Briefing on Potential Medical Isotope Production Licensing Actions Coquí RadioPharmaceuticals Corp.

<u>Topic:</u> Coqui's current status for the production of Mo-99.

Carmen Irene Bigles, President/ CEO May 11th Nuclear Regulatory Commission

Acronyms

- NRC Nuclear Regulatory Commission
- Coquí Coquí RadioPharmaceuticals Corp.
- MIPF Medical Isotope Production Facility
- ER Environmental Report
- Mo-99 Molybdenum 99
- FDA Food and Drug Administration
- GTRI Global Threat Reduction Initiative
- LEU Low Enriched Uranium

Coquí RadioPharmaceuticals Corp.



Coquí Commercial Domestic Producer

- Supply Capacity: 100% U.S. market
- First Private Sector Producer: Supply chain outages and decommissioning of existing reactors and the looming price increases assure transition of Mo-99 production from government to the private sector



 <u>Timing of Transition:</u> without proven technology, private sector commercial scale production in the U.S. could be delayed causing Mo-99 to be scarce in the U.S. together with substantial price and demand increases.



Coquí's Technology

- Supporting GTRI with Proven LEU Technologies: LEU reactor fuel and fission targets and radiochemical process, currently used in Australia, Argentina and South Africa
- **INVAP:** proven designs successfully executed worldwide.

- FDA Approved Product: Our end product is the same already approved by the FDA that is subsequently imported to the U.S. for patient use.
- <u>Capacity</u>: production design objective is 7,000 Six-Day Curies per Week and allows for maintenance and refueling downtime assuring stable supply.

Application Status

- March 15, 2010: Coquí submitted a Letter of Intent to the NRC indicating its intention of submitting an application to License the MIPF
- May 2010: Coquí submitted its first licensing strategy document to the NRC



- June 2010: Coquí submitted its second licensing strategy document to the NRC, which provided for the NRC staff's review a Safety and Licensing Plan for the technical portions of the application
- September 2010: The NRC responded to these submittals providing Coquí with important information on preparing its application

- October 2010: Coquí held its first public hearing at the NRC
- Currently: a sufficient amount of the technical portion of the application has already been prepared



Conceptual Site Layout



Site Selection

- Site and Location: Thanks to the efforts of Enterprise Florida, and the University of Florida Foundation a site has been chosen, which has been offered to Coquí by the Foundation
- NUREG 1537 Compliance
- Status: Phase I ER completed.

Financing

- <u>Demand for Mo-99 = Price Increase:</u>
 - continued increased worldwide demand
 - production shortfalls
 - scheduled decommissioning
- Investment Situation:
 - price increments will benefit the investment situation of proven Mo-99 production

Status: Coquí RadioPharmaceuticals Corp. is engaged in negotiations with investors to finance the licensing and the construction of the MIPF. Enterprise Florida also provided Coquí with a tax and workforce incentive package to establish the facility.



Moving Forward

- Coquí would like to take this opportunity to thank the NRC staff
- We are already well underway preparing our application, we have located a site and our technology is proven
- Long pole in the tent is financing. Once we have that lined up:

- We will eagerly complete our NRC submittal

Time Line Financing in Place

Id.	. Task	Months
1	Licensing Preparation (0 – 9)	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 51
2	Environmental Report Submission (5)	•
3	NRC Licensing and Review (5 – 17)	
4	Construction and Installation (14 – 42)	
5	NRC Commissioning and Operation Approvals (36 – 48)	
6	Preoperational Tests and Commissioning (34 – 48)	



Coquí RadioPharmaceuticals Corp.

Sustainable Design + Proven Technology + Finance = Saving Lives + Global Threat Reduction = A Better World

• Questions?

