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.
Production Device Overview

- a. Ion Source
- b. Accelerator
- c. Differential Pumping
- d. Tritium Gas Target
- e. Neutron Multiplier
- f. Target Solution Vessel (TSV)
- g. Neutron Reflector

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

- 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 (I$^{131}$-Xe-$^{133}$, and others)
Demonstration of reliable, repeatable particle beams at 20 mA, 275 keV
- Consistent neutron yield demonstrated
- 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 output, assess long-term reliability issues
  - System now operational, repeated demonstration of well focused, full current beam
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
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)
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
New Test Facility (~14,000 ft², 60-40 office / lab split)
Renderings of Production Facility on Site Location (Janesville, WI)
Aerial View of Janesville Site
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!
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
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 ft², will house 8 TSV’s, 3 hot cell trains, solution cleanup and others
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
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
## Summary Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
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<tbody>
<tr>
<td><strong>Tasks</strong></td>
<td><strong>Submit NRC CP application</strong></td>
<td><strong>NRC construction approval</strong></td>
<td><strong>Construction</strong></td>
<td><strong>Complete plant</strong>&lt;br&gt;<strong>Install equipment</strong></td>
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<td><strong>Demo prototypes</strong></td>
<td><strong>Final design / submit OL application</strong></td>
<td><strong>Early training</strong></td>
<td><strong>Testing &amp; training</strong></td>
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<td><strong>Establish Drug Master File</strong></td>
<td><strong>Site preparation</strong></td>
<td><strong>Production staff up</strong></td>
<td><strong>Ramp-up production</strong></td>
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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
Thank You!

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