Risk Factors Comparison 2022-09-28 to 2021-09-27 Form: 10-K

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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 the Pending Merger The Announcement and Pendency of the Merger May Have an Adverse Effect On Our Business Results, and a Failure to Complete the Merger Could Have a Material and Adverse Effect On Our Business. On September 27, 2022, we entered into the Merger Agreement with Viewpoint Molecular Targeting, Inc. as discussed in Item 1 – Business above. Consummation of the Merger is subject to the satisfaction or waiver of certain closing conditions. There is no assurance that all closing conditions will be satisfied, or that the Merger will be completed on the proposed terms, within the expected timeframe, or at all. The Merger may be delayed, and may ultimately not be completed, due to a number of factors, including: ● the failure to obtain requisite stockholder approval; ● the failure to obtain regulatory approvals from applicable governmental entities ; ● potential future stockholder litigation and other legal and regulatory proceedings, which could delay or prevent the Merger ; and ● the failure to satisfy the other conditions to the completion of the Merger, including the possibility that a material adverse effect may occur that would permit either party to elect not to close the Merger. If the Merger does not close, we may suffer other consequences that could adversely affect our business, financial condition, operating results, cash flows, and stock price, and our stockholders would be exposed to additional risks, including: ● to the extent that the market price of our stock reflects an assumption that the Merger will be completed, the price of our common stock could decrease if the Merger is not completed ; ● investor confidence in us could decline, stockholder litigation could be brought against us, relationships with existing and prospective business partners may be adversely impacted, we may be unable to retain key personnel, and our operating results and cash flows may be adversely impacted due to costs incurred in connection with the Merger ; and ● any disruptions to our business resulting from the announcement and pendency of the Merger, including adverse changes in our relationships with employees and other business partners, may continue or intensify in the event the Merger is not consummated or is significantly delayed. There can be no assurance that our business, relationships with other parties, liquidity, or financial condition will not be adversely affected, as compared to the condition prior to the announcement of the Merger, if the Merger is not consummated. Even if successfully completed, there are certain risks to our stockholders from the Merger, including: ● we may experience a departure of employees prior to the closing of the Merger ; and ● if the Merger is completed, our stockholders will forego the opportunity to realize the potential long- term value of the successful execution of our current strategy. While the Merger is Pending, We Are Subject to Business Uncertainties and Contractual Restrictions That Could Harm Our Business Relationships, Financial Condition, Operating Results, Cash Flows, and Business. During the period prior to the closing of the Merger, our business is exposed to certain inherent risks and certain restrictions on our business under the terms of the Merger Agreement that could harm our business relationships, financial condition, operating results, cash flows, and business, including: ● potential uncertainty regarding our future plans and strategy, including business model changes and transformation ; ● the possibility of disruption to our business and operations resulting from the announcement and pendency of the Merger, including diversion of management attention and resources ; ● our inability to attract and retain key personnel and recruit prospective employees, and the possibility that our current employees could be distracted, and their productivity decline as a result, due to uncertainty regarding the Merger ; ● the inability to pursue alternative business opportunities or make changes to our business pending the completion of the Merger, and other restrictions on our ability to conduct our business ; ● our inability to freely issue securities, incur indebtedness, or declare or authorize any dividend or distribution ; ● our inability to solicit other acquisition proposals during the pendency of the Merger ; ● the amount of the costs, fees, expenses and charges related to the Merger Agreement and the Merger, which may materially and adversely affect our financial condition and cash flows; and ● other developments beyond our control that may affect the timing or success of the Merger. If any of these effects were to occur, it could materially and adversely impact our business, cash flows, results of operations, or financial condition, as well as the market price of our common stock and our perceived value, regardless of whether the Merger is completed. Litigation May Arise in Connection with the Merger, Which Could Be Costly, Prevent Consummation of the Merger, Divert Management' s Attention, and Otherwise Materially Harm Our Business. Regardless of the outcome of any future litigation related to the Merger, such litigation may be time- consuming and expensive and may distract our management from running the day- to- day operations of our business. The litigation costs and diversion of management' s attention and resources to address any claims and counterclaims in any litigation related to the Merger may materially adversely affect our business, results of operations, prospects, cash flows, and financial condition. If the Merger is not consummated for any reason, litigation could be filed in connection with the failure to consummate the Merger. Any litigation related to the Merger may result in negative publicity or an unfavorable impression of us, which could adversely affect the price of our common stock, impair our ability to recruit or retain employees, damage our relationships with our customers and other business partners, or otherwise materially harm our operations and financial performance. We May Experience Difficulties Integrating Viewpoint' s Business. Achieving the anticipated benefits of the Merger will depend in significant part upon**

whether Isoray and Viewpoint integrate their businesses in an efficient and effective manner. Isoray has not yet determined the exact nature of how the businesses and operations of the companies will be combined after the Merger. The actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration plan may not be realized. The companies may not be able to accomplish the integration process smoothly, successfully, or on a timely basis. The necessity of coordinating geographically separated organizations, systems of controls, and facilities and addressing possible differences in business backgrounds, corporate cultures, and management philosophies may increase the difficulties of integration. The companies operate numerous systems and controls, including those involving management information, purchasing, accounting and finance, sales, billing, employee benefits, payroll, and regulatory compliance. The integration of operations following the Merger will require the dedication of significant management and external resources, which may temporarily distract management' s attention from the day- to- day business of the combined company and be costly. Employee uncertainty and lack of focus during the integration process may also disrupt the business of the combined company. Any inability of management to successfully and timely integrate the operations of the companies could have a material adverse effect on the business and results of operations of the combined company. Following the Merger, the Company May Be Controlled by Persons Who Are Unfamiliar With the Cesium Space. Upon the closing of the Merger, the size of our board of directors will increase to no less than five directors, with two of those directors being appointed by Viewpoint. Additionally, Lori Woods, our current CEO, will resign from her position as CEO and Thijs Spoor, Viewpoint' s current CEO, will be named the new CEO of Isoray. Mr. Spoor and the directors to be appointed by Viewpoint may not have prior experience in the Cesium- 131 space, and thus we may be controlled by persons who are unfamiliar with our current products and business, which may adversely affect our ability to effectively execute upon our business strategy . Risks Related to Our Industry and Operations The Novel Coronavirus (COVID- 19) Outbreak And Additional Outbreaks Due to Variants Could Materially Adversely Affect Our Financial Condition and Results of Operations. COVID- 19 and variants such as the Delta **, Omicron 4, and Omicron 5** ~~variant~~ **variants** may impact supply chain and product sales. Our Cesium supply comes from Russia and while at this time we are not aware of any shutdowns of nuclear facilities in Russia or limited staffing due to ongoing risk of ~~virus~~ **COVID- 19** transmission, this may occur in the future. We also depend on overseas flights, which were previously curtailed and are still not at their pre-pandemic levels, and any further flight cancellations may impact our supply chain. While our surgeries are not considered elective, in areas where hospitals are using most available space for COVID- 19 or other chronic conditions, surgeries required to implant our seeds may be postponed or cancelled. ~~If~~ **While** conditions ~~worsen with~~ **continue to improve following** the COVID- 19 ~~pandemic~~ **outbreak, should conditions worsen** , including **due to** any **new** variants, ~~this~~ **it** may have a material adverse effect on our business. ~~The continued precautions~~ **Precautions** due to COVID- 19 and its variants has caused us to modify our business practices (including employee travel, employee work locations, and cancellation of physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers, partners, and suppliers. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and our ability to perform critical functions could be harmed. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. In addition, quarantines, stay- at- home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact personnel at third- party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Our ability to obtain licensure at new locations has been subject to significant delays due to COVID- 19. The spread of COVID- 19, which has caused a broad impact globally, may **also** materially affect us economically. While the potential economic impact brought by, and the duration of, COVID- 19 may be difficult to assess or predict, it has introduced significant volatility into the global financial markets. A recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our common stock. The ultimate impact of the COVID- 19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, the effects could have a material impact on our operations, and we will continue to monitor the COVID- 19 situation closely. **Impact of Conflict in Ukraine. In February 2022, Russian military forces launched a military action in Ukraine, and sustained conflict and disruption in the region is likely to continue. The length, impact, and outcome of this ongoing military conflict is highly unpredictable and could lead to significant market and other disruptions, including significant instability in financial markets, supply chain interruptions, political and social instability, trade disputes or trade barriers, changes in consumer or purchaser preferences, as well as an increase in cyberattacks and espionage. Russia' s recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and military action against Ukraine led to substantial expansion of sanction programs imposed by the United States and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so- called Donetsk People' s Republic, and the so- called Luhansk People' s Republic. In retaliation against the sanctions and as part of measures to stabilize and support the volatile Russian financial and currency markets, the Russian authorities imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non- Russian parties, banned exports of various products, and imposed other economic and financial restrictions. The situation is rapidly evolving, and additional sanctions by Russia on the one hand, and by the other countries on the other hand, could adversely affect the global economy, financial markets, energy supply and prices, certain critical materials and metals, supply chains, and global logistics and could adversely affect our business, financial condition, and results of operations. While we had trouble with sending wires to Russia from our local bank in Richland, Washington due solely to its own internal policies which we have since resolved and were forced to redirect flights to obtain supply of our**

Cesium- 131, there has been no further impact on our operations and our relationship with our Russian rector suppliers remains excellent; however there is no assurance we will no experience disruptions from the banking system or our suppliers themselves in the future and this could result in a material adverse effect on our financial results. Any such disruption may also magnify the impact of other risks described in this Report. Because our supply of Cesium- 131 is obtained from nuclear reactors located in Russia, the Company is susceptible to any supply chain disruptions resulting from military actions, the sanctions, or otherwise, and any such disruption could materially affect our ability to obtain the Cesium- 131 needed for our products. Management and our Board of Directors are actively monitoring the situation in Ukraine and Russia and assessing its impact on our business, including our medical isotope suppliers. To date, we have not experienced any material interruptions in our medical isotope supplies needed to support our operations due to the conflict. However, we have no way to predict the progress or outcome of the military conflict in Ukraine or its impacts in Ukraine, Russia, Belarus, Europe, or the U. S. The extent and duration of the military action, sanctions, and resulting market disruptions could be significant and could potentially have substantial impact on the global economy and our business for an unknown period of time Our Revenues Depend Upon One Product with Multiple Applications. 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, the Russian Federation, India, and Peru; 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. We Rely Heavily On One Supplier for Our Cesium- 131 and Limited Suppliers for Other Components We Require. Our Only Supplier Is In Russia And We Must Rely Solely On Only One Nuclear Reactor From Time to Time. Beginning in the third quarter of fiscal year 2019, all of our Cesium- 131 has been supplied through JSC Isotope from two reactors located in Russia. Our current contract terminates on March 31, 2023. Management will seek to negotiate favorable pricing at each contract extension 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 (" Medikor ") to process the Company' s enriched barium at a specific 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 was shut down from December 2017 until August 2018, and the other Russian nuclear reactor was shut down for much of 2019, 2020 and 2021. As a result of these scheduled shutdowns, only one of the Company' s historic nuclear reactor sources was available during these periods. ~~The~~ **Additionally, at the end of July 2022, one of our key reactors in Russia had an unplanned service disruption. Typically, the Company could switch to the other reactor. However, this year the second reactor was scheduled for a planned outage for routine maintenance in August and could not cover our isotope requirements. This resulted in the Company being temporarily unable to supply our customers with product from mid- August 2022 through early September 2022, when isotope supply resumed. Although we have a** consignment agreement with Medikor **that** permits the Company to periodically rely on a second nuclear reactor for supply when it is operating ~~. Previously~~ , ~~about twenty~~ **we determined during this** ~~percent~~ **recent shutdown** ~~(20 %)~~ of **all available Russian reactors that reliance on this domestic reactor is not a viable solution for short term needs and therefore unplanned outages will result in the inability to supply** our **customers with** isotope ~~supply came from the domestic MURR facility. In early fiscal 2019, the Company terminated its supply agreement with MURR thereby eliminating all domestic suppliers of this critical component of its product. This decision means that the Company has no domestic supply capabilities for Cesium- 131. Management believes that with sufficient notice it may still obtain a supply of Cesium- 131 from MURR but there is no assurance as to the availability and timing of fulfillment if needed. Even if Cesium- 131 was supplied by MURR, MURR cannot manufacture enough supply to meet the Company' s increasing needs and requires additional cost in processing to meet the Company' s isotope specifications~~ . 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~~ **will** have a material adverse effect on seed production and **significant** ~~there may be a~~ delay before we ~~could~~ **can** locate alternative suppliers beyond the two reactors we currently use ~~and~~ **(** one **of** which is ~~currently~~ **typically** available **)** . We may not be able to locate additional suppliers outside of Russia 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 sanctions placed on financial transactions with Russian banking institutions; limitations on the availability of raw materials or manufacturing performance experienced by our suppliers; or a breakdown in our commercial relations with one or more suppliers. Some of these factors may be completely out of our and our supplier' s control. 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. We **Rely Heavily On Three Customers. Approximately forty- eight percent (48 %) of the Company' s revenues are dependent on three customers and approximately twenty- eight percent (28 %) 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** 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. In July 2019, CMS proposed a significant change to the way Medicare ~~currently~~ pays for radiation services in an out- patient setting. The Radiation Oncology Alternative Payment Model (RO APM) proposed a single, bundled payment for a 90- day episode of radiation therapy including LDR brachytherapy, IMRT, SBRT, proton therapy, and HDR brachytherapy. The RO APM proposal applied the same payment levels to services provided in physician offices, free-standing centers, and hospital outpatients. In addition, certain surgical codes were proposed to be included in the bundled payment such as those for gynecological treatments. This CMS proposal for a revised payment included brachytherapy sources. ~~All comments regarding the RO APM were due to CMS by mid- September 2019 and the Company submitted its comments prior to the deadline.~~ The final rule was published on September 18, 2020 **,** with an initial effective date of January 1, 2021; however, CMS subsequently delayed the effective date to July 1, 2021. ~~The Consolidated Appropriations Act, 2021 enacted December 27, 2020 included a provision that delayed the effective date to January 1, 2022. As published, the rule is effective for randomly selected Core- Based Statistical Areas (CBSAs) and the participating zip codes are included in the final rule. The selected zip codes include approximately thirty percent of all eligible Medicare fee- for- service (FFS) radiotherapy episodes nationally.~~ In July 2021, CMS proposed changes to the RO APM which ~~includes~~ **included** removing brachytherapy from the list of included modalities under the RO ~~Model~~ **APM** so that brachytherapy would still be paid under the current fee- for- service (FFS) model. In the proposed rule, CMS ~~explains~~ **explained** the exclusion of brachytherapy from the RO APM ~~is~~ **was** to ensure that providers would not be incentivized to forego brachytherapy in situations where a combination of brachytherapy and EBRT is clinically indicated. Additionally, the proposed rule ~~includes~~ **included** a five **-** year performance period for select zip codes of January 1, 2022 through December 31, 2026. ~~Management is currently evaluating the impact~~ **Effective November 2, 2021, CMS finalized** the proposed rule ~~may have~~ **from July 2021 and determined to keep all brachytherapy and sources** on **a fee-** ~~our business, financial condition, or~~ **for** ~~results~~ **- service model and removed it from the list** of ~~operations~~ **included modalities in the RO APM. While management believes that permitting billing for the Company' s Cesium- 131 product on a fee- for- service model remains favorable to the Company, there is no assurance as to when a new proposal will be proposed for an alternative billing method such as the bundled payment going into effect for many other treatment modalities under RO APM. Brachytherapy and sources or seeds will continue to be paid separately. In December 2021, Congress delayed the start of the RO APM, which was scheduled to start on January 1, 2023, and CMS is now considering whether a January 1, 2024, start date or an alternative start date will be feasible and whether such a date is likely to provide enough time to address the current challenges associated with starting the RO APM as CMS contemplates future rulemaking. CMS has also stated that it welcomes further dialogue with interested parties and RO participants about the design of the RO APM. The Company will continue to provide feedback to CMS and comment on any further proposed rulemaking for RO APM at the appropriate times** . 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 **. Management believes the lack of incremental reimbursement by CMS and private insurers for brachytherapy 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 in- patient brachytherapy** . In- patient procedures are covered by CMS and hospitals are paid based on the type and complexity of the surgery. 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 surgical, in- patient 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. Effective October 1, 2020, new codes took effect and now CMS can track the additional cost of the Cesium- 131 seed itself and reimburse the hospital through the DRG payment system for this additional costs when an in- patient brachytherapy procedure is performed. There is no assurance we will obtain the increases 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 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 current healthcare reform rates, 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. Although Cleared To Treat Any Malignant Tissue, Our Product Is Primarily Used To Treat A Single Type Of Cancer Which Is In A Flat Market. Currently, the Cesium- 131 seed is used almost exclusively for the treatment of prostate cancer (approximately seventy- ~~eight~~ **five** percent of our annual sales in fiscal ~~2021~~ **2022**). We have been treating brain cancer which amounted to approximately ~~fourteen~~ **fifteen** percent of our sales, lung cancer which amounted to approximately ~~three~~ **two** percent of our sales, gynecological cancer which amounted to approximately one percent of our sales, head and neck cancer which amounted to approximately one percent of our sales, and other cancers including pelvic cancer and colorectal cancer that combined constituted approximately ~~three~~ **six** percent of our sales in fiscal year ~~2021~~ **2022** . 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 the treatment of prostate cancer, a market with increasing competition and ongoing loss of market share by all brachytherapy products. Unfavorable Industry Trends In The Prostate Market. 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. Even though the past four fiscal years have shown improvements in the Company' s prostate revenues, since the U. S. Preventive Services Task Force (USPSTF) recommendation in 2012 to no longer routinely conduct prostate exams, the market for all prostate procedures has dramatically declined. 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. 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 have contributed to an increased incidence of screening (and therefore more prostate cancer cases) as opposed to an unscreened population. 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 ~~2021~~ **2022** , 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 ~~2022~~ **2023** ~~. We Rely Heavily On Three Customers. Approximately forty- two percent (42 %) of the Company' s revenues are dependent on three customers and approximately twenty- five percent (25 %) 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~~ . 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 product applications 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 product applications 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. 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 ~~. Due to anticipated future growth and to assure adequate supply for our Cesium- 131, we are investing in bringing a second supply of Cesium- 131 online. We have invested in additional enriched barium to facilitate bringing a second reactor online. We expect that during the initial setup of the new reactor we will be ordering additional isotope to handle the potential start- up variability in isotope supply and this will lower gross margins for the the six- month period ended December 31, 2021, and there is no assurance that future quarters will not require additional purchases to assure we have sufficient supplies of Cesium- 131~~ . 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. 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 often impacted by vacation schedules of our primary physician customers; ■ research and development, raw materials, 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 a competitive product and the rate of market penetration of competing product; ■ seasonality of purchasing behavior in our market; ■ shutdowns of hospitals or outpatient centers due to the COVID- 19 pandemic and any impact COVID- 19 may have on our employees; ■ 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 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 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 condition (s) 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 could 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. Radiation therapy is a key element of cancer treatment, and is delivered as external beam radiation therapy (EBRT) in the vast majority of cases. Brachytherapy with Isoray' s Cesium- 131 seed competes with EBRT as both primary and adjuvant therapy. 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 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, and the timetables to obtain licensure have been exacerbated by the COVID- 19 pandemic. Within the brachytherapy industry itself, our Cesium- 131 seed is more expensive and receives less favorable reimbursement in many cases than use of iodine. Therefore, when physicians use a brachytherapy product many third party reimbursement plans provide more favorable economic incentives to use an iodine product rather than use our Cesium- 131 seed. 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, delivery system, 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. Cost- Containment Efforts Of Our Customers, Purchasing Groups, Third- Party Payers And Governmental Organizations Could Adversely Effect 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. 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. 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 which promotes and supports 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, it is difficult to hire or retain skilled individuals to sell our product. Failure to retain our direct sales force could adversely effect 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 sales in foreign markets. 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 Isotope. 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 Cesium- 131 supply which could have a 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. Legal and Regulatory Risks If We Fail To Comply With Applicable Healthcare Regulations, We Could Face Substantial Penalties And Our Business, Operations And Financial Condition Could Be Adversely Effected. 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 **and criminal** 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 **federal** Health Information Technology for Economic and Clinical Health Act of 2009 ~~,~~ and **its** ~~their respective~~ implementing regulations, which impose requirements on ~~certain~~ **entities** covered **by HIPAA, including** 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 approved in 2017 which, when it went into effect in **May** ~~the spring of 2020~~ **2021** , imposed significant additional premarket and post-market requirements. This new EU Medical Device Regulation caused the Company to not renew its CE Mark due to the requirement of additional clinical trials that would have required a significant investment. 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, **and New Jersey** requiring reporting to state governments **or the banning** of **certain** 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 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. 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 implemented regulations under the ACA related to disclosure of payments made by manufacturers to physicians and teaching hospitals, which were 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. One of the patents that we license expired in fiscal year 2019 and others could now use the methods described in the patent without risk of infringing on our intellectual property **. Another of our patents is scheduled to expire in 2025**. Over the years, the Company has improved and changed our methods and we were only using a small portion of the methods described in the expired patent. 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, our delivery device patent, 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 pending or future 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 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 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. 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. 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, 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. If we obtain sufficient financing to relocate, we intend to shut down our leased manufacturing and office facility, finish the planning and construction of a new manufacturing and office facility to be owned by the Company, and move 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. 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. The costs of our director and officer insurance policy premiums increased nearly ~~15~~ **18** % for fiscal year ~~2021~~ **2022** (which management understands was not solely related to our operations but industry wide). 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. Risks Related to Our and Shares of Common Stock and Public Company Status We Have Incurred Significant Losses To Date, And There Is No Guarantee That We Will Ever Become Profitable. We incurred net losses of $ ~~3~~ **7** , ~~387~~ **297** , 000 and $ 3, ~~446~~ **387** , 000 in the fiscal years ended **2022 and** 2021 ~~and 2020~~ , respectively. In addition, we have accumulated deficit from the inception of business through June 30, ~~2021~~ **2022** of $ ~~91~~ **98** , ~~325~~ **622** , 000. 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. 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 $ 250 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 ~~2021~~ **2022** the closing price of one share of our common stock reached a high of $ ~~2~~ **0** . ~~47~~ **79** and a low of $ 0. ~~36~~ **26** . There is generally significant volatility in the market prices and limited liquidity of securities of companies which have failed to show profits. 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; the viability of non- prostate products; 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 rise or 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 stockholders for the foreseeable future. Stockholders 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.