Radioactive and Hazardous Materials Committee







Who We Are

A new healthcare company, leveraging IP licensed from Sandia National Laboratories, with financial investment from the Yates Family





What We Do

Eden is a healthcare company, producing medical isotopes for the \$4.2B radiopharmaceutical molecular imaging industry





Why Molecular Imaging Is Critical For Patients



Molecular Imaging is unique, as other imaging modalities, such as X-ray, CT, MRI, Ultrasound typically will show anatomical structure of bone or soft tissue.

Molecular imaging, through use of a radiopharmaceutical, is the visualization, characterization & biological functional processes at cellular levels.

Molecular imaging is commonly employed in the diagnosis and treatment of numerous medical conditions, including heart disease and cancer.





Eden Primary Products:

Eden's Mo-99, would be the primary material used to diagnose heart disease and a variety of cancers

Technetium Tc-99m (Mo-99's usable form) accounts for over 40 million WW molecular imaging procedures annually or ~85% of all nuclear medicine procedures (SPECT and PET)

Eden's Lutetium-177, would be the primary radiotherapy material used to target and treat a variety of cancers, such as prostate & neuroendocrine, along with several additional new cancer treatment options currently under clinical development



Eden's Management Team



Chris Wagner Chief Executive Officer

- Co-founder of Eden Radioisotopes.
- 40 years of extensive global experience in medical imaging, including policy making roles in industry.
- Held leadership roles managing the nuclear medicine businesses with Nordion and Mallinckrodt (n/k/a Curium

Edward Parma, Ph.D. Chief Science Officer

- 30+ year career at Sandia.
- Invented the unique all-target reactor concept and co-developed other Eden technologies.
- Extensive experience in reactor engineering and experimentation, including design and analysis of critical assemblies, reactor safety analysis, and research reactor start-up and operation.





Jim Saldarini Licensing Director



- Previous roles include Chief Nuclear & Environmental Engineer at Bechtel.
- Has extensive experience dealing with the NRC, DOE and other government agencies.



Paul Schlavin Facility Engineering Director

- 39 years' experience in the design, construction and project management of laboratory facilities including the design and construction of Sandia's Hot Cell modifications in support of the DOE sponsored Mo-99 program in the 90s.
- Responsible for Eden's facility design, infrastructure and construction.

Nuclear Engineering Director

Paul Helmick

- 33+ years' experience at Sandia and Los Alamos National Laboratories.
- Held a key role in Sandia's Hot Cell modifications in support of the DOE sponsored Mo-99 program in the 90s.
- Responsible for incorporation of regulatory requirements in design and managing the interface between the reactor and processing facilities.



Chris Montaño CFA, Interim CFO

- 20 years' experience in financial and investment analysis in startups and publicly traded companies.
- Previously held board seats on several companies.
- Has directly invested over \$42m of investments into early and mid stage internet technology companies.



Travis Steele VP & General Counsel

- VP & General Counsel for Abo Empire, LLC as well as several of Abo's portfolio companies.
- Actively involved in Eden's legal & business development activities.
- Previously a Partner at Butler Snow, LLP.
- Extensive experience in corporate governance, acquisition & combination transactions.

Active Consultant Expertise



Alexander Adams, Jr.

Former Branch Chief, U.S. Nuclear Regulatory Commission

- 35 years experience in the Research and Test Reactor (RTR) Licensing Branch U.S. NRC.
- Directed all aspects of licensing for all 31 RTRs.
- Managed the development, review and approval of two construction permits for medical isotope production facilities.

Anthony J. Mendiola

Former Branch Chief, U.S. Nuclear Regulatory Commission

- 35 years experience in the Research and Test Reactor (RTR) Licensing Branch U.S. NRC.
- Directed all aspects of regulatory oversight for all 31 RTRs, specifically, operational, security and reactive inspections; physical facility security programs, and RTR licensed operator programs.

Dale Simpson

Executive & Senior Leader in Manufacturing & R&D Program Mgmt.

35 + years at Mallinckrodt. Directed the activities of U.S. and International Nuclear Medicine finished radiopharmaceutical and Molybdenum-99 production operations including U.S. based radiopharmacy network comprised of 1200 employees with a combined budget over \$250 million.

Jerry Head

Nuclear Power Plant Engineering, Operations, and Licensing

- 30 + years experience including Nuclear Safety Culture, Corrective Action Program, Emergency Planning and Security, Design, Systems and Component Testing, Systems Engineering, Engineering Analysis and Nuclear Fuel.
- Experience includes both BWR (GE) and PWR (Westinghouse, CE, and B&W) NSSS designs.

Paul Dunn

Former DOE Division Leader, Los Alamos National Laboratories

- 35 + years experience with emphasis in nuclear weapon and actinide component process development, materials characterization and component fabrication of nuclear weapons, reactor fuel and intelligence programs
- Progressively increased responsibility in project, program and line management, nuclear fuel metallurgy assessment and component fabrication.

Sargent & Lundy

Architect Engineer (AE)

- Full service nuclear AE firm providing comprehensive consulting, licensing, engineering, design, and analysis services to a worldwide client base.
- One of the oldest, largest, and most experienced nuclear engineering companies in the United States.

Eden's Competitive Advantage



Purpose-built US-based medical isotope production facility

- Facility optimised for commercial scale production of medical isotopes which will resolve US domestic (& global) Mo-99 supply problem, among other isotopes.
- Fully-owned 240 acre site ideally located in nuclear-friendly New Mexico, close to waste disposal site.
- Fuel enrichment facility across highway from Eden.

Proven, patented proprietary technology under exclusive license

- Eden has an exclusive license from Sandia National Laboratories for the design for the reactor core and integrated hot-cell processing facility.
- This reactor core design is expected to outproduce the total output of today's producers, using only LEU.

Operational Flexibility

- Eden's facility is being designed to enable the production of Mo-99 and Lu-177 however it will also have the flexibility to accommodate other radioisotopes, such as Xe-133 and lodine-131, in the future.
- This flexibility will enable Eden to remain competitive as the market evolves over the coming years.



Management Team

- Eden's leadership and engineering team has been built to ensure deep experience across all key business areas including in nuclear medicine, reactor science & operations, and regulatory credentials.
- Members of Eden Management team were on original Sandia team which developed the technology now being licensed and commercialised.

Regulatory Engagement Plan

- Eden has designed a fast-track regulatory engagement plan in alignment with NRC expectations & feedback to minimise risks of delays to approval for its Construction Permit in 2026 and Commercial Production in 2029.
- Sargent & Lundy is core part of team, has 80+ years supporting customers working with NRC to this end.

Market-leading margins from FY29

- Once operational, the Eden facility's unique efficiencies and capacities will enable profitability, significantly above current market participants.
- Low power requirements given technology's efficiency.
- Reactor uses LEU fuel.
- All target concept results in no spent fuel, minimising waste costs.

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Nuclear Medicine Market Opportunity

Radiopharmaceutical therapies are an **opportunity for the growth and relevance** of Nuclear Medicine





Source: (radiotherapeutics and radiodiagnostics) 2019 MEDrays Intell Nuclear Medicine World Market Report Source (equipment): Siemens



Current & Emerging High Growth Market: Lu-177

In contrast to the Mo-99 market, the market for Lu-177 is dynamic and fast-growing as new therapeutic applications emerge from the global biopharma drug discovery & approval pipeline.

Focus on New Therapies

- Novartis: Two approved targeted cancer drugs in the market: Lutathera & Pluvicto
 - Pluvicto (prostate cancer) approved in Q1 2022 and already has annualized sales of >\$1 Billion; Novartis has stated it could quickly exceed \$2bn in annual sales as prescribing guidelines are expected to expand. Industry estimates show the global market for prostate cancer therapies as high as +\$24bn by 2028, so the Novartis estimates seem conservative.¹
- New entrants in the pipeline:
 - In Feb. 2023 there were more than 70 active/completed clinical trials involving Lu-177 in the FDA database.²
 - Of these trials, 46% involved Novartis; other players with multiple studies include Nordic Nanovector; FutureChem; Exelixis; POINT Biopharma; Telix International; and ITM Solucin GmbH

Estimated current production levels and capacity do not come close to meeting expected demand, even if reactors did not decommission on schedule.

(1) Nova 1 Advisor research, cited in Seeking Alpha: "The prostate cancer therapy market will soar," Jonathan Block, 9/25/2022

(2) Source: Clinicaltrials.gov





How Eden Serves the Radiopharmaceutical Industry

From Mo-99 Target to Patient in ~36 hrs.





Market Supply Chain Issues





• Capacity figures for govt. reactors shown are 80% of "nameplate capacity" to approximate output (allowing for planned and unplanned downtime)

• All figures in Ci/wk

Regulatory Considerations

The regulatory scope with respect to radiopharmaceuticals is twofold:

1) Regulations regarding the handling, use, and transport of nuclear materials

2) Regulations typically associated with drug safety, efficacy, and health authority approval. Molecular Imaging is subject to significant regulatory oversight given the sensitive and restricted materials that are utilized and produced

These groups include:

- Nuclear Regulatory Commission (NRC)
- Food and Drug Administration (FDA)
- European Union (EU), European Medicines Agency (EMA)
- Pharmaceuticals and Medical Devices Agency (PMDA - Japan)
- State Board of Pharmacy
- US/EU/Japan Departments of Transportation (DOT)
- Country Customs and Border
 Patrols
- Department of Homeland Security (DHS)
- Occupational Safety and Health Administration (OSHA)
- Environmental Protection Agency (EPA)



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Facility Location Overview

Strategically located in a "nuclear-friendly" region of New Mexico proximal to other nuclear-related companies and an educated workforce, the Eden Isotope Production Complex plans include multiple buildings in an integrated complex. At the center is the Eden Medical Isotope Facility (EMIF), the largest building of the complex.

- Eden-owned 240-acre site in near Eunice, NM (Lea County) purchased in 2020 and directly adjacent to URENCO
- Close to WCS (Waste Control Specialists), a secure option for radioactive waste disposal









Purpose-Built Reactor Facility Serves Two Markets

Eden's low-power nuclear fission reactor facility will initially produce both Mo-99 and Lu-177. The following slides outline the business opportunity for each. The facility will also accommodate production of other isotopes for the medical market, such as Xe-133 and Iodine-131.



Eden's Solution:

Purpose-built small-scale reactor colocated with hot cell facility built for medical isotope market

Patented, proprietary technology under exclusive license

Makes Mo-99 and Lu-177; flexibility to accommodate others

Eden's reactor technology is under exclusive license from Sandia National Laboratories. The technology was developed at Sandia as part of a **\$45m DOE investment** in creating backup sources for Mo-99.



Why Eden:

Top-quality team with deep industry, scientific and regulatory experience; includes original patent contributor

Fast track regulatory approval plan aligned with NRC expectations for construction permit approval in Q2 2026 and commercial production in 2029



Eden's Solution

Eden's purpose-built open-pool research-type reactor optimized for commercial scale production of Mo-99, Lu-177 and other critical medical isotopes will resolve the domestic (and much of the global) Mo-99 supply problem, with clear answers to the challenges currently facing the international community. It will also have capacity to supply a substantive portion of the expected demand for Lu-177 for radiotherapies.

THE EDEN REACTOR FACILITY

- Proven technology recognized to produce isotopes at commercial scale (fission reactor plus hot cell)
- Dedicated to medical isotope production
- Continuous, year-round operations
- Low-power (<2 MW) and small footprint
- U.S. location to serve domestic market in timely fashion
- Uses LEU, produces no spent fuel, and recycles 90% of uranium for additional isotope production
- Recycles Ytterbium-176 used in Lu-177 production

PRODUCTS

- Capacity for global Mo-99 demand AND substantial part of Lu-177 demand
- Produces bulk Mo-99 compatible with all leading commercial generators
- Produces bulk Lu-177 for direct delivery to radiopharmaceutical manufacturers; Eden's Lu-177 is NCA (non carrier added) – market preferred as it has high specific activity.
- Additional growth opportunities available from other activation isotopes beyond Lu-177; also from I-131 and Xe-133 which are produced along with Mo-99 and can be extracted concurrently.





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Eden's Solution: Proven, Proprietary Technology



Exclusive license to the design for the reactor core and integrated hot-cell processing facility.

- Developed at Sandia in 1990's and updated in 2008 to the present "all-target" core using LEU by members of the original team, now part of Eden.
- Eden has added significant proprietary design IP to the Sandia license which drives efficiency and capacity well beyond that of research reactors
- Because of the core design Eden's small reactor is expected to outproduce the total output of today's producers, using only LEU.
- Prior DOE project produced Mo-99; the output of the process was validated in FDA approved generator at BMS (now Lantheus) & Mallinckrodt (now Curium).



Advantages & Benefits: Lea County and the State of New Mexico

Advantages of Lea County:

- Product and waste transportation logistics
- Nuclear-friendly community
- Ease of low-level waste disposal (WCS)
- Yates family support in SE NM
- Ability to contribute to and draw from an educated work force

Benefits to Lea County & NM:

- +\$400 million state of the art, world-class medical isotope manufacturing facility
- Several hundred building trade jobs created during facility construction
- Over 100 permanent jobs created at avg compensation of ~\$92,000
- Tax revenues from \$10M annual payroll & several hundred million dollars in sales
- 10-Year Economic Impact: Taxable sales & purchases anticipated is \$5.3 Billion
- Potential collaboration with New Mexico colleges and universities
 - STEM
 - UNM College of Pharmacy Translational Radiopharmacy
 - UNM Nuclear Engineering Department
- Potential collaboration with New Mexico tribal universities STEM



Eden Policy Challenges

- City of Eunice Capabilities Eden Water & Sewer Needs
- Local Electric Utility Access Eden Electrical Supply Needs



Eden's Regulatory Risk Management Plan

Regulatory Timetable



- Eden's active management of the regulatory approvals process is an integral part of its plan to minimize risks related to regulatory delays.
- The Company's Licensing Director and the consulting team bring deep experience in working with the NRC, preparing materials and responding to requests.
- Strategy:
 - Use pre-licensing application meetings with NRC to avoid surprises and instill confidence.
 - Accelerate NRC review process by ensuring CPA informed by review of questions asked in prior medical isotope applications.
 - Leverage Eden's specialist consulting group to provide complete & timely responses to NRC questions.
 - Maintain NRC familiarity and focus through the project construction phase
- Sargent & Lundy have been engaged for the last 3 years as Eden's AE partner, progressing the design, and facilitating it's fast-track regulatory plan.
 - 80+ years' experience supporting customers working with NRC.



Funding Round

Future Series C* **\$70M SERIES B Equity Round Operating License Execution Construction Permit Execution** \$70M¹ 30 - 36 months **Target Close Date: Q4 2023** 24 months 1. 20% discount on first \$10M funded before July 15, 2023, Plant Construction Phase to accelerate permit development and filing process **NRC** Operating License Review Worker Hiring & Training Corp Dev to Lock In Initial Contracts Facility Startup & Commissioning Q2 2024 2H 2028 Q2 2026 Milestone: Milestone: **Construction Permit** Milestone: **Operating License Full Construction** Application Issued Permit Granted Filed & Docketed by NRC Net Working Capital & CapEx Need for Construction **Investor Liquidity Opportunities** Permitting \$70 million (Equity Funding) **Total CapEx to Operations \$390 million**

*Estimated \$365m fundraise required; anticipated split of c.\$91m equity and c.\$274m debt

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Questions

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