SHINE
Medical Technologies

SHINE: Technology and Progress

April 3, 2013

MORGRIDGE
INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE
Medical Technologies

Introduction to SHINE Medical Technologies

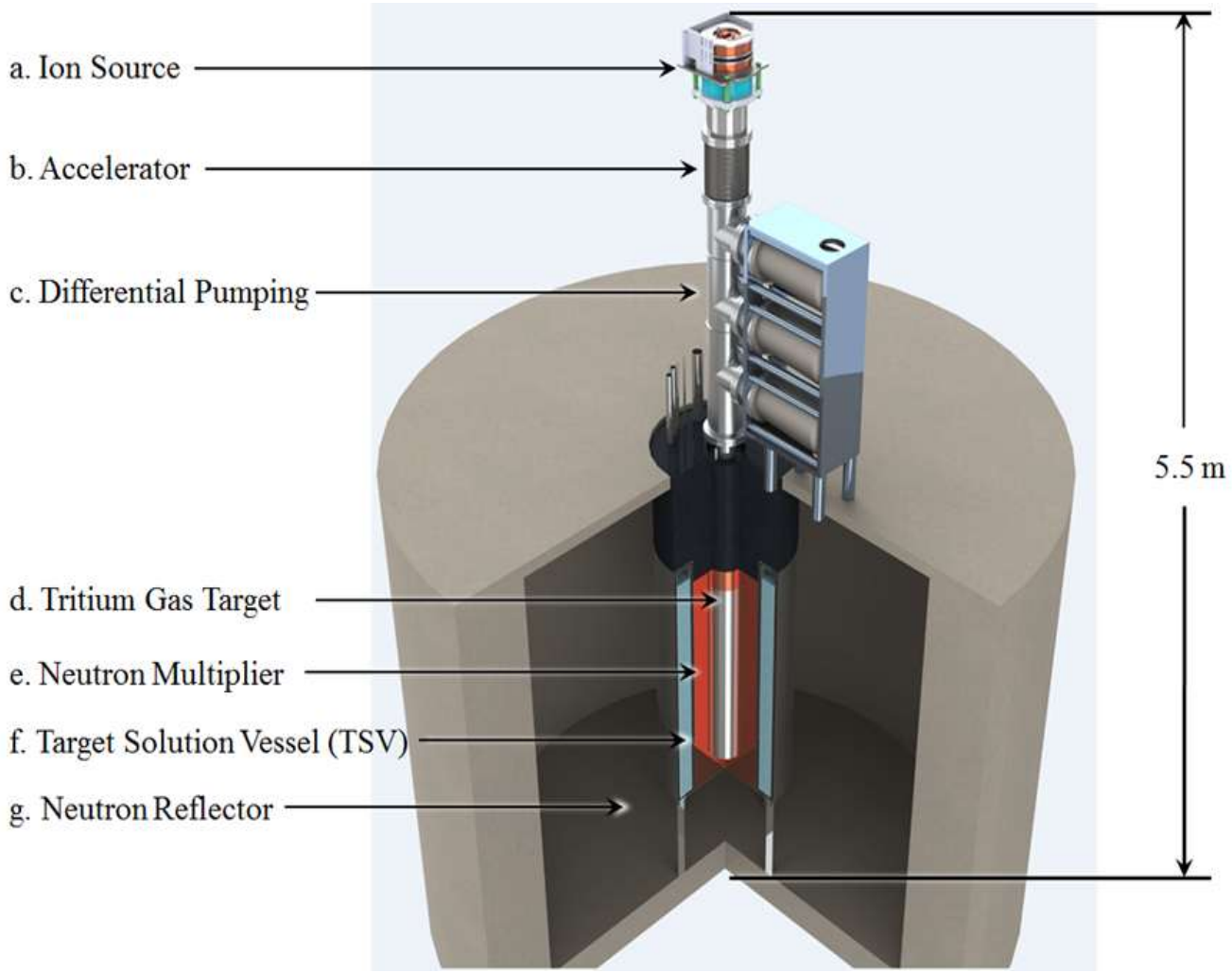
Health. Illuminated.

- SHINE Medical Technologies™ is dedicated to being the world leader in safe, clean, affordable production of medical tracers and cancer treatment elements.
- Highest priority is safely delivering a highly reliable, high-quality supply of the medical ingredients required by nearly 100,000 patients each day

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

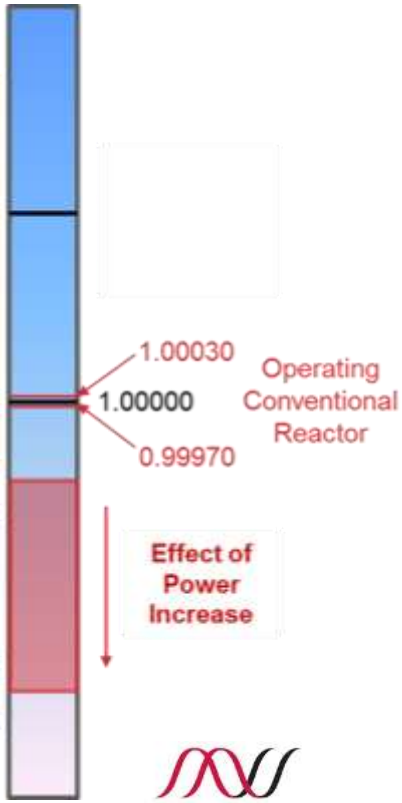
SHINE Medical Technologies

Production Device Overview



Technology Advantages

- Technology merges positive aspects from accelerators and AHRs, eliminates negatives
- DT accelerator advantages
  - Demonstrated technology, very high yield
  - Efficient and inexpensive, not self sustaining
- Subcritical aqueous target advantages
  - High multiplication while keeping safely away from critical
  - Small, bounded power changes in response to void and temperature
  - No control system "chasing" on instability
  - Cannot become critical after fill procedure completed
  - Easy separation, very low waste production
  - Minimal decay heat after shutdown; less than a hair dryer

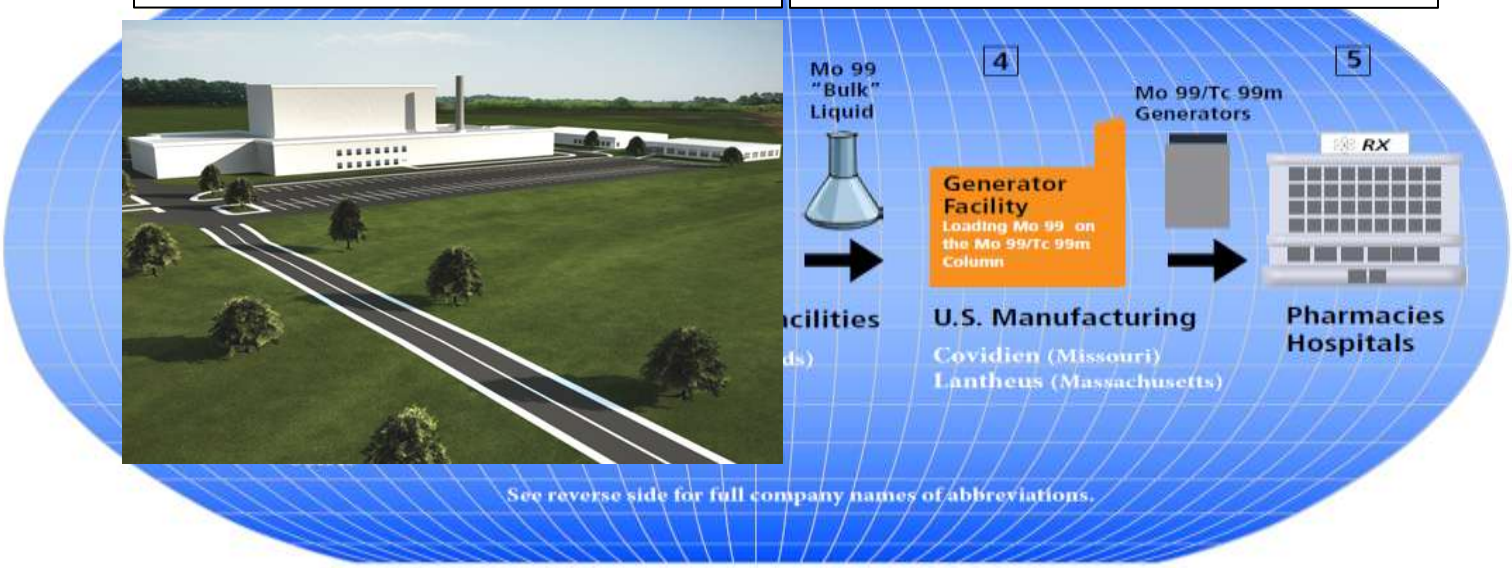


MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

SHINE Will Sell HSA (fission) ^{99}Mo Supply Chain

Centralized Business Model | Distributed Business Model



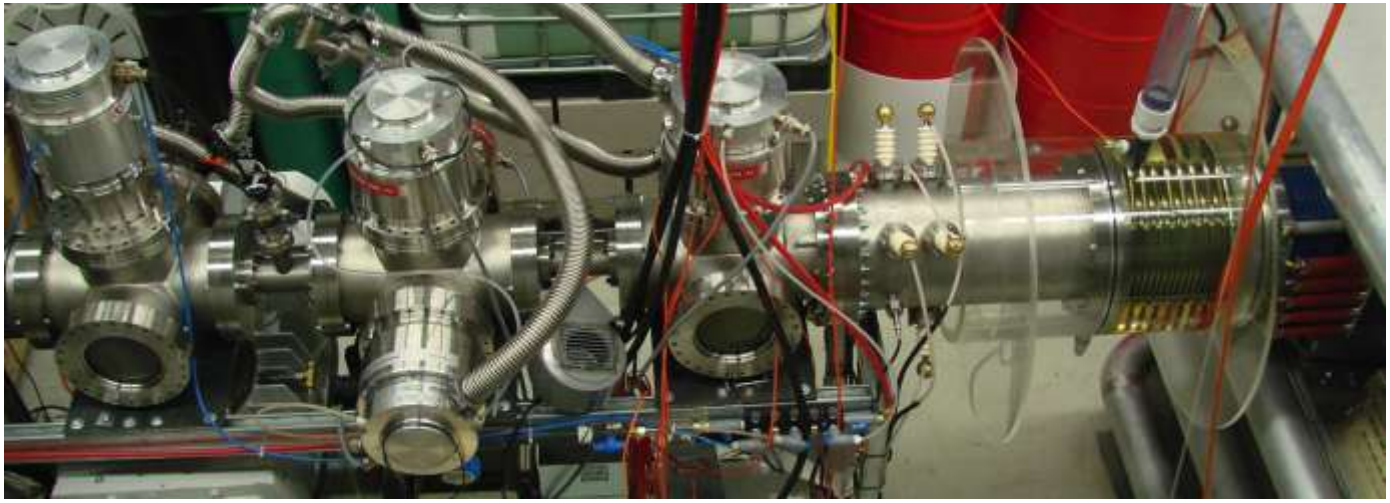
- SHINE produces ^{99}Mo and purifies it
- Bulk product is packaged for sale to radiopharmacies by existing generator manufacturers
- Other isotopes will also be delivered (I131-Xe-133, and others)

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

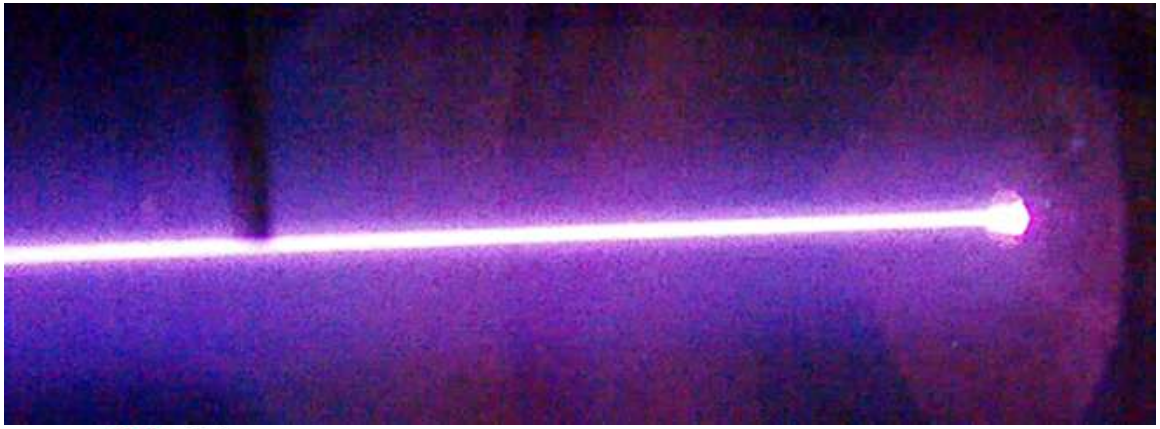
Excellent Progress Made on Driver Prototype I

- Demonstration of reliable, repeatable particle beams at 20 mA, 275 keV
  - Consistent neutron yield demostrated
  - 400+ hours of operational runtime
  - Now deployed at Picatinny Arsenal for use in neutron radiography of munitions



Prototype II Will Develop Experience on Plant-Scale Driver

- Designed for plant-scale operations
  - Full current / voltage (50 mA, 300 kV)
  - Plant configuration (geometry)
  - Purpose is to demonstrate full ouput, assess long-term reliability issues
  - System now operational, repeated demonstration of well focused, full current beam



MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Strong Progress Continues on Development of Target Solution Vessel (TSV)

- Physical optimization complete
  - Physical dimensions / materials chosen
  - Solution chemistry and volumes locked
  - Steady state behaviors analyzed
  - Output yields determined using MCNP5/ORIGEN-S
  - → Each accelerator / TSV system is capable of up to 1000 6-day Ci / wk
- Recent work has focused on operational and startup strategies
  - Startup will use solution fill to allow 1/M approach
  - Maximum multiplication occurs at startup, operational behaviors push multiplication factor downward

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Additional Work has Focused on Target Related Systems

- Offgas control
  - Radiation field during process results in radiolysis of water (hydrogen / oxygen generation)
  - Passive technology catalyzes recombination back into water
  - Prototype system built, testing underway—resembles plant system design
  - Will assess recombiner efficiency under plant-like conditions
- Development of Subcritical Assembly Support Structure (SASS)
  - Additional barrier between radionuclides and rest of plant
  - Provides protection against physical insults, unforeseen corrosion
  - Allows for periodic sampling to check for leaks in TSV
- TSV safety and monitoring systems

Isotope Purification Technology Selected, Demonstrated

- Plant scale process designed, prototyped
  - Primary separation of isotopes done with ion exchange
  - Subsequent purification to use modified LEU cintichem process
  - Hot cell process designed around chemical requirements, preliminary design complete
- Molybdenum separation efficiency demonstrated
  - > 97% recovery from uranyl sulfate solution of relevant concentration (LANL)
  - Very high recovery of uranium
  - Larger scale experiments expected on ANL mini-SHINE, subsequent LANL testing, but all indications are positive that sulfate will be workable
  - Additional testing being performed by Wisconsin Institute for Medical Research (WIMR)

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Infrastructure Development

- Team moved into new testing location in Monona, WI
- Site selected after consideration of multiple locations: Janesville WI
- Direct team has grown and now includes:
  - Nearly two dozen engineers
  - About a half dozen safety and quality staff
  - About a dozen support staff
- Key expertise added in nuclear operations and licensing
  - Over 200 years experience in nuclear ops
  - ~ 100 years experience in NRC licensing

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

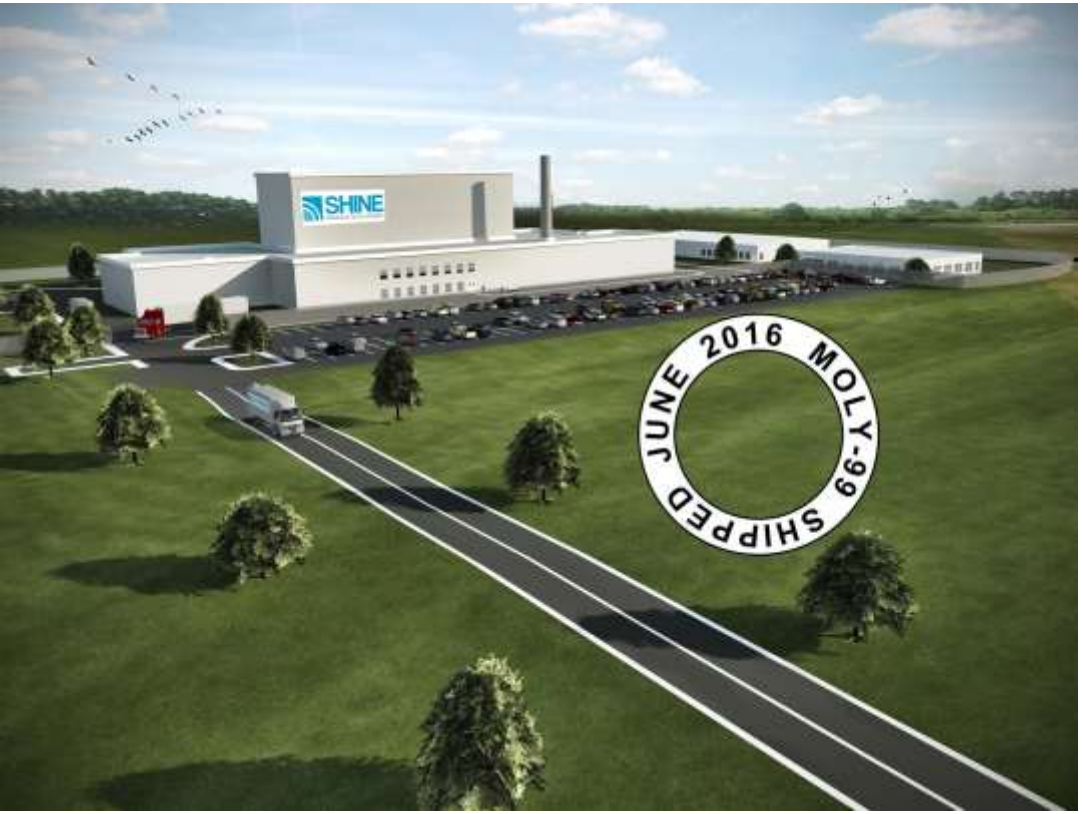
SHINE Medical Technologies

New Test Facility (~14,000 ft², 60-40 office / lab split)

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Renderings of Production Facility on Site Location (Janesville, WI)



MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

Aerial View of Janesville Site

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Frequent Engagement with NRC

- A series of preapplication meetings have covered a range of topics and we have found them to be useful:
  - Technology approach and overview
  - Content and structure of the proposed license application
  - Application submission and review structure
  - Facility designs
  - Physics and design of the subcritical assembly
  - Subcritical assembly and start-up philosophy
  - Security
  - Postulated accidents
  - Site selection
  - Environmental monitoring
  - Waste management
  - Transportation
- Thank you to NRC for agreeing to take part in this process!

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

NRC Environmental Report Submitted

- Represents 18 months of extensive data collection and analysis
- Covers things such as weather and groundwater data
- Migratory species movements, endangered species
- Socioeconomic studies of plant impacts on nearby communities
- Impacts of construction
- Study of plant activities impact on human environment
- **Report should kick of NRC review of SHINE construction permit application**

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Exceptional Progress on Facility Design

- Conceptual design completed
- Preliminary design nearly complete
  - Represents majority of work performed since last time
  - Forms cornerstone of NRC preliminary safety analysis report, sets baseline for final design
  - Includes system descriptions, mass balances, physical layouts, shielding, structural design and seismic analysis, selection of appropriate codes and standards, and safety related system designs
- Approximate facility size ~ 55,000 ft^2, will house 8 TSV's, 3 hot cell trains, solution cleanup and others

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Preliminary Safety Analysis Report

- Part II of submittal needed to receive CP
- Based on preliminary design and combined with safety analysis
- Considers accident scenarios, both credible and incredible (MHA)
- Includes preliminary integrated safety analysis
- Includes preliminary accident analysis
- Includes facility preliminary design documents and related analysis
- Expected to finish in April, 2013

Other Activities

- Waste handling and disposal strategy
- Development of environmental monitoring plan
- Fundraising
- Development of strategic relationships
- Preliminary interaction with FDA
- Development of quality systems and procedures
- Build up of project management infrastructure
- Preliminary discussions with construction companies
- Many other activities

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

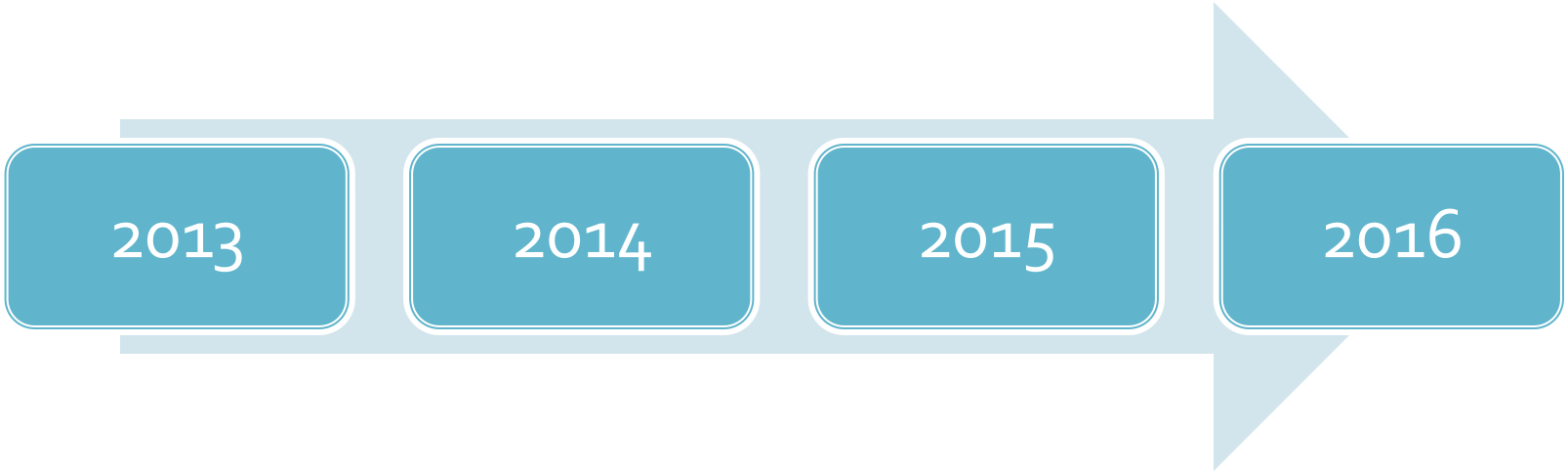
Next Steps (2013-2014)

- Demonstrate accelerator reliability, assess any weak spots from long term operation and improve
- Development and lock-down of secondary plant related system
- Model process hot-cells in plywood
- Complete final design, select constructor
- Submit Final Safety Analysis Report (FSAR)
- Secure vendors for long-lead time items
- Many other subtasks

MORGRIDGE INSTITUTE FOR RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Summary Timeline



2013	2014	2015	2016
• Submit NRC CP application	• NRC construction approval	• Construction	• Complete plant • Install equipment
• Demo prototypes	• Final design / submit OL application	• Early training	• Testing & training
• Establish Drug Master File	• Site preparation	• Production staff up	• Ramp-up production

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

21

SHINE Medical Technologies

Summary

- Excellent progress continues on many fronts:
  - Technology: continues to evolve toward production scale processes
  - Design: Conceptual design complete, preliminary design nearly complete
  - Regulatory: First part of construction permit application filed, second part will follow shortly. Preliminary interaction with FDA
  - Infrastructure: Team has expanded to ~40 very well motivated, capable staff members, strategic relationships being developed
- On track for 2016 product sales

MORGRIDGE INSTITUTE FOR RESEARCH
AT THE UNIVERSITY OF WISCONSIN-MADISON

SHINE Medical Technologies

Thank You!

Dr. Gregory Piefer
SHINE Medical Technologies, Inc.

www.SHINEmed.com
Greg.p@shinemed.com