4.3 Product/Technology and Competition

The FlexRfyne system consists of the **micropump, external controller, and programmable software**. It will be the first and only implantable dosing system that allows on-demand remote control of drug administration in a miniaturized form factor. This pump is widely applicable to research questions requiring precise and repeated administration of substances without animal handling and comparative effectiveness studies. The FlexRfyne pump possesses distinct advantages (Table 1). The electrolysis-based actuation method is space-saving, power efficient, and robust with only one moving part. The actuation mechanism can be scaled down for use in the mouse or scaled up for use in humans. The basis of our actuator allows the device to be "OFF" and consuming no power at its resting state, which is in stark contrast with our competitors' devices which are always "ON" and cannot be adjusted on-demand. On-demand adjustment of dosing duration and volume is enabled by electronic control and wireless operation. The refillable reservoir guarantees that the device operation lifetime, and hence experiments, will not be limited by drug volume.

Our wirelessly-operated micropumps can revolutionize animal laboratory and vivarium operations. The FlexRfyne system value propositions are that it is an enabling research tool for achieving better animal models, more viable drug candidates, and more reliable experimental results. These opportunities accelerate development of more effective drug delivery therapies for the human clinical market. With its unique remote-controlled on-demand dosing and automatic event logging and data storage, the benefits are increased worker productivity, acquisition of reliable data, efficient budgeting and cost management, reduced transcribing errors, and rapid deployment of digitally records of easily aggregate precisical data from research sites around the world. The FlexRfyne pump can complement sensors that are currently available or under development to enable closed-loop evidence-guided drug regimens to be investigated.

Competition: The only direct competitors are Dwnet Corporation and Primetech (Table 1). Dwnet Corp manufactures the Alzet osmotic pump, which is the de facto gold standard for the last 10 years and has the dominant market share with 2.7 million units sold per year. The advantages are its simplicity: it provides slow, single-rate continuous delivery in a compact pill-like package. However, drug payload is limited and the pump cannot be refilled (single-use and only suitable for short term experiments, Alzet pump, Dwnet Corp). For longer dosing studies (> 1 month), osmotic pumps must be surgically removed and replaced with significant risk to the animal.

Table 1. Implantable drug infusion pump competitors.

	FlexRfyne pump	Dwnet Corp. ALZET	Primetech iPrecio
Device Price	$100/unit $2500 base station $2000 software license	$200-400/10 devices	$270/unit $2000 base station
Actual size			
Programmable	✓		✓
Refillable	✓		✓
Memory compatible	✓	✗	
On-demand dosing	✓		

A relatively new player in the market is Primetech whose iPrecio pump offers basic electronic control of drug delivery and refillability, however this product is larger only suitable for rats, not mice. Once initiated, the device continuously pumps even when drug is not needed, has a limited number of steps to set different