surgical procedure, [redacted] will be used for repeated measurements in the control IP injection study, acute pump infusion experiment, and weekly pump infusion experiment. After 30 days, histological tissue analysis will be performed on dissected tissue surrounding the micropump. [redacted] studies described here are subcontracted to [redacted] which has access to the transgenic mice, the animal imaging core facility, and the histological core services.

Expected outcomes, potential problems, and solutions: Catheter-based delivery into the intravenous, intraventricular, intraocular, and intrathecal spaces typically does not experience clogging. Delivery into the subcutaneous, IP, intracranial, intramuscular, and intratumoral space may occasionally be at risk to clogging. Catheter-lock solution (heparin-glycerol [redacted] U/mL) can also be used to maintain catheter patency. Proper catheter selection and pretreatment of the inner lumen have been demonstrated to address these concerns [redacted]. An alternative approach to maintain catheter patency is to apply a small continuous sub-threshold flow rate to prevent stagnation around the catheter tip.

D.4 Timeline

The proposed work consisting of three aims over two years which will accelerate development efforts towards *in vivo* validation studies planned in Phase 2 where clinically relevant results in statistically significant preclinical studies will create the momentum for highest impact of this technology.

Table 1. Timeline

Task	Months (0-3 month)			
	0-6	6-12	12-18	18-24
1. Coil system (3 mo.)				
Benchtop testing (3 mo.)				
In vivo testing (3 mo.)				

D.5 Commercialization Goals

Market Entry: Establishing manufacturing techniques, satisfying performance specifications, and successful demonstration of dosing *in vivo* will significantly advance our product and establish our customer base. We have established a website (www.fluidsynchrony.com) and presented at a number of conferences/trade shows. We have shipped out prototype systems to early adopters across academia [redacted] and industry [redacted]. We are working to fill orders from [redacted] and [redacted] for our evaluation kits.

Strategic Partnerships: [redacted], a premier worldwide clinical research organization, has expressed interest in a cross marketing partnership. [redacted], an established worldwide distributor for implantable catheters, animal surgery tools, and infusion kits, is ready to sell and distribute our FluidSync™ micropump system. [redacted] wants to bundle our system with their wireless physiological monitoring products for socially housed small animals for a closed-loop dosing setup. [redacted] Corporation, an international manufacturer, wants to finance and co-develop our products.

Intellectual Property and Licensing: IP is protected under two awarded patents, one application with all claims allowed, and seven non-provisional applications. An exclusive license has been established with [redacted].

Long term strategy: We are developing medium ([redacted] µL) and large volume ([redacted] µL) pumps for larger animals and to enter the adjacent clinical research organization ($1.4B in animal research models, 10% CAGR) and veterinary care ($8B spent directly on pet medication and treatment, 8% CAGR) markets. Researchers at the [redacted] and local veterinary hospitals in [redacted] have expressed interest. Our animal research products would provide the scientific basis and credibility needed to adopt our electrolysis-based drug pump system, de-risk the clinical opportunity for outside investors, and gain momentum to penetrate into adjacent markets. In 2013, the injectable/implantable drug delivery market is estimated to be $16B (7.4% CAGR). Two top drug pump companies, [redacted] and [redacted], have expressed interest if we successfully demonstrate our patented micropumping technology. Our system can address a major national problem, improper drug administration which results in the preventable injury of approximately half a million Americans each year, 100,000 deaths annually, and is responsible for 10% of all hospital admissions. The annual costs are estimated at $140B. Our wirelessly enabled drug delivery system for remote automated dosing would personalize the drug regimen in a timely manner either in the clinical or home care setting. With patient compliance guaranteed by automated dosing, the wireless dosing system may offer greater drug efficacy, reduced side effects, improved treatment outcomes, and quality of life. We obtained FDA Humanitarian Use Device designation for our micropumps for metronomic chemotherapies to combat pediatric LM (the first step in the expedited Humanitarian Device Exemption regulatory pathway).