

# DEHYDRATION TECHNOLOGY FOR BIOMATERIALS



## REV Biomaterial Applications

EnWave's Radiant Energy Vacuum ("REV") technology combines microwave heating energy with a low pressure environment to achieve rapid, highly controlled dehydration at or below room temperatures. The Company's *bioREV*<sup>™</sup> and *freezeREV*<sup>™</sup> technologies are designed to dehydrate live or active materials such as antibodies, bacteria, enzymes and viruses in sterile vials to produce shelf-stable pharmaceuticals and non-regulated biological products.

EnWave is currently determining the feasibility of using *bioREV*<sup>™</sup> and *freezeREV*<sup>™</sup> to produce shelf-stable vaccines and other biologicals as a cost-effective alternative to the current industry standard of freeze drying (lyophilization). The Company believes that high-speed, low cost dehydration could reduce the expensive and complicated refrigeration "cold chain" currently necessary to preserve many biomaterials used to protect against pandemic diseases and bioterrorism threats, and reduce the cost of biomaterials used for scientific discovery and diagnostics.

## Market Potential

The overall global market for lyophilization equipment was estimated to be USD\$1.8bn in 2010, and is predicted to reach USD\$2.2bn in 2015.

The growth in this market is expected to come from an increase in the number of biotechnology drugs on the market as well as vaccines, both of which require rapid stabilization, long term shelf-life and end-user convenience.

Source: "Freeze Drying Equipment: A Global Strategic Business Report", Global Industry Analysts Inc, 2008.

### **bioREV**<sup>™</sup>

*bioREV*<sup>™</sup> technology provides high-speed dehydration of active pharmaceuticals at temperatures above freezing. This is an attractive method for formulations vulnerable to damage from freezing. EnWave has been able to achieve moisture levels as low as 3% using *bioREV*<sup>™</sup> while still providing a long product shelf-life, and has conducted successful tests on bacterial cultures, enzymes and other proteins.

### **freezeREV**<sup>™</sup>

*freezeREV*<sup>™</sup> provides high-speed dehydration of biomaterials from the frozen state. This is a microwave-assisted method for freeze drying where low moisture levels are shown to be imperative to shelf-life stability. The Company is now testing a multi-vial prototype version of this technology, and has successfully dried several biomaterials at the rate of 100 vials per hour.



Both *bioREV*<sup>™</sup> and *freezeREV*<sup>™</sup> dry live or active pharmaceutical formulations in hours compared to days required for conventional freeze drying. Both technologies are designed to offer the potential for significant reductions in processing costs through capital, energy, time and labour savings.

## Benefits of REV for Biomaterial Dehydration

Lyophilization (freeze drying) is the most commonly used method for dehydrating live materials. During lyophilization, formulations containing biomaterials are first frozen, then dried from the frozen state through the sublimation of water. This can be a complex process that is both time consuming and expensive.

EnWave has generated successful test results for a variety of antibodies, enzymes, bacteria, and one vaccine (rotavirus) demonstrating that *bioREV*<sup>™</sup> and *freezeREV*<sup>™</sup> dehydration may offer significant benefits over lyophilization, including:

- Reduction in loss of sensitive organisms
- Low post-dehydration moisture content
- Continuous throughput drying
- Reduction in processing time from days to hours
- Smaller equipment footprint
- Reduced energy consumption