

INTERNATIONAL ISOTOPES INC
Form 424B3
November 05, 2004

Filed pursuant
to Rule 424(b)(3)
Reg. No. 333-108776

REOFFER AND RESALE PROSPECTUS

INTERNATIONAL ISOTOPES INC.

20,000,000 Shares

Common Stock, \$.01 par value

This Prospectus relates to Shares (the "Shares") of the Common Stock, \$.01 par value ("Common Stock"), of International Isotopes Inc. ("I3" or the "Company"), a Texas corporation which may be offered from time to time by certain stockholders listed on the Selling Stockholders table (the "Selling Stockholders") for their own benefit. It is anticipated that the Selling Stockholders will offer the Shares for sale at prevailing prices in the over-the-counter market on the date of sale. The Company will receive no part of the proceeds of sales made hereunder. All expenses of registration incurred in connection with this offering are being borne by the Company, but all selling and other expenses incurred by the Selling Stockholders will be borne by such Selling Stockholders. None of the Shares offered pursuant to this Prospectus has been registered prior to the filing of the Registration Statement of which this Prospectus is a part.

The Selling Stockholders and any broker executing selling orders on behalf of the Selling Stockholders may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), in which event commissions received by such broker may be deemed to be underwriting commissions under the Securities Act.

The Common Stock of the Company is traded in the over the counter market in the "pink sheets." On November 4, 2004, the closing bid price of the Company's Common Stock, as reported on the OTCBB, was \$.12 (Symbol: INIS).

The securities offered hereby involve a high degree of risk. Prospective purchasers should carefully review the matters set forth in "Risk Factors" on page 7 and in the Company's reports filed with the Securities and Exchange Commission.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.

The date of this Supplemental Prospectus is November 5, 2004.

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No person is authorized to give any information or to make any representations, other than those contained in this Prospectus, in connection with the offering described herein, and, if given or made, such information or representations must not be relied upon as having been authorized by the Company or the Selling Stockholders. This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, nor shall there be any sale of these securities by any person in any jurisdiction in which it is unlawful for such person to make such offer, solicitation or sale. Neither the delivery of this Prospectus nor any sale made hereunder shall under any circumstances create an implication that the information contained herein is correct as of any time subsequent to the date hereof.

The Company hereby undertakes to provide without charge to each person to whom a copy of this Prospectus is delivered, upon written or oral request of any such person, a copy of any and all of the information that has been or may be incorporated by reference in this Prospectus, other than exhibits to such documents. Requests for such copies should be directed to the President, International Isotopes Inc., 4137 Commerce Circle, Idaho Falls, Idaho 83401. The Company's telephone number at that location is (208) 524-5300.

Except for the person set forth in the foregoing paragraph, the Company has not authorized any person to give any information or make any representations, other than those contained in this Prospectus, in connection with the Shares. If given or made, such information or representations must not be relied upon as having been authorized by the Company.

AVAILABLE INFORMATION

The Company is subject to the informational reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and in accordance therewith shall file reports, proxy statements and other information with the Securities and Exchange Commission (the "Commission"). Such reports, proxy statements and other information can be inspected and copied at the Public Reference Room of the Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Section of the Commission by calling the SEC at 1-800-SEC-0330. The Company makes filings pursuant to the Exchange Act with the Commission electronically, and such materials may be inspected and copied at the Commission's web site (<http://www.sec.gov>).

A Registration Statement on Form S-8 (the "Registration Statement") with respect to the Shares offered by this Prospectus has been filed with the Commission under the Securities Act. This Prospectus does not contain all of the information contained in such Registration Statement, certain portions of which have been omitted pursuant to the rules and regulations of the Commission. Accordingly, additional information concerning the Company and such securities can be found in the Registration Statement, including various exhibits and schedules thereto, which may be inspected at the Public Reference Section of the Commission. Copies of such material can be obtained from the Commission's Public Reference Section at prescribed rates.

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INTERNATIONAL ISOTOPES INC.

THE COMPANY

International Isotopes Inc., a Texas corporation, (together with its wholly

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owned subsidiary, International Isotopes Idaho Inc. ("I4") hereafter referred to as "we" or the "Company" or "I3") was initially formed as a Texas corporation in 1995 to produce, market, and distribute a broad range of products used in diagnostic and therapeutic nuclear medicine, research, and industry. In 2001, we changed our mission and business strategy somewhat to focus upon other radioisotope products, manufacture calibration and reference standards for nuclear medicine, and provide general radiological measurement capability for processed gemstones. In 2003, we put two new supply agreements in place for Lu-177 and I-131 radioisotopes and expanded our processing facility to include processing and distribution capability for these new isotopes. The following paragraphs provide some additional details on our various business areas.

Radioisotope Products

We offer a selection of radioisotopes and radiochemicals for various applications including clinical research, life sciences, and industrial applications. In the past these isotopes have included Cobalt-60 (Co-60), Cobalt-57 (Co-57), Cesium-137 (Cs-137), and Barium-133 (Ba-133), which were typically sold as radiochemicals to be used in the manufacture of various reference or calibration standards for industry or medicine. The Cobalt-60 isotope produced by the Company is unique in that it is very high specific activity material. This high specific activity material can only be produced in a few nuclear reactors around the world such as the Department of Energy Advanced Test Reactor at the Idaho National Laboratory, to which we currently have access. This high activity cobalt is sold in bulk to General Electric Nuclear who in turn fabricates sealed sources for the Leksell gamma knife.

During 2003 we put two new supply agreements in place with two independent producers to supply the additional isotopes of Lutetium-177 (Lu-177) and Iodine-131 (I-131) radiochemical. Lutetium-177 is currently being investigated in several different clinical applications including treatment of colon cancer, metastatic bone cancer, Non-Hodgkin's Lymphoma, and lung cancer. In published cancer statistics, it is estimated that there are over half a million new cases of these cancers occurring each year in the U. S. and nearly two million cases worldwide. Clinical research with Lutetium-177 has been ongoing for several years and the isotope has demonstrated certain chemical and radiological properties which make it potentially very well suited as a cancer therapy product. We are obtaining our Lutetium-177 through an agreement with the University of Missouri Research Reactor (MURR), which has been a leading developer of radioisotopes suitable for patient trials and has also been a very reliable production source for these isotopes.

Also in 2003, we entered into a distribution agreement with a major global supplier of Iodine-131 radiochemical and started distribution in 2004. Iodine-131 is currently being used on a large commercial scale within the U.S. for the treatment and diagnosis of various diseases of the thyroid such as Graves disease, thyroid cancer, and hyperthyroidism. Iodine-131 is also being used in a host of investigational and clinical trials such as for the treatment of breast, lung, prostate, and ovarian cancers.

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Calibration and Reference Standards

We are a contract manufacturer for a wide range of NIST traceable calibration standards and Quality Assurance check sources for various nuclear pharmacy and SPECT related equipment. These items include flood sources, dose calibrators, rod sources, flexible and rigid rulers, spot markers and penpoint markers. I3 is an exclusive contract manufacturer for Radqual LLC for these products. There are

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over 5,000 nuclear medicine centers around the country that require these types of products on a regular basis.

General Measurement and Radiological Services

The Company provides a host of analytical, measurement, and processing services on a contract basis to clients. Some of these services offered include detailed radioactivity analysis, gamma assay, ICP analysis, Type A package development and testing, and Health Physics consulting. The largest single product service in this area involves our packaging and post irradiation examination process for gemstone that has undergone irradiation for color enhancement. We have had an exclusive contract with Quali-Tech Inc. since 2001 to provide this service.

Fluorine products

We initiated evaluation and acquisition in 2003 of seven patents related to an entirely new product line for the Company - fluorine extraction process (FEP). We closed this acquisition on January 30, 2004. The FEP patents and intellectual property will be used for production of several high purity fluorine products and we will establish a new fluorine products division to capitalize upon this technology.

High purity fluorine gases are in ever-increasing demand for ion-implantation or chemical vapor deposition processes for microelectronics components and high-speed silicon chip manufacture. The FEP fluorine product is equal to or greater than 99.99% pure with no detectable uranium in the product gas. This makes our FEP products ideally suited to these specialty applications where ultra high purity gases are required. In addition, we anticipate that the production costs of FEP products will be low in comparison with ultra pure fluorine products manufactured by other common commercial methods, enabling us to effectively compete with existing high purity fluorine product suppliers both on cost and purity.

To support the start-up of FEP we have entered into a marketing and technology consulting agreement with individuals knowledgeable and experienced with the processing technology and market applications for FEP products and leased an additional industrial facility for production of FEP gases. We believe that the market size and growth outlook for high purity fluorine products is excellent and should provide the Company an opportunity to grow our revenue substantially in coming years.

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We believe that revenues generated from these business activities can be expected to have a positive effect upon our projections for continued growth in 2004 and should produce sufficient cash to meet our operational needs. However, prospective investors are cautioned regarding the speculative nature of any forward-looking projections. Also see "Risk Factors," below, for a discussion of these and other risk factors relating to the Company when considering an investment in our securities.

Company Licensing, Capabilities, and Qualifications

We are a participating member of the National Institute of Standards and Technology/ Nuclear Energy Institute's (NIST/NEI) Measurement Assurance Program (MAP) for the radiopharmaceutical industry. This program participation ensures that we can provide analytical methods and standards necessary for accurate radioactivity measurement and is a requirement for most of the products manufactured for nuclear medicine reference and calibration standards. We are also a registered Food and Drug Administration (FDA) medical device manufacturer

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for Class I medical devices, including Nuclear Sealed Calibration Sources (892.1400) and Nuclear Flood Source Phantoms (892.1380), and have a fully implemented Quality Assurance program which meets the requirements of ANSI/ASME NQA-1 and 10 CFR 830.120.

We have an operating license issued from the Nuclear Regulatory Commission which defines the types and amounts of radioactive materials permitted within our facility. In 2003 the Company completed two additional revisions to this licensing to allow expanded production of our new radioisotopes, Lutetium-177 and Iodine -131.

Industry Overview, Target Markets, and Competition

The industries and markets that require or involve the use of radioactive material are diverse. Our current operations involve products that are used in a wide variety of applications and in various markets.

Radioisotope products are supplied typically in a bulk form and are highly competitive. The target market's for these products are customers who 1) incorporate them into finished industrial or medical devices 2) use these products in clinical trials for various medical applications, or 3) further process and include the material into a pharmaceutical product for FDA approved therapy or imaging.

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. This 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 these products for Radqual LLC, which in turn sells the products to several distributors around the U.S. We directly ship these products to all 50 states and Canada. There are two other major producers of these products within the U.S. that directly compete with us for these products.

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Most of our general measurement and radiological services are performed in support of gemstone processing. This material has undergone color enhancement by irradiation at the University of Missouri Research reactor. The gemstones are used in commercial jewelry manufactured by other companies in overseas locations. The color enhancement process is a highly competitive industry and there are several alternatives to irradiation treatment. There are also other reactors located in other regions of the world that also offer this irradiation service capability. The jewelry manufacturing industry is also a highly competitive industry.

We are developing our fluorine products in 2004 to address an opportunity we see in the increased market demand for certain high purity fluorine compounds in the microelectronics industry. Emerging technologies such as the increased use of silicon germanium processing chips for the wireless industry will require the use of high purity fluorine compounds such as germanium tetra fluoride. We plan to establish some manufacturing capacity for at least one of these compounds in 2004. Several of these fluorine compounds are already under production by other businesses. Since the cost of the FEP process is low we anticipate being able to be very price competitive with our fluorine products. However, this price advantage may initially be our only competitive advantage in this market.

Government Regulation

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The Company has obtained a license from the Nuclear Regulatory Commission, Region IV that permits use and possession of by-product material. The scope of this license includes calibration and reference standard manufacturing and distribution, radioisotope processing and distribution, radioactive gemstone processing, environmental sample analysis, and various research and development activities. The existing license and permit's are adequate to allow all of our business operations. Expansion into FEP production will require additional permitting both through the NRC, State of Idaho, and the EPA. We will make every effort to prepare well planned and detailed applications for these additional permits, however, there can be no assurance of the time frame required for the various governmental agencies to review and approve these permits.

Regulation of Radioisotope Production Radioactive Waste

All of our manufacturing processes result in the generation of some radioactive waste. We must handle these wastes pursuant to the Low Level Radioactive Waste Policy Act of 1980, which states we are required to assure the safe disposal of mildly radioactive materials. The estimated costs for storage and disposal of these materials have been included into 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 operating permit from the NRC also requires that we maintain an adequate cash reserve, in the form of a certificate of deposit and irrevocable letter of credit to the NRC to support our estimated decommissioning and disposal costs for the facility. We do not handle "special nuclear materials" (i.e. nuclear fuels and weapons grade uranium, thorium and plutonium) and, therefore, our facility is not designated as a "nuclear" facility.

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Other Regulations

Our sale of the isotopes Lutetium-177 and Iodine -131 for medical applications could cause us to be subject to additional regulations of the Food and Drug Administration (FDA). The Company is registered as a medical device manufacturer through the U.S. FDA for several of our nuclear medicine reference and calibration standards.

RISK FACTORS

An investment in the securities offered hereby involves a high degree of risk. In addition to the other information in this Prospectus, the following Risk Factors should be considered carefully in evaluating an investment in the securities offered hereby.

International Isotopes has incurred and may continue to incur losses. With the exception of the three-month and six-month periods ended June 30, 2002, we have incurred net losses for most fiscal periods since our inception. From inception (November 1995) through December 31, 2003 the Company generated \$19,316,817 in revenues and had an accumulated deficit (including preferred stock dividends and returns) in the amount of \$87,968,650. However, although we cannot provide any assurance we believe the Company's continued growth and our new business products will produce sufficient revenue to meet our 2004 cash flow and operational needs.

We may need additional financing to continue operations. As of December 31, 2003 we have an outstanding debt of \$733,595 on a short term note with Texas State Bank. That note matures on February 1, 2006 and is secured with our accounts

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receivable and fixed assets. The Company also has a ten-year note for \$840,753 at 7% interest to our former Chairman of the Board. Principal and interest payments on this note are to be paid annually based upon net profits of the Company (annual principal payment to equal 30% of net pre-tax profits).

Remaining Company Obligations on the Texas State Bank Loan for the Waxahachie Property. In 2002 the Company and Texas State Bank agreed to have our loan assumed by an individual in consideration of our sale of the Waxahachie property. As of December 31, 2003 the remaining outstanding balance on this loan was \$329,357. Should this individual default on the assumed note, the liability for the loan would revert to the Company.

We will continue to be dependent upon our remaining facilities and equipment to function properly in order to provide consistent, timely shipments of products that meet our customers' specifications. If we experience equipment failures or breakdowns we may be unable to satisfy our customers, which could result in the cancellation of contracts and the loss of revenues.

There is no long-term contract in place with the DOE Contractor for continued HSA Cobalt production. The Company has put short term specific "work for non-government sponsor agreements" in place with the DOE contractor to continue sales of HSA cobalt irradiated at the Idaho reactor facility. We expect that these agreements will continue, however, there is no assurance these contracts will be equitable or continuing.

Operational hazards (i.e., spills, faults, ventilation failure, etc.) could result in the spread of contamination within our facility and require additional funding to correct. An irrevocable, automatic renewable letter of credit against a \$150,000 Certificate of Deposit at Texas State Bank has been used to provide the financial assurance required by the Nuclear Regulatory Commission for our Idaho facility license. If a contamination event resulted in greater liability to us we would have to borrow money or fund the liability from our future revenue.

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Government regulation could adversely affect our business. Operations within our Idaho facility are subject to the U.S. Nuclear Regulatory Commission and Food and Drug Administration regulations. Nuclear medicine calibration and reference standards are licensed and regulated. To the extent these regulations are or become burdensome, our business development could be adversely affected.

We are dependent upon key personnel. Our ongoing operations are dependent on Steve T. Laflin, President and Chief Executive Officer. The Company is highly dependent upon this person and the loss of this individual could have a material adverse effect on us. We have a \$2 million dollar key man life insurance policy on Mr. Laflin and a 5-year employment agreement with him extending through February 2007. The Company has revised our employee stock options to assist with offering incentives and retaining key personnel. In addition, there is no assurance the Company will be able to retain our existing personnel or attract additional qualified employees. Loss of any of these relationships would result in a significant decline in revenue.

We are dependent on various third parties in connection with our business operations. The production of HSA Cobalt is dependent upon the Department of Energy, and its prime-operating contractor, who controls the Idaho reactor and laboratory operations. Our gemstone production is tied to an exclusive agreement with Quali Tech Inc. and this current agreement expires in November 2004. Nuclear medicine calibration and reference standard manufacturing is conducted under an exclusive contract with RadQual, LLC, which in turn has agreements in

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place with several companies for marketing and sales.

We are subject to competition from other companies. Each of the business areas of the Company has direct competition from other businesses. HSA cobalt is supplied by other reactor facilities around the world. Nuclear medicine calibration and reference standards are being produced by several other manufacturers in the U.S. and overseas, and there is at least one other gemstone processor in Europe. Lutetium-177 and I-131 isotope is manufactured by several other companies in the world, and there are also other suppliers of high purity fluorine products. Each of our competitors has significantly greater financial resources than us and that could create a competitive advantage for them over us.

We are named as Defendant in a lawsuit filed by Iso-Science Laboratories Inc. A lawsuit has been filed by Iso-Science Laboratories, Inc. dba Isotope Products Laboratories against International Isotopes Inc. and others. The Company believes the allegations of the petition are totally without merit. However, there can be no guarantee of the outcome of this suit and an unfavorable outcome could result in the loss of a major line of revenues and require substantial payments to the Plaintiff.

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SELLING STOCKHOLDERS

The following table shows the names of the Selling Stockholders and the number of Shares to be sold by them pursuant to this Prospectus:

Name	Number of Shares
Steve Laflin	11,000,000
Daren Lords	1,500,000
John Miller	1,500,000
Edward Kennedy	1,500,000
Ralph Richart	1,000,000
Chris Grosso	1,000,000

PLAN OF DISTRIBUTION

The Company has been advised by the Selling Stockholders that they intend to sell all or a portion of the Shares offered hereby from time to time in the over-the-counter market and that sales will be made at prices prevailing at the times of such sales. The Selling Stockholders may also make private sales directly or through a broker or brokers, who may act as agent or as principal. In connection with any sales, the Selling Stockholders and any brokers participating in such sales may be deemed to be underwriters within the meaning of the Securities Act.

Any broker-dealer participating in such transactions as agent may receive commissions from the Selling Stockholders (and, if such broker acts as agent for the purchaser of such Shares, from such purchaser). Usual and customary brokerage fees will be paid by the Selling Stockholders, Broker-dealers may agree with the Selling Stockholders to sell a specified number of Shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for the Selling Stockholders, to purchase as principal any unsold Shares at the price required to fulfill the broker-dealer commitment to the Selling Stockholders. Broker-dealers who acquire Shares as principal may thereafter resell such Shares from time to time in transactions (which may

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involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) in the over-the-counter market, in negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such Shares commissions computed as described above.

The Company has advised the Selling Stockholders that Regulation M promulgated under the Exchange Act may apply to sales in the market, has furnished the Selling Stockholders with a copy of this Regulation and has informed them of the need for delivery of copies of this Prospectus. The Selling Stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the Shares against certain liabilities, including liabilities arising under the Securities Act. Any commissions paid or any discounts or concessions allowed to any such broker-dealers, and, if any such broker-dealers purchase Shares as principal, any profits received on the resale of such Shares, may be deemed to be underwriting discounts and commissions under the Securities Act.

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Upon the Company's being notified by the Selling Stockholders that any material arrangement has been entered into with a broker-dealer for the sale of Shares through a cross or block trade, the Company may, in its discretion, file a supplemental prospectus under Rule 424(c) under the Securities Act, setting forth the name of the participating broker-dealer(s), the number of Shares involved, the price of which such Shares were sold by the Selling Stockholders, the commissions paid or discounts or concessions allowed by the Selling Stockholders to such broker-dealer(s), and where applicable, that such broker-dealer(s) did not conduct any investigation to verify the information set out in this Prospectus.

Any securities covered by this Prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under that Rule rather than pursuant to this Prospectus.

There can be no assurances that the Selling Stockholders will sell any or all of the Shares of Common Stock offered hereunder.

SECURITIES TO BE OFFERED

The Shares offered hereby are Shares of Common Stock, \$.01 par value, of the Company. Holders of Company Common Stock are entitled to one vote per share on all matters to be voted upon by the stockholders. The holders of Company Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the Company's Board of Directors (the "Company Board") out of funds legally available therefor. In the event of a liquidation, dissolution or winding up of the Company, the holders of Company Common Stock are entitled to share ratably in all assets remaining after outstanding Shares of Company Preferred Stock. There are no redemption or sinking fund provisions applicable to the Company Common Stock. All outstanding Shares of Company Common Stock are fully paid and non-assessable.

INFORMATION INCORPORATED BY REFERENCE

There are hereby incorporated by reference into this Registration Statement and into the Prospectus relating to this Registration Statement pursuant to Rule 428 the following documents and information heretofore filed with the Commission:

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1. The Company's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003.
2. The Company's Quarterly Reports on Form 10-QSB for the quarters ended March 31, 2004 and June 30, 2004.
3. All reports and other documents filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, after the date hereof, and prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold, shall be deemed to be incorporated by reference herein and to be part of this Registration Statement from the date of filing of such reports and documents.

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LEGAL MATTERS

The validity of the Shares of Common Stock offered hereby will be passed upon for the Company by Locke Liddell & Sapp LLP, Austin, Texas.

EXPERTS

The consolidated balance sheets of International Isotopes Inc. and subsidiaries as of December 31, 2003, and 2002, and the consolidated statements of operations, stockholder deficit, and cash flows for the years then ended incorporated by reference in this prospectus, have been included in reliance upon the report of Hansen, Barnett & Maxwell, independent certified public accountants, given on the authority of that firm as experts in accounting and auditing.

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