A test fixture will be precisely position the secondary coil in space and acquire power measurements.

3.4 Objective 2B: Develop programmable dosing software

Control software will be developed for remote control of the pump system. Preliminary demonstration of remote-control capability will include flow rate and delivered volume measurements at the pump output to ensure accurate control at room temperature. Software operating procedures and instructions will be documented. Each feature described will be tested against the required performance specifications.

Calibration and validation of the PWM dosing capability will also be performed as part of this research effort. PWM duty cycle and period setting will be determined using calibrated flow rate and delivered volume measurements. The selection of appropriate PWM settings will be programmed into the software and linked to front panel flow rate controls.

3.5 Objective 3: Perform system validation of micropump technologies

Benchtop testing at 37 °C will be performed. Pump will be submersed in PBS or embedded in 0.5% agar. The pump will perform three dosing schemes (continuous, daily bolus, and hourly intermittent. Experiments will last for 30 days. Dosing volumes will be measured daily and compared with the volume set by the programmable dosing software. Accelerated lifetime testing at 100% humidity (submersed in PBS) and 65 °C will be performed for 9 days to simulate 6 months of *in vivo* conditions. Since the external and internal exposed surfaces are all coated with Parylene, the polymer properties for leachable and extractable are known and the manufacturer (Specialty Coatings Systems) which has documentation with the FDA. In SBIR Phase 2, we plan to perform system validation with *in vivo* mouse studies.

4 COMMERCIAL POTENTIAL

Our go-to-market strategy is two-tiered. Our **short-term strategy** is to establish a **beachhead market** in **preclinical drug screening/laboratory animal research**, a low capital, accessible, and unregulated market with established sales/distribution channels and customers dissatisfied with existing solutions. This strategy offers many advantages, including rapid time-to-market, early revenue returns, access to a large customer base with eager early-adopters, and opportunities to work with thought leaders in the field of drug discovery, drug delivery, animal models, and veterinary care. **Preorders have been received from early adopters (including Eli Lilly, early-stage biotechs, and institutional researchers).** Adoption of our animal pumps will generate scientific evidence, provide grass-root marketing, and establish credibility for more heavily regulated markets. The momentum will be leveraged to execute our **long-term strategy**, adapting our pumping innovation for **human clinical use**.

4.1 Market opportunity

Hundreds of millions of dollars are spent on animal studies using drug administration and are funded by government agencies, nonprofit organization, and pharmaceutical/biotechnology companies worldwide. The outsourcing of preclinical research is currently the fastest growing outsourcing market segment within the pharmaceutical and biotech industries with an estimated $4B spent in 2008 (16% CAGR). The rise in preclinical testing overseas and increasing complexity of drug screening drive this growth[39].

A more accurate and cost effective screening process is highly attractive to pharmaceutical companies early in the drug development process. Critical questions such as efficacy, safety and toxicity can be more rapidly and readily answered through a fully automated drug delivery system. Contract research organizations, e.g., Charles River Laboratories, welcome the opportunity to offer new drug testing capabilities, improve efficiency, and automate dosing and record-keeping (personal communications).