Budget Justification

A. Key Personnel

Support is requested for the following senior personnel:

Christian Gootz, Ph.D., is the Chief Technology Officer (CTO) who will serve as PI on this research project. He will lead the overall technical research and development effort. He is trained as both an electrical and biomedical engineer. He will be responsible for developing the manufacturing process for the bellows actuator, experimental characterization of the actuator, and its successful demonstration. He will commit 66.7% effort (4.0 calendar months) over the 6 month period at an annual rate of $100,000/yr ($33,333 total funds requested).

[Employee 2] is the co-founder and Chief Executive Officer (CEO) who will serve as project administrator as well as engineer. He has a background in neuroengineering and drug administration in animal models of human diseases. He will assist in the design, fabrication and testing of the pumps. He will coordinate the research collaborators, suppliers/vendors, and interns. He will also be responsible for all administrative duties, including, billing, payroll, invoice, and reports. He will commit 66.7% effort (4.0 calendar months) over the 6 month period at an annual rate of $100,000/yr ($33,333 total funds requested).

[Employee 3], is the co-founder and Chief Science Officer (CSO) who will provide scientific and engineering leadership in the design, fabrication, and testing of the microfabricated drug delivery devices. She will be the liason to the university to coordinate facilities access and provide training to other company employees and interns on relevant equipment, fabrication protocols, and testing procedures. . While [Employee 3] is an associate professor at the University of Southern California, her level of effort at You Company LLC is consistent with the faculty handbook (Section 3, Page 17-18, which permits up to 20% of her time in professional activities outside of university contractual responsibilities). She will commit 16.7% effort (1 calendar month) over the 6 month at an annual rate of $90,000/yr ($7,500 total funds requested).

The USC Faculty Handbook can be accessed at the Faculty Portal, www.usc.edu/faculty, and will be permanently available at the policies page, www.usc.edu/policies. She has disclosed her ownership position with the university Office of Compliance and the conflict of interest committee has approved a management plan.

[Employee 4]., is the software development specialist who will develop the user-friendly graphics-based interface to program the drug regimen, record the dosing activity, and remotely control the wirelessly-enabled implantable pumps. He will also assist in the assembly of the subsystems and testing of the pump system. He is trained as biomedical and electrical engineer and has experience working with the team since 2020. He will commit 66.7% effort (4.0 calendar months) over the 6 month period at an annual rate of $64,000/yr ($21,333 total funds requested).

Wage calculations for the key personnel are consistent with median wages provided by the US Bureau of Labor Statistics under occupation codes 11-1021 and 17-2031.

B. Other Personnel

[Employee 5] will consult as the product design specialist who will perform market research to identify the customer product requirements. She brings over 20 years of experience in the drug delivery industry. In addition she will serve as the business development specialist to identify and establish sales and distribution channels into the targeted market. She will commit 66.7% effort (4.0 calendar months) over the 6 month period at an annual rate of $66,000/yr. ($22,000 total funds requested).

C. Fringe Benefits
Support for fringe benefits is not requested as direct cost, it is included as part of indirect costs.

D. Equipment (Items of durable value exceeding $5,000)
Support for equipment is not requested.

[If needed, list the equipment you are requesting for the project. Include model no. and price quotes from a reputable source, listing name of source. Explain the necessity of the equipment to the project, and how this item will be used by the different parties in the proposal.]

E. Travel
Support is requested for travel to the annual NSF-sponsored SBIR meeting and a customer site-visit for the PI and another member. ($6,500 total funds requested).

G. Other Direct Costs
G1. Materials and Supplies
Support is requested to acquire necessary microfabrication supplies (wafers, masks, chemicals, raw materials, and labware), raw materials for construction of components, components need for experimental setups, machining services (including tooling), software design tools, and general labware and chemicals. ($80,985 total funds requested).

G2. Consultants
[Consultant 1] will consult as packaging engineer who will design and machine the pump components and housing. He brings over 20 years of experience in medical device development. He will commit 40 hours at a rate of $75/hr ($3,000 total contract).

[Consultant 2], will consult as the wireless technology engineer who will develop of our wireless power and telemetry systems. He has over 10 years of experience in development of wireless systems for implantable devices. He will commit 43 hours at a rate of $75/hr ($3,225 total contract).

[Consultant 3, Ph.D], is the product design engineer who will establish our quality controls and validation system. He is a highly-trained electrical engineer with successful experience productizing high technology merchandises, including the head-mounted Looxcie wireless video and telecommunication device. He will assist in developing test setups, wireless system, and dosing software to control the pump. He will commit 55 hours at a rate of $85/hr ($4,675 total contract).

I. Indirect Costs
I1. Company facilities and administrative costs are based on a total direct cost base of $117,500 (total of salaries and wages) and multiplied are by a rate of 35% to obtain the indirect cost of $41,125 for the 6 month period.

Indirect costs include office and manufacturing facilities monthly rent ($3,500) and utilities costs ($300), access and hourly usage fees for using University facilities ($2,500 access fee plus $50/hour/person), administrative costs (accounting, legal, HR) and fringe benefits for employees for the 6 month period. A majority of the work will be completed at the company facilities.

K. Fee
An operational and management fee of 7% is requested for the 6 month period, totaling $17,990.