

INTERNATIONAL ISOTOPES INC  
Form 10-K  
March 24, 2016

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

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934

For the fiscal year ended December 31, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF  
1934

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

Commission file number: 000-22923

**INTERNATIONAL ISOTOPES INC.**

(Exact name of registrant as specified in its charter)

**Texas**  
(State or other jurisdiction of incorporation  
or origination)

**74-2763837**  
(IRS Employer Identification Number)

**4137 Commerce Circle**

**Idaho Falls, Idaho**  
(Address of principal executive offices)

**83401**  
(Zip code)

**(208) 524-5300**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

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

-----  
COMMON STOCK, \$.01 PAR VALUE

(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

Edgar Filing: INTERNATIONAL ISOTOPES INC - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

---

Edgar Filing: INTERNATIONAL ISOTOPES INC - Form 10-K

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES  NO

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity at June 30, 2015, the last business day of our second fiscal quarter, was approximately \$15.3 million. For purposes of this calculation, all directors and executive officers of the registrant and holders of 5% or more of the registrant's common stock are assumed to be affiliates. This determination of affiliate status is not necessarily conclusive for any other purpose.

As of March 14, 2016, the number of shares outstanding of the registrant's common stock, \$.01 par value, was 402,421,525 shares.

Documents Incorporated by Reference

Certain information called for in Part III of this Annual Report on Form 10-K is incorporated by reference to the registrant's definitive proxy statement for the 2016 annual meeting of shareholders, which will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2015.



**INTERNATIONAL ISOTOPES INC.****FORM 10-K****TABLE OF CONTENTS**

	<u>Page No.</u>
<b>PART I</b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	9
Item 1B. <u>Unresolved Staff Comments</u>	16
Item 2. <u>Properties</u>	16
Item 3. <u>Legal Proceedings</u>	16
Item 4. <u>Mine Safety Disclosures</u>	16
<b>PART II</b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	16
Item 6. <u>Selected Financial Data</u>	17
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
Item 8. <u>Financial Statements and Supplementary Data</u>	28
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	28
Item 9A. <u>Controls and Procedures</u>	28
Item 9B. <u>Other Information</u>	29
<b>PART III</b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	29
Item 11. <u>Executive Compensation</u>	29
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	29
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	29
Item 14. <u>Principal Accounting Fees and Services</u>	29
Item 15. <u>Exhibits, Financial Statement Schedules</u>	29
<u>Signatures</u>	33



## Cautionary Note Regarding Forward-Looking Statements

*This Annual Report on Form 10-K (the Annual Report ) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding industry prospects and future results of operations or financial position, made in this Annual Report are forward-looking. Words such as: anticipates, believes, should, expects, future and intends and similar expressions identify forward-looking statements. In particular, statements regarding: The expected growth in various business segment revenues, our expansion into new markets, the ability of our products to compete with several larger companies and products, the results of market studies used to support our business model, our anticipated improvement in economic conditions, our ability to continue cobalt-60 production and manage costs, the commercial opportunity of the proposed depleted uranium and fluorine extraction processing facility, and the sufficiency of our available cash and revenues from operations to meet our operating needs; are forward- looking. Forward-looking statements reflect management s current expectations, plans or projections and are inherently uncertain. Actual results could differ materially from management's expectations, plans or projections. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. Certain risks and uncertainties that could cause actual results to differ significantly from management s expectations are described in the section entitled Risk Factors in this Annual Report. That section, along with other sections of this Annual Report, describes some, but not all, of the factors that could cause actual results to differ significantly from management s expectations. We do not intend to publicly release any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Readers are urged, however, to review the risks and other factors set forth in the other reports that we file from time to time with the Securities and Exchange Commission (the SEC ).*

## PART I

### Item 1. BUSINESS

#### General Business and Products Description

International Isotopes Inc. (the Company , we , us and our ) was formed as a Texas corporation in 1995. Our wholly-owned subsidiaries are International Isotopes Idaho Inc., a Texas corporation; International Isotopes Fluorine Products, Inc., an Idaho corporation; and International Isotopes Transportation Services, Inc., an Idaho corporation. Our core business consists of six reportable segments which include: Nuclear Medicine Standards, Cobalt Products, Radiochemical Products, Fluorine Products, Radiological Services, and Transportation.



During 2015 we focused our efforts on achieving profitability in each of our core business segments and reached several significant goals. During 2015, we:

Continued research into the expansion of radiochemical products through joint development agreements and continued work towards the submittal of a new generic drug product application to the U.S. Food and Drug Administration ( FDA );

Obtained trademark registration of I<sup>3</sup>odine/MAX<sup>TM</sup>, our sodium iodide radiochemical product (I-131) as an oral solution or capsules for use in the treatment and diagnosis of various thyroid diseases, thyroid cancer, and hyperthyroidism, and for the use in investigational and clinical trials for the treatment of breast, lung, prostate, and ovarian cancers;

Entered into several supply agreements with customers for the purchase of cobalt-60 which in some cases includes on-going services such as source manufacturing and source installation into therapy devices;

Continued to identify alternate sources of cobalt-60 for customers to stem the shortages in supply that have occurred in the past, and that will continue to occur until the first full cobalt irradiation services are complete in late 2017;

Were awarded several radiological services jobs through the DOE s Orphan Source Recovery Program ( OSRP ) in which we were able to use our mobile hot cell; and

Continued to support the essential tasks related to our de-conversion project and continued to pursue opportunities to obtain additional contracts for depleted uranium de-conversion services.

In 2016, we plan to continue efforts to further expand and improve upon our operations in our core business segments. We intend to continue to invest in these segments and work to pursue product development, reduce production costs and expand sales in each of them. The following paragraphs provide a brief description of each of our business segments. Certain financial information with respect to each of our business segments, including revenues from external customers, a measure of profit or loss, and total assets, is set forth in Note 14 in the Notes to our Consolidated Financial Statements which begin on page F-6.

#### Nuclear Medicine Standards

This segment consists of the manufacture of sources and standards associated with Single Photon Emission Computed Tomography (SPECT) imaging, patient positioning, and calibration or operational testing of dose measuring equipment for the nuclear pharmacy industry. Our nuclear medicine standards products include flood sources, dose calibrators, rod sources, flexible and rigid rulers, spot markers, pen point markers, and a host of specialty design items. These products are manufactured through an exclusive manufacturing agreement with RadQual, LLC ( RadQual ) of which we own a 24.5% interest. The manufacturing agreement provides that we will manufacture sources exclusively for RadQual and will not manufacture products that would directly compete with RadQual sources. The agreement also states that RadQual will only procure sources manufactured by us for distribution to RadQual customers. Should this agreement with RadQual terminate, we would be precluded from competing with RadQual in the nuclear medicine market for a period of two years. For this reason, we have worked to expand revenues from other segments to decrease our risk of dependency on RadQual. The initial term of the agreement with RadQual expired on December 31, 2008, but the agreement automatically renews each January 1<sup>st</sup> thereafter unless otherwise terminated by either party with 60 days written notice, and continues in effect currently.

There are over 5,000 nuclear medicine centers in the United States ( U.S. ) that require nuclear medicine products on a regular repeat basis. We have been manufacturing these products for RadQual since 2001. The majority of nuclear medicine product sales are to U.S. customers; however, in recent years we have seen an increase in foreign sales. All of these products contain radioactive isotopes that decay at a predictable rate. Therefore, customers are required to periodically replace most of these products when they reach the end of their useful lives. The useful life of these products varies depending on the isotope used in manufacture, but in most cases averages 18 months to two years. The isotopes used in manufacturing these nuclear medicine products are available from various sources world-wide and we are not dependent on a single supplier. In addition to the products themselves, we have developed a complete line of specialty packaging for the safe transportation and handling of these products.

RadQual has numerous distributors for direct sales of its products. Formerly, the largest distributor was Technology Imaging Services Inc. ( TIS ). In December 2010, we formed a 50/50 joint venture with RadQual to acquire the assets of TIS, and those assets were used to create TI Services, LLC ( TI Services ). We believed that this joint venture would provide growth opportunities in existing and future RadQual product lines both domestically and internationally by using TI Services as a marketer for RadQual products.

### Cobalt Products

Our cobalt products segment includes the production of bulk cobalt (cobalt-60), fabrication of cobalt capsules for radiation therapy or various industrial applications, and recycling of expended cobalt sources.

Although historically bulk cobalt sales have accounted for a significant amount of the total revenue from this business segment, as further described below, during the past several years we have not had any bulk sales because of limited access to the irradiation positions in the U.S. Department of Energy s ( DOE ) Advanced Test Reactor ( ATR ) located in Idaho. However, through continued discussions, in October 2014, we entered into a ten year agreement with the DOE for the irradiation of cobalt material which should increase our supply of cobalt material from the ATR beginning in late 2017. Cobalt material requires approximately two to three years of irradiation at the ATR in order to achieve the desired level of activity.

The year-over-year demand for cobalt products has continued to remain strong as a result of the introduction of several new types of cobalt therapy units and we have continued to see robust growth in the demand for cobalt manufactured products for those devices. We continue to explore opportunities to further develop cobalt products sales through increased production of finished source products. The production, use, transport, and import/export of these products are all heavily regulated, but we have developed an experienced staff of technicians, drivers, and supervisors to comply with the regulations and support cost effective and timely delivery of these products. One reason we established our Transportation segment was to support the delivery of cobalt products.

Historically, most of our cobalt production has been dependent upon the DOE and its prime operating contractor, which controls the ATR operations and, therefore, controls the continued production of cobalt in the government-funded ATR. In June 2012, a leak of a cobalt target at the ATR belonging to another commercial business resulted in the curtailment of all further cobalt handling and production activities at the ATR pending completion of several corrective actions. During 2013, we worked with the prime operating contractor to resolve some of the issues related to the corrective actions, and in October 2013, we were able to resume shipments of some cobalt material to our production facility in Idaho Falls, Idaho. During 2014, we continued to work with the contractor to complete a new cobalt target design that could be used in the ATR and to negotiate a new cobalt production agreement with the DOE. In October 2014, we entered into a ten year agreement for cobalt production with the DOE and in early 2015, the DOE resumed cobalt irradiation in the ATR. Subsequent to completing the agreement with the DOE, we began putting commercial sales agreements in place with our customers. In accordance with those agreements we began receiving pre-payments from customers on future cobalt shipments which we have recorded as unearned revenue. We expect to recognize significant sales of our cobalt-60 material beginning in late 2017, however, for the next year our access to supplies of high activity material will be limited. In the meantime, we will rely on obtaining recycled material and material procured in small quantities from other sources to fulfill some of our customer demand.

We are continuing to work with the DOE on the possibility of resuming production and sale of an older version of cobalt targets that we own and have stored at the ATR. However, at this point, it appears that the cost to further irradiate these targets may not be cost beneficial and we may have the targets shipped to our facility at their current levels of activity and use them for lower activity source production. We are working with the DOE to obtain some additional cost information for loading and shipping these older targets before making a final determination on the disposition of this material.

### Radiochemical Products

This segment includes production and distribution of various isotopically pure radiochemicals for medical, industrial, or research applications. These products are either directly produced by us or are purchased in bulk from other producers and distributed by us in customized packages and chemical forms tailored to meet customer and market demands. Sodium Iodide (Iodine-131) radiochemical products account for the largest portion of sales within this segment. Our Iodine-131 is supplied to us through an agreement with NTP Radioisotopes (Pty) Ltd. ( NTP ) in South Africa and is imported as a radiochemical intended for medical applications. Although there are other manufacturers of Iodine-131, in August 2013, we renewed our agreement with NTP for the supply of Iodine-131 that allows us to purchase iodine at a mutually agreeable pre-determined price through July 2018. Either party may terminate the agreement by giving three months notice prior to the expiration of the term.

Generally, Iodine-131 is used in the treatment and diagnosis of various diseases of the thyroid gland such as Graves disease, thyroid cancer and hyperthyroidism. There are also several investigational and clinical trials underway to explore the use of Iodine-131 for such applications as the treatment of breast, lung, prostate, and ovarian cancers.

Other less significant sales of radiochemical in this segment consist of sales of isotopes such as Cobalt-57 (Co-57), Cesium-137 (Cs-137), Sodium-22 (Na-22), and Barium-133 (Ba-133).

### Fluorine Products

We established the fluorine products business segment in 2004 to support production and sale of the gases produced using our Fluorine Extraction Process ( FEP ) that we intended to use in conjunction with the operation of the proposed depleted uranium de-conversion facility in Lea County, New Mexico. The FEP is a process that produces ultra-high-purity fluoride gas products through a solid-to-solid reaction between depleted uranium tetrafluoride ( DUF4 ) and various solid metal oxides such as silicon. High-purity fluoride gases are in high demand for

processes such as ion-implantation and chemical vapor deposition and also for the manufacture of organic complexes used in a host of industrial applications and manufacturing processes. The FEP products have very high purity, which makes them ideally suited to these specialty applications.

We acquired seven patents for the FEP in January 2004 and built a pilot production facility in Idaho that began operation in 2006. In 2010, we were granted an additional process patent on FEP based upon information gained through the operation of the pilot facility. Our pilot facility was not used for commercial gas production but instead focused upon production of high-purity products and examined methods of scaling up the size of the production operations in support of the proposed de-conversion facility in New Mexico. By the end of 2012, we had completed our testing of individual components and analytical processes and in April 2013, we shut down the pilot facility and terminated our lease on that property.

Near the end of 2013, due to changes in the nuclear industry, we placed further engineering work on the proposed uranium de-conversion facility on hold. Further activity within this segment will be deferred until market and industry conditions change and justify resuming design and construction of the facility. In the meantime, we expect to continue to incur costs associated with the maintenance of licenses and other necessary project investment, and the Company expects to continue to keep certain agreements in place that will support resumption of project activities at the appropriate time.

### Radiological Services

This segment includes a wide variety of miscellaneous services such as processing gemstones, decommissioning disused irradiation units, and performing sealed source exchanges in irradiation and therapy units. In May 2004, we entered into an exclusive contract with Quali-Tech, Inc., for gemstone processing and, historically, this contract has accounted for the majority of sales in this segment. In May 2012, we modified and renewed the contract, which remains in effect until either party gives a minimum of six months notice to the other that it does not intend to continue the contract. The contract provides that we will act as the exclusive processor of gemstones for Quali-Tech, Inc., for the term of the contract and two years beyond.

We are licensed through the Nuclear Regulatory commission ( NRC ) to perform certain field service activities in connection with the DOE s Orphan Source Recovery Program ( OSRP ). These activities include services to support recovery of disused sources under the DOE s OSRP and installation or removal of certain cobalt therapy units. We designed and built a mobile hot cell unit to use in this field service work and during 2015 and 2014 used the unit to perform numerous OSRP field service jobs. This type of field service work is expected to generate the majority of revenue within this business segment in the coming years.

### Transportation

This segment was established in 2006 through our subsidiary, International Isotopes Transportation Services ( IITS ), to provide transportation of our products (such as cobalt sources) and to offer for hire transportation services of hazardous and non-hazardous cargo materials. A major factor in our decision to establish this subsidiary and business segment was the high cost of third-party transportation services and high volume of regulations involving the security and tracking of shipments of cobalt. IITS provides us with considerable savings for the transportation of our own products and produces a small revenue stream through the transportation of products for other companies. We expect to expand transportation services to support our expanding field services work and to support delivery of other products in other business segments.

### **Uranium De-conversion Facility**

In 2004, we began a major undertaking to construct the first commercial uranium de-conversion facility in the U.S. At that time, it was our belief that such an undertaking would provide an excellent commercial opportunity to us in the future.

In October 2012, we received the NRC construction and operating license for the planned de-conversion facility. This is a forty (40) year operating license and is the first commercial license of this type issued in the U.S. There are no other companies with a similar license application under review by the NRC and the license does not require us

to begin construction of the project by any specific date. Therefore, the NRC license represents a significant competitive barrier and we believe that it provides us with a very valuable asset now and in the future when we are ready to resume formal design and engineering work on the plant.

In 2013, we placed this project on hold due to changing market conditions and the need for additional funding; however, we still consider this project to be an excellent future commercial opportunity. The changes to market conditions were the result of changes in the outlook for growth in the nuclear industry. When we began pursuing this project, there were several companies planning for construction of new commercial uranium enrichment plants in the U.S. We were successful in executing a de-conversion service agreement with one of these companies, Urenco USA (UUSA), that would use approximately 50% of the installed processing capacity of our proposed de-conversion facility. However, plans to obtain additional contracts with the other enrichment companies that would commit 100% of the planned facility's capacity have been delayed because of the slowdown in nuclear industry growth. Having contracts in place is necessary for us to obtain funding for the project. In addition, both the Fukushima, Japan disaster and low natural gas prices in the U.S. continue to negatively impact growth in the nuclear industry and there is no serious discussion of constructing additional nuclear capacity in the U.S. in the near term. Meanwhile, however, the facility operated by UUSA continues to produce and stockpile depleted uranium tails and, therefore, we believe there is still an opportunity to provide commercial depleted uranium de-conversion services at some point in the future. Unless and until that opportunity emerges, we will keep this project on hold and focus our efforts on our other business segments and continue to work towards achieving profitability in those areas.

## **Industry Overview, Target Markets, and Competition**

The industries and markets that require or involve the use of radioactive material are diverse. Our current core business operations involve products that are used in a wide variety of applications and in various markets. The following provides an explanation of the markets and competitive factors affecting our current business segments.

### Nuclear Medicine Standards

Calibration and reference standards are required for the daily operational checks and calibration of the measurement of SPECT imaging devices frequently used in nuclear medicine. Calibration and quality assurance testing is required as a routine part of the normal operations of this equipment to ensure its reliability and accuracy. We exclusively manufacture many of these reference standard products for one customer, RadQual, which in turn has several distributors who make direct sales around the U.S. and internationally. We directly ship these products to all 50 states and many overseas locations. There is only one other producer of these products in the world that directly competes with us for these products. Most of the products manufactured by our competitor are similar in design to our products because all must meet Original Equipment Manufacturer (OEM) dimensional and performance standards. However, we attempt to differentiate our products from our competitor's products through increased levels of quality control and customer service. We received ISO-9001:2008 and ISO-13485-2003 quality program certifications in 2011 that have allowed us to start selling these products into several foreign countries that require this additional quality certification for manufacturers. We use a small number of suppliers for the isotopes and other materials used in manufacturing these nuclear medicine products, and if we were to lose any of these suppliers, others would be available.



In December 2010, we formed TI Services, a joint venture with RadQual, with the expectation that we would use TI Services as a distributor of nuclear medicine and nuclear cardiology products. In 2014, we began selling a new lightweight flood source, the Rad-Lite, that we developed in collaboration with RadQual. This new product was introduced to the market in April 2014 and is being marketed by TI Services.

Cobalt Products

Historically, we have sold high-activity bulk cobalt to one customer that used it to fabricate several models of sealed sources for medical and industrial applications. However, due to problems at the DOE's ATR during 2012, as described above, we were forced to discontinue the irradiation of our in-process cobalt targets and have not recorded any bulk cobalt sales for the past several years. With some residual cobalt material that we held at our facility, we were able to manufacture a variety of sealed source products through the beginning of 2014. Pursuant to the 10-year agreement that we entered into with the DOE in 2014, we anticipate that cobalt shipments to customers will resume

in late 2017. Our cobalt products are used in applications such as radiation therapy, security devices, and radiography examination. While there are other technologies available to provide external radiation therapy, there are several new state-of-the-art devices that depend on cobalt sources for several of their specialized applications. There are currently no other producers of high specific activity cobalt in the U.S., however, there is one producer of medium specific activity material and there are at least three significant producers of high specific activity material in other parts of the world. In addition to us, there is only one other company in the U.S. currently licensed to handle large quantities of cobalt.

We manufacture cobalt sources as well as recycle used cobalt sources by recovering the cobalt for re-use in the manufacture of new sealed sources for teletherapy devices, irradiators, and other source applications. We are the only company in the U.S. that provides this unique service. There has been a significant increase in regulation by the NRC in recent years that has created a significant barrier to new entrants to this market. We expect growth in the demand for cobalt in several of the newer applications, and coupled with an expected decline in reactors around the world that are capable of producing this type of high-activity material, we expect increased demand for our cobalt products over the next five years. Nonetheless, we are at present dependent upon our contract relationship with the DOE for access to its ATR in Idaho for continued cobalt production. The interruption to cobalt production experienced in 2012 had a significant negative impact on our cobalt products business segment, and although we currently have a ten-year irradiation contract in place with the DOE, future interruptions in the operation of the ATR could have a negative impact on our cobalt products business segment. With our new cobalt production contract in place with the DOE we anticipate our market position in this business segment will continue to grow in future years.

### Radiochemical Products

We typically supply radiochemical products in bulk form. The markets for most radiochemicals are highly competitive. The target markets for these products are customers who (1) incorporate them into finished industrial or medical devices; (2) use radioisotope products in clinical trials for various medical applications; or (3) further process and include the radioisotope products into a pharmaceutical product FDA approved therapy or imaging. We are the only U.S. company that supplies Iodine-131 radiochemical directly to radiopharmacies. There is one major foreign company that produces a similar product as an FDA approved pharmaceutical product that competes with our sales.

Continuation of business in this segment is highly dependent upon maintaining a low-cost, high-quality product meeting all of the current Good Manufacturing Practices ( cGMP ). We are currently taking steps to advance into the manufacture of generic drug products using these basic radiochemicals. We have received trademark approval for I<sup>3</sup>ODINE/MAX<sup>TM</sup>, our Iodine-131 oral solution and we are in the process of submitting an abbreviated New Drug Application (aNDA) to the U.S. Food and Drug Administration (FDA) for approval of this product as a generic drug.

The time required for FDA approval of the I<sup>3</sup>ODINE/MAX<sup>TM</sup> product is unknown. Once approved, however, we anticipate it will significantly expand the sales of this product. We are also considering other generic drug opportunities and plans to significantly expand the range of products offered within this business segment in the coming years.

### Fluorine Products

Our Fluorine Products segment was developed in conjunction with uranium de-conversion in order to take advantage of the anticipated need for depleted uranium de-conversion services. Our FEP patents provide a unique opportunity to provide certain high-purity fluoride compounds while also offering a for fee de-conversion service to the uranium enrichment industry. Although during 2013 we curtailed the formal engineering work on the de-conversion facility, we believe that in the future there will be a resumption of nuclear growth overseas that will positively impact the front end of the nuclear fuel cycle. Once that occurs the ground work we have completed on the depleted uranium de-conversion and fluorine extraction project should put us in an excellent position to take advantage of our position in the industry and should serve to justify the financial investment in this uranium de-conversion project in the future. We intend to continue to maintain our licenses and other necessary project investments so that the project activities can be resumed when market conditions improve.

## Radiological Services

Historically, most of our radiological services have been performed in support of gemstone processing for Quali-Tech, Inc. Gemstone processing has fluctuated in recent years but has remained a significant contributor to this segment's revenue.

In 2012, we obtained our first amendment to our NRC license to permit certain field service activities and since that time radiological field service work has become a significant contributor to revenue within the segment. In both 2015 and 2014 we were awarded several contracts for field service activities in connection with the DOE's OSRP project. We designed and built a mobile hot cell unit for use in this field service work and in 2014 and 2015 we were granted additional amendments to our NRC license that have allowed us to expand the types of services we can provide. We will use the mobile hot cell to support these expanded services. While there are other companies that compete with us for field services work, we believe our mobile hot cell gives us a unique competitive advantage in some of these opportunities. In 2015 we worked to further increase these field service opportunities in the U.S. and abroad and expect that field services will be the major source of revenue within this business segment.

## Transportation

IITS was formed in order to support transportation of our own products and to provide for hire transportation services. IITS specializes in the transportation of hazardous, radioactive materials including large cobalt shipments. These types of shipments face a significant amount of increased regulation and enhanced security requirements and IITS is well suited to meeting these requirements while significantly reducing our transportation costs. IITS has specially trained drivers and specially equipped vehicles intended to meet the standards for transportation of large cobalt shipments. Therefore, IITS is capable of providing unique transportation services that we believe only one or two other commercial carriers in the U.S. can also provide. The transportation segment directly supports the sale and delivery of our cobalt products and the performance of field service projects and as such is a cost saving operation for us.

## **Government Regulation**

### *Licensing*

We currently operate under two NRC licenses, one for broad scope operations and another for exempt distribution. Our broad scope license covers calibration and reference standard manufacturing and distribution, radioisotope processing and distribution, large scale cobalt processing and recycle operations, radioactive gemstone processing, environmental sample analysis, certain field service activities, and research and development. The exempt distribution license permits the release and distribution of irradiated gemstones to unlicensed entities in the U.S. All

of our existing licenses and permits are adequate to allow current business operations. We do not handle special nuclear materials (i.e. nuclear fuels and weapons grade uranium, thorium or plutonium); therefore, our facility is not designated as a nuclear facility that would require additional licensing.

In October 2012, we were granted a Part 40 construction and operating license by the NRC for the de-conversion facility. The de-conversion facility, which is to be located in Lea County, New Mexico, is proposed to initially de-convert up to approximately 11 million pounds of depleted uranium hexafluoride ( DUF<sub>6</sub> ) annually into fluoride products and depleted uranium oxides ( DUO ). Further engineering work on the proposed de-conversion facility was placed on hold in 2013 until additional contracts for utilization could be obtained. There is no specific timeline required by the NRC for the start of construction on this project. The de-conversion facility will require a ground water permit from the state of New Mexico before operation.

As a condition of our NRC licenses in Idaho, we are required to provide financial assurance for decommissioning activities. We fulfill this license requirement with a letter of credit and a restricted certificate of deposit in the amount of \$450,630, held at Wells Fargo Bank, which names the NRC as beneficiary. The letter of credit is supported by a restricted certificate of deposit. Similar financial assurances will be required to fund the decommissioning of the proposed de-conversion facility.

*Regulation of Radioisotope Production Waste*

All of our manufacturing processes generate some radioactive waste. We must handle this waste pursuant to the Low Level Radioactive Waste ( LLRW ) Policy Act ( LLRW Act ), which requires the safe disposal of mildly radioactive materials. The estimated costs for storage and disposal of these materials have been included in the manufacturing and sales price of our products. However, actual disposal costs are subject to change at the discretion of the disposal site and are ultimately applied at the time of disposal. We have obtained all necessary permits and approvals for the disposal of our waste materials and we do not anticipate any negative changes in capacity or regulatory conditions that would limit or restrict our waste disposal capabilities.

*Nuclear Regulatory Commission Oversight*

We operate under two NRC licenses and are subject to NRC oversight of our operations. In August 2015, one of our employees received an elevated radiation exposure in excess of legal limits but with no apparent resulting injury. As a result of this exposure incident, the NRC may impose a violation which could also include a civil penalty. However, we do not expect the civil penalty to be material in amount due to the prompt and complete corrective actions taken by us.

*Other Regulations*

We are registered as a medical device manufacturer through the FDA for several of our nuclear medicine reference and calibration standards. We are registered with the U.S. Department of Transportation for the shipment of radioactive materials. We also have an NRC license for the import and export of radioactive materials. Because of increasing security controls and regulations, it is likely that we may encounter additional regulations affecting transportation, storage, sale, and import/export of radioactive materials. We are also subject to inspection by the FDA to be in compliance with cGMP for our sodium iodide product and are registered with the FDA as an Active Pharmaceutical Ingredient manufacturer and a manufacturing facility.

We are subject to government regulation and intervention both in the U.S. and in all foreign jurisdictions in which we conduct business. Compliance with applicable laws and regulations results in higher capital expenditures and operating costs and changes to current regulations with which we must comply can necessitate further capital expenditures and increases in operating costs to enable continued compliance.

**Employees**

As of December 31, 2015, we had 27 total employees including 25 full-time employees.

### **Distribution Methods for Products**

We sell our products directly to our customers who, in some cases, are both end users and distributors. We use common commercial carriers and our own IITS subsidiary for delivery of our products. For smaller quantities of material, and overnight and next-day delivery, we utilize other commercial carriers. For our products that involve large quantities of radioactive material, most commonly cobalt-60, and that invoke certain special transportation requirements, we use our IITS transportation subsidiary.

### **Dependence on Customers**

During 2015, one major customer, RadQual, accounted for 27% of our total gross revenue. This total includes both sales under an exclusive sales agreement with RadQual and its sales as a distributor of the products we manufacture for them and also includes sales reported by TI Services, our joint venture with RadQual. Historically, the majority of the radiochemical products sold by the Company were done so through a supply agreement with RadQual. In September 2014, upon mutual agreement, we ended this radiochemical supply agreement with RadQual and began direct sales to customers of all radiochemical products.

Combined sales, on which we are dependent, to our three largest customers, accounted for 40% of our total gross revenues in 2015 and accounted for 46% of our total gross revenues in 2014. We are making efforts to reduce our dependency on a small number of customers by expanding sales in both domestic and foreign markets and through our establishment of the joint venture, TI Services, to expand distribution of products. We also have several agreements in place for the sale of cobalt products and services and anticipate additional opportunities for revenue from expanded radiological services.

### **Patents, Trademarks, Licenses and Royalty Agreements**

In 2004, we obtained certain patents related to the FEP. In July 2010, we were granted a new patent on the FEP process which provides patent protection of this intellectual property through 2019. These patents will be important to the future operation and production capacity of the de-conversion facility. We believe these patents will provide a commercial opportunity once companies resume planning and construction of any new uranium enrichment facilities in the U.S. In 2009, patent applications were made in Brazil, Canada, China, Europe, Japan, Russia, and South Africa for other FEP related production techniques. In 2013, the FEP process patent was granted in Russia and in 2014 the FEP process patent was approved in South Africa. In 2015, the FEP process patents in China and Japan were abandoned. The applications in the other countries mentioned above are still in process.

In September 2015, we obtained approval from the U.S. Patent and Trademark office for the trademark registration of I<sup>131</sup>odine/MAX<sup>TM</sup>. The trademark is for Iodine-131 radiochemical product as solution or capsules for use in the treatment and diagnosis of diseases of the thyroid, thyroid cancer, and hyperthyroidism and for use in investigational and clinical trials for the treatment of breast, lung, prostate, and ovarian cancers.

### **Research and Development**

We had research and development expenses totaling \$821,453 in 2015, compared with \$464,206 in 2014. These expenses were primarily associated with current product development activities related to generic radiochemical products.

### **Available Information**

Our internet website address is <http://www.internationalisotopes.com>. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ) are available free of charge through our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information on our website is not incorporated by reference into this report or other reports filed with the SEC.



**Item 1A. RISK FACTORS**

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

**Risks Related To Our Current Business Operations**

*We are dependent on various third parties in connection with our business operations.* The production of high-specific activity cobalt is dependent upon the DOE, and its prime-operating contractor, which controls the Idaho reactor. Current activity at the Idaho ATR may continue to affect the supply of cobalt material needed for the manufacture of cobalt sources. Loss of the ability to use, or cost-effectively use, these irradiation services would significantly impact our cobalt products business segment because there is not currently another reactor available in the United States that is capable of providing this type of service for us. Our nuclear medicine calibration and reference standard manufacturing is conducted under an exclusive contract with RadQual, which in turn has agreements in place with several distributors for marketing and sales. Our radiochemical iodine is supplied to us

through two supply sources with a third source expected to become available during 2016. Unanticipated contract terminations by any of these suppliers and other third parties would have a material adverse impact on our operations, financial results, and cash flow.

***We are dependent on a limited number of customers in connection with our current business operations.*** During 2014 and 2015 sales to RadQual represented 27% of our total gross revenues for each year. Combined sales to our three top customers accounted for 40% of our total gross revenues during 2015, and combined sales to our top three customers accounted for 46% of gross revenue in 2014. Although we are making efforts to reduce our dependency on a small number of customers, the loss of any one of these customers could have a significant impact on our future results of operations and financial condition. Unanticipated contract terminations by any of these current customers could have a material adverse impact on operations, financial results, and cash flow.

***We are subject to competition from other companies.*** Each of our existing business areas has direct competition from other businesses. High-specific activity cobalt is supplied by other reactor facilities around the world. Nuclear medicine calibration and reference standards are being produced by one other major manufacturer in the United States. Most of our radiochemicals are also manufactured by several other companies in the world, and there are other providers of radiological field services. Most of our competitors have significantly greater financial resources that could give them a competitive advantage over us.

### **Risks Related To Our Company Generally**

***We have incurred, and may continue to incur, losses.*** With the exception of 2002, we have incurred net losses for most fiscal periods since our inception. From inception through December 31, 2015, we have generated \$90,675,941 in revenues and an accumulated deficit (including preferred stock dividends and returns) in the amount of \$120,060,449. The negative cash flow we have sustained has materially reduced our working capital, which in turn could materially and negatively impact our ability to fund future operations and continue to operate as a going concern. Management has taken and continues to take actions to improve our results. The availability of necessary working capital, however, is subject to many factors beyond our control, including our ability to obtain favorable financing, economic cycles, market acceptance of our products, competitors' responses to our products, the intensity of competition in our markets, and the level of demand for our products.

***Our operations expose us to the risk of material environmental liabilities.*** We are subject to potential material liabilities related to the remediation of environmental hazards and to personal injuries or property damages that may be caused by hazardous substance releases and exposures. The materials used in our operations subject us to risks of environmental contamination that subject us to liability, including remediation obligations that could be very costly. In addition, the discovery of previously unknown contamination could require us to incur costs in the future that would have a negative effect on our financial condition or results of operations. We have a Standby Letter of Credit in place supported by funds in a restricted certificate of deposit to provide the financial assurance required by the NRC for our Idaho facility license for decommissioning and a similar mechanism will be required to fund the decommissioning of the proposed new depleted uranium facility. However, if a contamination event occurred within, or outside of, our facility we would be financially responsible to remediate such contamination and could have to borrow money or fund

the remediation liability from our future revenue. We may not be able to borrow the funds, or have available revenue, sufficient to meet this potential liability, which could have a significant negative impact on our results of operations.

***We are dependent upon key personnel.*** Our ongoing operations are dependent on Steve T. Laflin, President and Chief Executive Officer. The loss of Mr. Laflin could have a material adverse effect on our business. We have a \$2 million key man life insurance policy on Mr. Laflin and an employment agreement that extends through February 28, 2017. However, there is no assurance that we will be able to retain Mr. Laflin or our existing personnel or attract additional qualified employees. The loss of any of our key personnel or an inability to attract additional qualified employees could result in a significant decline in revenue.

***General economic conditions in markets in which we do business can impact the demand for our goods and services. Decreased demand for our products and services can have a negative impact on our financial performance and cash flow.*** Demand for our products and services, in part, depends on the general economic conditions affecting the countries and industries in which we do business. A downturn in economic conditions in the

U.S. or industry that we serve may negatively impact demand for our products and services, in turn negatively impacting our operations and financial results. Further, changes in demand for our products and services can magnify the impact of economic cycles on our businesses. For instance, our topaz gemstone processing is affected by the demand for luxury items such as jewelry as well as by the instability of foreign markets which are key factors in the manufacture of products using irradiated gemstones.

***Volatility in raw material and energy costs, interruption in ordinary sources of supply and an inability to recover unanticipated increases in energy and raw material costs from customers could result in lost sales or significantly increase the cost of doing business.*** Market and economic conditions affecting the costs of raw materials, utilities, energy costs, and infrastructure required for the delivery of our goods and services are beyond our control and any disruption or halt in supplies, or rapid escalations in costs could affect our ability to manufacture products or to competitively price our products in the marketplace. For instance, an interruption in the supply of isotopes such as cobalt-57, cobalt-60, or iodine-131 could result in lost sales of nuclear medicine and calibration standards sales, cobalt product sales and radiochemical products.

***We are subject to extensive government regulation in jurisdictions around the globe in which we do business. Regulations address, among other things, environmental compliance, import/export restrictions, healthcare services, taxes and financial reporting, and can significantly increase the cost of doing business, which in turn can negatively impact our operations, financial results and cash flow.*** We are subject to government regulation and intervention both in the United States and in all foreign jurisdictions in which we conduct business. Compliance with applicable laws and regulations results in higher capital expenditures and operating costs and changes to current regulations with which we must comply can necessitate further capital expenditures and increases in operating costs to enable continued compliance. Additionally, from time to time, we may be involved in legal or administrative proceedings under certain of these laws and regulations. Significant areas of regulation and intervention include the following:

***Radioactive Waste.*** All of our manufacturing processes generate some radioactive waste. We must handle this waste pursuant to the Low Level Radioactive Waste Policy Act, which requires the safe disposal of mildly radioactive materials. The estimated costs for storage and disposal of these materials have been included in the manufacturing and sales price of our products. However, actual disposal costs are subject to change at the discretion of the disposal site and are ultimately applied at the time of disposal. The NRC is revising its regulations on the disposal of depleted uranium waste at LLRW disposal facilities that accept substantial quantities of depleted uranium. If commercial LLRW disposal facilities are not readily available to us, we may not be able to provide the de-conversion services at the level assumed by our business model.

***Health Compliance.*** Health regulations, dictated by the United States Occupational Safety and Health Administration and NRC are extensive in our business. There is no assurance that our activities will not at times result in liability under health regulations. Costs and expenses resulting from such liability may materially negatively impact our operations and financial condition. Overall, health laws and regulations will continue to affect our business worldwide.

***NRC License Enforcement Actions.*** The NRC may take enforcement action in the event that the Company is found to be in violation of NRC regulations or in violation of any of our license requirements. Consequences of violations depend upon the severity of the violations as well as the adequacy and timeliness of corrective actions implemented by the licensee to investigate and correct the cause of the violation and to prevent reoccurrence. The NRC has discretionary authority in the action they choose to take against license violations but these actions can include civil penalties and restrictions upon licensee operations or license suspension.

***Environmental Regulation.*** We are subject to various federal, state, local and foreign government requirements regulating the discharge of materials into the environment or otherwise relating to the protection of the environment. These laws and regulations include, but are not limited to the Comprehensive Environmental Response, Compensation, and Liability Act, the Resource Conservation and Recovery Act and state statutes such as the Idaho Hazardous Waste Management Act, the Low Level Radioactive Waste Policy Act, NRC regulations concerning various irradiated, radioactive, and depleted uranium materials, and United States Department of Transportation regulations concerning shipment of radioactive materials. Certain of these laws and regulations can impose substantial fines and criminal sanctions for violations, and require installation of costly equipment or

operational changes to limit emissions and/or decrease the likelihood of accidental hazardous substance releases. We have incurred, and expect to continue to incur, capital and operating costs to comply with these laws and regulations. In addition, changes in laws, regulations and enforcement of policies, or the imposition of new clean-up requirements or remedial techniques, could require us to incur costs in the future that would have a negative effect on our financial condition or results of operations.

***Import/Export Regulation.*** We are subject to significant regulatory oversight of our import and export operations due to the nature of our product offerings. Penalties for non-compliance can be significant and violations can result in adverse publicity. We also have an NRC license for the export of radioactive materials. Because of increasing security controls and regulations, it is likely that we may encounter additional regulations affecting transportation, storage, sale, and import/export of radioactive materials.

***Taxes.*** We structure our operations to be tax efficient and to make use of tax credits and other incentives. Nevertheless, changes in tax laws, actual results of operations, final audit of tax returns by taxing authorities, and the timing and rate at which tax credits can be utilized can change the rate at which we are taxed, thereby affecting our financial results and cash flow.

***Financial Accounting Standards.*** Our financial results can be impacted by new or modified financial accounting standards.

***We may incur material losses and costs as a result of product liability claims that may be brought against us.*** We face an inherent business risk of exposure to product liability claims in the event that products supplied by us fail to perform as expected or such failures result, or are alleged to result, in bodily injury. Although we have purchased insurance with coverage and in amounts that we believe to be adequate and reasonable in light of our current and planned operations, including our planned uranium de-conversion and fluoride gas production business, if a successful product liability claim were brought against us in excess of our available insurance coverage or established reserves, it would have a material adverse effect on our business and financial results.

***We may need additional financing to continue operations.*** Because we may continue to experience negative cash flow, we may need to obtain additional financing to continue operations. Management will continue to plan and take actions to improve our financial results which could enhance our ability to obtain debt financing. However, obtaining additional financing is subject to many factors beyond our control and may not be available to us on acceptable terms or at all.

***Our earnings, cash flow and financial position are exposed to financial market risks worldwide, including interest rates.*** Fluctuations in domestic and world markets could adversely affect interest rates and impact our ability to obtain credit or attract investors. Such market risk could have a negative impact on future business opportunities including our ability to raise additional capital for planned business expansion. We also purchase some of our radiochemical products from overseas suppliers and the price of those products could be adversely affected through

changes in currency exchange rates.

***Catastrophic events such as natural disasters, pandemics, war and acts of terrorism could disrupt our business or the business of our suppliers or customers, and any such disruptions could have a negative impact on our operations, financial results and cash flow.*** Our operations are at all times subject to the occurrence of catastrophic events outside our control, ranging from severe weather conditions such as hurricanes, floods, earthquakes and storms, to health epidemics and pandemics, to acts of war and terrorism. Any such event could cause a serious business disruption that could affect our ability to produce and distribute our products and possibly expose us to third-party liability claims. Additionally, such events could impact our suppliers, thereby causing energy and raw materials to become unavailable to us, and our customers, who may be unable to purchase or accept our products and services. Any such occurrence could have a negative impact on our operations and financial condition.

***Our future growth is largely dependent upon our ability to develop new technologies that achieve market acceptance with acceptable margins.*** Our businesses operate in global markets that are characterized by rapidly changing technologies and evolving industry standards. Accordingly, our future growth rate depends upon a number of factors, including our ability to (i) identify emerging technological trends in our target end-markets, (ii) develop

and maintain competitive products, (iii) enhance our products by adding innovative features that differentiate our products from those of our competitors, and (iv) develop, manufacture, and bring products to market quickly and cost-effectively. Our ability to develop new products based on technological innovation can affect our competitive position and requires the investment of significant resources. These development efforts divert resources from other potential investments in our businesses, and they may not lead to the development of new technologies or products on a timely basis or that meet the needs of our customers as fully as competitive offerings. In addition, the markets for our products may not develop or grow as we currently anticipate. The failure of our technologies or products to gain market acceptance due to more attractive offerings by our competitors could significantly reduce our revenues and adversely affect our competitive standing and prospects.

### **Risks Related To Our Common Stock**

***Trading in our common stock is limited and the price of our common stock may be subject to substantial volatility.***

Our common stock has historically been quoted on the Over The Counter Bulletin Board® ( OTCBB ) under the ticker symbol INIS.OB. In February 2015, we listed our common stock on the OTCQB Marketplace under the U.S. trading symbol INIS . The market for our securities is limited, the price of our stock is volatile, and the risk to investors in our common stock is greater than the risk associated with stock trading on other markets. These factors may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to sell shares to third parties or to otherwise dispose of their shares. This could cause our stock price to decline.

***We currently do not intend to pay dividends on our common stock.*** We do not plan to pay dividends on shares of our common stock in the near future. Consequently, an investor in our common stock can only achieve a return on its investment in us if the market price of our common stock appreciates.

***We are contractually obligated to issue shares in the future, which will dilute your interest in us.*** As of December 31, 2015, there were approximately 23,241,667 shares of common stock issuable upon exercise of vested stock options outstanding, at a weighted-average exercise price of \$.04 per share. An additional 22,484,824 shares were reserved for issuance under our 2015 Incentive Plan and our International Isotopes Inc. Employee Stock Purchase Plan as of December 31, 2015. We expect to issue additional options to purchase shares of our common stock to compensate employees, consultants and directors, and we may issue additional shares to raise capital to expand our manufacturing capability, develop additional products, or fund our planned uranium de-conversion plant. Any such issuances will have the effect of further diluting the interest of the holders of our securities. Also outstanding as of December 31, 2015, were Series H Warrants for the issuance of 1,913,892 shares of common stock, Series I Warrants for the issuance of 12,924,887 shares of common stock, Series K Warrants for the issuance of 2,419,172 shares of common stock, and Series L Warrants for the issuance of 25,000,000 shares of common stock. The weighted average exercise price for all outstanding warrants as of December 31, 2015 was \$0.18. Both the Series H and the Series I Warrants, totaling 14,838,779 warrants, expired on January 31, 2016.

### **Risks Related to Our Proposed De-Conversion and FEP Produced Fluoride Gas Business**



***We will need to raise additional funds to complete the construction of our de-conversion and FEP facility.*** We need to secure more customer contracts and raise approximately \$125 million in additional funds to complete the design and construction of a de-conversion facility with a production-scale FEP operation. We may not be able to raise the additional capital required to complete the facility on acceptable terms, or at all. In addition, the total funds required to complete this project have been based upon early preliminary estimates and, while we believe these estimates are conservative, there can be no assurance that unforeseen expenses will not be incurred and additional funding will not be required to complete the project.

***We do not have an operating history with respect to our strategy to combine de-conversion services and FEP-produced fluoride gas products and this business may not succeed.*** We have no operating results with respect to providing de-conversion services or producing high volumes of fluoride gas products using FEP to date and, therefore, we do not have an operating history upon which you can evaluate this business or our prospects. Our prospects must be considered in light of the risks and uncertainties encountered in entering a new line of business.

Some of these risks relate to our potential inability to:

construct our planned de-conversion and FEP production plant, including the effective management of the cost of the design and construction of the facility, and obtain the additional financing necessary for such construction;

maintain the necessary regulatory approvals for the facility and the ongoing operations of the facility;

obtain the groundwater permit from the state of New Mexico;

produce commercially economic volumes of high-purity fluoride products using FEP;

effectively manage this new business and its operations;

successfully establish and maintain our intended low-cost structure; and

successfully address the other risks described throughout this Annual Report.

If we cannot successfully manage these risks, our business and results of operations and financial condition will suffer.

***The market for our de-conversion services may be adversely affected if planned enrichment facilities that would create by-products suitable for our de-conversion services are not completed.*** As funding becomes available to us, we intend to build a de-conversion and FEP production plant, in part, to process the anticipated  $\text{DUF}_6$  by-product from the URENCO USA (UUSA) enrichment plant in New Mexico or from the DOE depleted uranium stockpiles in either Portsmouth, OH or Paducah, KY. There had been several other enrichment facilities planned by companies, including USEC, AREVA, and GE-Hitachi Nuclear Energy's Global Laser Enrichment. However, all of those plans have been delayed and may never be constructed. We currently have a de-conversion service agreement in place with UUSA, however, all of our performance milestone dates have passed. When and if the Company resumes work on the construction of the facility we will seek to renegotiate the milestone dates in the agreement with UUSA. If none of the other anticipated enrichment facilities are completed or if UUSA decides not to process their depleted uranium stockpile we may not have sufficient demand for our de-conversion services to realize the expected economic benefit from building this facility.

***We currently have only one contract to provide de-conversion services to an enrichment firm.*** We currently have only one de-conversion services agreement with UUSA. The agreement is conditional upon, among other things, each party obtaining necessary third party and government approvals, UUSA obtaining the approval of the NRC to the amendment of a provision in its materials license that prohibits shipments of depleted uranium to de-conversion facilities employing anhydrous hydrofluoric acid in the de-conversion process, and our meeting certain performance milestones in the construction and start-up of the planned facility. The initial term of the agreement extends for a period sufficient to cover five years of de-conversion services once our planned uranium de-conversion facility is operational, based on operations that were to have started no later than January 1, 2014. UUSA has indicated they are willing to discuss possible modification of the agreement commitment dates once we establish firm dates for start of construction. If we cannot demonstrate certain production capacities in accordance with the agreement, UUSA has the option to terminate the agreement and we would have no opportunity to cure pursuant to the terms of the agreement.

***There is no history of large-scale commercial fluoride gas production utilizing FEP.*** We have successfully demonstrated the feasibility of using FEP to produce some fluoride gases and Starmet Corporation ( Starmet ), which originally developed and patented the technology, also used FEP to produce a fluoride gas. However, FEP has not been used for large-scale commercial production of the size and magnitude envisioned in conjunction with the de-conversion process and there may be technical issues and process challenges related to the utilization of FEP for large-scale commercial production. Unforeseen issues associated with constructing and scaling up these new FEP operations could significantly impact our proposed schedule and our overall ability to produce high-purity fluoride gas in the quantities anticipated.

***Prior to the start of operations of the facility, we must obtain a Ground Water Permit from the State of New Mexico, and we cannot guarantee the amount of time required to obtain this permit from the State of New Mexico for operation of these facilities.*** The operation of the planned depleted uranium de-conversion facility requires a ground water permit from the State of New Mexico. There is no assurance that the ground water permit will be issued to us by the State of New Mexico. We also have no control over the actual time required by the State of New Mexico to review and approve the application for the ground water permit. Failure to obtain the permit, or any delay in obtaining the permit, could delay the construction of our planned depleted uranium de-conversion facility, thereby delaying revenue-generating operations at the facility.

***The DOE is obligated to take depleted uranium from enrichment companies.*** The DOE has constructed two depleted uranium de-conversion facilities. These facilities are obligated to process depleted uranium produced from United States commercial uranium enrichment facilities. We cannot assure you that enrichment companies will not select the DOE as their de-conversion service provider. If UUSA terminates our agreement and other enrichment companies do not resume their enrichment facility construction plans, we will not be able to realize the expected economic benefit from our planned de-conversion and FEP production plant.

***We may be handling large quantities of DUF<sub>6</sub> and fluoride gases, which are radioactive and hazardous materials, respectively, and are subject to intense regulation.*** The hazardous nature of DUF<sub>6</sub> and fluoride gases affects the actions we are required to take for licensing, air permitting, environmental review, emergency response, liability insurance, personnel training, and generally increases the level of concern by the general public with respect to our handling of these materials. All of these factors complicate the licensing and operations processes and involve a host of additional regulatory factors that could affect the timeline for completing our de-conversion and FEP facility and cost estimates, and involve political pressures that could negatively influence operations. Additionally, the NRC is revising its regulations on the disposal of depleted uranium waste at Low Level Radioactive Waste ( LLRW ) disposal facilities that accept substantial quantities of depleted uranium. Any changes to the current regulations may result in increased disposal costs that we intend to pass through to our customers, which, depending on the significance of the increased cost, may cause potential customers to continue to store their DUF<sub>6</sub> rather than pay for de-conversion and disposal services.

***We will be subject to competition from the DOE and other companies.*** While there are no currently operating commercial DUF<sub>6</sub> de-conversion facilities in the United States, the DOE is operating two de-conversion plants intended to process DUF<sub>6</sub> from the DOE's existing 1.5 billion-pound stockpile. Additionally, AREVA currently operates a de-conversion plant in France, UUSA is constructing a facility in the U.K., and the State Atomic Energy Corporation ROSATOM has constructed a facility in Russia. We cannot assure you that the operators of the existing DUF<sub>6</sub> de-conversion facilities will not build additional facilities to expand their operations and compete with us in providing de-conversion services or that commercial enrichment companies will not choose to ship their depleted DUF<sub>6</sub> overseas for processing in France, the U.K., or Russia.

***We currently hold conditional title to the property in Lea County, New Mexico where the proposed plant is to be constructed.*** The property location for our planned facility is located in Lea County, New Mexico. Lea County, New Mexico has transferred the property to us under the provisions of the New Mexico Local Economic Development Act, Project Participation Agreement. Under the original agreement we were obligated to meet certain performance objectives; namely starting Phase I construction no later than December 31, 2014, completing Phase I and hiring at

least 75 employees by December 31, 2015, in order to retain title to the property. We did not meet either of those deadlines. However, in July 2015, we executed an amendment to the PPA that extends the due date of the Phase I construction to December 31, 2016, and Phase I completion and hiring at least 75 employees to December 31, 2017. It is likely that we will seek an additional modification to the agreement to further extend these dates. However, if Lea County does not agree to that modification and we do not retain title to the property, it could have a material adverse impact on our planned de-conversion and FEP project since another location would need to be selected and evaluated for environmental compliance.

***Our business may be harmed if we fail to protect our proprietary FEP technology utilized in our planned de-conversion and FEP production facility.*** We rely on patents to protect our intellectual property rights to the FEP technology to be used in our planned de-conversion and FEP production plant. Although we have filed international Patent Cooperation Treaty ( PCT ) applications to seek international protection for the FEP process in certain countries, we cannot be certain that our competitors will not be able to design around our patents and that the laws

of some countries in which our FEP patents are or may be practiced will protect our products or intellectual property rights to the same extent as do the laws of the United States, increasing the possibility of piracy of our patents. Although we intend to vigorously defend our intellectual property rights, we may not be able to prevent misappropriation of our FEP technology. Our competitors may also independently develop technologies that are substantially equivalent or superior to our technology.

## **Item 1B. UNRESOLVED STAFF COMMENTS**

We are a smaller reporting company, and therefore, are not required to provide the information required by this item.

## **Item 2. PROPERTIES**

We lease one property which serves as our main corporate headquarters and houses all of our current manufacturing operations for our core business segments. We also hold the conditional title to 640 acres of land in Lea County, New Mexico. The following paragraphs provide a brief summary of these properties.

4137 Commerce Circle, Idaho Falls, Idaho The facility located on this property houses our main corporate headquarters and all of our current manufacturing operations. We hold this property pursuant to a lease that extends through April 2021. The facility was new when leased in March 2001 and remains in excellent condition. We have a purchase option and a right of first refusal on this property that allows us to purchase this property at any time for a stated amount.

Land - Lea County, New Mexico In August 2011, we received land from Lea County, New Mexico, pursuant to a PPA, whereby the land was deeded to us for no monetary consideration. In return, we committed to construct a uranium de-conversion and FEP facility on the land. In order to retain title to the property, we were to begin construction of the de-conversion facility no later than December 31, 2014, and complete Phase I of the project and have hired at least 75 persons to operate the facility no later than December 31, 2015, although commercial operations need not have begun by that date. We did not meet those milestones but have executed an amendment to the PPA to extend the deadlines for these performance objectives and we will likely have to request further modification to that agreement. If we do not succeed in reaching the performance dates in the agreement then we may, at our sole option, either purchase or re-convey the property to Lea County, New Mexico. The purchase price of the property would be \$776,078, plus interest at the annual rate of 5.25% from the date of the closing to the date of payment. We have not recorded the value of this property as an asset and will not do so until such time that sufficient progress on the project has been made to meet our obligations under the agreements for permanent transfer of the title.

**Item 3. LEGAL PROCEEDINGS**

As of December 31, 2015, we were not a party to any litigation that we believe to be material and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results, financial condition or cash flows.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

**Item 5.**

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

During 2014, our common stock was quoted on the OTCBB under the trading symbol INIS.OB. In February 2015, we listed our common stock on the OTCQB under the trading symbol INIS. High asked prices and low bid prices reported by the OTCBB during the periods indicated are shown below, which reflect inter-dealer prices, without retail mark-up, mark-down, or commission and may not reflect actual transactions:

<b>Fiscal Year</b>	<b>Quarter</b>	<b>High</b>	<b>Low</b>
2015	1st	\$0.06	\$0.03
2015	2nd	\$0.11	\$0.04
2015	3rd	\$0.10	\$0.06
2015	4th	\$0.10	\$0.06
2014	1st	\$0.06	\$0.04
2014	2nd	\$0.06	\$0.04
2014	3rd	\$0.05	\$0.04
2014	4th	\$0.05	\$0.03

As of March 14, 2016, there were 540 holders of record of our common stock. We have never paid any cash dividends on our common stock. In the future, and based upon our profit performance, our Board of Directors (the Board ) will evaluate and determine whether to issue dividends or retain funds for research and development and expansion of our business. We do not anticipate paying any dividends to shareholders for the foreseeable future.

#### **Item 6. SELECTED FINANCIAL DATA**

We are a smaller reporting company, and therefore, are not required to provide the information required by this item.

#### **Item 7.**

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

*The following discussion of our results of operations and financial condition should be read in conjunction with the accompanying financial statements and related notes thereto included in Item 8, Financial Statements and Supplementary Data, within this Annual Report.*

#### **Overview**



We manufacture a full range of nuclear medicine calibration and reference standards, a wide range of products including cobalt teletherapy sources, and a varied selection of radioisotopes and radiochemicals for medical research, and clinical devices. We also provide a host of transportation, recycling, and processing services on a contract basis for customers. A more detailed description of each of these product lines and services along with a description of our business segments can be found in Item 1, Business under General Business and Products Description, within this Annual Report.

In 2015, we pursued research and development of new products and services in three of our business segments. We also continued to make investments in our facility to improve our manufacturing processes, and entered into new agreements that we believe will increase future revenues. The following are highlights of some of our significant accomplishments in 2015:

Continued research into the expansion of radiochemical products through joint development agreements and continued work towards the submittal of a new generic drug product application to the Food and Drug Administration ( FDA );

Completed an expansion of the nuclear medicine product manufacturing area that will permit approximately a 40% increase in production capacity;

Obtained trademark registration of I<sup>3</sup>odine/MAX<sup>TM</sup>, our sodium iodide (I-131) radiochemical product ( Iodine-131 ), as an oral solution or capsules for use in the treatment and diagnosis of various thyroid diseases, thyroid cancer, and hyperthyroidism, and for use in investigational and clinical trials for the treatment of breast, lung, prostate, and ovarian cancers;

Entered into several supply agreements with customers for the purchase of cobalt-60 which in some cases includes on-going services such as source manufacturing and source installation into therapy devices;



Continued to identify alternate sources of cobalt-60 for customers to stem the shortages in supply that have occurred in the past, and that will continue to occur until the first full cobalt irradiation services are completed in 2017;

Were awarded several radiological services jobs through the U.S. Department of Energy's (DOE) Orphan Source Recovery Program (OSRP) in which we were able to use our mobile hot cell; and

Continued to support the essential tasks related to our de-conversion project and continued to pursue opportunities to obtain additional contracts for depleted uranium de-conversion.

### **Business Strategy and Core Philosophies**

Broadly defined, our business strategy is to continue to build our reputation as a leader in the cobalt, radiochemical, field services, and nuclear medicine product industries, as well as seek ways to improve our customer service and expand our market share, with the ultimate goal of providing greater return to our shareholders. Specifically, we are continuously working with our customers to improve and develop products to better serve the needs of the end user which, ultimately, we believe will boost product sales. A key part of our short-term and long-term business strategies is to develop and market new products in our core business segments that will offer customers a high quality and desirable product as well as increase our revenues, secure additional customer contracts, and pursue financial support so that we can further expand our products and services.

Our core philosophy is to strive to provide high quality products and services as a profitable and environmentally conscious business, while offering excellent customer service and providing a safe and high quality working environment for our employees. We operate in accordance with an ISO Quality Management System and in accordance with all current Good Manufacturing Practices under which we seek to maintain the highest level of quality and continuously improve our product manufacturing processes.

### **Critical Accounting Policies**

*Revenue recognition* - We recognize revenue when products are shipped or services are performed. We have contracted with several customers for the purchase of cobalt-60 material which is currently undergoing irradiation. We have collected advance payments from these customers for project management and up-front handling and irradiation charges and these prepayments have been recorded as unearned revenue. Our estimated future recognition of this unearned revenue is based on an irradiation completion and shipment schedule which has been provided to us by the DOE in an irradiation services contract.

*Patents and other intangibles* - We amortize our patents and intangibles using the straight-line method over their estimated useful lives. Patents and other intangibles are evaluated for impairment at least annually or when events or circumstances arise that indicate the existence of impairment. We evaluate the recoverability of intangible assets whenever events or changes in circumstances indicate that an intangible asset's carrying amount may not be recoverable. Such circumstances could include, but are not limited to (1) a significant decrease in the market value of an asset, (2) a significant adverse change in the extent or manner in which an asset is used, or (3) an accumulation of costs significantly in excess of the amount originally expected for the acquisition of an asset. If impairment indicators exist, we measure the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized. The impairment loss would be calculated as the amount by which the carrying value of the asset exceeds its fair value.

*Impairment of long-lived assets* - As part of our year-end procedures we test our long-lived assets for signs of impairment when indicators of impairment exist.

## Critical Accounting Estimates

*Asset retirement obligation* The asset retirement obligation is based on the expected future cash flows of the decommissioning funding plan. The decommissioning funding plan is based on the estimated number of hours of specific personnel, estimated wages and disposal costs. Once the decommissioning funding plan has been developed, we use a discount rate to determine the estimated current value of the liability.

*Stock-based compensation* We estimate the fair value of each stock-based award on the measurement date using the Black-Scholes option valuation model which incorporates assumptions as to stock price volatility, the expected life of the options, risk-free interest rate and dividend yield. Our assumptions are based upon the following considerations:

-

*Volatility* based upon the Company's historical stock valuation;

-

*Expected life of options* simplified approach determined based upon the life of the option and related vesting period;

-

*Risk-free interest rate* US Treasury rate for the exercise period of the option; and

-

*Dividend yield* assumption of no dividend yield as the Company has not historically paid dividends and does not have plans to do so in the future.

## Results of Operations

Below is a summary of results of operations for 2015:

.

Revenue in 2015 was approximately \$7.1 million;

.

Pursued research and development of new products and services in three of our business segments;

Sales in both our Radiological Services and Transportation business segments were up as compared to 2014;

Our total gross profit rate decreased from 40% in 2014 to 38% in 2015;

Our operating costs for 2015 increased approximately 10% as compared to operating costs for 2014; and

Net loss for 2015 increased by approximately 19% compared to 2014.

### Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

The following table presents comparative Revenues for the years 2015 and 2014:

	<b>For the year ended December 31, 2015</b>	<b>For the year ended December 31, 2014</b>	<b>\$ change</b>	<b>% change</b>
<b>Revenues</b>				
Radiochemical Products	\$ 1,698,475	\$ 1,742,495	(44,020)	-3%
Cobalt Products	929,970	1,791,906	(861,936)	-48%
Nuclear Medicine Standards	3,135,094	3,267,254	(132,160)	-4%
Radiological Services	1,181,957	621,431	560,526	90%
Fluorine Products	-	-	-	-
Transportation	116,700	113,775	2,925	3%
Total Segments	7,062,196	7,536,860	(474,664)	-6%
Corporate revenue	-	-	-	-

Total Consolidated	\$	7,062,196	\$	7,536,860	\$	(474,664)	-6%
--------------------	----	-----------	----	-----------	----	-----------	-----

**Revenues**

Total revenues in 2015 were \$7,062,196, compared to \$7,536,860 in 2014, which represents a decrease of \$474,664, or approximately 6%. The details of each segment are discussed below.

<b>Revenues</b>	<b>For the year</b>		<b>For the year</b>	
	<b>ended</b>	<b>% of Total</b>	<b>ended</b>	<b>% of Total</b>
	<b>December 31, 2015</b>	<b>Revenues 2015</b>	<b>December 31, 2014</b>	<b>Revenues 2014</b>
Radiochemical Products	\$ 1,698,475	24%	\$ 1,742,495	23%
Cobalt Products	929,970	13%	1,791,906	24%
Nuclear Medicine Standards	3,135,094	44%	3,267,254	43%
Radiological Services	1,181,957	17%	621,431	8%
Fluorine Products	-	-	-	-
Transportation	116,700	2%	113,775	2%
Corporate revenue	-	-	-	-
<b>Total Segments</b>	<b>\$ 7,062,196</b>	<b>100%</b>	<b>\$ 7,536,860</b>	<b>100%</b>

**Radiochemical Products**

Sales of radiochemical products accounted for approximately 24% of our total sales revenue in 2015 and approximately 23% of total sales revenue in 2014. Sales in this segment decreased by \$44,020, or approximately 3% to \$1,698,475, as compared to \$1,742,495 in 2014. Although sales of radiochemical products were similar in amount for both years, during 2014 we reported \$50,000 of consulting income in this segment, whereas we had no consulting income to report in 2015. We do not expect to receive any consulting income in this segment in 2016. In addition, we are continuing to work on product enhancements and the introduction of new radiochemical and generic drug products in the coming years.

In September 2015, the Company obtained approval from the U.S. Patent and Trademark office for the trademark registration of I<sup>3</sup>odine/MAX<sup>TM</sup>. The trademark is for Iodine-131 radiochemical product, provided in solution or capsules, for use in the treatment and diagnosis of diseases of the thyroid, thyroid cancer, and hyperthyroidism and for use in investigational and clinical trials for the treatment of breast, lung, prostate, and ovarian cancers. This is the first of several potential generic drug products we plan to submit to the FDA in the coming years. We believe that the both product enhancements we have made in addition to the generic drug products we plan to submit to the FDA will increase sales in this business segment.

**Cobalt Products**



Cobalt products sales accounted for approximately 13% of our total sales revenue in 2015 and approximately 24% of total sales revenue in 2014. Sales in this segment decreased by \$861,936 in 2015 to \$929,970, as compared to \$1,791,906 in 2014. The decrease was the direct result of an interruption in cobalt supply from the DOE's ATR in 2012, and our inability to procure sufficient amounts of cobalt-60 material since that time and at reasonable cost for source fabrication. Our sealed source manufacturing generates the majority of our revenue within this segment and sealed source sales depend on our ability to produce or procure cobalt material.

In October 2014, we entered into a ten year agreement with the DOE for the irradiation of cobalt targets. It takes approximately two to three years to irradiate the cobalt targets to the desired level of activity and we anticipate having high specific activity cobalt available for our customers in the late 2017, and every year thereafter, through at least 2024. The agreement gives us the ability to purchase the current full capacity of the DOE's ATR throughout the ten year period.

During 2015, we entered into several cobalt-60 supply agreements with customers. Pursuant to these contracts, we will supply bulk cobalt-60 to customers and, in some cases, these agreements include source manufacturing and installation. The terms of these cobalt contracts require quarterly progress payments from each customer. The funding received under these contracts has been recorded as unearned revenue under long-term liabilities in our consolidated financial statements. We will begin recognizing the revenue when actual sales begin in 2017.

Until we are able to ship the cobalt material currently under irradiation at the ATR, we will rely on obtaining recycled material and material procured in small quantities from other sources to fulfill some of our customer demand.

As of December 2015, we continued to hold many in-progress old design cobalt targets at the ATR. In connection with our year-end procedures, we reviewed the carrying value of these older targets and concluded that some of those with a lower activity level no longer held commercial value. We expensed \$102,857 for the impairment of this obsolete inventory to cost of goods sold at that time. We believe that the remaining older targets have significant but varying degrees of market value depending on their specific activity levels and we are currently evaluating the costs of transporting and processing these old targets in their current condition to recover their value. We believe we will be able to start transporting and selling some of this material during 2016. At the end of 2016 and each year thereafter we will continue to review the residual value of this material and make adjustments as appropriate for material that has decayed to a point where it has no market value.

### Nuclear Medicine Standards

Sales of nuclear medicine standards accounted for approximately 44% and 43%, of our total sales revenue in 2015 and 2014, respectively. Sales in this segment decreased by \$132,160, or approximately 4%, to \$3,135,094 in 2015, as compared to \$3,267,254 in 2014. This year-to-year comparison includes sales from TI Services, LLC ( TI Services ), a 50/50 joint venture that we formed with RadQual in December 2010, to distribute products and services for nuclear medicine, nuclear cardiology and Positron Emission Tomography imaging. The following table presents 2015 and 2014 sales for the nuclear medicine standards segment:

	<b>For the year ended December 31, 2015</b>	<b>For the year ended December 31, 2014</b>	<b>\$ change</b>	<b>% change</b>
<b><u>Nuclear Medicine Standards</u></b>				
Sales to RadQual	\$ 1,932,992	\$ 1,909,774	\$ 23,218	1%
Misc nuclear medicine sales	20,884	39,398	(18,514)	-47%
TI Services LLC	1,181,218	1,318,082	(136,864)	-10%
	<b>\$ 3,135,094</b>	<b>\$ 3,267,254</b>	<b>\$(132,160)</b>	<b>-4%</b>

Sales of products to RadQual increased to \$1,932,992 in 2015, from \$1,909,774, in 2014. This is an increase of \$23,218, or approximately 1%. TI Services sales for 2015 were \$1,181,218 as compared to \$1,318,082 for 2014, a decrease of \$136,864, or approximately 10%. This decrease in TI Services sales is attributable to a drop in sales of paper products used in nuclear medicine imaging, which is the result of clinics shifting towards maintaining electronic records, as well as a drop in source sales during the last quarter of 2015. The drop in TI Services source sales was also the result of a planned maintenance outage, during September 2015 in the nuclear medicine production area of our Idaho manufacturing facility. The planned maintenance outage of our manufacturing processes was necessary to conduct periodic maintenance of equipment and to expand product manufacturing capacity that will permit approximately a 40% increase in production capacity.

Radiological Services

Revenues from our Radiological Services segment accounted for approximately 17% of our total sales revenue in 2015, and approximately 8% in 2014. Sales in this segment increased by \$560,526, or approximately 90%, from \$621,431 in 2014, to \$1,181,957 in 2015. Gemstone processing accounted for approximately 29% of Radiological Services sales in 2015 and approximately 66% in 2014. Revenues from gemstone processing increased by \$124,689, from \$214,103 in 2014, to \$338,792 in 2015. This is an increase of approximately 58% and was the result of an increase in the volume of material shipped to us for processing and the increased demand for luxury items such as jewelry.

Radiological Field Services accounted for approximately 71% of the Radiological Services segment sales in 2015 and approximately 66% in 2014. Radiological Field Services revenue increased from \$407,328 in 2014, to \$843,165 in 2015 which is an increase of approximately 107%. The increase in field services revenue is largely the result of jobs performed under the DOE's OSRP. Additionally, during 2015 we performed work under a support services agreement with one customer to perform field service work related to source design and installation. We expect this source removal and installation work to continue through 2016. Based upon the current and anticipated contract commitments for this type of work we expect that field services will continue to be the primary source of revenue within this segment in 2016.

The following table presents radiological services revenue for the two years ended December 31, 2015 and 2014:

	For the year		For the year			
	ended		ended			
	December 31,		December 31,			
<u>Radiological Services</u>	2015		2014		\$ change	% change
Gemstone Processing	\$	338,792	\$	214,103	\$ 124,689	58%
Radiological Field Services		843,165		407,328	435,838	107%
	\$	1,181,957	\$	621,431	\$ 560,526	90%

#### Fluorine Products

There was no revenue to report from the Fluorine Products segment for 2015. We had been developing our fluorine products in conjunction with uranium de-conversion project, in order to take advantage of the anticipated need for depleted uranium de-conversion services. We established the Fluorine Products segment in 2004 to support production and sale of the gases produced using our Fluorine Extraction Process ( FEP ). Our FEP patents offer a unique opportunity to provide certain high-purity fluoride compounds while also offering a for fee de-conversion service to the uranium enrichment industry. From 2004 to 2012, we used a pilot facility to develop production processes for various high-purity products and to test methods of scaling up the size of FEP production in support of the planned de-conversion facility in Lea County, New Mexico. In 2012, we completed our testing of individual components and analytical processes and in 2013 we closed the pilot plant facility. Also, in 2013, we made the decision to place continued formal design work on the proposed de-conversion facility on hold until such time that we are able to secure additional de-conversion services contracts. Until such time that work resumes on the project we will limit our expenditures to essential items such as maintenance of the NRC license, land use agreements, communication with our prospective FEP product customers, and interface with the State of New Mexico and Lea County officials.

During 2015, we incurred \$356,492 of planning and other expenses related to the de-conversion project, as compared to \$418,887 in 2014. This decrease of approximately \$62,395, or approximately 15%, was the result of limiting our costs to essential items such as the NRC licensing and continued interactions with our customers, the state of New

Mexico, and Lea County, New Mexico.

Transportation

Revenues from our Transportation segment accounted for approximately 2% of our total revenues in 2015 and 2014. Sales in this segment increased by approximately 3% to \$116,700 in 2015, as compared to \$113,775 in 2014. The increase in revenue was attributable to increased opportunities for transportation of our cobalt products and transportation support for radiological services performed during the period. We primarily use our transportation services to support the jobs performed in these two business segments. There are numerous regulations that apply to, and agencies which monitor, the security and tracking of cobalt shipments and our Transportation segment specializes in the transport of hazardous, radioactive materials, including large cobalt shipments.

**Cost of Revenues and Gross Profit**

Cost of revenue for 2015 was \$4,359,234, as compared to \$4,559,745 in 2014, a decrease \$200,511 or approximately 4%. Gross profit percentage decreased to 38% for 2015, from 40% in 2014. The following table presents revenues and cost of revenues information:

	<b>For the year</b>		<b>For the year</b>	
	<b>ended</b>	<b>% of Total</b>	<b>ended</b>	<b>% of Total</b>
	<b>December 31,</b>	<b>Revenues</b>	<b>December 31,</b>	<b>Revenues</b>
	<b>2015</b>	<b>2015</b>	<b>2014</b>	<b>2014</b>
Total Revenues	\$ 7,062,196		\$ 7,536,860	
Cost of Revenues				
Radiochemical Products	\$ 1,248,699	18%	\$ 1,266,246	17%
Cobalt Products	376,151	5%	802,059	11%
Nuclear Medicine Standards	2,136,902	30%	2,135,507	28%
Radiological Services	584,134	8%	345,010	5%
Fluorine Products	-	-	-	-
Transportation	13,347	1%	10,923	0%
Total Segments	\$ 4,359,234	62%	\$ 4,559,745	61%
Gross Profit	\$ 2,702,962		\$ 2,977,115	
Gross Profit %	38%		40%	

During 2015 we continued to monitor and control direct costs. Raw materials used in both our radiochemical products and our nuclear medicine standards manufacturing represent the bulk of direct costs in each of these business segments and we have purchase agreements in place with suppliers to obtain optimum pricing. Periodically, the cost of these raw materials increases and we may also use alternate supply sources for our material which may not carry pricing as favorable as our contracted suppliers. We were able to control some freight costs by using our own transportation vehicles for higher cost, cross-country shipments of material, particularly in our cobalt products segment. In addition, during December 2015, we recorded a cobalt inventory impairment of approximately \$103,000 due to the decline in market value as a result of the decay of some old design cobalt targets held by the ATR contractor. With the exception of the cost of cobalt material, we are not aware of any significant future price increases that may potentially affect our cost of revenues.

**Operating Costs and Expenses**

Total operating costs and expenses for 2015 were \$4,144,620, as compared to \$3,762,999 in 2014; this is an increase of \$381,621, or approximately 10%.

The following table presents Operating Costs and Expenses for 2015 as compared to 2014:

	<b>For the year ended December 31, 2015</b>	<b>For the year ended December 31, 2014</b>	<b>% change</b>	<b>\$ change</b>
Operating Costs and Expenses:				
Salaries and Contract Labor	\$ 1,675,020	\$ 1,690,034	-1%	\$ (15,014)
General, Administrative and Consulting	1,648,147	1,608,759	2%	39,388
Research and Development	821,453	464,206	77%	357,247
Total operating expenses	\$ 4,144,620	\$ 3,762,999	10%	\$ 381,621

Salaries and contract labor decreased 1% in 2015, as compared to 2014. Salaries and contract labor included approximately \$147,000 in non-cash equity-based compensation in 2015 which was recorded as a result of stock options outstanding. Non-cash equity-based compensation recorded in 2014 was approximately \$244,000. This is a decrease of approximately \$97,000 and is the result of our recording non-cash equity based compensation in 2014 for the re-pricing of an aggregate of 14,500,000 outstanding options held by executive officers and members of the Board of Directors (the Board), as well as equity compensation recorded for 11,500,000 incentive and non-

qualified stock options granted in October 2014. During 2015 there was no re-pricing activity nor were additional stock options granted.

General administrative and consulting expenses increased to \$1,648,147 in 2015, as compared to \$1,608,759 in 2014, an increase of \$39,388, or approximately 2%. General administrative and consulting expense in 2014 includes an adjustment to accretion expense in the amount of \$84,527 which decreased the expense recorded for the year. This adjustment was the result of a periodic review of funding for decommissioning, as required by the NRC. At the time of the review, it was determined that we had accrued excess lease obligation expense that we report as a long-term liability on our balance sheet. The liability was reduced and recorded against our capitalized lease obligation and accretion expense.

Research and development expense was \$821,453 for 2015 as compared to \$464,206 for 2014. This is an increase of \$357,247, or approximately 77%. The majority of this increase in research and development expense is the result of costs associated with development work being done in our radiochemical products business segment. During both 2015 and 2014 we limited further investment in the planned de-conversion facility and limited further spending on the project only for expenses necessary to maintain licensing and continued interactions with New Mexico and Lea County. We will continue to delay further engineering work on the de-conversion project until we are able to secure additional contracts for de-conversion services.

***Other Income (Expense)***

Other Income (Expense) in 2015 was (\$384,322) compared to (\$753,347) in 2014.

<b>For the year ended December 31, 2015</b>	<b>For the year ended December 31, 2014</b>
---	---