relatively high-energy of Cs-131 will allow it to become a leader in the brachytherapy market, and Cs-131 represents the first major advancement in brachytherapy technology in approximately 30 years with attributes that could make it the long-term "seed of choice" for internal radiation therapy procedures.

Brachytherapy seeds are small devices containing a therapeutic dose of radiation used in an interstitial radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word "brachytherapy" is derived

from Greek and means close therapy). A primary advantage of seed brachytherapy is the ability of the seeds to deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure (damage) to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation directly to the tumor. A seed contains a radioisotope sealed within a titanium capsule. When brachytherapy is the only treatment (monotherapy) used in the prostate, approximately 70 to 120 seeds are permanently implanted in the prostate during an outpatient procedure. The number of seeds used varies based on the size of the prostate gland, the isotope used and the activity level specified by the physician. When brachytherapy is combined with another treatment method (dual-therapy), fewer seeds are used (approximately 40 to 80) in the procedure. The isotope decays over time (half-life) and eventually the seeds become inert (typically over 6 half-lives). The seeds may be used as a primary treatment (monotherapy) or as an adjunct therapy with other treatment modalities, or as treatment for residual disease after excision of primary tumors. The number of seeds for treatment sites other than prostate vary widely (as few as 8 seeds to more than 100 seeds) depending on the type of cancer, the tumor location, the prescribed activity level and any additional type of therapy being utilized.

IsoRay began the production and sales of Cs-131 brachytherapy seeds in October 2004 for the treatment of prostate cancer after receiving clearance of its premarket notification (510(k)) by the Food and Drug Administration. Prostate cancer treatment represents over 85% of the business of IsoRay today.

In late 2014, the first report of five-year clinical outcomes for patients treated with Cs-131 brachytherapy was published in a peer-reviewed medical journal (Benoit, et al., *Five Year Prostate-specific Antigen Outcomes after Caesium Prostate Brachytherapy*, Clin Oncol 25 (December 2014)). In this study of 485 prostate cancer patients treated with Cs-131 brachytherapy seeds, a “biochemical relapse free” success rate of 96% was reported for low risk patients after five years.

Work is ongoing to employ Cs-131 brachytherapy seeds where trends are emerging in prostate cancer treatment, including the use of Cs-131 implants in combination with intensity modulated radiation therapy (IMRT – a form of external beam radiation) for high risk localized prostate cancer (dual-therapy). For low-risk prostate cancer, studies are ongoing to evaluate the use of Cs-131 in “focal,” or sub-total brachytherapy of the prostate. It is hypothesized that low-risk patients using focal brachytherapy may achieve rates of prostate cancer control comparable to that of full gland treatment while significantly reducing side effects. (M.H. Mendez, et al., *Current trends and new frontiers in focal therapy for localized prostate cancer,* Current Urology Report 16, 35 (June 2015)).

The Company's core product is its Cs-131 sealed source brachytherapy "seed." These seeds can be inserted individually into the prostate gland until the physician is satisfied with the radiation dose delivered. The Company also sells "pre-loaded" needles with Cs-131 brachytherapy seeds inserted in them. In addition to the five year cancer control data mentioned above, a report from 2017 describes favorable long-term quality of life outcomes following Cs-131 brachytherapy in the treatment of prostate cancer (S.M. Glaser, et al., *Long-Term Quality of Life in Prostate Cancer Patients Treated With Cesium*, 131 Int J Radiat Oncol Biol Phys. 98(5):1053-1058 (2017)).

Individual seeds can also be placed via needle into the female reproductive tract for the treatment of various gynecologic cancers. This effort has been led by Dr. Jonathan Feddock of the University of Kentucky. In June 2016, the lead physician from the University of Kentucky conducted two presentations on gynecological cancer patients who underwent treatment with permanent implantation of Cs-131 brachytherapy seeds. In the first presentation, it was noted that 21 out of 26 recurrent cancer patients remained visually free of cancer at a median of 14 months after implantation which equates to 80.7% local control (J. Feddock, et al., *Permanent interstitial re-irradiation with cesium-131: a highly successful second chance for cure in recurrent pelvic malignancies,* Brachytherapy 15 (S1)S78-9 (2016)). In the second presentation, a series of 22 women with pelvic cancer underwent Cesium-131 brachytherapy seed implantation with other forms of radiation therapy treating patients who were recently diagnosed and had not yet undergone any treatment. All these cancers were successfully controlled at a median follow-up of 16 months. Side effects using the Cs-131 brachytherapy seeds were minor and all treatments were performed as outpatient procedures. (J. Feddock, et al., *Outpatient interstitial implants - integrating cesium-131 permanent interstitial brachytherapy into definitive treatment for gynecologic malignancies,* Brachytherapy 15 (S1):S93-4 (2016)). Dr. Feddock and his team are continuing ongoing research.

While the FDA clearance granted in August 2009 to permit loading Cesium-131 seeds into bio-absorbable braided sutures or "braided strands" gives the Company the ability to treat brain, lung, head and neck, colorectal, and chest wall cancers, and gynecological cancer, the Company is currently pursuing the brain and gynecological cancers applications in addition to its primary focus on prostate cancer. The Company has also received CE Mark clearance to commercially deliver Cs-131 brachytherapy seeds that are pre-loaded into braided strands in Europe. This clearance permits the product to be commercially distributed in Europe for treatment of prostate, brain, lung, and head and neck tumors as well as tumors in other organs.

Starting in 2012, multiple institutions began utilizing Cs-131 brachytherapy seeds loaded in braided strands for treatment of brain and head cancers. The application of Cs-131 brachytherapy seeds loaded in braided strands to date has been primarily in salvage cases as a treatment of last resort for brain and head cancers where aggressive tumors had reoccurred multiple times following standard of care treatment. From 2014 to 2016 there have been numerous published abstracts and society presentations which have been presented and support the effectiveness of treating very difficult and aggressive cancers with Cs-131 in multiple body sites. Dr. Gabriella Wernicke's group, at Weill Cornell Medical College at the NY Presbyterian Hospital, published four papers on the efficacy, favorable side-effect profile and cost-effectiveness of Cs-131 brachytherapy seeds in the treatment of metastatic brain cancer. (A. Pham, et al., *Neurocognitive function and quality of life in patients with newly diagnosed brain metastasis after treatment with intra-operative cesium-131 brachytherapy: a prospective trial*, J Neurooncol 127(1):63-71 (2016); A.G. Wernicke, et al., *Surgical technique and clinically relevant resection cavity dynamics following implantation of cesium-131*

brachytherapy in patients with brain metastases, Operative Neurosurgery 12(1):49-60 (2016); A.G. Wernicke, et al., *Cesium-131 brachytherapy for recurrent brain metastases: durable salvage treatment for previously irradiated metastatic disease,* J Neurosurg DOI: 10.3171/2016.3.JNS152836 (Published online June 3, 2016); A.G. Wernicke, et al., *The cost-effectiveness of surgical resection and cesium-131 intraoperative brachytherapy versus surgical resection and stereotactic radiosurgery in the treatment of metastatic brain tumors,* J Neurooncol 127(1):145-53 (2016)). At the same institution, Dr. Bhupesh Parashar has published two journal articles on the effectiveness of Cs-131 brachytherapy seeds in the treatment of both head and neck and lung cancer. (B. Parashar, et al., *Analysis of stereotactic radiation vs. wedge resection vs. wedge resection plus Cesium-131 brachytherapy in early stage lung cancer*, Brachytherapy 14(5):648-54 (2015); A. Pham, et al., *Cesium-131 brachytherapy in high risk and recurrent head and neck cancers: first report of long-term outcomes*, J Contemp Brachytherapy 7(6):445-52 (2015).) In 2017, Dr. Wernicke's group published favorable results on a series of patients with large brain metastases treated with Cs-131 in braided strands. A. G. Wernicke, et al., *Clinical Outcomes of Large Brain Metastases Treated With Neurosurgical Resection and Intraoperative Cesium-131 Brachytherapy: Results of a Prospective Trial,* Int J Radiat Oncol Biol Phys. 98 (5):1059-1068 (2017)).

During fiscal 2013, the Company began providing technical assistance and selling Cs-131 brachytherapy seeds for embedding in collagen tiles by physicians at Barrow Neurological Institute (Barrow) to treat malignant meningioma, primary brain cancers and metastases of cancers to the brain. These physicians from Barrow have formed a company, GammaTile LLC, and further refined this technology which integrates Cs-131 brachytherapy seeds and has resulted in the issuance of multiple patents to GammaTile LLC for the treatment of brain cancers. In December 2014 and June 2016, physicians representing Barrow presented their findings at two society conferences for neuro-oncologists. Highlights of the presentation included a new treatment delivery system of Cs-131 brachytherapy seeds to the brain while embedded in collagen tiles by applying directly to brain tissue after tumor removal. The trial presented included 16 patients with 20 tumors. The patients in the study had multiple reoccurrences of tumors following previous surgeries in conjunction with treatments with external beam radiation and had an increased risk for additional reoccurrences. Following treatment with Cs-131, 95% of the treated tumors had no evidence of regrowth at the operative site (local control). The incidence of radiation side effects to the brain from Cs-131 brachytherapy seeds (a common side effect) occurred in only 2 of the 20 treatments. (D. Brachman, *Prospective trial of surgery and permanent intraoperative brachytherapy (S+BT) using a modular, biocompatible radiation implant for recurrent aggressive meningiomas*, Society of Neuro-Oncology Conference on Meningioma, Toronto, Canada (June 18, 2016)).

In November of 2016, Dr. Emad Youssef of the Barrow Neurological Institute presented a study conducted on 13 patients with recurrent high grade gliomas (primary brain cancer) at the annual meeting of the Society for Neuro-Oncology meeting. (E. Youssef, et al; *Rthp-23. Cs131 Implants For Salvage Therapy Of Recurrent High Grade Gliomas (Hgg)*, Neuro-Oncology Volume 18, Issue suppl_6, 1 November 2016, Pages vi179). These patients were reported to have achieved a 92% rate of local control of their cancers during the follow-up interval. Due to the fact that the GammaTile™ treatment has displayed promising results in difficult to control recurrent brain cancers, the Company has collaborated with GammaTile LLC in filing applications to: the U.S. Food and Drug Administration (FDA) to clear GammaTile™ for clinical use; and a New Technology Add-on Payment to the Center for Medicare and Medicaid Services (CMS) seeking re-imbursement for the GammaTile™ treatment in the in-patient setting. The application with the FDA is ongoing, however, the NTAP referenced herein is not currently under consideration and the Company plans to re-file the NTAP in October 2017. In the meantime, CMS has allowed properly licensed medical centers to apply for re-imbursement under an existing Diagnostic Related Groups (DRG) code that allows partial recovery of the GammaTile™ treatment cost.

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Industry Information

Prostate Cancer Treatment

According to the American Cancer Society, approximately one in seven men will be diagnosed with prostate cancer during his lifetime. It is the most common form of cancer in men after skin cancer, and the second leading cause of cancer deaths in men following lung cancer. The American Cancer Society estimates there will be about 161,360 new cases of prostate cancer diagnosed and an estimated 26,730 deaths associated with the disease in the United States in 2017.

Prostate cancer treatment remains a key focus of the Company. Most doctors use the American Joint Committee on Cancer (AJCC) TNM system to stage prostate cancer. This system is based on three key pieces of information:

§ The extent of the main tumor (T category);
§ Whether the cancer has spread to nearby lymph nodes (N category); and
§ Whether the cancer has metastasized (spread) to other parts of the body (M category).

These factors are combined to determine an overall stage, using Roman numerals I through IV (1-4). The lower the number, the less the cancer has spread. A higher number, such as stage IV, means a more advanced cancer.

Once diagnosed, prostate cancer can generally be divided into either localized or advanced disease. Further, within the localized category the disease can be further categorized to one of the three “risk groups”: low, intermediate and high risk. As the risk increases so does the probability of advanced cancer at diagnosis and the probability of failing treatment with cancer progression or recurrence.

IsoRay’s Cs-131 brachytherapy seeds are an option in the treatment of prostate cancers of all risk levels of localized disease. The diagnosis of prostate cancer – and especially low risk prostate cancer – has been potentially reduced with the introduction of guidelines dissuading the use of serum PSA screening at the general practitioner level as a means to detect prostate cancer early in men with no symptoms of prostate cancer. Effective July 2012, the U.S. Preventative Services Task Force (USPSTF) recommended against the use of the PSA test as a screening tool. As a result of the recommendation, prostate cancer diagnosis dropped by 12.2% the month after the recommendation and has continued to drop. (D.A. Barocas, et al., *Effect of the USPSTF Grade D Recommendation against Screening for Prostate Cancer on Incident Prostate Cancer Diagnoses in the United States,* J Urol 194(6) The Journal of Urology (2015)).

In 2017, the USPSTF changed its recommendation from advising against screening to the position that the decision for men between 55 and 69 to undergo PSA-based screening should be made by a man in consultation with his doctor. This change may contribute to an increased incidence of prostate screening (and therefore more prostate cancer cases) as opposed to an unscreened population – although this conclusion will await future trending information.

Furthermore, the deferral of potentially cancer-eradicating (definitive) prostate cancer treatments such as surgery and radiation therapy has become more popular as some men with prostate cancer have decided to “watch” the cancer using a variety of diagnostic tools – a trend known as “active surveillance.”

As such, the industry has experienced an overall decrease in the number of low risk cases of prostate cancer diagnosed due to reduced PSA screening, as well as a larger number of men who are deferring treatment altogether at a higher rate than seen historically. Intense competition in the space due to numerous established treatment options along with added entrants such as robotic surgery and proton therapy has further eroded the overall brachytherapy market share. The industry continues to focus on the significant data that supports the use of brachytherapy in treating prostate cancer. Management believes the current review of cost effective treatment comparisons with other treatment options, the aging population worldwide and the efficacy of treatment could contribute to the revitalization of brachytherapy treatment for prostate cancer in the future.

Minimally invasive brachytherapy such as that provided by the Company's Cs-131 brachytherapy seeds provides significant advantages over competing treatments including lower cost, equal or better survival data, fewer side effects, faster recovery time and the convenience of a single outpatient implant procedure that generally lasts less than one hour (Grimm, et al., *Comparative analysis of prostate-specific antigen free survival outcomes for patients with low, intermediate and high risk prostate cancer treatment by radical therapy. Results from the Prostate Cancer Results Study Group***,** British Journal of Urology International, Vol. 109 (Suppl 1), (2012); Merrick, et al., *Effect of prostate size and isotope selection on dosimetric quality following permanent seed implantation*, Techniques in Urology Vol. 7 (2001); Potters, et al., *12-Year Outcomes Following Permanent Prostate Brachytherapy in Patients with Clinically Localized Prostate Cancer*, Journal of Urology (May 2005); Sharkey, et al., *Brachytherapy versus radical prostatectomy in patients with clinically localized prostate cancer*, Current Urology Reports, (2002)).

In addition to permanent, low-dose rate (LDR) brachytherapy, such as Cs-131, localized prostate cancer can be treated with prostatectomy surgery (RP for radical prostatectomy), external beam radiation therapy (EBRT), three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), dual or combination therapy, permanent, high dose rate brachytherapy (HDR), cryosurgery, hormone therapy, proton therapy and active surveillance (watchful waiting). The success of any treatment is measured by the feasibility of the procedure for the patient, morbidities associated with the treatment, overall survival, and cost. When the cancerous tissue is not completely eliminated, the cancer typically returns to the primary site, often with metastases to other areas of the body.

The National Cancer Data Base (NCDB) contains a total of 1,547,941 patients with localized prostate cancer that were identified from 1998 to 2010. Overall, 13.4% of patients were treated with brachytherapy, with an additional 2.6% treated with brachytherapy boost, which is the addition of a brachytherapy implant in addition to external beam radiation therapy, compared with 49.8% treated with surgery, 26.3% with non-brachytherapy radiotherapy, 24.1% who received hormone therapy, and 7.8% who received no treatment. (J.M. Martin, et al., *The rise and fall of prostate brachytherapy: Use of brachytherapy for the treatment of localized prostate cancer in the National Cancer Data Base,* Cancer 120:2114–2121 (2014)).

Prostatectomy Surgery Options. In the radical prostatectomy operation, a surgeon will remove the entire prostate gland plus some of the tissue around it, including the seminal vesicles. New methods such as laparoscopic and robotic

prostatectomy surgeries are currently being used more frequently in order to minimize the damage that leads to impotence and incontinence, but these techniques require a high degree of surgical skill. (American Cancer Society, 2016) Surgical resection accounted for approximately 44% of treatments before the introduction of robotic prostatectomy in the early 2000s and then rose to 60% in 2010. (J.M. Martin, et al. *The rise and fall of prostate brachytherapy: Use of brachytherapy for the treatment of localized prostate cancer in the National Cancer Data Base,* Cancer 120:2114–2121 (2014); J.M. Martin, et al., *Use of brachytherapy for the treatment of localized prostate cancer in the National Cancer Data Base,* Cancer 120:2114–2121 (2014), Duke University, International Focal Therapy Conference, (June 2016)).

External Radiation Therapy. Primary External Beam Radiation Therapy (EBRT), Three-dimensional Conformal Radiation Therapy (3D-CRT), Stereotactic Radiotherapy (SBRT), Intensity Modulated Radiation Therapy (IMRT) and Proton Therapy all involve directing a beam of radiation from outside the body at the prostate gland to destroy cancerous tissue. Treatments are received on an outpatient basis with the patient usually receiving five treatments per week over a period of several weeks (up to nine). While the treatments each last only a few minutes, getting the patient and equipment in place for each treatment takes longer. The use of EBRT as a whole doubled from 11.6% in 2004 to 24% in 2009. The increase in the number of cases being treated with EBRT during 2004 to 2008 were cases that historically would have been treated with brachytherapy. During that period there was a nearly complete transition to IMRT as the predominant method with IMRT treatment increasing from 0.15% to 95.9% of EBRT treatments from 2000 to 2008. (U. Mahmood, et al., *Declining use of brachytherapy for the treatment of prostate cancer,* Brachytherapy 13:157–162 (2014). Side effects of these treatments can include bowel problems, bladder problems, urinary incontinence, impotence, fatigue, lymphedema, and urethral stricture.

Proton beam radiation therapy. Proton beam therapy focuses beams of protons instead of x-rays on the cancer. Unlike x-rays, which release energy both before and after they hit their target, protons cause little damage to tissues they pass through and release their energy only after traveling a certain distance. This means that proton beam radiation can, in theory, deliver more radiation to the prostate while doing less damage to nearby normal tissues. Proton beam radiation can be aimed with techniques similar to 3D-CRT and IMRT.

Although in theory proton beam therapy might be more effective than using x-rays, so far studies have not shown if this is true. As of the filing of this Annual Report, proton beam therapy is not widely available. The machines needed to make protons are very expensive, and they are not available in many centers in the United States. Management believes proton beam radiation is not covered by all insurance companies as of the filing of this Report.

Dual or Combination Therapy. Dual therapy is the combination of IMRT or 3-dimensional conformal external beam radiation and seed brachytherapy to treat extra-prostatic disease or high-risk prostate cancers that have metastasized or grown outside the prostate. Combination therapy treats high risk patients with a course of IMRT or EBRT over a period of several weeks. When this initial treatment is completed, the patient must then wait for several more weeks to months to have the prostate seed implant. The process could also involve the seed implant be performed first, followed by the course of external radiation. Management estimates that at least 25% of all U.S. prostate implants are now dual therapy cases.

High Dose Rate Temporary Brachytherapy (HDR). HDR temporary brachytherapy involves placing soft nylon tubes (catheters) into the prostate gland and then giving a series of radiation treatments through these catheters. The catheters are then removed and no radioactive material is left in the prostate gland. Radioactive source containing either Iridium-192 or Cesium-137 is placed into the catheters. This procedure is typically repeated multiple times over a period of several days while the patient is hospitalized.

Additional Treatments. Additional, less frequently used, treatments include cryotherapy, hormone therapy, vaccine treatment and chemotherapy.

Watchful Waiting and Active Surveillance. Because prostate cancer often grows very slowly, some men (especially those who are older or who have other major health problems) may never need treatment for their cancer. Instead, their doctor may suggest watchful waiting or active surveillance, terms physicians may use differently or interchangeably.

§ Active surveillance is often used to mean watching the cancer closely with PSA blood tests, digital rectal exams (DREs), and ultrasounds at regular intervals to see if the cancer is growing. Prostate biopsies may be done as well to

see if the cancer is starting to grow faster. If there is a change in a patient's test results, the doctor would then talk to the patient about treatment options.

§ Watchful waiting (observation) is sometimes used to describe a less intense type of follow-up that may mean fewer tests and relying more on changes in a man's symptoms to decide if treatment is needed.

So far, no large randomized studies have compared active surveillance to treatments such as surgery or radiation therapy. Some early studies of men who are good candidates for active surveillance have shown that only about a third of the men need to go on to treatment with radiation or surgery.

Low Dose Rate Permanent Brachytherapy (LDR). In this approach, pellets (seeds) of radioactive material are placed inside thin needles, which are inserted through the skin in the area between the scrotum and anus and into the prostate. The pellets are left in place as the needles are removed and give off low doses of radiation for weeks or months. Radiation from the seeds travels a very short distance, so the seeds can give off a large amount of radiation in a very small area. This limits the amount of damage to nearby healthy tissues.

Iodine-125 (I-125) and Palladium-103 (Pd-103) are two isotopes, other than Cesium-131, that are currently used for LDR permanent brachytherapy. A number of published studies describing the use of I-125 and Pd-103 LDR brachytherapy in the treatment of early-stage prostate cancer have been very positive when compared to other treatment options. A study of 2,963 prostate cancer patients who underwent brachytherapy as their sole therapeutic modality at 11 institutions across the U.S. concluded that low-risk patients (who make up the majority of localized cases) who underwent adequate implants experienced rates of PSA relapse survival of greater than 90% between eight and ten years (M.J. Zelefsky et al., *Multi-institutional analysis of long-term outcome for stages T1-T2 prostate cancer treated with permanent seed implantation* International Journal of Radiation Oncology, Biology, Physics Volume 67, Issue 2, 327-333 (2007)).

Other studies have demonstrated similar, durably high rates of control following brachytherapy for localized prostate cancer out to 15 years post-treatment (J. Sylvester, et al., *15-year biochemical relapse free survival in clinical stage T1-T3 prostate cancer following combined external beam radiotherapy and brachytherapy; Seattle experience* International Journal of Radiation Oncology Biology Physics, Vol. 67, Issue 1, 57-64 (2007)). The cumulative effect of these studies has been the conclusion by leaders in the field that brachytherapy offers a disease control rate as high as surgery, though with a lesser side-effect profile than surgery (J.P. Ciezki , *Prostate brachytherapy for localized prostate cancer*, Current Treatment Options in Oncology Volume 6, 389-393 (2005)).

Long-term survival data is now available for brachytherapy with I-125 and Pd-103, supporting the efficacy of brachytherapy in the treatment of clinically localized cancer of the prostate gland. Clinical data indicate that brachytherapy offers success rates for early-stage prostate cancer treatment that are equal to or better than those of RP or EBRT. While historically clinical studies of brachytherapy have focused primarily on results from brachytherapy with I-125 and Pd-103, management believes that these data are also relevant for brachytherapy with Cs-131. In fact, it appears that Cs-131 offers comparable and potentially improved clinical outcomes over I-125 and Pd-103, perhaps due to its shorter half-life. (A.B. Shah, et al., *A comparison of AUA symptom scores following permanent low dose rate prostate brachytherapy with iodine-125 and cesium-131*, Brachytherapy 12 (Suppl. 1) S64 (2013)).

In May 2017 a collaborative group of Canadian researchers published the results of a study that randomized intermediate- to high-risk localized prostate cancer to an external beam dose escalation and a permanent implant brachytherapy dose escalation (Morris 2017). These patients all underwent standard external beam radiation therapy and hormonal therapy. This study, known as the “ASCENDE-RT” study, demonstrated a significant therapeutic advantage to the patients who underwent permanent implant brachytherapy boost, reporting a 20% advantage (83% versus 63%) in biochemical relapse-free survival at nine years following treatment.

This study is the first in many years to successfully randomize a group of newly diagnosed, localized prostate cancer patients and demonstrate a statistically significant advantage to one treatment over another – in this case iodine-125 brachytherapy boost over external beam radiation therapy boost. The impact on the number of patients considered for “combination therapy” (external beam and brachytherapy) could be substantial, especially once men are informed of these study results.

Sexual impotence and urinary incontinence are two major concerns men face when choosing among various forms of treatment for prostate cancer. Studies have shown that brachytherapy with existing sources results in lower rates of impotence and incontinence than surgery (C. Buron, et al., *Brachytherapy versus prostatectomy in localized prostate cancer: results of a French multicenter prospective medico-economic study*, International Journal of Radiation Oncology, Biology, Physics Volume 67, 812-822 (2007)). Combined with the high disease control rates described in many studies, these findings have driven the adoption of brachytherapy as a front-line therapy for localized prostate cancer.

Comparing Cesium-131 to I-125 and Pd-103 Clinical Results

The Company's Cs-131-based permanent brachytherapy treatment was introduced in 2004, as compared to the other permanent brachytherapy sources - Iodine-125 (introduced 1965) and Palladium-103 (introduced 1986). Thus, it has only been recently that the achievement of significant follow-up in patient studies has occurred for the Company's Cs-131 product.

Management believes that the Cs-131 brachytherapy seed has specific clinical advantages for treating cancer over I-125 and Pd-103, the other isotopes currently used in brachytherapy seeds. The table below highlights the key differences of the three seeds. The Company believes that the short half-life, high-energy characteristics of Cs-131 will increase brachytherapy growth and facilitate meaningful penetration into the treatment of other forms of cancer such as brain cancer.

		Isotope Delivery Over Time		
Isotope	**Half-Life**	**Energy**	**90% Dose**	**Total Dose**
Cs-131	9.7 days	30.4 keV	33 days	115 Gy
Pd-103	17 days	20.8 keV	58 days	125 Gy
I-125	60 days	28.5 keV	204 days	145 Gy

As stated earlier, Company management believes that the long-term results already reported for Iodine-125 and Palladium-103 based prostate brachytherapy confirm the validity of permanent prostate brachytherapy, and at least comparable long-term outcomes are likely with Cs-131 treatment. A recent clinical report supports this contention (R.M. Benoit, et al., *Five year prostate-specific antigen outcomes after caesium prostate brachytherapy*, Clinical Oncology Volume 26, 776-780 (2014)).

However, management also believes that Cs-131 will ultimately prove to possess clinical advantages over the two other permanently implantable isotopes. These advantages include better performance in rapidly growing cancers and a more favorable side effect profile. Both advantages are related to the combination of a shorter half-life of Cs-131 and high energy level as compared to the other two isotopes.

The most recent clinical data was presented at the annual meeting of the American Brachytherapy Society in April 2014. Dr. Brian Moran of the Chicago Prostate Center reported a 92.6% rate of success at five years after treatment for 69 patients with prostate cancer following treatment with Cesium-131 brachytherapy (B.J. Moran, et al., *PSA Outcomes in a Single Institution, Prospective Randomized 131Cs/125I Prostate Brachytherapy Trial*, Brachytherapy 13(S1) S34 (2014)). At the same meeting, Dr. Rajagopalan of the University of Pittsburgh Medical Center reported a six year success rate of 95.4% in 243 Cs-131 treated patients (*Six-year biochemical outcome in patients treated with Cs-131 brachytherapy as monotherapy for prostate cancer*, Brachytherapy 13(S1) S38 (2014)).

When taken together with the multi-institutional five-year outcome presentation by Dr. Prestidge and others, where a group of 100 patients from multiple institutions exhibited a PSA disease-free rate of 98% at five years (B. Prestidge, et al., *Five-year biochemical control following Cesium-131 Permanent Prostate Brachytherapy in a Multi-Institutional Trial*, Brachytherapy 10(3S1) S27 (2011)), a strong case for an outstanding rate of durable PSA (biochemical) success can be made.

Furthermore, in all three reports a significant proportion of “intermediate risk” patients (who are at greater risk of failure following any treatment compared to most prostate cancer patients) were included in the studies. Despite this added risk – 37% of patients across all three studies were intermediate risk — the three studies together average a 95% rate of success at five-years and beyond for a total of 412 patients under study.

Improved side-effect profile.

In addition to the cancer-related outcomes described for prostate brachytherapy, a significant portion of patients who undergo I-125 or Pd-103 brachytherapy experience acute urinary irritative symptoms following treatment – more so than with surgery or external beam radiation therapy (S.J. Frank, et al., *An assessment of quality of life following radical prostatectomy, high dose external beam radiation therapy, and brachytherapy Iodine implantation as monotherapies for localized prostate cancer,* Journal of Urology Volume 177, 2151-2156 (2007)). These irritative symptoms can range from an increased frequency of urination to significant pain upon urination. Because the portion of the urethra that runs through the prostate takes high doses from the implant, these side effects are fairly common following prostate brachytherapy.

Recent completed studies show that Cs-131, with the shortest available half-life of the commonly used implantable isotopes, results in a quicker resolution of these irritative symptoms based on the shorter time interval over which normal tissue receives radiation from the implanted sources than for longer lived isotopes such as I-125. (H. Shah H, et al., *A comparison of AUA symptom scores following permanent low-dose-rate prostate brachytherapy with Iodine-125 and Cesium-131*, Brachytherapy 12(SI) S64 (2013)).

A Cs-131 monotherapy trial for the treatment of prostate cancer was fully enrolled in February 2007. The trial was a 100 patient multi-institutional study that sought to (1) document the dosimetric characteristics of Cs-131, (2) summarize the side effect profile of Cs-131 treatment, and (3) track biochemical (PSA) results in patients following Cs-131 therapy. Some of the significant and specific findings were as follows:

1. Patient reported irritative urinary symptoms (IPSS Scores) were mild to moderate with relatively rapid resolution within 4-6 months. (B.R. Prestidge, et al., *Clinical outcomes of a Phase II, multi-institutional Cesium-131 permanent prostate brachytherapy trial*, Brachytherapy Volume 6, Issue 2, 78 (April-June 2007)).

2. Gland coverage was excellent and the dose delivered to critical structures outside the prostate was well within acceptable limits. (W.S. Bice, et al., *Cesium-131 permanent prostate brachytherapy: The dosimetric analysis of a multi-institutional Phase II trial*, Brachytherapy (6) 88-89 (2007)).

3. An abstract detailing the outcomes of the 100 patient multi-institutional Cesium-131 study was prepared for the 32nd Annual Meeting of the American Brachytherapy Society (April 2011). Notably, the PSA control rate at 5 years was reported as 98%. No other study of brachytherapy utilizing the competing isotopes Iodine-125 and Palladium-103 has reported five-year rates as high as 98%.

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The advantage of the Company's Cs-131 brachytherapy seed is the resolution of urinary side effects as pictured in the graphic below has been observed in a second study, presented at the 2013 Annual Meeting of the American Brachytherapy Society (A.B. Shah, et al). The following graph is a comparison of elevated side effect (AUA) symptom scores following permanent low dose rate prostate brachytherapy with Iodine-125 and Cesium-131. (Brachytherapy 12(Suppl. 1) S64 (2013)):

As seen in the plot of these AUA scores, the duration of an elevated side effect score profile resolved to pre-treatment levels more quickly with the Cs-131 group than with the Iodine-125 group. All patients were treated at the same institution by the same physicians, and the difference in the time to resolution was considered significant.

Further evidence of the favorable side effect profile of Cs-131 was published by a group from the University of Pittsburgh Medical Center (UPMC) in August 2017 (Glaser 2017). This report concluded that only minimal long-term changes were noted to the urinary and bowel quality of life measures, and that men treated with Cs-131 for their prostate cancers are able to return to baseline measure of quality of life after treatment.

Non-Prostate Product Offerings

Brain Cancer Treatment Options

An estimated 23,800 new cases of malignant primary tumors of the brain or spinal cord are expected to be diagnosed in 2017. About 16,700 people are expected to die from brain and spinal cord tumors in 2017. In addition to primary tumors, metastasis of brain tumors from other body sites are estimated at over 100,000 new cases per year. The chance that a person will develop a malignant tumor of the brain or spinal cord is about 1 in 140 for a man and 1 in 180 for a woman. These numbers would be much higher if benign tumors were also included. (American Cancer Society, 2017).

The treatment of brain cancer with Cs-131 brachytherapy seeds now has two commercially available delivery methods, those being the use of braided strands, and braided strands sutured to a bioabsorbable mesh to apply the Cs-131 brachytherapy seeds which generally dissolves after about 45 days. Cs-131 brachytherapy seeds deliver 90% of their dose in 33 days and are therefore well-suited to use with bioabsorbable mesh, single seed applications, implantable strands, and by implantable device. Beginning in 2012, Barrow began embedding Cs-131 in collagen tiles (the GammaTile™ technique) and applying these tiles directly to brain tissue after tumor removal which is not currently

commercially available. During the fiscal year 2017, there were sixty-five patients treated with Company products for brain cancer.

In October 2016, the Company filed with the Center for U.S. Center for Medicare and Medicaid Services (CMS) an application for GammaTile™ to be considered for reimbursement under the Diagnosis Related Group (DRG) system, the primary means by which hospitals are reimbursed by Medicare and other payors for in-patient services. The Company also applied for GammaTile™ to be recognized by the International Classification of Diseases (ICD) system version 10.

Both applications are proposed to track and reimburse GammaTile™ treatment should Company receive clearance to market GammaTile™ by the U.S. Food and Drug Administration (FDA). In July 2017, the Company announced that it had received a request from FDA to supply further information related to its March 2017 510(k) filing for GammaTile™. Company is in the process of scheduling this requested testing and plans to complete it and file with the FDA by third fiscal quarter of 2018, but there is no assurance this timetable will not be delayed.

Gynecological Cancer Treatment Options (Cervical, Vaginal and Vulvar Cancer)

An estimated 23,650 new cases of cervical (12,820), vaginal (4,810) and vulvar (6,020) cancers are expected to be diagnosed in the United States in 2017. A combined estimate of 6,600 deaths are expected to occur from cervical, vaginal and vulvar cancers in the United States in 2017 (American Cancer Society, 2017; National Cancer Institute, 2017). In addition to brachytherapy to treat gynecological cancers such as cervical, vaginal and vulvar cancers, other treatment options include surgery, laser surgery, radiation therapy, chemotherapy, and topical treatments.

During 2016, two abstracts (J. Feddock, et al., *Permanent interstitial re-irradiation with cesium-131: a highly successful second chance for cure in recurrent pelvic malignancies,* Brachytherapy 15(S1):S78-9 (2016); J. Feddock, et al., *Outpatient interstitial implants - integrating cesium-131 permanent interstitial brachytherapy into definitive treatment for gynecologic malignancies*, Brachytherapy 15(S1):S93-4 (2016)) and presentations were presented at the World Brachytherapy Conference in San Francisco on the treatment of Re-Irradiation with Cs-131 in recurrent pelvic malignances in women who have recurrent cancers. Physicians at the University of Kentucky, College of Medicine reported local control in 80.7% after Cs-131 implantation for the recurrent patients and reported successful control of 22 women with pelvic cancer that had not had previous treatment. Based upon the positive results seen in the Cs-131 treatment of recurrent of gynecological cancers, physicians at the University of Kentucky are currently moving Cs-131 treatment into the primary treatment of these cancers. During the fiscal year 2017, there were forty-five patients treated with Company products for gynecological cancers.

In April 2017, the group from the University of Kentucky published a paper in the journal Brachytherapy that described the early experience with a template-based approach using Cs-131 in the treatment of gynecologic cancers. Although reporting on only five patients, the University of Kentucky physicians demonstrated the feasibility and safety of replacing a high dose-rate isotope (Iridium-192) with Cesium-131. This report builds on the earlier published and presented work that strongly suggests a role for Cesium-131 in the treatment of gynecologic cancers.

Head and Neck Cancer Treatment Options

An estimated 49,670 new cases of head and neck cancer are expected to be diagnosed in the United States in 2017. (American Cancer Society, 2017).

Surgery is the most common option to treat head and neck cancers. Chemotherapy is often used in conjunction with surgery or radiation therapy depending on the type and stage of the cancer. External beam radiation therapy and brachytherapy have been used together or in combination with surgery or chemotherapy. (American Cancer Society, 2017).

Cs-131 brachytherapy seeds allow oncologists to add targeted radiation treatment to head and neck cancers after surgical resection. This targeted radiation treatment is especially needed in patients whose neck cancer has recurred following previous radiation therapy. Often these patients cannot tolerate further external beam radiation therapy for fear of over radiating critical head and neck structures.

Management believes Cs-131brachytherapy seeds continue to represent an improved approach to brachytherapy treatment of specific head and neck cancers. During the fiscal year 2017, twenty patients were treated with Company products for head and neck cancers.

Lung Cancer Treatment Options

An estimated 222,500 new cases of lung cancer are expected in 2017, accounting for 13% of all cancer diagnoses in the United States. Approximately 26% of all cancer deaths are from lung cancer and it accounts for the most cancer related deaths in both men and women in the United States. An estimated 155,870 deaths will result from lung cancer in 2017. (American Cancer Society, 2017).

Lung cancer has historically been treated utilizing surgery, radiofrequency ablation (RFA), radiation therapy, chemotherapy and targeted therapy including LDR brachytherapy. More than one kind of treatment may be used, depending on the stage of the patient’s cancer and other factors. (American Cancer Society, 2017).

The Company believes that Cs-131, with its shorter half-life (faster rate of decay) and relatively high energy, is better suited for treating lung cancer in Stages I and II than I-125. The bioabsorbable mesh used in this procedure to apply the Cs-131 brachytherapy seeds generally dissolves after about 45 days. Cs-131 delivers 90% of its dose in 33 days and is therefore well-suited to use with bioabsorbable mesh. A report was published in May of 2015 describing outcomes from a series of 52 patients treated with a limited surgical resection and Cs-131 brachytherapy. (B. Parashar, et al., *Analysis of stereotactic radiation vs. wedge resection vs. wedge resection plus Cesium-131 brachytherapy in early stage lung cancer,* Brachytherapy 14 (5):648-54 (2015)). During fiscal year 2016, thirteen patients were treated with Company products for lung cancer, and a nominal amount were treated in fiscal 2017.

Financial Information About Segments

The Company has determined that it operates in only one segment, as it only reports profit and loss information on an aggregate basis to its chief operating decision maker.

Financial Information About Geographic Areas

All of the Company's long-lived assets are located in the United States. Revenue by geographic region is based on the shipping addresses of the Company's customers. The following summarizes revenue by geographic region:

	For the year ended June 30,					
	2017		2016		2015	
United States	99.94	%	99.64	%	99.57	%
Non – United States	0.06	%	0.36	%	0.43	%
Total	100.00	%	100.00	%	100.00	%

Our Strategy

The key elements of IsoRay's strategy for fiscal year 2018 include:

Invest significant capital in sales and marketing development activities to gain more market share in the U.S. market for prostate cancer. Prostate cancer treatment represents the original and core business for the Company's Cs-131 product. With five-year data relating to biochemical (PSA) control of prostate cancer now presented to the prostate cancer field, IsoRay intends to aggressively increase the number of centers using Cs-131 through its direct sales force and through its international distributors. Because intermediate- to long-term follow-up data is required to convince clinicians and patients to consider any particular therapy for localized prostate cancer, the availability of five-year data with Cs-131 in the treatment of prostate cancer represents a significant milestone. IsoRay hopes to capture much of the incremental market growth if and when seed implant brachytherapy recovers market share from other treatments, take market share from existing competitors, and expand the use of Cs-131 as a dual therapy option where it has experienced success. In 2016, the Company started its aggressive sales and marketing approach by hiring industry sales and marketing veterans to assist in this market development effort, including the hire in March 2016 of a Vice-President of Sales and Marketing and a consultant Director of Marketing, who, together with the rest of the management team, are developing a comprehensive strategy to expand the presence of the Company's Cesium-131 products in the prostate market. In addition, the Company filled five regional sales positions with experienced sales staff from the prostate brachytherapy industry. In April 2016, the Company contracted with a marketing firm to design a new brand logo for the Company's products and provide website development and a consumer-focused public relations and social media campaign, all as part of the Company's new sales and marketing strategy. A redesigned website for IsoRay.com was launched in September 2016 that focused its message to specific decision makers including the physician, patient, family and friends. The new website supports management's focus on the growth of product sales from the treatment of prostate cancer and the Company's efforts to expand into brain, gynecological, and other cancers.

Increase utilization of Cesium-131 in treatment of other solid tumor applications such as brain, gynecological, and other cancers. IsoRay Medical has clearance from the FDA for its premarket notification (510(k)) for Cs-131 brachytherapy seeds that are preloaded into bioabsorbable braided sutures and bioabsorbable braided sutures attached to bio absorbable mesh. This FDA clearance allows commercial distribution for treatment of brain, gynecological, head and neck and lung tumors as well as tumors in other organs. The Company continues to sell product to physicians treating brain, gynecological, head and neck and lung cancer while continuing to compile treatment outcomes for publication. IsoRay will continue to explore licenses or joint ventures with other companies to develop the appropriate technologies and therapeutic delivery systems for treatment of other solid tumors.

Early clinical data support management's initiatives into brain cancers and early stage non-small cell lung cancers. Local control – defined as success in preventing the re-growth of cancer in the immediate vicinity of the treatment area – has been excellent to date. The Company has continued to provide technical assistance and sell brachytherapy seeds for the use of the GammaTile™ system (multiple patents issued to GammaTile LLC) at the Barrow to treat malignant

meningioma cancer, primary brain cancer and brain metastasis of cancers. IsoRay plans to continue to support studies and research and assist in the development of new application devices for Cesium-131. The utilization of the GammaTile™ system over the past three years has developed a product with consistent and repeatable results as evidenced by the June 2016 presentation at the Society of Neurologic Oncologists. Management intends to continue to facilitate ongoing research and development of the GammaTile™ product.

Support clinical research and sustained product development. The publication and presentation of speculative and real-world data contribute to the acceptability of Cs-131 in the oncologic marketplace. Discussion in the medico-scientific community of established and novel Cs-131 applications is considered a prerequisite to expansion into untapped markets. The Company structures and supports clinical studies on the therapeutic benefits of Cs-131 for the treatment of solid tumors and other patient benefits. We are and will continue to support clinical studies with several leading radiation oncologists to clinically document patient outcomes, provide support for our product claims, and compare the performance of our seeds to competing seeds. IsoRay plans to sustain long-term growth by implementing research and development programs with leading medical institutions in the U.S. and other countries to identify and develop other applications for IsoRay’s core radioisotope technology. The Company has deployed a secure, regulatory environment compliant, online information system capable of large usable databases to participating investigators.

During fiscal year 2017, five presentations were accepted at the annual meeting of the American Society for Radiation Oncology (ASTRO) in September 2016 covering topics related to Cesium-131 treatment of brain metastases, gynecologic cancers and prostate cancer. The Company will continue to seek to increase the number of reports made to society meetings and the peer reviewed literature in order to seek to enhance the standing of its products in the scientific community.

Maintain ISO 13485:2003 certification evidencing quality control. In August 2008, the Company obtained its initial ISO 13485:2003 certification. This permitted the Company to register its products in Europe in 2008 and in Canada and Russia during fiscal year 2009. The ISO 13485:2003 certification demonstrates that the Company is in compliance with this internationally recognized quality standard and the initial certification was valid for a three year period. In June 2012, the Company received a recertification to ISO 13485:2003 for an additional three year period, which was affirmed through a surveillance audit in June 2013.

In October 2015, IsoRay underwent an unannounced inspection by British Standards Institution (BSI), IsoRay's representative to the European Union and designator of IsoRay's CE Marks, with no nonconformities found. BSI also conducted a microbiologic audit and a surveillance audit in November 2015 and March 2016 respectively. In March 2017, BSI conducted its full system inspection and recertification and found no nonconformities to ISO 13485:2003 medical device standards. IsoRay has scheduled a special BSI audit for March 2018 for the transition from ISO 13485:2003 standard to ISO 13485:2016 standard. This transition will move IsoRay's quality system into the current state of the art Quality Management System. The Company must comply with ISO 13485:2016 by end of February 2019 in order to maintain its CE Marks. The Company is subject to a recertification audit by BSI every three years, two annual maintenance audits and one additional unannounced audit during each three year period for a total of four audits during each three year period. The successful audits confirm the Company's success in meeting the standards of manufacturing and quality systems required for the Company to market its products in Canada and Europe.

Products

CS-1 Cesium-131 Source

IsoRay markets the CS-1 Cesium-131 brachytherapy seed for the treatment of prostate cancer, brain cancer, lung cancer, head and neck cancers, gynecological cancer, pelvic/abdominal cancer, colorectal cancer, and ocular melanoma. The Company intends to market Cs-131 for the treatment of other malignant diseases as opportunities are identified in the future through the use of existing proven technologies that have received FDA-clearance. The strategy of utilizing existing FDA-cleared technologies reduces the time and cost required to develop new applications of Cs-131 and deliver them to market.

Cesium-131 Manufacturing Process and Suppliers

Product Overview

Cs-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130 (Ba-130). To produce the Cs-131 brachytherapy seed, a proprietary chemical separation is performed that results in 99.9% pure Cs-131 isotope. Purified Cs-131 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.

Isotope Suppliers

The Company has identified key reactor facilities in the U.S., Russia**,** Belgium and South Africa that are capable of meeting the specific requirements of Cs-131 production. On December 15, 2016, Medical entered into a new supply contract (the INM Agreement) with The Open Joint Stock Company, Isotope, a Russian company (JSC Isotope). With the INM Agreement, Medical can purchase Cs-131 from the Institute of Nuclear Materials, within the quality standards and within the time periods specified, through December 31, 2017.

Due to a planned outage at the INM reactor from November 2017 to July 2018, the Company plans to negotiate an agreement in order to receive supply from the Research Institute of Atomic Reactors (RIAR) during this outage. The Company has in the past been supplied by RIAR and does not foresee any risk of isotope availability during the INM outage. INM will begin re-supplying on a 50/50 basis with RIAR beginning approximately August 2018, and INM will again be the 100% supplier of Russian-sourced Cs-131 beginning in January 2019.

In order to maximize the efficiency of Cs-131 production from the RIAR reactor, the Company has consigned its supply of “enriched” Barium to the RIAR facility. “Enriched” in this context refers to a Barium Carbonate supply that contains a greater proportion of the non-radioactive isotope Barium-130 than is found in nature. This higher proportion of Barium-130 leads to a greatly increased yield of Cesium-131 when it is placed in a high flux neutron environment such as that available at RIAR and a small number of other reactors worldwide.

The Company also receives irradiated barium from the University of Missouri Research Reactor (MURR), located in the United States. For the fiscal year 2017, approximately eighty-five percent (85%) of our Cs-131 was supplied by our Russian supplier and approximately fifteen percent (15%) of Cs-131 was generated by the irradiated barium from MURR. The Company has expanded the amount of Cs-131 provided by the MURR reactor by approximately 100% beginning in fiscal year 2018. This increase in Cesium-131 production is expected to allow the Company to fill additional orders compared to previous periods.

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Management believes that failure to obtain deliveries of Cs-131 from its Russian supplier, <<JSC Isotope>> (which provides supply from both the INM and RIAR reactors), would have a material adverse effect on seed production. Management has developed a three-step process to insulate the Company isotope supply from unplanned outages at the Russian supplier. Step One: management has negotiated a new supply agreement with its existing domestic supplier that will provide additional isotope beginning in fiscal year 2018. Step Two: the Company is planning an expansion of on-site services at the MURR facility, which will allow for a chemical separation to occur in or adjacent to the MURR reactor facility. This on-site chemical processing will in turn allow for a significant increase in isotope yield without incurring significant additional irradiation costs. Step Three: the Company has transferred its stock of enriched barium to the Russian RIAR reactor as a contingency in the case of an outage at one or both of its current isotope providers or at a new isotope supplier in Russia.

Quality Controls

In July 2008, IsoRay had its baseline inspection by the FDA at its manufacturing and administrative offices in Richland, WA. This inspection was carried out over a five day period during which the investigator performed a complete inspection following Quality Systems Inspection Techniques (QSIT). At the end of the inspection, no report of deviations from Good Manufacturing Practices or list of observations (FDA Form 483) was issued to IsoRay. An additional inspection of IsoRay was conducted by FDA in April 2013. Again the FDA reported no deviations from Good Manufacturing Practices and did not list any observations (FDA Form 483). In August 2017, FDA conducted an announced QSIT inspection of the Richland facility and again, did not find any nonconformance to U.S. medical device regulations and did not issue a Form 483.

In October 2015, IsoRay underwent an unannounced inspection by British Standards Institution (BSI), IsoRay's representative to the European Union and designator of IsoRay's CE Marks with no nonconformities found. BSI also conducted a microbiologic audit and a surveillance audit in November 2015 and March 2016 respectively. In March 2017, BSI conducted its full system inspection and recertification and found no nonconformities to ISO 13485:2003 medical device standards. IsoRay has scheduled a special BSI audit for March 2018 for the transition from ISO 13485:2003 standard to ISO 13485:2016 standard. This transition will move IsoRay's quality system into the current state of the art Quality Management System. The Company is subject to a recertification audit by BSI every three years, two annual maintenance audits and one additional unannounced audit during each three year period for a total of four audits during each three year period. The successful audits confirm the Company's success in meeting the standards of manufacturing and quality systems required for the Company to market its products in Canada and Europe.

The Federal Aviation Administration (FAA) also conducted an unannounced audit in May 2016. Because IsoRay ships hazardous materials on flights in the U.S., IsoRay is subject to regulation by the FAA. No findings were made in this audit.

Regulatory Developments

In June of 2017, the Company received a “notice of timely renewal” from the Washington State Department of Health (WA DOH) in response to its application to renew Company’s Radioactive Materials License. The WA DOH acts as an agent of the U.S. Nuclear Regulatory Commission and grants Company its ability to receive and ship radioactive material. The notice of timely renewal grants the Company the ability to operate under its existing license until the WA DOH conducts an inspection and issues the definitive Radioactive Materials License. This license is in effect for 10 years as long as the Company operates without actionable breaches of the license. The previous license was issued in June of 2007 and expired July 31, 2017. Notices of timely renewal which are in effect prior to final licensing are common practice in the radioactive material handling regulatory environment.

Order Processing

The Company has implemented a just-in-time production process that is responsive to customer input and orders to ensure that individual customers receive a higher level of customer service than received from our competitors who have the luxury of longer lead times due to longer half-life products. Time from order confirmation to completion of product manufacture is reduced to several working days, including receipt of irradiated barium (from the domestic supplier’s reactor) or unpurified Cs-131 (from the international supplier's reactor), separation and purification of Cs-131, isotope labeling of the core, loading of cores into pre-welded titanium “cans” for final welding, testing, quality assurance and shipping.

It is up to each physician to determine the dosage necessary for implants and acceptable dosages vary among physicians. Many physicians order more seeds than necessary to assure themselves that they have a sufficient quantity. Upon receipt of an order, the Company either delivers the seeds from its facility directly to the physician in either loose or preloaded form or sends the order to an independent preloading service that delivers the seeds preloaded into needles or cartridges just prior to implant. If the implant is postponed or rescheduled, the short half-life of the seeds makes them unsuitable for use and therefore they must be re-ordered.

Due to the lead time for obtaining and processing the Cs-131 isotope and its short half-life, the Company relies on sales forecasts and historical knowledge to estimate the proper inventory levels of isotope needed to fulfill all customer orders. Consequently, some portion of the isotope is lost through decay and is not used in an end product. Management continues to reduce the variances between ordered isotope and isotope deliveries and is continually improving its ordering process efficiencies.

Pre-loading Services

In addition to providing loose seeds to customers, most brachytherapy manufacturers offer their seed product to the end user packaged in various configurations provided in a sterile or non-sterile package depending on the customer's preference. These include:

§ *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 bioabsorbable rigid “carrier sleeve”);
§ *Preloaded strands* (strands of seeds loaded into a needle);
§ *Pre-loaded braided strands (*seeds loaded into a flexible bioabsorbable braided suture); and
§ *Pre-loaded braided strands attached to bioabsorbable mesh* (creates planar implants out of braided sutures and bioabsorbable mesh).

In fiscal year 2017, the Company delivered approximately 48% of its Cs-131 seeds to customers configured in Mick® cartridges, approximately 31% of the Cs-131 seeds configured in stranded and pre-loaded in a needle form, 9% of the Cs-131 seeds configured in a braided strand form, 3% of the Cs-131 seeds sold in a loose configuration and the remaining 9% configured in either a pre-loaded in a needle or stranded form.

The role of the pre-loading service is to package, assay and certify the contents of the final product configuration shipped to the customer. A commonly used method of providing this service is through independent radiopharmacies. Manufacturers send loose seeds along with the physician’s instructions to the radiopharmacy which, in turn, loads needles and/or strands the seeds according to the doctor’s instructions. These radiopharmacies then sterilize the product and certify the final packaging prior to shipping directly to the end user.

In fiscal year 2012, IsoRay obtained a CE mark which allows shipment of seeds loaded into flexible braided strands and flexible strands attached to bioabsorbable mesh into the European Union.

Manufacturing Facility

The Company maintains a production facility located at Applied Process Engineering Laboratory (APEL) in Richland, Washington. The APEL facility became operational in September 2007. The production facility has over 15,000 square feet and includes space for isotope separation, seed production, order dispensing, a clean room for radiopharmacy work, and a dedicated shipping area. In 2015, the Company entered into a modification to the production facility lease that modified the requirement to return the facility to ground at the time of exit at Company discretion, exercised an extension in 2017 to increase the lease term to April 30, 2021, and reduced the required notice to terminate the lease early from twelve months to six months. This lease modification provides the flexibility required for the Company to plan, design and construct its own production facility, which is expected to reduce operational cash flow requirements and provide for long-term security of production capabilities for the Company. The construction of a new facility is subject to obtaining acceptable financing. No assurances can be given at this time regarding the ability of the Company to obtain such financing. The Company has completed the design process for a new facility and has permit ready plans to build when the Company needs to move into a new facility. Management believes that construction of the facility will take 18 to 24 months to complete from the time that ground is broken.

GliaSite® Radiation Therapy System

IsoRay discontinued the GliaSite® RTS in March 2016.

15

Sales and Marketing

Marketing Strategy

In 2017, the Company implemented and began to execute a new sales and marketing strategy. This strategy involves a more direct focus on the prostate cancer market and existing Cesium-131 customers, with a secondary focus on developing opportunities in emerging applications, including brain tumors, gynecological cancers and head and neck tumors. This focus was supported by a complete redesign of the Company brand, website and collateral materials. This effort was initiated in fall 2016.

This follows the changes to the sales and marketing team that occurred in 2016, when the Company hired a Vice President of Sales and Marketing, Michael Krachon, who brings more than twenty years of experience of progressive growth in sales and marketing with the past fifteen years in the brachytherapy market. Management also engaged the consulting services of industry veteran Lori Woods, who contributes more than twenty years of experience in the oncology medical device and services industry. Ms. Woods previously served IsoRay from 2006 to 2010 as a Vice-President and eventually as Chief Operating Officer.

Further to support the new marketing strategy, the Company has started the process of reestablishing its medical advisory boards to provide professional input and insight regarding the Company's current products and research and developments efforts. The boards will vary by cancer type/site and the supporting specialties that treat that cancer. They will include, but not be limited to, radiation oncologists, surgeons, urologists, and physicists. The boards will be a mix of customers and non-customers, which the Company believes will provide increased insight regarding the perception of its products and opportunities to meet the needs of the market. The Company held its first advisory meeting for prostate cancer in September 2016, with the next meeting scheduled at the American Society of Therapeutic Radiation Oncologists (ASTRO) professional meeting in San Diego; in September 2017, and is looking to continue to build additional advisory boards as the other applications grow in viability.

The market for treatments for localized prostate cancer is very competitive and largely hinges upon two factors: the demonstration of long term follow-up data that has been presented to the prostate cancer treatment profession and the economic and strategic dynamics of the different therapeutic options. Cs-131 was introduced to the prostate cancer marketplace more than a decade after Iodine-125 and Palladium-103, and the resulting time for mature clinical data to be developed has proven an obstacle to widespread market acceptance. The time to publish these results is lengthy and includes time to enroll patients in protocols which may take multiple years depending on the size of the enrollment population, time to aggregate the results at five years from the final patient treatment, time to analyze the data and author the article followed by the time for peer review, and publication in a medical journal. The total time for this process may approach a decade from start to publication. Management believes that the impressive results achieved for treatment with Cs-131 at the five-year mark should create further scientific support for Cs-131 as an attractive

treatment for localized prostate cancer, overcoming at least some of the initial resistance predicated on the lack of long-term follow-up reports. The data that was published in fiscal year 2015 is discussed in the section titled Industry Information, Prostate Cancer Treatment, "*Comparing Cesium-131 to I-125 and Pd-103 Clinical Results."* In addition to the challenges presented by the limited published results for Cs-131, the prostate brachytherapy market has been pressured by the economic differences and strategic dynamics of competing treatment options such as robotic surgical devices and external beam radiation facilities. These factors have combined to result in the current multi-year contraction of the prostate brachytherapy market. The declining market has impacted the competitive landscape, reducing the number of competitors and their respective investments in sales, marketing and product development efforts. Based upon Company market review and research, there appears to be an opportunity for IsoRay to expand its current market opportunity with an investment in sales and marketing efforts. The Company believes its recent hires of both sales and marketing veterans with regional sales support will lead to growth of their market share in the prostate cancer treatment business. The Company also believes that an increased share of the prostate brachytherapy market share will assist in facilitating Cs-131 brachytherapy cancer treatment growth in other body sites.

The professional and patient market segments each play a role in the ultimate choice of cancer treatment and the specific isotope chosen for seed brachytherapy treatment. The Company has developed a customized brand message for each audience. The Company's new website was launched in the fall of 2016, and delivers the message that Cs-131 is a treatment option for cancers throughout the body. IsoRay is developing and/or refreshing print, visual and digital media (including physician brochures discussing the clinical advantages of Cs-131, clinical information materials, and digital content for the website and social media awareness efforts). In addition, the Company attends national professional meetings, including:

§ American Brachytherapy Society (ABS);
§ American Society for Therapeutic Radiation and Oncology (ASTRO);
§ Association of American Physicists in Medicine (AAPM);
§ American Urological Association (AUA);
§ Society for Neuro-Oncology (SNO);
§ American Association of Neurological Surgeons (AANS);
§ American Association for Thoracic Surgery (STS);
§ Large Urology Group Practice Association (LUGPA); and
§ various local chapter meetings.

The Company also continues to consult with noted contributors from the medical physics community and expects that articles for professional journals regarding the benefits of and clinical trials involving Cs-131 will continue to be submitted.

In addition, the Company continues to promote the clinical findings of the various protocols and publications through presentations by respected thought leaders. The Company will continually review and update all marketing materials as more clinical information is gathered from the protocols and studies.

Apart from clinical studies and papers sponsored by the Company, several physicians across the country have independently published papers and studies on the benefits of Cs-131.

In today's U.S. health care market, patients are more informed and involved in the management of their health than in the past. Many physicians relate incidents of their patients coming for consultations armed with articles researched on the Internet and other sources describing new treatments and medications. In many cases, these patients are demanding a certain therapy or drug and the physicians are complying when medically appropriate.

Because of this consumer-driven market factor, we also promote our products directly to the general public. We target the prostate cancer patient, his spouse, family, care givers and loved ones. We emphasize to these segments the specific advantages of the Cs-131 brachytherapy seed through our newly developed website (located at www.isoray.com), patient advocacy efforts, informational patient materials and patient testimonials, other awareness efforts through social media channels, and advertisements in specific markets supporting brachytherapy. None of our websites should be considered a part of this Report.

The Company's marketing plan with regard to non-prostate segments includes identifying and exhibiting at scientific meetings attended by specialty physicians who perform procedures related to Company's product offerings, direct sales contact with such physicians (for example thoracic surgeons and neuro-surgeons), the development and dissemination

of training videos and other media that outline the Company's products, and the implementation of local training events to provide product and procedure information to potential customers.

Further, the Company is partnering with key clinicians within each application to support early experiences and identify additional facilities that may be interested in the applications. The Company continues to work with its existing radiation oncology physician customers and to educate them as to additional or new Company products and expand utility of Cs-131 within the facility and across different disease sites. To facilitate this expanded position, the Company's sales managers call on existing radiation oncology physicians and other key decision makers within an organization to discuss the available clinical results and experiences in coordination with key Company scientific personnel to educate the customer representatives about different Cs-131 applications and comparisons to competing treatments.

Sales and Distribution

In the prostate cancer market, the sales organization targets radiation oncologists and medical physicists as well as urologists and facility administrators as key clinical decision-makers in the type of radiation therapy offered to prostate cancer patients.

With respect to non-prostate applications, the Company targets neurosurgeons, thoracic surgeons, gynecologic oncologists and other surgeons in addition to radiation oncologists. After these clinicians identify the value of the Company's Cs-131 products, the Company then also needs support for the procedure from the medical physicists on staff and facility administrators. The sales cycle for non-prostate applications has proved to be a longer process than for prostate applications and often takes nine months or longer before the Company is licensed in a new hospital and can make its first sale.

IsoRay has a direct sales organization consisting of territory sales managers, and a Vice-President of Sales and Marketing responsible for the development of the team and the execution of the sales plan. The Company's territory sales managers are responsible for all sales activities in their respective territories and solicit potential specialist physicians in all areas of the body. This approach allows our territory sales managers to call on a single location for all applications of our products, resulting in a more efficient sales approach.

With the hiring of the Vice-President of Sales and Marketing, the addition of two new senior territory managers, and the addition of the Director of Marketing and product manager, the commercial team is fully committed to and is in the process of executing the commercial plan for the development of new sales materials, training materials, and website assistance.

The Company expects to continue to explore the opportunity to extend its customer base outside the U.S. market through use of established distributors in target markets of other countries. As of September 1, 2017, the Company had independent distributors in Italy, Switzerland and Russia. The Company's initial focus on the international markets was for the sale of the GliaSite® RTS, which was discontinued in March 2016. This has shifted to targeted prostate and gynecological centers in the targeted markets. Although it still has two international distribution agreements in place, the Company continues to experience difficulties in generating sales of Cs-131 products through its international distributors.

Reimbursement

Reimbursement by third party payers is the primary means of payment for all IsoRay products. The Centers for Medicare and Medicaid Services (CMS) is the primary payer, providing coverage for approximately 65% of all prostate brachytherapy cases and a majority of non-prostate procedures. Well established brachytherapy coverage and payment policies are currently in place by CMS and other non-governmental payers for out-patient procedures. For surgical procedures provided in an in-patient setting, payment is provided as part of a DRG code, which includes the surgical elements of the procedure.

In the hospital outpatient prospective payment system (HOPPS) out-patient setting, brachytherapy sources are legislated to be paid individually. Under this umbrella, in 2003, CMS established a unique HCPCS code for Cs-131 brachytherapy seeds that permitted providers to report the use of Cs-131 directly to payers. In July 2007, CMS established two separate Cs-131 codes for providers to report loose seeds and stranded seeds due to the cost differential of these two products. Reimbursement for prostate brachytherapy services and sources is well established in the U.S. and most providers (hospitals and physicians) are not faced with reimbursement challenges when providing this treatment option to patients.

In June 2016, the Company rejoined the Coalition for the Advancement of Brachytherapy (CAB). CAB is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB has dedicated significant resources to the clinical use of brachytherapy including the treatment of prostate and other types of cancer as well as vascular disease. In addition, on an annual basis, CAB performs a review of the existing reimbursement structure for its members, allowing CAB members to have input into the future reimbursement structure for their products. In July, 2017, CAB disbanded, due to shrinking funding as a result of the consolidation of the brachytherapy market. The Company is pursuing consulting relationships with key support members of the former CAB organization to ensure that the key actions are performed, with a dedicated focus to the impact of reimbursement policies on Cesium-131.

As noted above, there are two different methodologies for CMS payment. The first, the out-patient setting, includes prostate brachytherapy, and a limited range of other procedures, including some gynecological implants, and as such, is covered by the CMS Outpatient Prospective Payment System, which since 2010 has provided a fixed reimbursement per seed for stranded and loose seeds. Iodine, Palladium and Cesium each have their own reimbursement values for stranded and loose seeds. If reported correctly when seeds are submitted for payment to CMS, providers are reimbursed at a flat rate that is determined by median costs of the seeds. It is expected that this reimbursement system established in January 2010 will continue as currently scheduled through calendar 2018 but there is no assurance that this will occur. CMS has generally continued its historical trend of declining year over year reimbursement with few exceptions. Private insurance companies have historically followed the CMS reimbursement policies. The Company expects that CMS will continue its annual review of payments provided as reimbursement for our various products and that CMS will continue to provide favorable reimbursement rates for our Cs-131 brachytherapy seeds, but there is no assurance this will continue.

The other payment method is for in-patient procedures, where the patient remains in the hospital for more than 24 hours. Lung, brain and head and neck implant procedures utilizing brachytherapy sources require the patient to be admitted to the hospital. In-patient procedures are covered by CMS which remits a set amount depending on the kind of surgery being performed and the status of the patient. Under this Diagnostic Related Group (DRG) system, the hospital pays for all the items involved in the care of the patient excluding physician fees. The brachytherapy seeds in these in-patient cases are not paid for separately by CMS, but rather included as part of the DRG payments from CMS. Because the Company's seeds may not be reimbursed by CMS, there can be difficulty in convincing hospitals to use the Company's products. The Company contracted with a reimbursement consultant in April of 2016 to review opportunities to establish incremental reimbursement from CMS for in-patient care for brachytherapy. The Company submitted for and was granted an ICD-10 code for the use of Cesium-131 with surgical brain procedures.
The Company plans on considering additional applications for DRG codes for intraoperative brachytherapy treatments in the future. Receipt of additional DRG codes in the future for brachytherapy applications will assist in the sales to hospitals and institutions that currently are not reimbursed for brachytherapy radiation for intraoperative care. Management believes the lack of incremental reimbursement for brachytherapy by CMS and private insurers placed at the time of surgery rather than delivered at a point in time following surgery may be impeding the faster and broader adoption of intraoperative brachytherapy and unfortunately short of new legislation changing this system will remain an ongoing deterrent for use of these products.

In October 2016, the Company submitted a New Technology Add-on Payment (NTAP) application. This filing formally requests additional reimbursement for the Cesium-131 based GammaTile™ treatment for brain cancer. Because the Company's 510(k) filing with the U.S. Food and Drug Administration is still pending, this application is currently not under consideration. The Company plans to re-file the NTAP application in October 2017.

Other Information

Customers

The following are the Company's top three customers, facilities or physician practices that utilize multiple surgical facilities at which primarily prostate brachytherapy procedures are performed, accounted for approximately 37.6% of the total Company product sales for the twelve months ended June 30, 2017:

Facility	Location	% of revenue	
El Camino, Los Gatos, and other facilities[1]	Northern CA	22.9	%
University of Pittsburg Medical Center – Mercy	PA	7.9	%
Bon Secours DePaul	VA	6.8	%
Total		37.6	%

1. The head of the single largest physician practice also serves as the Company's medical director. As the medical director, this physician advises the Company Board of Directors and management, provides technical advice related to product development and research and development, and provides internal training to the Company sales staff and professional training to our sales staff and to other physicians. Revenue from this practice decreased by $119k in the year ended June 30, 2017 when compared to the year ended June 30, 2016.

The loss of either the single largest physician practice or a combination of the other significant facilities and customers could have a material adverse effect on the Company's revenues, which would continue until the Company located new customers to replace them. There can be no assurance this would occur in a timely manner or at all.

Proprietary Rights

The Company relies on a combination of patent, copyright and trademark laws, trade secrets, software security measures, license agreements and nondisclosure agreements to protect its proprietary rights. Some of the Company's proprietary information may not be patentable.

Our management believes that certain aspects of the IsoRay seed design and construction techniques are patentable innovations. These innovations resulted in a patent granted by the USPTO under Patent Number 7,410,458, in August 2008, with an expiration date of December 5, 2025. Certain methodologies regarding isotope production, separation, and seed manufacture are retained as trade secrets and are embodied in IsoRay's procedures and documentation. Four patents have been granted by the USPTO relating to methods of deriving Cs-131 developed by IsoRay employees: Patent Number 7,479,261, with an expiration date of April 6, 2027; Patent Number 7,531,150, with an expiration date of July 13, 2027; Patent Number 7,316,644, with an expiration date of August 5, 2025; and Patent Number 7,510,691, with an expiration date of July 19, 2027. The Company has two patents that were issued on April 23, 2014 and are effective in Canada (Canada 2576907 and 2571349). The Company has patents granted in the Russian Federation which expire at various times in 2024 and 2025. The Company has a single patent granted in each of the Netherlands and India that both expire on June 22, 2025. The Company has a single patent pending in the EU and Hong Kong. The Company is continuing its efforts to develop and patent additional methods of deriving Cs-131 and other isotopes.

There are specific conditions attached to the assignment of the Cs-131 Trust patent from the late Lane Bray. In particular, the associated Royalty Agreement provides for 1% of gross profit payment from seed sales to Lane Bray and 1% of gross profit from any use of the Cs-131 process patent for non-seed products. If IsoRay reassigns the Royalty Agreement to another company, these royalties increase to 2%. The Royalty Agreement has an anti-shelving clause that requires IsoRay to return the patent if IsoRay permanently abandons sales of products using the invention. During fiscal years 2017 and 2016, the Company recorded royalty expense of $21,000 and $18,000, respectively, related to this patent.

The terms of a license agreement with the Lawrence Family Trust (successor to Don Lawrence) for a patent application and related "know-how" 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 remains applicable. To date, management believes that there have been no product sales incorporating the "know-how," and therefore believes no royalty is due. Management believes that ultimately no royalties will be paid under this agreement as there is no intent to use this "know-how" in the future.

The Lawrence Family Trust 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. After additional settlement discussions, which ended in April 2008, the parties failed to reach a settlement. The parties may demand binding arbitration at any time.

Research and Development

During the three-year period ended June 30, 2017, IsoRay and its subsidiaries incurred approximately $2.11 million in costs related to research and development activities. The Company expects to continue ongoing research and

development activities for the foreseeable future. Chief among R&D expenditures in fiscal year 2017 are new product development (GammaTile™ and others) and the support of clinical research studies that are accumulating data on the subjects of prostate and head and neck cancers. Other clinical research, including the study of Cs-131 in the treatment of brain, gynecological and other cancers, are currently funded by sources other than the Company.

Government Regulation

The Company's present and future intended activities in the development, manufacture and sale of cancer therapy products are subject to extensive laws, regulations, regulatory approvals and guidelines. Within the United States, the Company's therapeutic radiological devices must comply with the U.S. Federal Food, Drug and Cosmetic Act, which is enforced by the U.S. Food and Drug Administration (FDA). The Company is also required to adhere to applicable FDA Quality System Regulations, also known as the Good Manufacturing Practices, which include extensive record keeping and periodic inspections of manufacturing facilities. The Company's predecessor obtained FDA 510(k) clearance in March 2003 to market its Cs-131 seed for the treatment of localized solid tumors and other malignant disease and IsoRay obtained FDA 510(k) clearance in November 2006 to market preloaded brachytherapy seeds and in August 2009 for preloading flexible braided strands and bioabsorbable mesh.

In the United States, the FDA regulates, among other things, new product clearances and approvals to establish the safety and efficacy of these products. We are also subject to other federal and state laws and regulations, including the Occupational Safety and Health Act and the Environmental Protection Act.

The Federal Food, Drug, and Cosmetic Act and other federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record keeping, approval, distribution, use, reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications, disqualification from sponsoring or conducting clinical investigations, preventing us from entering into government supply contracts, withdrawal of previously approved applications, and criminal prosecution.

In the United States, medical devices are classified into three different categories over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Most Class I devices are exempt from premarket notification 510(k); most Class II devices require premarket notification 510(k); and most Class III devices require premarket approval. Our Cs-131 seed is a Class II device and received 510(k) clearance in March 2003.

Approval of new Class III medical devices is a lengthy procedure and can take a number of years and require the expenditure of significant resources. There is a shorter FDA review and clearance process for Class II medical devices, the premarket notification or 510(k) process, whereby a company can market certain Class II medical devices that can be shown to be substantially equivalent to other legally marketed devices. Since brachytherapy seeds have been classified by the FDA as a Class II device, we have been able to achieve market clearance for our Cs-131 seed using the 510(k) process.

In August 2011, IsoRay Medical received clearance from the FDA for its premarket notification 510(k) for the GliaSite® RTS. The GliaSite® RTS is the only FDA-cleared balloon catheter device used in the treatment of brain cancer. In May 2014, the Company received clearance from the FDA for its pre-market notification 510(k) for the radiotherapy solution Cesitrex® (liquid Cs-131) for use with the GliaSite® RTS. The Company has since discontinued sales of the GliaSite® RTS.

As a registered medical device manufacturer with the FDA, we are subject to inspection to ensure compliance with FDA's current Good Manufacturing Practices, or cGMP. These regulations require that we and any of our contract manufacturers design, manufacture and service products, and maintain documents in a prescribed manner with respect to manufacturing, testing, distribution, storage, design control, and service activities. Modifications or enhancements that could significantly affect the safety or effectiveness of a device or that constitute a major change to the intended use of the device require a new 510(k) premarket notification for any significant product modification.

The Medical Device Reporting regulation requires that we provide information to the FDA on deaths or serious injuries alleged to be associated with the use of our devices, as well as product malfunctions that are likely to cause or contribute to death or serious injury if the malfunction were to recur. Labeling and promotional activities are regulated by the FDA and, in some circumstances, by the Federal Trade Commission.

As a medical device manufacturer, we are also subject to laws and regulations administered by governmental entities at the federal, state and local levels. For example, our facility is licensed as a medical device manufacturing facility in the State of Washington and is subject to periodic state regulatory inspections. Our customers are also subject to a wide variety of laws and regulations that could affect the nature and scope of their relationships with us.

In support of IsoRay's global strategy to expand marketing to Canada, the European Union (EU) and Russia, we initiated the process in fiscal year 2008 to obtain the European CE Mark, Canadian registration, and certification to ISO 13485:2003, an internationally recognized quality system. During the fiscal year 2014, the CE Mark was renewed for an additional five years. European law requires that medical devices sold in any EU Member State comply with the requirements of the European Medical Device Directive (MDD) or the Active Implantable Medical Device Directive (AIMDD). IsoRay's brachytherapy seeds are classified in Europe as an active implantable and are subject to the AIMDD. Compliance with the AIMDD and obtaining a CE Mark involves being certified to ISO 13485:2003 and obtaining approval of the product technical file by a notified body that is recognized by competent authorities of a Member State. Compliance with ISO 13485:2003 is also required for registration of a company for sale of its products in Canada. Many of the recognized EU Notified Bodies are also recognized by Health Canada to conduct the ISO 13485:2003 inspections for Canadian registration. During fiscal year 2009, the Company received its certification to ISO 13485:2003 and obtained approval from Health Canada for its Canadian registration. The Company has had no success in selling the product in the Canadian market and through its distributors is currently focusing on the markets in Switzerland, Italy, and the Russian Federation. On June 18, 2014, the Company entered into an agreement with MedikorPharma-Ural LLC as the distributor in the Russian Federation. The agreement provides the distributor with the ability to sell the entire product line. As of June 30, 2017, this agreement is no longer in effect. On July 14, 2017, the Company entered into an agreement with a new distributor in Russia that provides for the ability to sell the entire product line in the Russian Federation. The agreement has a one-year initial term with two additional one-year terms which automatically renew unless either party invoke their right to terminate earlier under the provisions of the agreement. On August 1, 2016, the Company entered into an agreement with a distributor in Italy for the territory of Italy and Switzerland, as its prior Italian distribution agreement, with an affiliate of the new distributor, had expired without any sales.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive byproduct material, we are subject to extensive regulation by not only federal governmental authorities, such as the FDA and FAA, but also by state and local governmental authorities, such as the Washington State Department of Health, to ensure such devices are safe and effective. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission (NRC), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our Cs-131 brachytherapy seeds constitute both medical devices and radioactive sealed sources and are subject to these regulations.

Moreover, our use, management, and disposal of certain radioactive substances and wastes are subject to regulation by several federal and state agencies depending on the nature of the substance or waste material. We believe that we are in compliance with all federal and state regulations for this purpose.

Seasonality

The Company believes that some seed implantation procedures are deferred around physician vacations (particularly in the summer months), holidays, and medical conventions and conferences resulting in a seasonal influence on the Company's business. These factors cause a momentary decline in revenue which management believes is ultimately realized in prior or following periods. Because a material portion of the Company's business is dependent on three customers, physician practices or facilities, simultaneous or extended vacations by the physicians at these facilities or by our single largest physician whose total revenue alone represents a material portion of the Company's business could cause significant drops in the Company's productivity during those reporting periods.

Employees

As of September 1, 2017, IsoRay employed 36 full-time individuals. The Company's future success will depend, in part, on its ability to attract, retain, and motivate highly qualified sales, technical and management personnel. From time to time, the Company may employ independent consultants or contractors to support its research and development, marketing, sales, accounting and administrative organizations. None of the Company's employees are represented by any collective bargaining unit. On September 1, 2017, the Company employed six direct sales people.

Competition

The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. In general, the IsoRay Cs-131 brachytherapy seed competes with conventional methods of treating localized cancer, including, but not limited to, all forms of prostatectomy surgery and external beam radiation therapy which includes intensity modulated radiation therapy, stereotactic radiosurgery and proton therapy, as well as competing permanent and temporary brachytherapy devices.

Management believes the Company's patented Cs-131 separation process is likely to provide a sustainable competitive advantage. Production of Cs-131 also requires specialized facilities that represent high cost and long lead time if not readily available. In addition, a competitor would need to develop a method for isotope attachment and seed assembly, would need to conduct testing to meet NRC and FDA requirements, and would need to obtain regulatory clearances before marketing a competing device. Best Medical received FDA 510(k) clearance to market a Cs-131 seed on June 6, 1993 but to date has not produced any products for sale.

The Company's brachytherapy products used in non-prostate applications typically compete with temporary (high dose-rate, HDR), external beam radiation therapy (EBRT), which can be provided as conventional or intensity modulated radiation therapy, or as stereotactic radiosurgery, a technique that delivers high doses of radiation to a target in a much lower number of sessions than other forms of EBRT. Manufacturers of EBRT equipment include Varian Medical Systems, Siemens Healthcare, Elekta AB, and Accuray Incorporated, among others.

In the cases of lung and brain tumors (and other solid tumors), a surgeon will remove the tumor if it is medically prudent and this offers the patient some benefit in terms of controlling the growth of the cancer or its symptoms. In many cases, radiation therapy is added following the surgery; this is known as “adjuvant” radiation therapy. The Company believes that its form of adjuvant radiation therapy deployable in such cases offers advantages over external beam methods. However, external beam holds the vast majority of the market for adjuvant radiation therapy.

ITEM 1A – RISK FACTORS

You should carefully consider the following factors regarding information included in this Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, financial condition and operating results could be materially adversely affected.

Risks Related to Our Industry and Operations

Our Revenues Depend Upon One Product. Our revenues depend solely upon the successful production, marketing, and sales of the Cesium-131 brachytherapy seed in its various delivery formats. The rate and level of market acceptance of this product varies depending on the perception by physicians and other members of the healthcare community of its safety and efficacy as compared to that of competing products, if any; the clinical outcomes of the patients treated; the effectiveness of our sales and marketing efforts or those of our distributors in the United States, Italy, Switzerland and the Russian Federation; any unfavorable publicity concerning our product or similar products; our product’s price relative to other products or competing treatments; any decrease in current reimbursement rates from the Centers for Medicare and Medicaid Services or third-party payers; regulatory developments related to the manufacture or continued use of the product; availability of sufficient supplies of barium for Cesium-131 seed production; ability to produce sufficient quantities of Cesium-131; the ability of physicians to apply the correct dosage of seeds and avoid excessive levels of radiation to patients; and the ability to use this product to treat multiple types of cancers in various organs. Because of our reliance on this product as the sole source of our revenue, any material adverse developments with respect to the commercialization of this product may cause us to continue to incur losses rather than profits in the future.

Although Cleared To Treat Any Malignant Tissue, Our Product Is Primarily Used To Treat A Single Type Of Cancer Which Is In A Declining Market. Currently, the Cesium-131 seed is used almost exclusively for the treatment of prostate cancer (approximately eighty-eight percent of our sales). We have been treating brain cancer which amounted to approximately six percent of our product sales, gynecological cancer which amounted to approximately three percent of our product sales, head and neck cancer which amounted to approximately two percent of our product sales, lung cancer which amounted to less than one percent of our product sales, and other cancers including groin cancer, pelvic cancer and colorectal cancer that combined constituted less than one percent of our product sales in fiscal year

2017. Management believes the Cesium-131 brachytherapy seed will continue to be used to treat other types of cancers as the Company identifies existing delivery systems that can be utilized or develops new delivery methods for the product, however these delivery systems may not prove as effective as anticipated. Management believes that clinical data gathered by select groups of physicians under treatment protocols specific to other organs will be needed prior to widespread acceptance of our product for treating other cancer sites. If our current and future products do not become accepted in treating cancers of other sites, our sales will continue to depend primarily on treatment of prostate cancer, a market with increasing competition and ongoing loss of market share by all brachytherapy products. Even though the past two fiscal years have shown improvements in prostate revenue, since the U.S. Preventive Services Task Force recommendation in 2012 to no longer routinely conduct prostate exams, the market for all prostate procedures has dramatically declined. In 2017, the USPSTF changed its recommendation from advising against screening to the position that the decision for men between 55 and 69 to undergo PSA-based screening should be made by a man in consultation with his doctor (https://screeningforprostatecancer.org/). This change may contribute to an increased incidence of screening (and therefore more prostate cancer cases) as opposed to an unscreened population – although this conclusion will await future trending information.

Unfavorable Industry Trends in the Prostate Market. Several factors which began in fiscal 2009 have caused our revenues to significantly decline. However, since fiscal 2015 we have experienced steady marginal increases in sales, but this improvement is still not back to the amount of revenues we had in fiscal 2011 or 2012. Beginning in the fall of 2008, U.S. consumers significantly curtailed all spending (even for life saving medical procedures) which impacted the brachytherapy industry as a whole. In February of 2009, noted urologists announced at a medical conference that prostate specific antigen (PSA) testing was not as necessary as previously believed. Their statements were widely publicized. In May 2012, the U.S. Preventive Services Task Force (USPSTF) recommended against routine PSA screenings for healthy men without symptoms. This recommendation has led to substantial declines in PSA screenings. In addition, there has been an increase in “active surveillance,” a practice where no immediate medical treatment is provided but the physician and patient closely monitor the patient’s cancer for signs that the cancer is growing. We believe that declines in PSA screenings have led to a decline in the number of men diagnosed with prostate cancer, which in turn leads to a decline in the number of procedures to treat prostate cancer, including brachytherapy procedures. An increase in the proportion of men diagnosed with prostate cancer but not seeking immediate medical treatment ultimately also leads to a decline in the number of procedures to treat prostate cancer.

Also, the emergence of IMRT as the preferred treatment alternative as a result of a much higher reimbursement rate to physicians compared to brachytherapy treatments has resulted in declining market share for brachytherapy treatment. In fiscal 2017, each of these factors continued to impact the performance of the Company in the prostate market and the industry as a whole and there is no assurance that they will not continue to impact sales of the Company in the prostate market through fiscal 2018.

We Rely Heavily On Three Customers. Approximately thirty-eight percent (38%) of the Company's revenues are dependent on three customers and approximately twenty-three percent (23%) on one customer. The loss of any of these customers would have a material adverse effect on the Company's revenues which may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments.

We Rely Heavily On A Limited Number Of Suppliers. Some materials used in our product are currently available only from a limited number of suppliers. In fiscal 2017, approximately eighty-five percent (85%) of our Cesium-131 was supplied through JSC INM from a reactor located in Russia. Our current contract with JSC INM terminates on December 31, 2017, and will have to be renegotiated. Management will seek to negotiate favorable pricing but there is no assurance as to the outcome of these negotiations. On August 25, 2017, the Company executed a consignment inventory agreement with MedikorPharma-Ural LLC to process the Company's enriched barium at another nuclear reactor in Russia beginning in November 2017. The term of the consignment agreement is 10 years. Our source of supply of Cesium-131 from Russia is historically produced using one of two nuclear reactors which supply the irradiation needed for Cesium-131 production. One of the Russian nuclear reactors will be shut down from December 2017 to mid-2018, and the other Russian nuclear reactor is scheduled to be shut down for much of 2019. As a result of these upcoming shutdowns, only one of the Company's historic Russian suppliers of Cesium-131 will be available during these periods. Medikor will use the barium carbonite consigned by the Company to contract with a third-party manufacturer to produce and supply Cesium-131 to the Company. This arrangement has the effect of minimizing the impact on the Company of the planned temporary shutdown of the nuclear reactors that serve as its sources of Cesium-131 from Russia. Management negotiated a new contract with MURR in 2017 which it believes will increase the supply it receives from MURR and the Company is currently researching the ability to process Cesium-131 at the MURR reactor site, which could increase domestic supply approximately 100% from current production volume.

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 political or civil unrest. Failure to obtain deliveries of Cesium-131 from multiple sources could have a material adverse effect on seed production and there may be a delay before we could locate alternative suppliers beyond the three currently contracted with.

We may not be able to locate additional suppliers outside of Russia, other than MURR, capable of producing the level of output of Cesium at the quality standards we require. Additional factors that could cause interruptions or delays in our source of materials include limitations on the availability of raw materials or manufacturing performance experienced by our suppliers and a breakdown in our commercial relations with one or more suppliers. Some of these

factors may be completely out of our and our suppliers' control.

Virtually all titanium tubing used in brachytherapy seed manufacture comes from a single source, Accellent Corporation. We currently obtain a key component of our seed core from another single supplier, C5 Medical Werks, LLC. We do not have formal written agreements with Accellent Corporation. We do have a purchase agreement with C5 Medical Werks, LLC which calls for fixed quantity of seed cores to be shipped over a 36 month period at a fixed unit price. Any interruption or delay in the supply of materials required to produce our product could cause harm to our business if we were unable to obtain an alternative supplier or substitute equivalent materials in a cost-effective and timely manner. To mitigate any potential interruptions, the Company continually evaluates its inventory levels and management believes that the Company maintains a sufficient quantity on hand to alleviate any potential disruptions.

While we work closely with suppliers to assure continuity of supply and maintain high quality and reliability, these efforts may not be successful. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of components. The loss or disruption of our relationships with outside vendors could subject us to substantial delays in the delivery of our product to customers. Significant delays in the delivery of our product could result in possible cancellation of orders and the loss of customers.

Due to the stringent regulations and requirements of the FDA and similar non-U.S. regulatory agencies regarding the manufacture of our product, we may not be able to quickly establish additional or replacement sources for certain components or materials. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Any casualty, natural disaster or other significant disruption of any of our suppliers' operations, or any unexpected loss of any existing exclusive supply contract could have a material adverse effect on our business.

Although we expect our suppliers to comply with our contract terms, we do not have control over these suppliers. Our inability to provide a product that meets delivery schedules could have a material adverse effect on our reputation in the industry, which could have a material adverse effect on our financial condition and results of operations.

Further, any single source suppliers or contract manufacturers may operate through a single facility. If an event occurred that resulted in material damage to this manufacturing facility or our supplier/manufacturing contractor lacked sufficient labor to fully operate the facility, we may be unable to transfer the manufacture of our product or supply of the component to another facility or location in a cost-effective or timely manner, if at all. This potential inability to transfer production could occur for a number of reasons, including but not limited to a lack of necessary relevant manufacturing capability at another facility, or the regulatory requirements of the FDA or other governmental regulatory bodies. Even if there are many qualified suppliers or contract manufacturers available around the country and our product or its components are relatively easy to manufacture, such an event could have a material adverse effect on our financial condition and results of operations.

Doctors And Hospitals May Not Adopt Our Product And Technologies At Levels Sufficient To Sustain Our Business Or To Achieve Our Desired Growth Rate. To date, we have attained very limited penetration of the total potential market for our product, particularly in non-prostate applications. Our future growth and success depends upon creating broad awareness and acceptance of our product by doctors, hospitals and freestanding clinics, as well as patients. This will require substantial marketing and educational efforts, which will be costly and may not be successful. The target customers for our product may not adopt its related technologies or may adopt them at a rate that is slower than desired. We depend extensively on long term protocol results and publications by independent physicians.

Unfavorable protocol results or publications would have an impact on the success of our product. In addition, potential customers who decide to utilize any of our devices may later choose to purchase competitors' products. Important factors that will affect our ability to attain broad market acceptance of our product include:

- doctor and/or patient awareness and acceptance of our product;
- the real or perceived effectiveness and safety of our product;
- the relationship between the cost of our product and the real or perceived medical benefits of our product;
- the relationship between the cost of our product and the financial benefits to our customers using our product, which will be greatly affected by the coverage of, and reimbursement for, our product by governmental and private third-party payors; and
- market perception of our ability to continue to grow our business and develop enhancements to our product.

We must promote our product effectively. Factors that could affect our success in marketing our product include:

- the adequacy and effectiveness of our sales force and that of any distributor's sales force;
- the adequacy and effectiveness of our production, distribution and marketing capabilities and those of our distributors;

§ the success of competing treatments or products; and

§ the availability and extent of reimbursement from third-party payors for our product.

If we fail to maintain our working relationships with health care professionals, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products, which could cause a decline in our earnings and profitability. The research, development, marketing, and sales of many of our new and improved products is dependent upon our maintaining working relationships with health care professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us as researchers, marketing and product consultants, inventors, and public speakers. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our consolidated earnings, financial condition, and/or cash flows.

If our product fails to achieve market acceptance, we may not be able to market and sell the product successfully, which would limit our ability to generate revenue and could harm our business.

We Rely On Two Russian Suppliers For Most of Our Cesium-131. In December 2015, the Company entered into an agreement with The Open Joint Stock Company <<JSC Isotope>> for the supply of Cs-131 on a fixed cost per curie basis until March 2017. In December 2016, the Company agreed to an addendum extending the expiration period to December 31, 2017. As a result, the Company relies on JSC Isotope to obtain Cesium-131 from its single Russian reactor source. Through the isotope agreement, we have obtained fixed pricing for our Russian Cesium-131 through the termination of the contract on December 31, 2017. There can be no guarantee that JSC Isotope will always be able to supply us with sufficient Cesium-131 or will renew our existing contract on favorable terms in December 2017, which could be due in part to risks associated with foreign operations and beyond either our or JSC INM's control. If we are unable to obtain supplies of isotope from Russia in the future, our overall supply of Cesium-131 could be reduced significantly. The Company has negotiated an inventory consignment agreement to process the Company's inventory of enriched barium with MedikorPharma-Ural LLC at another nuclear reactor in Russia starting in November 2017. Our source of supply of Cesium-131 from Russia is historically produced using two nuclear reactors which supply the irradiation needed for Cesium-131 production. One of the Russian nuclear reactors will be shut down from December 2017 to mid-2018, and the other Russian nuclear reactor is scheduled to be shut down for much of 2019. As a result of these upcoming shutdowns, only one of the Company's historic Russian suppliers of Cesium-131 will be available during these periods. Medikor will use the barium carbonite consigned by the Company to contract with a third-party manufacturer to produce and supply Cesium-131 to the Company. This arrangement has the effect of minimizing the impact on the Company of the planned temporary shutdown of the nuclear reactors that serve as its sources of Cesium-131 from Russia. It is anticipated that this reactor will be able to produce an equivalent volume of Cesium-131 to replace the production of INM while the reactor is shut down for maintenance from November 2017 to July 2018. While management is in the final discussions to substantially increase the supply of isotope from the MURR facility, until MURR has installed an additional hot cell in its reactor, it is not capable of supplying all of the isotope presently required by the Company on a monthly basis and even when installed, we will still depend on our Russian suppliers. Currently, the planned installation of this additional hot cell is not scheduled until the second half of fiscal 2018 and even with this new installation, there is no assurance the Company will reach

acceptable terms with MURR to increase its supply from this domestic reactor.

Increased Prices For, Or Unavailability Of, Raw Materials Used In Our Product Could Adversely Affect Our Revenues. Our revenues are affected by the prices of the raw materials and sub-assemblies used in the manufacture of our product. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel related delivery costs, competition, import duties, tariffs, currency exchange rates, and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payers, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. If the cost of key components or raw materials increases, and we are unable fully to recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials or sub-assemblies that cannot be recovered through productivity gains, price increases or other methods could adversely affect our results of operations.

We Are Subject To Uncertainties Regarding Reimbursement For Use Of Our Product. Hospitals and freestanding clinics may be less likely to purchase our product if they cannot be assured of receiving favorable reimbursement for treatments using our product from third-party payers, such as Medicare and private health insurance plans. Currently, Medicare reimburses hospitals at fixed rates that cover the cost of stranded and loose seeds. Clinics and physicians performing procedures in a free standing center are reimbursed at the actual cost of the seeds. It is expected that CMS will continue to reimburse providers using this same methodology in 2018 but there is no assurance this will occur.

Brachytherapy seeds have two CMS codes – one code for loose seeds and a second code for stranded seeds. Reimbursement amounts are reviewed and revised annually based upon information submitted to CMS on claims by providers. Changes in reimbursement can positively or negatively affect market demand for our product. We monitor these changes and provide comments, as permitted, when changes are proposed, prior to implementation.

In-patient procedures are covered by CMS and hospitals are paid based on the type of surgery and the status of the patient. These procedures are done as part of a Diagnostic Related Group or DRG system under which the hospital pays for all items involved in the care of the patient exclusive of the physician fees. Hospitals are less receptive to treatments which require out of pocket costs such as procedures we use for certain non-prostate applications. Certain of our DRG reimbursement amounts coupled with out-of-pocket costs imposed on hospitals make some of our non-prostate procedures not financially viable. We rely on our reimbursement consultant to assist us to improve the rate of reimbursement so that our product reimbursement will create greater incentives to be used. There is no assurance we will obtain the increase necessary to keep certain procedures viable and improve the margins of others.

Historically, private insurers have followed Medicare guidelines in establishing reimbursement rates. However, third-party payers are increasingly challenging the pricing of certain medical services or devices, and we cannot be sure that they will reimburse our customers at levels sufficient for us to maintain favorable sales and price levels for our product. There is no uniform policy on reimbursement among third-party payers, and we can provide no assurance that our product will continue to qualify for reimbursement from all third-party payers or that reimbursement rates will not be reduced. A reduction in or elimination of third-party reimbursement for treatments using our products would likely have a material adverse effect on our revenues.

Our success in international markets also depends upon the eligibility of our product for coverage and reimbursement through government-sponsored health care payment systems and third-party payors. Reimbursement practices vary significantly by country. Many international markets have government-managed insurance systems that control reimbursement for our new product and procedures. Other foreign markets have both private insurance systems and government-managed systems that control reimbursement for our new product and procedures. Market acceptance of our product may depend on the availability and level of coverage and reimbursement in any country within a particular time. In addition, health care cost containment efforts similar to those we face in the United States are prevalent in many of the other countries in which we intend to sell our product and these efforts are expected to continue.

Furthermore, any federal and state efforts to reform government and private healthcare insurance programs, such as those passed by the federal government in 2010, could significantly affect the purchase of healthcare services and our product in general and demand for our product in particular. Approximately 60% of men diagnosed with prostate cancer are of Medicare age (65+), providing Medicare with a significant influence in the marketplace. We are unable to predict the ultimate impact of the healthcare reform passed in 2010, those reforms that may be enacted in the future both in the United States and in other countries, whether other healthcare legislation or regulations affecting the business may be proposed or enacted in the future or what effect any such legislation or regulations would have on our business, financial condition or results of operations.

Our Operating Results Will Be Subject To Significant Fluctuations. Our quarterly revenues, expenses, and operating results are likely to fluctuate significantly in the future. Fluctuation may result from a variety of factors, which are discussed in detail throughout this “RISK FACTORS” section, including:

§ demand and pricing for the Company's product;
§ effects of aggressive competitors;
§ hospital, clinic and physician purchasing decisions;
§ research and development and manufacturing expenses;
§ patient outcomes from our product and unfavorable recommendations related to PSA testing;
§ physician acceptance of our product;
§ government or private healthcare reimbursement policies;
§ healthcare reform;
§ our manufacturing performance and capacity;
§ incidents, if any, that could cause temporary shutdown of our manufacturing facility;
§ the amount and timing of sales orders;
§ rate and success of future product approvals;
§ timing of FDA clearance, if any, of competitive product and the rate of market penetration of competing product;
§ seasonality of purchasing behavior in our market;
§ overall economic conditions;
§ the successful introduction or market penetration of alternative therapies; and
§ the outcome of the FDA's evaluation of the clearance process for class II devices.

We Are Subject To The Risk That Certain Third Parties May Mishandle Our Product. We rely on third parties, such as Federal Express, to deliver our Cesium-131 seed, and on other third parties to package our product in certain specialized packaging forms requested by customers. We are subject to the risk that these third parties may mishandle our product, which could result in adverse effects, particularly given the radioactive nature of our product.

We May Encounter Manufacturing Problems Or Delays That Could Result In Lost Revenue. Manufacturing our product is a complex process. We (or our critical suppliers) may encounter difficulties in scaling up or maintaining production of our product, including:

§ problems involving production yields;
§ quality control and assurance;
§ component supply shortages;
§ import or export restrictions on components, materials or technology;
§ shortages of qualified personnel; and
§ compliance with state, federal and foreign regulations.

If demand for our product exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace could be damaged.

Failure Of Any Clinical Studies Or Third-Party Assessments To Demonstrate Desired Outcomes In Proposed Endpoints May Reduce Physician Usage Or Result In Pricing Pressures That Could Have A Negative Impact On Business Performance. We may directly conduct or support third party clinical studies designed to test a variety of endpoints associated with product performance and use across a number of applications. If, as a result of poor design, implementation or otherwise, a clinical study conducted by us or others fails to demonstrate statistically significant results supporting performance or use benefits or comparative or cost effectiveness of our product, physicians may elect not to use our product as a treatment for conditions that may benefit from them. Furthermore, in the event of an adverse clinical study outcome, our product may not achieve “standard-of-care” designations, where they exist, for the conditions in question, which could deter the adoption of our product. Also, if serious device-related adverse events are reported during the conduct of a study it could affect continuation of the study, product approval and product adoption. If we are unable to develop a body of statistically significant evidence from our clinical study program, whether due to adverse results or the inability to complete properly designed studies, domestic and international public and private payers could refuse to cover our product, limit the manner in which they cover our product, or reduce the price they are willing to pay or reimburse for our product. In the case of a pre-approval study or a study required by a regulatory body as a condition of clearance or approval, a regulatory body can revoke, modify or deny clearance or approval of the study and/or the product in question.

Other Treatments May Be Deemed Superior To Brachytherapy. Our Cesium-131 seed may face competition not only from companies that sell other radiation therapy products, but also from companies that are developing alternative therapies for the treatment of cancers. It is possible that advances in the pharmaceutical, biomedical, or gene therapy fields could render some or all radiation therapies, whether conventional or brachytherapy, obsolete. If alternative therapies are proven or even perceived to offer treatment options that are superior to brachytherapy, physician adoption of our brachytherapy product could be negatively affected and our revenues from our brachytherapy product could decline.

Our Industry Is Intensely Competitive. The medical device industry is intensely competitive. We compete with both public and private medical device, biotechnology and pharmaceutical companies that have been in existence longer than we have, have a greater number of products on the market, have greater financial and other resources, and have other technological or competitive advantages. As physicians migrate to medical devices such as external beam radiation and robotic surgery that have a much higher capital cost to repay and higher profit margins, this puts increasing pressure on all brachytherapy products to compete regardless of their superior treatment results. The market share for brachytherapy continues to decline as a result of this pressure from increasing usage by oncologists of external beam radiation. In addition, centers that wish to offer the Cesium-131 seed must comply with licensing requirements specific to the state, province, and/or country in which they do business and these licensing requirements may take a considerable amount of time to comply with. Certain centers may choose not to offer our Cesium-131 seed due to the time required to obtain necessary license amendments. We also compete with academic institutions, government agencies, and private research organizations in the development of technologies and processes and in acquiring key personnel. Although we have patents granted and patents applied for to protect our isotope separation processes and Cesium-131 seed manufacturing technology, we cannot be certain that one or more of our competitors will not attempt to obtain patent protection that blocks or adversely affects our product development efforts. In the case of brain tumors, a surgeon will remove the tumor and radiation therapy is added following the surgery; this is known as “adjuvant” radiation therapy. The Company believes that its form of adjuvant radiation therapy deployable in such cases offers advantages over external beam methods. However, external beam holds the vast majority of the market for adjuvant radiation therapy.

Cost-Containment Efforts Of Our Customers, Purchasing Groups, Third-Party Payers And Governmental Organizations Could Adversely Affect Our Sales And Profitability. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs, combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these third-party payors. The cost containment measures that healthcare providers are instituting both in the U.S. and internationally could harm our business. Some healthcare providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our product or the price at which we can sell our product. Some healthcare providers have sought to consolidate and create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide our product has become and will continue to become more intense. This has resulted and likely will continue to result in greater pricing pressures and the exclusion of certain suppliers from important marketing segments.

Outside the United States, we expect to experience pricing pressure from centralized governmental healthcare authorities due to efforts by such authorities to lower healthcare costs. Implementation of healthcare reforms and competitive bidding contract tenders may limit the price or the level at which reimbursement is provided for our product and adversely affect both our pricing flexibility and the demand for our product. Healthcare providers may respond to such cost-containment pressures by substituting lower cost product or other therapies for our product. We may be required to engage in competitive bidding for the sale of our product to governmental purchasing agents and hospital groups. Our failure to offer acceptable prices to these customers could adversely affect our sales and profitability in these markets. Distributors of our product may also negotiate terms of sale more aggressively to increase their profitability. Failure to negotiate distribution arrangements having advantageous pricing and other terms

of sale could cause us to lose market share and would adversely affect our business, results of operations, financial condition and cash flows.

If We Fail To Comply With Applicable Healthcare Regulations, We Could Face Substantial Penalties And Our Business, Operations And Financial Condition Could Be Adversely Affected. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business, without limitation. The laws that may affect our ability to operate include, but are not limited to:

§ the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the referral of an individual for the furnishing or arranging for the furnishing of any item or service, or the purchase, lease, order, arrangement for, or recommendation of the purchase, lease, or order of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- the civil federal False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal federal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the Veterans Health Care Act of 1992 which requires manufacturers of “covered drugs” to offer them for sale to certain federal agencies, including but not limited to, the Department of Veterans Affairs, on the Federal Supply Schedule, which requires compliance with applicable federal procurement laws and regulations and subjects manufacturers to contractual remedies as well as administrative, civil and criminal sanctions;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act (ACA), and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required reporting to CMS by the 90th day following each calendar year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the Foreign Corrupt Practices Act, a U.S. law that regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals), and state law equivalents of the federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payors, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances many of

which differ from each other in significant ways, with differing effect.

The U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business. Global enforcement of anti-corruption laws has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and non-U.S. governmental agencies, and assessment of significant fines and penalties against companies and individuals. Our international suppliers create the risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors, because these parties are not always subject to our control. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, and result in a material adverse effect on our reputation, results of operations, financial condition, and cash flows.

Governmental regulations outside the U.S. have become increasingly stringent and more common, and we may become subject to more rigorous regulation by governmental authorities in the future. In the European Union, for example, a new Medical Device Regulation was published in 2017 which, when it enters into full force, will impose significant additional premarket and post-market requirements. Penalties for a company's non-compliance with governmental regulation could be severe, including fines and revocation or suspension of a company's business license, mandatory price reductions and criminal sanctions. Any governmental law or regulation imposed in the future may have a material adverse effect on us.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota, requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a company may inadvertently run afoul of one or more laws.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we, our distributors or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare, Medicaid and other government programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully or clearly interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Healthcare Reform Measures Could Hinder Our Product's Commercial Success. In both the United States and certain foreign jurisdictions there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our product profitably. In the United States, the Patient Protection and Affordable Care Act (the "ACA") and the Health Care and Education Affordability Reconciliation Act of 2010 (together "the law" or "the legislation") provide for a number of healthcare policy changes that are or will be applicable to us. However, there are many programs and requirements under the law for which the consequences are not fully understood, and it is unclear what the full impacts will ultimately be from the law. The legislation provides for significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales that commenced in January 2013 which would apply to all of our product sales. Although the excise tax has been suspended by Congress until the end of 2017, its status is unclear for 2018 and subsequent years. Under the legislation, the total cost to the medical device industry is expected to be approximately $20 billion over 10 years. The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing

costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending.

Currently, the U.S. Congress is considering legislation to repeal and replace the ACA. We cannot predict whether the ACA will be repealed, replaced, or modified or how such repeal, replacement or modification may be timed or structured. As a result, we cannot quantify or predict the effect of such repeal, replacement, or modification might have on our business and results of operations. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to make and implement healthcare reforms may adversely affect:

§ our ability to set a price we believe is fair for our product;
§ our ability to generate revenues and achieve or maintain profitability;
§ the availability of capital; and
§ our ability to obtain timely approval of any future product modifications.

CMS has published final regulations that implement provisions in ACA related to disclosure of payments made by manufacturers to physicians and teaching hospitals, effective April 2013. Because we manufacture devices that are covered by the regulations, all payments that we make to physicians and teaching hospitals are subject to this reporting requirement even if the payment relates to a device that is not considered a covered device. The tracking and reporting of these payments could have an adverse impact on our business and/or consolidated results of operations and financial condition and on our relationships with customers and potential customers.

We May Be Unable To Adequately Protect Or Enforce Our Intellectual Property Rights Or Secure Rights To Third-Party Patents. Our ability and the abilities of our distributors to obtain and maintain patent and other protection for our product will affect our success. We are assigned, have rights to, or have exclusive licenses to patents and patents pending in the U.S. and numerous foreign countries. The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions. Our patent rights may not be upheld in a court of law if challenged. Our patent rights may not provide competitive advantages for our product and may be challenged, infringed upon or circumvented by our competitors. We cannot patent our product in all countries or afford to litigate every potential violation worldwide.

Because of the large number of patent filings in the medical device and biotechnology field, our competitors may have filed applications or been issued patents and may obtain additional patents and proprietary rights relating to our product or processes competitive with or similar to ours. We cannot be certain that U.S. or foreign patents do not exist or will not be issued that would harm our ability to commercialize our product and future product candidates.

Pending And Future Patent Litigation Could Be Costly And Disruptive And May Have An Adverse Effect On Our Financial Condition And Results Of Operations. We operate in an industry characterized by extensive patent litigation. Potential patent claims include challenges to the coverage and validity of the Company's patents on our product or processes as well as allegations that the Company's product infringes patents held by competitors or other third parties. A loss in any of these types of cases could result in a loss of patent protection or the ability to market our product, which could lead to a significant loss of sales, or otherwise materially affect future results of operations.

The Company's commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Intellectual property litigation is expensive and complex and outcomes are difficult to predict. Any pending or future patent litigation may result in significant damage awards, including treble damages under certain circumstances, and injunctions that could prevent the manufacture and sale of an affected product or force us to make significant royalty payments in order to continue selling the affected product. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. As a healthcare supplier, we can expect to face claims of patent infringement in the future. A successful claim of patent or other intellectual property infringement against us could adversely affect our results of operations and financial condition.

The Value Of Our Granted Patents, and Our Patents Pending, Is Uncertain. Although our management strongly believes that our patent on the process for producing Cesium-131, our patents on additional methods for producing Cesium-131 and other isotopes, our patent on the manufacture of the brachytherapy seed, and anticipated future patent applications, which have not yet been filed, have significant value, we cannot be certain that other like-kind processes may not exist or be discovered, that any of these patents is enforceable, or that any of our patent applications will result in issued patents.

Failure To Comply With Government Regulations Could Harm Our Business. As a medical device and medical isotope manufacturer, we are subject to extensive, complex, costly, and evolving governmental rules, regulations and restrictions administered by the FDA, the FAA and other federal and state agencies, and by governmental authorities in other countries. Compliance with these laws and regulations is expensive and time-consuming, and changes to or failure to comply with these laws and regulations, or adoption of new laws and regulations, could adversely affect our business.

In the United States, as a manufacturer of medical devices and devices utilizing radioactive by-product material, we are subject to extensive regulation by federal, state, and local governmental authorities, such as the FDA and the Washington State Department of Health, to ensure such devices are safe and effective. Regulations promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act, govern the design, development, testing, manufacturing, packaging, labeling, distribution, marketing and sale, post-market surveillance, repairs, replacements, and recalls of medical devices.

The FAA has authority to regulate, through its Office of Hazardous Materials Safety, the offering for shipment of hazardous materials, including radioactive materials of the type marketed by the Company. Because we ship hazardous materials on flights in the U.S., the Company is subject to these regulations, including periodic audit and, if applicable, enforcement action by the FAA. As they apply to the Company, the FAA regulations concern the packaging and labeling of hazardous materials. If we fail to comply with these regulations, the Company could face civil or criminal penalties. In Washington State, the Department of Health, by agreement with the federal Nuclear Regulatory Commission (NRC), regulates the possession, use, and disposal of radioactive byproduct material as well as the manufacture of radioactive sealed sources to ensure compliance with state and federal laws and regulations. Our Cesium-131 brachytherapy seeds and constitute medical devices and radioactive sealed sources and are subject to these regulations.

Under the FDC Act, medical devices are classified into three different categories, over which the FDA applies increasing levels of regulation: Class I, Class II, and Class III. Our Proxcelan® Cesium-131 seed has been classified as a Class II device and has received clearance from the FDA through the 510(k) pre-market notification process. Any modifications to the device that would significantly affect safety or effectiveness, or constitute a major change in intended use, would require a new 510(k) submission. As with any submittal to the FDA, there is no assurance that a 510(k) clearance would be granted to the Company.

The FDA has been considering legislative, regulatory and/or administrative changes to the FDA’s 510(k) program. Various committees of the U.S. Congress have also indicated that they may consider investigating the FDA’s 510(k) process. Under the current 510(k) rules, certain types of medical devices can obtain FDA approval without lengthy and expensive clinical trials. We have received FDA approval under the 510(k) rules for our product as sold in various formats. Our R&D programs and new product programs contemplate obtaining any required FDA approvals under the current 510(k) rules. Any changes to the current 510(k) or related FDA rules that make such rules more stringent or require more clinical data can significantly increase the time and costs associated with bringing new product formats or product modifications to market. This may have a material adverse effect on our business, financial condition and results of operations.

In addition to FDA-required market clearances and approvals for our product formats, our manufacturing operations are required to comply with the FDA's Quality System Regulation (QSR), which addresses requirements for a company’s quality program such as management responsibility, good manufacturing practices, product and process design controls, and quality controls used in manufacturing. Compliance with applicable regulatory requirements is monitored through periodic inspections by the FDA Office of Regulatory Affairs (ORA). We anticipate both announced and unannounced inspections by the FDA. Such inspections could result in non-compliance reports (Form 483) which, if not adequately responded to, could lead to enforcement actions. The FDA can institute a wide variety of enforcement actions ranging from public warning letters to more severe sanctions such as fines; injunctions; civil penalties; recall of our product; operating restrictions; suspension of production; non-approval or withdrawal of pre-market clearances for new products or existing products and criminal prosecution. There can be no assurance that we will not incur significant costs to comply with these regulations in the future or that the regulations will not have a material adverse effect on our business, financial condition and results of operations.

In addition to the ACA, various healthcare reform proposals have also emerged at the state level. Like the ACA, these proposals could reduce medical procedure volumes and impact the demand for our product or the prices at which we sell our product. The impact of these proposals could have a material adverse effect on our business and/or consolidated results of operations and financial condition.

The automatic spending cuts of nearly $1 trillion over the next 10 years that were included under the Budget Control Act of 2011, including up to a 2% cut to Medicare providers and suppliers, took effect in 2013. Medicaid is exempt from these cuts. Any cuts to Medicare reimbursement which affect our product could have a material adverse effect on our business and/or our consolidated results of operations and financial condition.

The marketing of our product in foreign countries will, in general, be regulated by foreign governmental agencies similar to the FDA. Foreign regulatory requirements vary from country to country. The time and cost required to obtain regulatory approvals could be longer than that required for FDA clearance in the United States and the requirements for licensing a product in another country may differ significantly from FDA requirements. We will rely, in part, on foreign distributors to assist us in complying with foreign regulatory requirements. We may not be able to obtain these approvals without incurring significant expenses or at all, and the failure to obtain these approvals would prevent us from selling our product in the applicable countries. This could limit our sales and growth.

Quality Problems With Our Product Could Harm Our Reputation For Producing A High-Quality Product And Erode Our Competitive Advantage, Sales, And Market Share. Quality is extremely important to us and our customers due to the serious and costly consequences of product failure, which can include patient harm. Our operating results depend in part on our ability to sustain an effective quality control system and effectively train and manage our employee base with respect to our quality system. Our quality system plays an essential role in determining and meeting customer requirements, preventing defects and improving our product. While we have a network of quality systems throughout our business lines and facilities, quality and safety issues may occur with respect to any of our product formats. A quality or safety issue may result in a public warning letter from the FDA, product recalls or seizures, monetary sanctions, injunctions to halt manufacturing and distribution of products, civil or criminal sanctions, refusal of a government to grant clearances or approvals or delays in granting such clearances or approvals, import detentions of any future products made outside the United States, restrictions on operations or withdrawal or suspension of existing approvals. Negative publicity regarding a quality issue could damage our reputation, cause us to lose customers, or decrease demand for our product and product formats. Any of the foregoing events could disrupt our business and have an adverse effect on our results of operations and financial condition.

Our Business Exposes Us To Product Liability Claims. Our design, testing, development, manufacture, and marketing of our product involve an inherent risk of exposure to product liability claims and related adverse publicity. Our brachytherapy seed product delivers a highly concentrated and confined dose of radiation directly to the organ in which it is implanted from within the patient's body. Surrounding tissues and organs are typically spared excessive radiation exposure. It is an inherent risk of the industries in which we operate that we might be sued in a situation where our product results in, or is alleged to result in, a personal injury to a patient, health care provider, or other user. Although we believe that as of the date of this Annual Report, we have adequate insurance to address anticipated potential liabilities associated with product liability, any unforeseen product liability exposure in excess of, or outside the scope of, such insurance coverage could adversely affect our financial condition and operating results. Any such claim brought against us, with or without merit, could result in significant damage to our business. Insurance coverage is expensive and difficult to obtain, and, although we currently have a five million dollar policy, in the future we may be unable to obtain or renew coverage on acceptable terms, if at all. If we are unable to obtain or renew sufficient insurance at an acceptable cost or if a successful product liability claim is made against us, whether fully covered by insurance or not, our business could be harmed. The FDA's medical device reporting regulations require us to report any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction reoccurred. Any required filing could result in an investigation of our product and possibly subsequent regulatory action against us if it is found that one of our products caused the death or serious injury of a patient.

Our Business Involves Environmental Risks. Our business involves the controlled use of hazardous materials, chemicals, biologics, and radioactive compounds. Manufacturing is extremely susceptible to product loss due to radioactive, microbial, or viral contamination; material or equipment failure; vendor or operator error; or due to the very nature of the product's short half-life. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of accidental contamination or injury. In addition, radioactive, microbial, or viral contamination may cause the closure of the manufacturing facility for an extended period of time. By law, radioactive materials may only be disposed of at state-approved facilities. At our leased facility we use commercial disposal contractors. Subject to obtaining financing, we are in the planning process of shutting down our leased manufacturing and office facility, planning the construction of a new manufacturing and office facility to be owned by the Company on an adjacent property and moving to the new manufacturing facility. Assuming it is constructed and licensed, we will incur costs related to the clean-up and disposal of hazardous materials, chemicals and radioactive components of the leased facility. While management believes it has reserved a sufficient amount of funds for this process, the Company may need more than the amount of the asset retirement obligation to meet the lease requirements and to receive clearance from the Washington State Department of Health. We may incur substantial costs related to the disposal of these materials. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages, and penalties that could harm our business.

In addition, certain environmental laws assess liability on current or previous owners or operators of real property for the costs of investigation, removal or remediation of hazardous substances or materials at their properties or at properties which they have disposed of hazardous substances. Liability for investigative, removal and remedial costs under certain U.S. federal and state laws are retroactive, strict and joint and several. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. The ultimate cost of site cleanup and timing of future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup, the interpretation of applicable laws and regulations, and alternative cleanup methods.

We Rely Upon Key Personnel. Our success will depend, to a great extent, upon the experience, abilities and continued services of our executive officers, sales staff and key scientific personnel. If we lose the services of several officers, sales personnel, or key scientific personnel, our business could be harmed. Our success also will depend upon our ability to attract and retain other highly qualified scientific, managerial, sales, and manufacturing personnel and their ability to develop and maintain relationships with key individuals in the industry. Competition for these personnel and relationships is intense and we compete with numerous pharmaceutical and biotechnology companies as well as with universities and non-profit research organizations. We are highly dependent on our direct sales organization who promote and support our brachytherapy product. There is intense competition for skilled sales and marketing employees, particularly for people who have experience in the radiation oncology market. Accordingly, we could find it difficult to hire or retain skilled individuals to sell our product. Failure to retain our direct sales force could adversely affect our growth and our ability to meet our revenue goals. There can be no assurance that our direct sales and marketing efforts will be successful. If we are not successful in our direct sales and marketing, our sales revenue and results of operations are likely to be materially adversely affected. We may not be able to continue to attract and retain qualified personnel.

Our Ability To Operate In Foreign Markets Is Uncertain. Our future growth will depend in part on our ability and the ability of our distributors to establish, grow and maintain product sales in foreign markets, particularly in the European Union (EU). However, we have limited experience in marketing and distributing our product in other countries. Foreign operations subject us to additional risks and uncertainties, including our customers' ability to obtain reimbursement for procedures using our product in foreign markets; the burden of complying with complex and changing foreign regulatory requirements; time-sensitive delivery requirements due to the short half-life of our product; language barriers and other difficulties in providing long-distance customer service; potentially increased time to collect accounts receivable; significant currency fluctuations, which could cause third-party distributors to reduce the amount of our product they purchase from us because the cost of our product to them could fluctuate relative to the price they can charge their customers; reduced protection of intellectual property rights in some foreign countries; and the possibility that contractual provisions governed by foreign laws would be interpreted differently than intended in the event of a contract dispute. In addition, the significant appreciation of the U.S. dollar during the past year has made our product much more expensive in overseas markets. Any future foreign sales of our product could also be adversely affected by export license requirements, the imposition of governmental controls, political and economic instability, trade restrictions, changes in tariffs, and difficulties in staffing and managing foreign operations. Many of these factors may also affect our ability to import Cesium-131 from Russia under our contract with JSC INM. Sanctions placed on financial transactions with Russian banking institutions may interfere with the Company's ability to transact business in Russia on a temporary or other basis resulting in an interruption of the Cs-131 supply which could have a temporary material adverse effect on the Company's business, operating results and financial condition.

Our Ability To Expand Operations And Manage Growth Is Uncertain. Our efforts to expand our operations will result in new and increased responsibilities for management personnel and will place a strain upon the entire company. To compete effectively and to accommodate growth, if any, we may be required to continue to implement and to improve our management, manufacturing, sales and marketing, operating and financial systems, procedures and controls on a timely basis and to expand, train, motivate and manage our employees. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to support our future operations. If the Cesium-131 seed were to rapidly become the "seed of choice," it is unlikely that we could immediately meet demand. This could cause customer

discontent and invite competition. There can be no assurance that our personnel, systems, procedures, and controls will be adequate to immediately react to that growth.

We Rely On The Performance Of Our Information Technology Systems And Those of Third Parties, The Failure Of Which Could Have An Adverse Effect On Our Business And Performance. Our business requires the continued operation of sophisticated information technology systems and network infrastructure. These systems are vulnerable to interruption by fire, power loss, system malfunction, computer viruses, cyber-attacks and other events, which may be beyond our control. Systems interruptions could reduce our ability to accept customer orders, manufacture our product, or provide service for our customers, and could have an adverse effect on our operations and financial performance. The level of protection and disaster-recovery capability varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be totally effective. In addition, security breaches of our information technology systems could result in the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, partners, customers, or our suppliers, which may result in significant costs and potential government sanctions. In particular, if we are unable to adequately safeguard individually identifiable health information, we may be subject to additional liability under domestic and international laws respecting the privacy and security of health information.

We also rely on third party vendors to supply and/or support certain aspects of our information technology systems. Third party systems may contain defects in design or manufacture or other problems that could result in system disruption or unexpectedly compromise the information security of our own systems, and we are dependent on these third parties to provide reliable systems and software and to deploy appropriate security programs to protect their systems.

If we are unable to maintain reliable information technology systems and prevent disruptions, outages, or data breaches, we may suffer regulatory consequences in addition to business consequences. We have programs to ensure compliance with such laws and regulations. However, there is no guarantee that we will avoid enforcement actions by governmental bodies. Enforcement actions may be costly and interrupt regular operations of our business. In addition, there has been a developing trend of civil lawsuits and class actions relating to breaches of consumer data held by large companies or incidents arising from other cyberattacks.

Our information technology systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving legal and regulatory standards, the increasing need to protect patient and customer information, and the information technology needs associated with our changing products and services. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future. Any significant breakdown, intrusion, interruption, corruption, or destruction of these systems, as well as any data breaches, could have a material adverse effect on our business. If our information technology systems, products or services or sensitive data are compromised, patients or employees could be exposed to financial or medical identity theft, and we could lose existing customers, have difficulty attracting new customers, have difficulty preventing, detecting, and controlling fraud, be exposed to the loss or misuse of confidential information, have disputes with customers, physicians, and other health care professionals, suffer regulatory sanctions or penalties under federal laws,

state laws, or the laws of other jurisdictions, experience increases in operating expenses or an impairment in our ability to conduct our operations, incur expenses or lose revenues as a result of a data privacy breach, product failure, information technology outages or disruptions, or suffer other adverse consequences including lawsuits or other legal action and damage to our reputation.

Fluctuations In Insurance Cost And Availability Could Adversely Affect Our Profitability Or Our Risk Management Profile. We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

We Have Incurred Significant Losses To Date, And There Is No Guarantee That We Will Ever Become Profitable. We incurred net losses of $6,161,798 and $4,710,808 in the fiscal years ended 2017 and 2016, respectively. In addition, we have accumulated deficit from the inception of business through June 30, 2017 of $72,604,106. The costs for research and product development of our product formats along with marketing and selling expenses and general and administrative expenses have been the principal causes of our losses. We may not ever become profitable.

We May Need Additional Capital In The Future To Maintain Our NYSE MKT Listing And For Acquisitions And Expansion Into Other Markets. Our Common Stock is currently listed on the NYSE MKT stock exchange which will consider delisting a company's securities if, among other things, the company fails to maintain minimum stockholder's equity. With our existing cash reserves we believe we will not be able to maintain our listing on the NYSE MKT unless we raise capital in the next nine to 12 months assuming we maintain our projected budgeted expenses and contemplated level of revenues. In the event that our common stock is delisted from the NYSE MKT, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock. We may also need to raise capital for strategic acquisitions or expansion into other markets and there is no assurance management will not pursue this additional capital if available.

Risks Related to Our Stock and Reporting Requirements

Our Reporting Obligations As A Public Company Are Costly. Reporting requirements of a public company change depending on the reporting classification in which the Company falls as of the end of its second quarter of each fiscal year. The Company is currently a "smaller reporting company" which falls in the non-accelerated filer category of filer with a public float less than $75 million. If the Company were to be reclassified to the category of "accelerated filer," the Company would have the additional requirement and cost of a Section 404 audit as part of its Form 10-K filing, as well as other expenses making the public reporting process more costly.

Our Stock Price Is Likely To Be Volatile. The market price of our common stock has experienced fluctuations and is likely to fluctuate significantly in the future. For example, during fiscal 2017 the closing price of one share of our common stock reached a high of $0.87 and a low of $0.51. There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage medical product companies. Contributing to this volatility are various events that can affect our stock price in a positive or negative manner. These events include, but are not limited to: governmental approvals or refusals to approve of regulations or actions; market acceptance and sales growth of our product; litigation involving the Company or our industry; developments or disputes concerning our patents or other proprietary rights; changes in the structure of healthcare payment systems; departure of key personnel; future sales of our securities; fluctuations in our financial results or those of companies that are perceived to be similar to us; swings in seasonal demands of purchasers; investors' general perception of us; and general economic, industry and market conditions. In addition, the securities of many medical device companies, including us, have historically been subject to extensive price and volume fluctuations that may affect the market price of their common stock. If any of these events occur, it could cause our stock price to fall.

The Price Of Our Common Stock May Be Adversely Affected By The Future Issuance And Sale Of Shares Of Our Common Stock Or Other Equity Securities. We cannot predict the size of future issuances or sales of our common stock or other equity securities for future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock.

We Do Not Expect To Pay Any Dividends For The Foreseeable Future. We do not anticipate paying any dividends to our shareholders for the foreseeable future except for dividends on the Series B Preferred Stock, which we intend to pay on or before December 31, 2017. Shareholders must be prepared to rely on sales of their common stock after price appreciation to earn an investment return, which may never occur. Any determination to pay dividends in the future will be made at the discretion of our Board of Directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable laws and other factors that our Board deems relevant.

Certain Provisions of Minnesota Law and Our Charter Documents Have An Anti-Takeover Effect. There exist certain mechanisms under Minnesota law and our charter documents that may delay, defer or prevent a change of control. Anti-takeover provisions of our articles of incorporation, bylaws and Minnesota law could diminish the opportunity for shareholders to participate in acquisition proposals at a price above the then-current market price of our common stock. For example, while we have no present plans to issue any preferred stock, our Board of Directors, without further shareholder approval, may issue shares of undesignated preferred stock and fix the powers, preferences, rights and limitations of such class or series, which could adversely affect the voting power of the common shares. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our Board of Directors that could have the effect of delaying, deterring or preventing a change in control. Further, as a Minnesota corporation, we are subject to provisions of the Minnesota Business Corporation Act (MBCA) regarding "business combinations," which can deter attempted takeovers in certain situations. Pursuant to the terms of a shareholder rights plan adopted in February 2007 and renewed in February 2017, each outstanding share of common stock has one attached right. The

rights will cause substantial dilution of the ownership of a person or group that attempts to acquire the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. The effect of these anti-takeover provisions may be to deter business combination transactions not approved by our Board of Directors, including acquisitions that may offer a premium over the market price to some or all shareholders. We may, in the future, consider adopting additional anti-takeover measures. The authority of our Board to issue undesignated preferred or other capital stock and the anti-takeover provisions of the MBCA, as well as other current and any future anti-takeover measures adopted by us, may, in certain circumstances, delay, deter or prevent takeover attempts and other changes in control of the Company not approved by our Board of Directors.

ITEM 1B – UNRESOLVED STAFF COMMENTS

We have no unresolved written comments from the SEC staff regarding our filings under the Exchange Act.

ITEM 2 – PROPERTIES

The Company's executive offices are located at 350 Hills Street, Suite 106, Richland, WA 99354, where it leases approximately 15,300 square feet of office and laboratory space for approximately $23,200 per month plus janitorial expenses of approximately $440 per month from Energy Northwest, the owner of the Applied Process Engineering Laboratory (the APEL facility). The Company is not affiliated with this lessor. The monthly rent is subject to annual increases based on the Consumer Price Index. The current lease was entered into May 2, 2007, and, as extended, expires on April 30, 2021.

The Company executed a modification to the existing lease in October 2015 that stipulates the tenant improvements, machinery, equipment and fixtures (TIs) are permitted to be abandoned at lease termination provided the facility is released by the Washington Department of Health. The modification also reduces the required notice to terminate early from twelve months to six months. Subject to obtaining acceptable debt financing, this lease modification provides the flexibility to consider in the future a newly designed production facility on adjacent property described below which management believes will reduce operational cashflow requirements and provide for long-term security of production capabilities for the Company.

In the spring of 2017, the Company purchased an adjacent property of approximately 4.2 acres in anticipation of constructing a facility to meet its requirements for production, laboratory, and administrative offices. The new facility is anticipated to be a similar size to the current facility but the final design is dependent on anticipated future requirements. The property also provides for additional future building(s) as needed or subdivision, if required and is located within the Technology and Business Campus of the Port of Benton. While the Company has completed the design of the facility as of the date of this Report, the construction of the facility is subject to acceptable financing and other unanticipated factors which may influence such an operational decision.

The Company's management believes that the facilities currently occupied by the Company are adequate for present requirements, and that the Company's current equipment is in good condition and is suitable for the operations involved.

ITEM 3 – LEGAL PROCEEDINGS

The Company may, in the ordinary course of business, be subject to various legal proceedings. We provide the following information concerning those legal proceedings, including the name of the lawsuit, the court in which the lawsuit is pending, and the date on which the petition commencing the lawsuit was filed.

Class Action Lawsuit Related to Press Release

In Re IsoRay, Inc. Securities Litigation; U.S. District Court for the Eastern District of Washington, filed October 16, 2015.

On May 22, 2015, the first of three lawsuits was filed against IsoRay, Inc. and two of its officers – Dwight Babcock (the Company's retired CEO) and Brien Ragle (former CFO who was later dismissed from the lawsuits) – related to a press release on May 20, 2015 regarding a May 19 online publication of the peer-reviewed article in the journal Brachytherapy titled "*Analysis of Stereotactic Radiation vs. Wedge Resection vs. Wedge Resection Plus Cesium-131 Brachytherapy in Early-Stage Lung Cancer*" by Dr. Bhupesh Parashar, et al. The lawsuits were class actions alleging violations of the federal securities laws. By Order dated August 17, 2015, the three lawsuits were consolidated into one case – In re IsoRay, Inc. Securities Litigation; Case No. 4:15-cv-05046-LRS, in the U.S. District Court for the Eastern District of Washington.

As IsoRay previously disclosed, on March 9, 2017, the parties settled this matter and the court entered an order and final judgment that (i) dismissed with prejudice and released the claims asserted in the complaint against the defendants, including IsoRay, and (ii) approved the payment of the $3,537,500 settlement fund (paid by IsoRay's insurers), minus the payment of attorneys' fees and costs to plaintiff's counsel, to members of the settlement class. This lawsuit is now concluded.

Derivative Complaint related to Shareholder Value

On September 29, 2016, David M. Kitley, purportedly on behalf of IsoRay, filed a derivative lawsuit in the United States District Court for the District of Minnesota under the case caption Kitley v. IsoRay, Inc., Case No. 0:16-cv-03297-DTS. The complaint named as defendants current and former IsoRay directors Dwight Babcock, Thomas LaVoy, Philip J. Vitale and Michael W. McCormick, alleging that they violated their fiduciary duties to IsoRay in connection with a press release allegedly containing false and misleading statements concerning the results from a peer reviewed study of its Cesium-131 isotope seeds for the treatment of non-small cell lung cancers, thereby artificially inflating the price of IsoRay stock. The complaint sought unspecified damages, in an amount not presently determinable, among other forms of relief.

On November 17, 2016, IsoRay moved to dismiss the complaint, arguing that plaintiff was not entitled to pursue his derivative claims due to his failure to serve a pre-suit demand on IsoRay's board. Rather than respond to the motion to dismiss, plaintiff filed an amended complaint on January 23, 2017. The amended complaint alleges the same derivative claims as the original, and adds IsoRay director Alan Hoffmann as a defendant. Plaintiff seeks an award of damages and an order directing IsoRay to undertake reforms of its corporate governance and internal procedures. IsoRay moved to dismiss the amended complaint on March 9, 2017. Plaintiff responded on April 20, 2017, and IsoRay replied on May 17, 2017. The court heard oral argument on the motion on August 22, 2017, and took the matter under advisement at that time. As of the date of this Form 10-K, an order on the motion has not been filed.

Class Action Lawsuit re Equity Plans

On January 31, 2017, a putative class action complaint was filed against IsoRay and certain current and former directors in the Superior Court of the State of Washington in and for Benton County under the case caption Griffith v. IsoRay, Inc., Case No. 17-2-00194-2. The complaint alleged that IsoRay's board permitted certain employee compensation plans to be implemented without receiving the requisite percentage of votes by IsoRay shareholders. On May 16, 2017, the parties executed a settlement for $195,000 of the individual Plaintiffs' claims. The action was dismissed on July 10, 2017.

ITEM 4 –MINE SAFETY DISCLOSURES

Not applicable

PART II

ITEM 5 – MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The Company's common stock is listed on the NYSE MKT under the symbol "ISR" and as of September 25, 2017 there were 55,017,419 shares outstanding.

The high and low sale prices as reported on the NYSE MKT for each quarter during the last two fiscal years are as follows:

Fiscal 2017	Q1	Q2	Q3	Q4
High	$0.87	$0.72	$0.69	$0.63
Low	$0.70	$0.54	$0.52	$0.51

Fiscal 2016	Q1	Q2	Q3	Q4
High	$1.68	$1.65	$0.99	$1.30
Low	$1.32	$0.86	$0.55	$0.75

Holders

As of September 25, 2017, there were approximately 230 common stockholders of record. The number of common stockholders was determined from the records of our stock transfer agent and does not reflect persons or entities that

hold their shares in nominee or “street” name through various brokerage firms.

Dividends

The Company has never paid cash dividends on its common stock and does not plan to pay cash dividends on its common stock in the foreseeable future. Our Board of Directors anticipates that any earnings that might be available to pay dividends will be retained to finance operations.

Securities Authorized for Issuance Under Equity Compensation Plans

On May 27, 2005, the Company adopted the 2005 Stock Option Plan (the Option Plan) and the 2005 Employee Stock Option Plan (the 2005 Employee Plan). The Option Plan and the 2005 Employee Plan terminated on May 27, 2015 and no further options may be granted under either Plan. On August 15, 2006, the Company adopted the 2006 Director Stock Option Plan (the Director Plan) pursuant to which it may grant equity awards to eligible persons. The 2006 Director Stock Plan terminated on August 15, 2016 and no further options may be granted under the plan. On May 15, 2014, the Company adopted the 2014 Employee Stock Option Plan (the 2014 Employee Plan) pursuant to which it may grant equity awards to eligible persons. The 2014 Employee Plan allowed the Board of Directors to grant options to purchase up to 2,000,000 shares of common stock to officers and key employees of the Company. On April 19, 2016, the Company approved a 2016 Equity Plan. The 2016 Equity Incentive Plan allowed the Board of Directors to grant up to 4,000,000 shares of common stock to directors, officers, employees and consultants in a combination of equity incentive forms including incentive stock options (ISO), non-qualified stock options (NQSO), stock appreciation rights (SAR) and restricted shares (RSU) of common stock. Options granted under all 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 (based on the trading price on the NYSE MKT) on the date of the grant, and with varying vesting periods as determined by the Board. The Board cancelled the 2016 Plan on May 4, 2017. As a result of the Special Shareholder meeting held June 15, 2017, the 2014 Employee Stock Option Plan was terminated and all options granted under the 2014 Plan voided and revoked. On June 15, 2017, the Shareholders approved the 2017 Equity Incentive Plan (2017 Incentive Plan). The 2017 Incentive Plan allows the Board of Directors to grant up to 4,000,000 shares of common stock to directors, officers, employees and consultants in a combination of equity incentive forms including incentive stock options (ISO), non-qualified stock options (NQSO), stock appreciation right (SAR) or restricted shares (RSU) of common stock. Options granted under all 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 (based on the trading price on the NYSE MKT) on the date of the grant, and with varying vesting periods as determined by the Board.

As of June 30, 2017 the following options had been granted under the option plans.

Plan Category	**Number of securities to be issued on exercise of outstanding options, warrants, and rights (a)**	**Weighted-average exercise price of outstanding options, warrants, and rights (b)**	**Number of securities remaining available for future issuance under equity compensation Plans (excluding securities in columns (a) and (b)**
Equity compensation plans approved by shareholders	2,105,000	$ 0.61	1,895,000

Equity compensation plans not approved by shareholders	1,729,559	$ 1.48	158,334
Total	3,834,559	$ 1.27	2,053,334

Performance Graph

As a smaller reporting company, the Company is not required to provide a performance graph.

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6 – SELECTED FINANCIAL DATA

As a smaller reporting company, the Company is not required to provide Item 6 disclosure in this Annual Report.

ITEM 7 – MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

Management's 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 the related disclosure of contingent liabilities. On an on-going basis, management evaluates past estimates and judgments, including those related to bad debts, inventories, accrued liabilities, derivative 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 Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

Revenue Recognition

Revenue is generally realized or realizable and earned when there is persuasive evidence an arrangement exists, delivery has occurred or services rendered, the price is fixed and determinable, and collection is reasonably assured. The Company records revenue from its product sales when the price is fixed and determinable at the date of sale, title and risk of ownership have been transferred to the customer, and returns can be reasonably estimated.

Stock-Based Compensation

The Company measures and recognizes expense for all share-based payments at fair value. The Company uses the Black-Scholes option valuation model to estimate fair value for all stock options on the date of grant. 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.

Research and Development Costs

Research and development costs, including salaries, benefits, and share-based compensation, research materials, facility overhead, lab supplies, depreciation, administrative expenses and contractor fees, are charged to operations as incurred.

Legal Contingencies

The Company may, in the ordinary course of business, be involved in legal proceedings involving securities, contractual and employment relationships, product liability claims, patent rights, environmental matters, and a variety of other matters, the outcomes of which are not within the Company's complete control and may not be known for extended periods of time. Legal costs associated with defending these matters are expensed as incurred.

The Company records a liability in its consolidated financial statements for damages and/or costs related to claims, settlements, and judgments where the Company has assessed that the loss is probable and an amount can be reasonably estimated. Legal proceedings are discussed in Note 15 of our Consolidated Financial Statements, which is incorporated by reference in Part III, Item 15. We refer you to that discussion for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought.

We provide the following additional information concerning those legal proceedings, including the name of the lawsuit, the court in which the lawsuit is pending, and the date on which the petition commencing the lawsuit was filed.

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Results of Operations

Financial presentation

The following sets forth a discussion and analysis of the Company's financial condition and results of operations for the fiscal years 2017, 2016 and 2015. This discussion and analysis should be read in conjunction with our consolidated financial statements appearing elsewhere in this Report. The following discussion contains forward-looking statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Item 1A — Risk Factors," beginning on page 23 of this Report. (In thousands)

	2017	% of Rev	2016	% of Rev	% of Change	2015	% of Rev	% of Change
Product sales, net	$4,761	100 %	$4,769	100 %	0 %	$4,606	100 %	4 %
Cost of Product sales	3,923	82 %	4,640	97 %	-15 %	4,439	96 %	5 %
Gross profit (loss)	838	18 %	129	3 %	550 %	167	4 %	-23 %
Operating expenses:								
Research and development	771	16 %	528	11 %	46 %	615	13 %	-14 %
Collaboration arrangement, net of reimbursement	194	4 %	-			-		
Sales and marketing	2,310	49 %	1,353	23 %	71 %	1,488	32 %	-9 %
General and administrative	3,918	82 %	3,786	79 %	4 %	2,401	52 %	53 %
Change in estimate of asset retirement obligation (Note 9)	(48)	-1 %	(456)	-10 %		-	0 %	
Total operating expenses	7,145	150 %	5,211	109 %	37 %	4,504	98 %	16 %
Operating loss	(6,307)	-132%	(5,082)	-107%	24 %	(4,337)	-94 %	17 %

Product sales

Fiscal 2017 product sales, net remained flat compared to fiscal 2016. Flat sales are attributed to the transition in our sales and marketing team during the second half of fiscal 2016 and continuing into early fiscal 2017 as well as revamping our entire marketing strategy with a renewed focus on marketing.

Fiscal 2016 product sales, net increased 4% compared to fiscal 2015. Increased use of Cs-131 brachytherapy seeds treating prostate, brain, head-neck and gynecological cancers attributed to the increase in product sales, net during a year when GliaSite® RTS sales decreased and the product line was discontinued on March 31, 2016. (In thousands)

Treatment	2017	% of Rev	2016	% of Rev	% of Change	2015	% of Rev	% of Change
Prostate Brachytherapy	$4,173	88 %	$4,094	86 %	2 %	$3,993	87 %	3 %
Other Brachytherapy	588	12 %	658	14 %	-11 %	502	11 %	31 %
GliaSite® RTS	-	0 %	17	0 %	-100 %	111	2 %	-85 %
	$4,761		$4,769		4 %	$4,606		4 %

Prostate Brachytherapy.

Modest sales growth in fiscal 2017 was accomplished during a transitionary period where the Company added a Vice-President of Sales and Marketing, a Senior Marketing Consultant as well as two Senior Account Managers bringing approximately 45 years of combined experience in the prostate cancer treatment and related markets during the second half of fiscal 2016. Management believes continued growth in prostate brachytherapy revenues will be the result of physicians, payors, and patients increasingly considering overall treatment advantages including costs compared with non-brachytherapy treatments, better treatment outcomes and improvement in the quality of life for patients but there is no assurance as to the timing of a recovery in use of brachytherapy as a whole.

Management believes increased pressure to deliver effective healthcare in both terms of outcome and cost drove treatment options in fiscal 2016 with prostate brachytherapy receiving more consideration than in previous years.

Other Brachytherapy.

Other brachytherapy includes but is not limited to brain, lung, head/neck, and gynecological treatments. Other brachytherapy treatments experienced sales decline of 11% in fiscal 2017 primarily related to a decline in lung cancer revenue related to overall decline in use of brachytherapy to treat lung cancer, as well as a decline in brain cancer revenue related to a shift in strategy of one of our customers. This decline was partially offset by increased cases in head/neck and gynecological cancers. Initial applications for these other brachytherapy treatments are primarily used in recurrent cancer treatments or salvage cases that are generally difficult to treat aggressive cancers where other treatment options are either ineffective or unavailable.

Other brachytherapy treatments are subject to the influence of a small pool of innovative physicians who are the early adopters of the technology who also tend to be faculty at teaching hospitals training the next generation of physicians. This causes the revenue created by these types of treatment applications to be more volatile and varies significantly from year to year. Additionally, with other brachytherapy surgical procedures there remains inconsistency and uncertainty regarding reimbursement for the procedures. This unreliable reimbursement for these new procedures will remain until specific coding and coverage policies are established, which could take years. Individual centers weigh the value of the procedure with their other treatment priorities on a patient by patient basis. IsoRay believes that additional clinical data will begin to build a compelling argument to support reimbursement and increased adoption of the procedures; however, any growth will be inconsistent in the near term.

GliaSite® RTS.

In March 2016, the Company discontinued the GliaSite® RTS as product sales had significantly declined due to currency fluctuations which contributed to the cost competitiveness of the product internationally where it had its strongest presence. Also contributing to the discontinuation was the increased acceptance and use of Cs-131 brachytherapy seeds in particular, the braided strand configuration became commercially available for the treatment of brain cancer at major institutions in the United States and the Company also focused on use of the GammaTile™ configuration which is not currently commercially available but is in a proof of concept stage at Barrow Neurological Institute.

Cost of product sales

Cost of product sales consisted primarily of the costs of manufacturing and distributing the Company's products. The fiscal 2017 decrease is primarily the result of reduction in the number of full time employees as well as a re-allocation of resources to assist in research and development activities. The fiscal 2016 increase was a combination of increased payroll from the addition of production employees, the awarding of payroll cost of living increases, the cost of share-based compensation awards, the increased cost of employee benefits, material costs, and third-party seed loading costs partially offset by decreases of medical device taxes, occupancy and depreciation expenses.

During both fiscal 2016 and 2017, the Company purchased isotope in excess of known customer orders to provide enough isotope to fill anticipated orders which may or may not materialize. The excess isotope is utilized in the production of upcoming orders where possible considering the decay rates of Cesuim-131. Any loss of isotope to decay is also included as a cost of production during the current period.

Research and development expenses

Research and development consisted primarily of the costs related to employee and third-party research and development activities. Contributing to the fiscal 2017 increase were re-allocating resources from cost of product sales to assist with research and development projects, an increase in share-based compensation expense, as well as an increase related to the collaborative agreement with GammaTile, LLC. The fiscal 2016 decrease was caused by reduced protocol expenses and legal expenses related to intellectual property.

Sales and marketing expenses

Sales and marketing expenses consist primarily of the costs related to the internal and external activities of the Company's sales, marketing and customer service division. The fiscal 2017 increase relates to management's focus on expanding the marketing message, and changes to the branding message coupled with recent hiring to fill key positions. The fiscal 2016 decrease was primarily due to payroll expenses not incurred with regard to unfilled staff positions. The fiscal 2015 increase was primarily due to increased payroll, benefits, and share-based compensation as well as increased costs associated with attending trade shows to increase awareness of the benefits associated with the Company's products.

General and administrative expenses

General and administrative expenses consist primarily of the costs related to the executive, quality assurance and regulatory affairs (QA/RA), finance, human resources and information technology functions of the Company. Fiscal 2017 general and administrative expenses increased 3% compared to fiscal 2016 and represented 82% of total sales. These increases were primarily due to full year of expense for filling positions in QA/RA and HR and were offset by non-recurring legal fees related to securities litigation and discontinuation of GliaSite® RTS product in fiscal 2016. Fiscal 2016 general and administrative expenses increased 58% compared to fiscal 2015 while they represented 79% of total sales. These increases were primarily due to legal fees related to securities litigation and corporate charges resulting from the retirement of the former CEO and the subsequent hiring of a new CEO. Other factors include filling two key positions: one in QA/RA, one in finance, combined with the costs associated with discontinuing the GliaSite® RTS product.

Gain on change in change in Asset Retirement Obligation (ARO) estimate

In fiscal 2017 there was a gain of approximately $48,000 related to change in ARO estimate related to lease extension executed during the current year. In fiscal 2016 there was a gain on change in ARO estimate of approximately $456,000. This change in ARO estimate is not expected to recur in the future unless there are material changes to the assumptions used in ARO calculation. This gain resulted from the three year lease extension coupled with a revised estimate that facility clean-up costs would be less than originally anticipated.

Liquidity and capital resources

The Company assesses its liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company has historically financed its operations through selling equity to investors. During fiscal 2017, 2016, and 2015 the Company used existing cash reserves from prior capital raises to fund its operations and capital expenditures.

Our cash flows for fiscal 2017, 2016, and 2015 respectively, are summarized as follows (in thousands):

	For the years ended June 30,		
	2017	2016	2015

Net cash used by operating activities	$(5,712)	$(3,884)	$(3,522)
Net cash provided by investing activities	1,514	8,757	784
Net cash provided by financing activities	(9)	39	285
Net increase (decreases) in cash and cash equivalents	$(4,207)	$4,912	$(2,453)
Working Capital	$9,185	$12,536	$15,233
Current Ratio	9.30	12.47	14.95

Cash flows from operating activities

Net cash used by operating activities in fiscal 2017 was primarily due to a net loss of $6.16 million net of approximately $433,000 in adjustments for non-cash activity such as depreciation and amortization expense, the change in estimate of asset retirement obligation, the change in fair value of the warrant derivative liability, and share-based compensation. Changes in operating assets and liabilities contributed approximately $17,000 in the cash used by operating activities.

Also included in operating activities is the one-time payment of $195,000 for settlement of litigation that was not covered by insurance.

Net cash used by operating activities in fiscal 2016 was primarily due to a net loss of $4.71 million net of approximately $426,000 in adjustments for non-cash activity such as depreciation and amortization expense, the change in estimate of asset retirement obligation, the change in fair value of the warrant derivative liability, share-based compensation and a write-off of inventory associated with GliaSite® RTS. Changes in operating assets and liabilities contributed approximately $401,000 to the cash provided by operating activities, such as improved effectiveness from accounts receivable collection efforts.

Net cash used by operating activities in fiscal 2015 was primarily due to a net loss of $3.68 million net of approximately $515,000 in adjustments for non-cash activity such as depreciation and amortization expense, the change in fair value of the warrant derivative liability, share-based compensation. However, changes in operating assets and liabilities contributed approximately $356,000 to the cash used by operating activities, due to accounts receivable collection efforts, bulk inventory purchases and the timing of payments to suppliers.

Cash flows from investing activities

Investing activities for all years are presented by primary transaction category. Investing activities consisted of transactions related to the purchase of fixed assets as well as the purchase and subsequent maturity of certificates of deposit. Management will continue to invest in technology and machinery that improves and streamlines production processes and to invest and reinvest maturing certificates of deposit in low-risk investment opportunities that safeguard assets and provide greater assurance those resources will be liquid and available for business needs as they arise.

Included in investing activities is a payment of $197,900 for the default of the development plan for the land purchased from the Port of Benton. See Property Transaction between Medical and The Port of Benton of Note 15 to the consolidated financial statements contained in this Form 10-K.

Cash flows from financing activities

Financing activities for all years are presented by primary transaction category. Financing activities in fiscal 2017, 2016 and 2015 were primarily due to sales of common stock through warrant and option exercises net of preferred dividends paid.

Projected 2018 liquidity and capital resources

Operating activities

Management forecasts that fiscal 2018 cash requirements will be similar to previous years and that current cash and cash equivalents along with certificates of deposit (current and non-current) will be sufficient to meet projected operating cash needs for the coming year. While monthly operating expenses are budgeted to increase for sales and marketing and decrease for general and administrative expenses, management believes the total monthly expense amount will not substantially change. Assuming no extraordinary expenses occur (whether operating or capital), if management is successful at implementing its strategy to focus on renewed emphasis to drive the consumer to the prostate market and meets or exceeds its growth targets of twenty percent increase in revenue in fiscal 2018 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. These assumptions do not incorporate any significant growth in the non-prostate application as they generate nominal revenues today but if they show significant improvement, cashflow break-even could occur sooner. There is no

assurance that the targeted sales growth will materialize but management is encouraged by the depth and experience of its restructured sales team.

Capital expenditures

Management is in the design process of a future production and administration facility. If financing is obtained and the facility constructed, it is believed that the new facility will have non-cash depreciation cost equal to or less than the monthly rental cost of the current facility. Management is reviewing all aspects of production operations (including process automation), research and development, sales and marketing, and general and administrative functions to evaluate the most efficient deployment of capital to ensure that the appropriate materials, systems, and personnel are available to support and drive product sales. Management is expecting to invest approximately $250,000 during fiscal 2018 in the automation of production processes which is expected to impact thirteen functions in the seed manufacturing and loading process. This investment is designed to allow the Company to significantly increase the output of Cs-131 brachytherapy seeds while allowing the Company to control the highest cost inputs to seed production while improving the overall safety of our operations.

Financing activities

There was no material change in the use of proceeds from our public offering as described in our final prospectus supplement filed with the SEC pursuant to Rule 424(b) on March 24, 2014. Through June 30, 2017, the Company had used the net proceeds raised through the March 2014 offering as described in the public offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

On August 25, 2015, the Company filed a registration statement on Form S-3 to register securities up to $20 million in value for future issuance in our capital raising activities. The registration statement became effective on November 19, 2015, and the SEC file number assigned to the registration statement is 333-206559.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders, Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders.

Other Commitments and Contingencies

The Company's purchase commitments and obligations include all open purchase orders and contractual obligations entered into in the ordinary course of business, including commitments with contract manufacturers and suppliers, for which we have not received the goods or services and acquisition and licensing of intellectual property. Although open purchase orders are considered enforceable and legally binding, the terms generally allow us the option to cancel, reschedule, and/or adjust our requirements based on our business needs prior to the delivery of goods or performance of services. Non-cancellable purchase commitments and obligations that will exist beyond fiscal 2017 and that are not separately presented as a liability on the balance sheet are listed below (in thousands):

Contractual obligations	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Operating lease obligations	$1,092	$285	$570	$237	$ -
Seed core purchase obligation	468	156	311	-	-
Asset retirement obligation	682	-	-	682	-
Total	$2,242	$441	$881	$919	$ -

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

New Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09 Revenue Recognition, replacing guidance currently codified in Subtopic 605-10 Revenue Recognition-Overall with various SEC Staff Accounting Bulletins providing interpretive guidance. The guidance establishes a new five step principle-based framework in an effort to significantly enhance comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets. The standard will be effective for the Company in the first quarter of its fiscal year 2019, but early adoption is permitted starting in the first quarter of fiscal year 2018. The Company intends to adopt the new standard in the first quarter of fiscal year 2019 and expects to use the modified retrospective method. The Company has evaluated the impact of the future adoption of ASU 2014-09 on its consolidated financial statements and does not currently expect significant changes in the timing of revenue recognition compared to the existing methodology.

In July 2015, the FASB issued ASU No. 2015-11: Inventory. The guidance requires an entity's management to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted. The ASU became effective for the Company on July 1, 2017. This update is not expected to have a material impact on the Company's consolidated financial statements upon adoption.

In November 2015, the FASB issued an ASU 2015-17 to simplify the balance sheet classification of deferred taxes. This update requires all deferred tax assets and liabilities to be reported as non-current in the consolidated balance sheets. The ASU became effective for the Company on July 1, 2017. This update is not expected to have a material impact on the Company's consolidated financial statements upon adoption.

In February 2016, the FASB issued ASU 2016-02 Leases (Subtopic 842), which will require lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by most leases. The update is effective for annual and interim reporting periods beginning after December 15, 2018. Early adoption is permitted. The ASU will be effective for the Company in the first quarter of fiscal year 2020. We are currently evaluating the impact of the guidance on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15 Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The update provides guidance on classification for cash receipts and payments related to eight specific issues. The update is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of implementing this update on the consolidated financial statements.

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial

condition, results of operations, cash flows or disclosures.

ITEM 7A – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions.

Interest Rate Risk

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We are exposed to market risk primarily in the area of changes in United States Treasury interest rates. All investments are in certificates of deposit of varying terms and in FDIC insured amounts. Accordingly, we have not had nor do we anticipate any material exposure to market risk.

To minimize market risk, we have in the past and, to the extent possible, will continue in the future, to hold debt securities to maturity at which time the debt security will be redeemed at its stated or face value.

Foreign Currency Risk

All of our manufacturing operations are conducted in the United States and all transactions, have been made in United States Dollars (USD). All distributor agreements specify settlement in USD. Accordingly, we have not had nor do we anticipate any material exposure to foreign currency rate fluctuations.

ITEM 8 – FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Information required by this Item 8 is incorporated by reference to our Consolidated Financial Statements and the Report of Independent Registered Public Accounting Firm beginning at page 68 of this Report.

ITEM 9 – CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

There were no disagreements or reportable events with DeCoria, Maichel & Teague, P.S.

ITEM 9A – CONTROLS AND PROCEDURES

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 (Exchange Act), as of June 30, 2017. 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. 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 are designed to provide a reasonable level of assurance that the objectives of the system will be met.

Management’s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance concerning both the reliability of our financial reporting and the preparation of our financial statements in accordance with generally accepted accounting principles. This control includes policies and procedures that obligate us to maintain reasonably detailed records that accurately and fairly reflect our transactions and the disposition of our assets, provide assurance that our transactions are properly recorded, ensure that our receipts and expenditures are authorized by management and, where applicable, our board of directors, and prevent or allow us to timely detect material unauthorized acquisitions, uses or dispositions of our assets.

We have evaluated the effectiveness of our internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control Integrated Framework (2013). This evaluation was performed under the supervision and with the participation of our management, including our chief executive officer and our principal financial and accounting officer, both of whom concluded that our internal control over financial reporting was effective as of June 30, 2017. Our evaluation of the effectiveness of our internal control over financial reporting in future periods may differ due to changing conditions or non-compliance with the policies and procedures we have established.

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.

ITEM 9B – OTHER INFORMATION

Not applicable

PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board Membership and Board Committees

The directors serving the Company as of June 30, 2017 were as follows:

Name	Type	Age	Audit Committee	Compensation Committee	Nominations Committee	Litigation Committee
Thomas LaVoy, Chairman and Chief Executive Officer	Employee	57	N/A	N/A	N/A	N/A
Philip Vitale, MD	Independent	71	Member	Chairman	Member	N/A
Alan Hoffmann	Independent	56	Chairman	Member	Member	Chairman
Michael McCormick	Independent	54	Member	Member	Chairman	Member

Each member of the Board of Directors serves a one-year term and is subject to reelection at the Company’s Annual Meeting of Shareholders held each year. A special litigation committee was formed on September 14, 2017.

The Company’s directors, as named above, will serve until the next annual meeting of the Company’s shareholders or until their successors are duly elected and have qualified. Directors will be elected for one-year terms at the annual shareholders meeting. There is no arrangement or understanding between any of the directors or officers of the Company and any other person pursuant to which any director or officer was or is to be selected as a director or officer, and there is no arrangement, plan or understanding as to whether non-management shareholders will exercise their voting rights to continue to elect the current directors to the Company's board. There are also no arrangements, agreements or understandings between non-management shareholders that may directly or indirectly participate in or influence the management of the Company’s affairs.

Thomas LaVoy – Mr. LaVoy has been a Director of the Company since 2005 and served as Chair of the Audit Committee until his resignation from the Audit Committee Chair position and all other Board committees effective January 13, 2016. He was appointed Chairman of the IsoRay Board effective January 7, 2016 and took office as Chief Executive Officer of the Company on February 15, 2016. Mr. LaVoy served as Deputy Chief Operations Officer and President of Corporate Services of Veolia Transportation on Demand (VTOD), the parent company of SuperShuttle International Inc. and its subsidiaries, from January 2014 to February 2016. He concurrently served as Chief Financial Officer of SuperShuttle International, Inc. and its subsidiaries from July 1997 and as Secretary from March 1998, resigning from both positions in February 2016. He has also served as a director of Alanco Technologies, Inc. (OTCBB: ALAN) since 1998 and served on its audit committee from 2012 to 2015. 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 (Inactive) in the State of Minnesota. Mr. LaVoy brings to the Board over ten years of service on the Board and experience in both small and large public companies with capital raising and acquisitions.

Philip Vitale, MD – Dr. Vitale has been a Director of the Company since 2014 and is a board certified urologist. He practiced Urology from 1978 to 2005 at Lovelace Health Systems in Albuquerque. He also served on the Board of Governors for 9 years and held various administrative positions including Chief Medical Officer and Senior Vice President at Lovelace. He was a staff urologist at Albuquerque VA Medical Center from 2005 until his retirement in November 2014. He served as Chief of the Urology section from 2008 to November 2013. Dr. Vitale was also an Assistant Professor at the University of New Mexico, Division of Urology. He is a member of the American Urological Association and the South Central Section of the American Urological Association. Prior to his retirement, Dr. Vitale's clinical trials included: chemotherapy after prostatectomy (cap); a phase III randomized study for high risk prostate carcinoma; RTOG 0415 a phase III randomized study of hypofractionated 3d-crt/IMRT versus conventionally fractionated 3d-crt/IMRT in patients with favorable-risk prostate cancer; RTOG 0815 a phase III prospective randomized trial of dose-escalated radiotherapy with or without short-term androgen deprivation therapy for patients with intermediate-risk prostate cancer; and YP19A1 gene and pharmacogenetics of response to testosterone therapy. Dr. Vitale holds a B.A. in Biology from LaSalle College and obtained his M.D. from the New Jersey College of Medicine and Dentistry. He received his M.S. in Health Services Administration from the College of St. Francis. Dr. Vitale brings to the Board medical expertise in the industries the Company is targeting.

Alan Hoffmann – Mr. Hoffmann has been a Director of the Company since January 2016. He is the owner of Alan Hoffmann, CPA, PC, a certified public accounting firm he founded in 1996. The firm performs audits and reviews of private companies. In addition, Mr. Hoffmann currently serves as CFO for Cognitive Research Corporation, a privately-held, full-service contract research organization that specializes in central nervous system product development for pharmaceutical, nutraceutical, biotechnology and medical device companies. In 2011, he served as CFO for an international manufacturing company, Kinematics Manufacturing, Inc. His prior employment included Price Waterhouse from 1985-1989, where he held multiple positions including Senior Tax Analyst, and Tax Manager from 1989-1996 in public accounting. After receiving his undergraduate accounting degree with honors from the University of Wisconsin-Milwaukee in 1985, he became a Certified Public Accountant in 1989. He also served in the United States Marine Corps and was honorably discharged in 1985. He brings over 26 years of public accounting experience to the Company and the Board. Mr. Hoffmann brings to the Board his experience as a public accountant and understanding of oversight and review of financial statements prepared by the Controller.

Michael McCormick – Mr. McCormick has been a Director of the Company since June 2015 and brings over 25 years of senior executive positions in global management, sales, and marketing to the Company. He serves as a founder and partner of GO Intellectual Capital, which offers marketing services with a focus on the medical and aviation industries, as well as financial services. Previous to his service with GO, Mr. McCormick served as Executive Vice President of Global Sales and Marketing for Columbia Sportswear from 2006-2012, where his team successfully launched several new patented technologies, including Omni-Heat® Reflective and Omni-Freeze® Zero. During Mr. McCormick's tenure, Columbia built an intellectual property portfolio with over 200 patents. Mr. McCormick started his career with Nike, working in several senior management roles and ultimately becoming the Director of National Sales, U.S., prior to his departure in 1999. He also served as Chief Marketing Officer of Golf Galaxy from 2003-2006 and Executive Vice President of Global Sales and Marketing of Callaway Golf from 2000-2003. Mr. McCormick brings over 25 years of marketing experience in a diverse group of industries to his service on the Company's Board.

Executive Officers

The executive officers serving the Company as of June 30, 2017 were as follows:

Name	Age	Position Held
Thomas LaVoy[1]	57	Chairman & Chief Executive Officer
Matthew Branson[2]	40	Controller, Principal Financial and Accounting Officer
William Cavanagh III	51	Chief Operating Officer, Chief Scientific Officer[3]
Michael Krachon	46	Vice President, Sales and Marketing
Jennifer Streeter	47	Vice President, Human Resources

1. Mr. LaVoy's biographical information is incorporated by reference in the board membership section of Part III, Item 10.

2. Following Mr. Branson's departure on June 30, 2017, the Company appointed Mark Austin as Controller, Principal Financial and Accounting Officer. Mr. Austin took office on July 24, 2017.

3. Mr. Cavanagh began serving as Chief Scientific Officer on August 15, 2016, and continues to serve as COO as well.

Matthew Branson – Mr. Branson served as Controller of IsoRay Medical, Inc. from April 2016 to June 30, 2017. Effective January 17, 2017, Mr. Branson was also appointed Principal Financial and Accounting Officer until he resigned effective June 30, 2017. He was previously an Accounting Manager at IsoRay Medical, Inc. from March 2015 to March 2016. From June 2013 to March 2015 he held the position of Accountant II for the City of Richland, Washington. Between September 2011 and June 2013 he served as the Purchasing and Warehouse Supervisor for the City of Richland, Washington. Mr. Branson is a Certified Public Accountant and received his Bachelor of Accounting degree from Brigham Young University and his Master of Accounting, Tax from Weber State University.

William Cavanagh III – Mr. Cavanagh joined IsoRay Medical, Inc. in January 2010 and served as Vice President, Research and Development until March 3, 2016, other than serving as interim Chief Executive Officer for IsoRay from January 7, 2016 to February 14, 2016. He was appointed Chief Operating Officer of IsoRay effective March 3, 2016 and Chief Scientific Officer effective August 15, 2016. Immediately prior to joining IsoRay Medical, Mr. Cavanagh was 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 attended two years of medical school before beginning his career in research management.

Michael Krachon – Mr. Krachon brings more than 20 years' experience of progressive growth in sales and marketing in the medical industry to the Company. He joined IsoRay in March 2016 as Vice President, Sales and Marketing. Prior to joining IsoRay, Mr. Krachon was employed by C.R. Bard Inc. since 2001, and was a key member of the Bard Urological and Medical Division which developed brachytherapy devices and delivery systems for the U.S. and international markets. He was the leader of the brachytherapy commercial team, which grew to be the global brachytherapy market leader. Mr. Krachon assisted in the business unit's strategic planning, development of the international business segment and creating and delivering the international product launches which resulted in market leadership across Europe, Japan and Africa. His responsibilities included: the development of strategic brachytherapy sales and marketing programs; the implementation of industry leading national and international training programs; and supporting the product development process. Finally, Mr. Krachon has been instrumental in successfully supporting the industry through congressional lobbying efforts to establish and maintain reimbursement codes for brachytherapy. He served as Chairman of the Coalition for Advancement of Brachytherapy from 2009 to 2016 and has been recognized as a national speaker for brachytherapy by the industry. Mr. Krachon received a B.S.E. in biomedical engineering from Duke University and his M.B.A. from the Goizueta Business School at Emory University.

Jennifer Streeter – Mrs. Streeter brings more than 10 years' experience of progressive growth in the Human Resources field. She joined IsoRay in July 2016 as Vice President of Training. In September 2016, she accepted responsibility as Vice President of Human Resources. Prior to joining IsoRay, Mrs. Streeter was employed by Supershuttle International as the Vice President of Learning Development, where she lead a team of training managers providing overall training and organizational development activities. Previously Mrs. Streeter has facilitated both on ground and online courses at the undergraduate and graduate levels for universities including Grand Canyon University, Ottawa University and Western International University. The courses focused on Human Resource and Organizational Development. Mrs. Streeter received her Bachelor's Degree in Management/Marketing and her Master's Degree in Leadership Studies.

There are no agreements or understandings for any officer or director to resign at the request of another person, and none of the officers or directors is acting on behalf of, or will act at the direction of, any other person. There are no family relationships among our executive officers and directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of beneficial ownership and reports of changes in beneficial ownership of our Common Stock. The rules promulgated by the SEC under Section 16(a) of the Exchange Act require those persons to furnish us with copies of all reports filed with the SEC pursuant to Section 16(a). The information in this section is based solely upon a review of Forms 3, Forms 4, and Forms 5 received by us.

We believe that IsoRay's executive officers, directors and 10% shareholders timely complied with their filing requirements during the year ended June 30, 2017, except as follows – Michael Krachon (one Form 4 with one transaction), William Cavanagh (one Form 4 with two transactions), Thomas LaVoy (one Form 4 with two transactions), Alan Hoffmann (one Form 4 with one transaction), Matthew Branson (one Form 4 with two transactions) and Jennifer Streeter (one Form 3 with one transaction & one Form 4 with two transactions). Each of these Form 3s and Form 4s was filed late.

Code of Ethics

We have adopted a Code of Conduct and Ethics that applies to all of our officers, directors and employees and a separate Code of Ethics for Chief Executive Officer and Senior Financial Officers that supplements our Code of Conduct and Ethics.

The Code of Conduct and Ethics was previously filed as Exhibit 14.1 to our Form 10-KSB for the period ended June 30, 2005, and the Code of Ethics for Chief Executive Officer and Senior Financial Officers was previously filed as Exhibit 14.2 to that same report. The Code of Ethics for Chief Executive Officer and Senior Financial Officers is also available to the public on our website at http://www.isoray.com/corporate_governance. Each of these policies comprises written standards that are reasonably designed to deter wrongdoing and to promote the behavior described in Item 406 of Regulation S-K promulgated by the Securities and Exchange Commission. Any amendments to or waivers of the Codes will be promptly posted on our website at www.isoray.com or in a Report on Form 8-K, as required by applicable laws.

Nominating Procedures

There have been no material changes to the procedures by which our shareholders may recommend nominees to the Board of Directors during our last fiscal year.

Audit Committee

The Audit Committee was established on December 8, 2006, the date on which its Charter was adopted. The Audit Committee Charter lists the purposes of the Audit Committee as overseeing the accounting and financial reporting processes of the Company and audits of the financial statements of the Company and providing assistance to the Board of Directors in monitoring (1) the integrity of the Company's financial statements, (2) the Company's compliance with legal and regulatory requirements, (3) the independent auditor's qualifications and independence, and (4) the performance of the Company's internal audit function, if any, and independent auditor.

The Board of Directors has determined that Mr. Hoffmann is an "audit committee financial expert" as defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC, and each Audit Committee member is independent under applicable NYSE MKT standards. The Board's conclusions regarding the qualifications of Mr. Hoffmann as an audit committee financial expert were based on his service as a chief financial officer, his experience as a certified public accountant and his degree in accounting.

ITEM 11 – EXECUTIVE COMPENSATION

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during our past two fiscal years awarded to, earned by or paid to each of the following individuals. Salary and other compensation for these officers are set or recommended to the Board by the Compensation Committee.

Summary Compensation Table

						Non-equity	Nonqualified deferred	

Name and principal position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($)[1]	incentive plan compensation ($)	compensation earnings ($)	All other compensation ($)	Total ($)
Thomas LaVoy	2017	300,583	-	-	329,901	12,023	-	-	642,507
Chairman and CEO	2016	98,267	-	-	199,440[4]	-	-	33,835 [(3)]	331,542
William Cavanagh	2017	201,700	-	-	103,815	8,068	-	-	313,583
COO/CSO[2]	2016	186,021	10,000	-	81,600 [4]	4,893	-	-	282,514
Michael Krachon	2017	225,000	-	-	103,815	9,000	-	-	337,815
VP – S&M	2016	60,577	-	-	72,700 [4]	-	-	-	133,277

1. Amounts represent the ASC 718*, Compensation – Stock Compensation* valuation for the fiscal years 2017, 2016, respectively. All such options were awarded under one of the Company's two stock option plans. Options awarded vest in three to five equal annual installments and expire ten years after the date of grant. All options were granted at the fair market value of the Company's stock on the date of grant and the Company used a Black-Scholes methodology as discussed in the footnotes to the financial statements to value the options.

2. Mr. Cavanagh served as the Company's Vice-President of Research and Development until January 2016 when he was named Interim Chief Executive Officer (CEO) upon the retirement of Dwight Babcock. Mr. Cavanagh served as Interim CEO until Mr. LaVoy took office as CEO on February 15, 2016. Mr. Cavanagh was then named Chief Operating Officer, and later also Chief Scientific Officer.

3. This amount represents the amount paid in fees earned or paid in cash to the current Chief Executive Officer for his prior service on the board of directors and as the audit committee chairman prior to becoming a Chief Executive Officer. He received no other consideration as a director or for services on the Committee.

4. These option awards were all cancelled effective June 15, 2017.

Outstanding Equity Awards at Fiscal Year-End

Option awards

Equity Incentive Plan awards:

Name	Number of securities underlying unexercised options (#) exercisable		Number of securities underlying unexercised options (#) unexercisable		Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Thomas LaVoy	178,750	1	536,250	1	-	0.605	06/27/2027
William Cavanagh	56,250	1	168,750	1	-	0.605	06/27/2027
Chief Operating Officer	6,660	2	-		-	0.98	06/27/2022
	20,000	3	-		-	2.46	06/17/2024
Michael Krachon	56,250	1	168,750	1	-	0.605	06/27/2027
Vice-President of Sales and Marketing							

1. Represents a June 27, 2017, grant, one-fourth of which became exercisable on June 27, 2017, one-fourth of which will become exercisable on June 27, 2018, one-fourth of which will become exercisable on June 27, 2019, and the final fourth will become exercisable on June 27, 2020.
2. Represents a June 27, 2012, grant, all of which were exercisable as of June 27, 2015.
3. Represents a June 17, 2014, grant, all of which were exercisable as of June 17, 2017.

Option Exercises and Stock Vested

There were no option exercises or stock vesting by named executive officers (NEOs) during fiscal 2017.

The Company has a 401(k) plan that covers all eligible full-time employees of the Company. Contributions to the 401(k) plan are made by participants to their individual accounts through payroll withholding. Additionally, the 401(k) plan provides for the Company to make contributions to the 401(k) plan in amounts at the discretion of management. The Company has not made any contributions to the 401(k) plan and does not maintain any other retirement plans for its executives or employees.

Fiscal Year 2017 Director Compensation

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Non-qualified deferred compensation ($)	All other compensation ($)	Total ($)
Alan Hoffmann	42,500	-	2,076	-	-	-	44,756
Michael McCormick	42,500	-	2,076	-	-	-	44,756
Philip Vitale MD	42,500	-	2,076	-	-	-	44,756

During fiscal year 2016, each non-employee director received cash compensation of $3,000 per month. Until Mr. LaVoy resigned as Chair of the Audit Committee, he received an additional $1,000 per month for serving in that role. In addition, each non-employee director received $1,000 per Board meeting attended in person or $500 per Board meeting attended via telephone and $500 per committee meeting attended.

Each non-employee director had stock options to purchase shares of the Company’s common stock outstanding as of June 30, 2017 as follows - Mr. Hoffmann had stock options to purchase 55,000 shares of common stock, Mr. McCormick had stock options to purchase 55,000 shares of common stock, and Dr. Vitale had stock options to purchase 55,000 shares of common stock.

During the fiscal year 2017, the independent directors received $3,000 per month for their service. In addition, each non-employee director received $1,000 per Board meeting attended in person or $500 per Board meeting attended via telephone and $500 per committee meeting attended. Employee directors do not receive any compensation for their service on the Board.

Compensation Discussion and Analysis

This Compensation Discussion and Analysis (CD&A) describes IsoRay's executive compensation program for fiscal year 2017. In particular, this CD&A explains how the Compensation Committee (the Committee) of the Board made 2017 compensation decisions for the following NEOs:

- Thomas LaVoy - Chairman and Chief Executive Officer
- William Cavanagh - Chief Operating Officer and Chief Scientific Officer
- Michael Krachon - Vice President, Sales and Marketing

Our Executive Compensation Program Framework

We design our named executive officer compensation programs to attract, motivate and retain the key executives who drive our success and help us maintain a strong position in our industry. We are committed to industry standards for the region in which we operate for base pay, bonuses and equity awarded to our named executive officers. In addition, we design our executive compensation program to encourage long-term commitment by our named executive officers to IsoRay.

Please read the "Executive Compensation" section of this Annual Report. That section of the Annual Report, which includes our named executive officer compensation tables and related narrative discussion, provides historical details on our compensation programs and policies for our named executive officers.

At our fiscal 2017 annual meeting, our shareholders approved, on an advisory basis, the compensation of our named executive officers.

Program Objectives

The compensation paid to the Company's named executive officers is intended to align their interests with the long term interests of the Company's shareholders and is based on a pay-for-performance philosophy. It is straightforward, consisting principally of salary, which must be competitive to retain the skills and experience of excellent employees, short-term incentives (quarterly and annual bonuses) and equity compensation to encourage long term commitment and team performance. Not all elements of our compensation package may be provided every year, depending on the performance of the Company and the executive.

We design our executive compensation program to achieve the following objectives:

§ Motivate and reward executives whose knowledge, skills and performance are essential to our success;

§ Align the performance of our executives and the interests of our shareholders;

§ Recruit and retain executive talent; and

§ Support the corporate business strategy by rewarding revenue growth and cost control measures.

We believe our executive compensation program promotes good governance and operates in the best interests of our stockholders; a summary of our compensation governance practices are listed below:

What we do	**What we do not do**
ü Place an emphasis on variable compensation, which includes cash incentives that are dependent on the achievement of short-term financial goals, and equity awards that are dependent on stock price	×Offer compensation-related tax gross ups
ü Use stock options to align our executive's interests with those of shareholders	×Have any significant perquisites
ü Have an executive compensation clawback policy to ensure accountability	×Have special retirement programs
ü Have an independent compensation consultant advising the Compensation Committee	×Reprice or cash out underwater stock options ×Guarantee bonuses

Decision Making Process

Role of the Compensation Committee

The Compensation Committee of our Board has the primary responsibility for determining compensation of our executives. Our Board has determined that each member of our Compensation Committee is "independent" as that term is defined by applicable NYSE MKT rules, and a "non-employee" director as defined under Section 16 of the Exchange Act.

Our Compensation Committee determines all compensation matters for our named executive officers, including base salary, bonuses, and equity compensation. Utilizing input from our Chief Executive Officer, the Compensation Committee makes an independent decision on compensation for each executive officer other than the CEO. The Compensation Committee also primarily relies on the judgment of the Chief Executive Officer in making compensation determinations of our non-executive staff. The primary goal of our Compensation Committee is to closely align the interests of our named executive officers and staff with those of our shareholders. The Compensation Committee assesses performance on a number of subjective and objective factors.

In making decisions regarding executive compensation, our Compensation Committee considers, among other things:

§ Past compensation levels of each executive and the executives as a group;

§ Consistency of current compensation with previous compensation decisions and benchmarks;

§ Existing levels of stock and stock option ownership among our executives, previous stock option grants and vesting schedules to ensure executive retention and alignment with shareholder interests;

§ Results of competitive analyses and recommendations of the Committee's independent consultant;

§ Management recommendations;

- General trends in executive compensation; and
- Meeting ongoing revenue growth and cost control objectives.

The Compensation Committee conducts an annual review of the Chief Executive Officer's performance and reports its evaluation to the Board. The Board reviews the Compensation Committee's evaluation and recommendation and also evaluates the Chief Executive Officer's performance according to the goals and objectives established periodically by the full Board. This review serves as the basis for the recommendation of the Compensation Committee on Chief Executive Officer compensation.

Role of the Chief Executive Officer

As discussed above, the Chief Executive Officer makes recommendations to the Committee and the full Board for the establishment of performance targets and individual performance objectives for the other NEOs.

The Chief Executive Officer reviews the performance of each of the other NEOs against his objectives and presents his evaluation of such NEO's performance to the Committee. Decisions regarding individual compensation elements and total compensation are ultimately made by the Committee, using its judgment, focusing primarily on each NEO's performance against his individual financial and strategic objectives, as well as the Company's overall performance.

The Committee and the Chief Executive Officer also consider a variety of qualitative factors, including the business environment in which the results were achieved. Therefore, the Chief Executive Officer makes recommendations regarding each of the other NEOs' compensation based on multiple factors, including the competitive market and Company and individual performance. The Committee ultimately approves all compensation plans for senior management (including for the Chief Executive Officer's compensation).

The Chief Executive Officer does not participate in the deliberations of the Committee regarding his own compensation.

Role of the Compensation Consultant

Pursuant to its Charter, the Compensation Committee has the authority to engage independent compensation consultants and other professionals to assist in the design, formulation, analysis, and implementation of compensation programs for our executive officers. During fiscal 2017 the Committee engaged Pearl Meyer to review various elements of the Company's overall compensation program, including performing reviews of the Company's 2017 executive compensation plans.

Role of Benchmarking and Peer Groups

As part of our pay philosophy, our executive compensation program is designed to attract, motivate and retain our executives in an increasingly competitive market. To this end, during fiscal 2017 we evaluated industry-specific and general market compensation practices and trends to ensure that our program features and NEO pay opportunities remain appropriately competitive. When determining salaries, target bonus opportunities and long-term incentive grants for NEOs, the Committee considers the performance of the Company and the individual, the nature of an individual's role within the Company, experience in the officer's current role, as well as input from its independent compensation consultant, among other variables.

In fiscal 2017, to facilitate its review and determination of executive compensation, the Committee engaged Pearl Meyer to conduct a comprehensive competitive review of our executive compensation program. In connection with this review and in consultation with Pearl Meyer and senior management of the Company, the Committee identified a peer group comprised of healthcare equipment, pharmaceutical and biotechnology companies roughly similar to the Company in revenue size or market capitalization, and focused on cancer treatments to the extent possible; the peer group consists of the 16 companies listed below:

Apricus Biosciences, Inc.	Cytori Therapeutics, Inc.	Pieris Pharmaceuticals, Inc.
ArQule Inc.	Fate Therapeutics, Inc.	Sunesis Pharmaceuticals, Inc.
Cancer Genetics, Inc.	Fortress Biotech, Inc.	TRACON Pharmaceuticals, Inc.
Capricor Therapeutics, Inc.	Northwest Biotherapeutics, Inc.	ViewRay, Inc.
Cleveland BioLabs, Inc.	OncoGenex Pharmaceuticals, Inc.	
Cyclacel Pharmaceuticals, Inc.	Onconova Therapeutics, Inc.	

The median (50th percentile) revenue size of the peer group was approximately $4 million, while the median market capitalization was $56 million; IsoRay's revenue of $5 million and market capitalization of $32 million were roughly at the 55th and 40th percentiles of the peer group, respectively.

In addition to peer group data, five published or private compensation surveys were also utilized in Pearl Meyer's 2017 report and comparisons to survey benchmark positions were made based on the Company's size. Pearl Meyer completed its review in June 2017 and presented its analysis of the Company's executive compensation program relative to peer and survey 25th , 50th and 75th percentile levels. Overall, the study suggested that all components of compensation were generally below the 25th percentile market levels except for target short-term incentives. Actual short and long-term incentive levels fell significantly below market levels.

Our Executive Compensation Program Framework