INVITATION FOR EXPRESSION OF INTEREST REGARDING

"DEVELOPMENT OF ADVANCED COCHLEAR IMPLANT SYSTEM"

1. EXPRESSION OF INTEREST

1.1. Chief Executive (CE), Society for Biomedical Technology (SBMT), Bangalore invites Expression of Interest (EoI) from professionally competent, reputed R&D institutions/Indian Industries for the following developmental task. SBMT is a registered society operating from Defence Bio-Engineering and Electromedical Laboratory (DEBEL), DRDO, Bangalore.

Description	Due Date
Development of Advanced Cochlear Implant System with External electronics and Clinical Programming Software as per Specification	The proposal shall be submitted within 21 days from the date of submission of EoI

2. INTRODUCTION

2.1. As per WHO estimates, over 5% of the world's population – or 430 million people – require rehabilitation to address their 'disabling' hearing loss (432 million adults and 34 million children). It is estimated that by 2050 nearly 2.5 billion people are projected to have some degree of hearing loss and at least 700 million people – or one in every ten people – will have disabling hearing loss and will require hearing rehabilitation. As per WHO estimates in India, there are approximately 63 million people, who are suffering from Significant Auditory Impairment; this places the estimated prevalence at 6.3% in Indian population. Of these, a large percentage is children between the ages of 0 to 14 years.

2.2. The average cost of a cochlear implant ranges from Appx 5 lakhs to 15 lakhs. This leaves out a large section of the population ranging from middle to low-income groups in India from affording an implant. Also the cost of these implants are not usually covered under insurance, making it an out of pocket expense.

2.3. Cochlear implantation is an established and well accepted mode of rehabilitation for children and adults with profound/severe deafness who do have any benefit from other hearing aids. Cochlear Implants (CI) are being manufactured by a few of the multinational companies only in the world and these have been in clinical use for last three decades after clearance from regulatory agencies such as the US FDA.

2.4. The Govt of India, through Min of Social Justice & Family Welfare, have plans (ADIP) to provide the cochlear implant to the needy numbering many thousands annually. Considering the dire necessity for affordable cochlear implants in the country, an indigenous CI system was developed under the aegis of SBMT through the labs of DRDO.

2.5. The developed product named 'Sravan' was subjected to safety and toxicological studies and has been proved safe. Currently, the implant system is in the stage of clinical trials after obtaining permission from the O/o the Drug Controller General of India. The trials are being carried out under the aegis SBMT in association with trial centres of repute spread across India.

2.6. As the clinical trial feedback has proven the working design of the implant, it needs to be brought out to a commercially viable CI system which is compliant with state of art subsystem technology and standards in quality and performance. It should also be possible for large scale production at an affordable price suiting our population needs. This mandates the development of the Advanced Cochlear Implant System which is under the scope of current EoI

2.7. A cochlear implant system has two parts:

2.7.1. The External Speech Processor – which captures the external sound and carries out the sound processing and transmits the same to the implant through an RF Transcutaneous link

2.7.2. The Implant - that is surgically placed under the skin and attached to an electrode array that is placed in the inner ear which, based on the signals received from the External Sound Processor, stimulates the auditory nerve with electrical signals.

3. SYSTEM SPECIFICATIONS

3.1. The detailed specification of the Advanced Cochlear Implant system is detailed in the Specification Document, Doc No SBMT/CI/SPEC/01 dt March 2022 which will be shared after signing an NDA.

4. DELIVERABLES

4.1. Qty 200 Advanced Cochlear Implant system with External Speech Processor with CoC and Test Certificates

4.2. Qty – 15 Nos of Field Test Rigs for Pre-Implantation checks

4.3. Clinical Programming Software with Perpetual License

5. MILESTONES & PAYMENT STAGES

5.1. The maximum duration of the contract will be 48 months. Stage payment, if desired, will only be milestone based (typically not more than FOUR milestones), against specific deliverables. A preliminary implementation review and a critical implementation review are mandatory in the course of the development effort. The review will be conducted by a committee duly constituted by CE, SBMT and will include members from the Development Partner, DEBEL, Subject Experts/Academia and Medical Professionals.

5.2. In addition to the above major reviews, the committee will also conduct monthly progress reviews. The committee will verify the realization of the relevant deliverables for milestone-based payment.

5.3. The tentative milestones are as listed below

Sl No.	Milestone	Time Schedule	Payment
a.	Completion of the design of the electronic and mechanical modules including the product engineering	8 Months	1st payment - 30% of the total cost
b.	Realisation of prototypes and preliminary evaluation	6 Months	-
c.	Completion of bio compatibility studies and cadaver trials	6 Months	2nd payment - 30% of the total cost
d.	Completion of documentation for DCGI clearance, IEC testing & production clearance	5 Months	-
e.	Realisation of Deliverables, Field Test Rigs & Software	15 Months	3rd payment - 30% of the total cost
f.	Final testing of deliverables, packaging and sterilisation	8 Months	4th payment - 10% of the total cost

6. VENUE FOR DEVELOPMENT

6.1. The design, development and integration effort will be carried out jointly by SBMT & Development Partner.

6.2. Hardware fabrication and integration activities may be carried out at a venue chosen by the development partner

6.3. A suitable team of engineers, including a project leader, shall be allocated by the development partner for the project.

6.4. SBMT will not be able to provide residential accommodation, free boarding or transport for the deputed personnel. The personnel will be subject to the rules and regulations applicable within the SBMT premises, including security restrictions and checks. A police verification certificate for character and antecedents of all personnel is mandatory and the development partner shall arrange the same prior to deployment of personnel at SBMT.

7. STANDARDS AND DOCUMENTATION

7.1. The development shall meet the requirements of the following standards of latest issue.

7.1.1. BS EN 45502-1: Implants for surgery – Active implantable medical devices, Part 1, general requirements for safety, marking and for information to be provided by the manufacture.

7.1.2. ISO 14708-7 Implant for surgery –Active implantable medical devices, Part 7 particular requirement for Cochlear Implant system.

7.1.3. IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

7.1.4. IEC 60601-1-2: Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests.

7.1.5. IEC 62304: Medical Device Software – Software Life Cycle Processes

7.1.6. ISO 13485: Medical Devices – Quality Management Systems

7.1.7. IEC 62366-1 medical devices in general Part 1 – Application of usability engineering to medical devices follow ISO 13485 Quality Management System for medical devices

7.2. The following documents shall be issued along with the Equipment:

7.2.1. User Manual

7.2.2. Maintenance Manual

7.2.3. Illustrated Parts Catalogue

7.2.4. Repair & Overhaul Manual

7.2.5. Acceptance Test Report

7.3. Detailed requirements capture Shall be carried out using requirement capture tools. Detailed design and test documentation is required, unit tests for hardware and software with greater than 95% coverage is required. Detailed solid models and fabrication drawings shall be provided for all mechanical components. Detailed wiring diagrams shall be provided for all cable harnesses. The documentation as a whole shall be suitably cross-referred.

7.4. Packaged software installers shall be provided for unattended installation of all software components on the computers.

8. ESSENTIAL PREREQUISITES FOR PARTICIPATION IN THE EoI

8.1. The following paragraphs broadly cover the terms and conditions that will be part of the commercial RFP. It may be noted, however, that the terms and conditions in the RFP may differ from those outlined herein.

8.2. Firms interested in responding to this EoI shall satisfy the following minimum criteria.

8.2.1. The firm shall be Indian and registered in India.

8.2.2. The firm shall not have been blacklisted by DRDO or any other Government of India organization.

8.3. It is also desirable that firms responding to this EoI satisfy the following additional criteria.

8.3.1. The firm shall have suitable tools to realize electronic hardware, product engineering, mechanical components, ASIC conforming to safety and performance standards.

8.3.2. Suitable infrastructure shall be available to manufacture implant subsystems, integration, testing, packaging and sterilisation for clinical use.

8.3.3. The firm shall have experience in the relevant field and latest technical knowledge in speech processing and RF communication for any acoustic devices generally used in medical sector.

8.3.4. Registration with any DRDO or other Government of India organization.

8.3.5. Experience in development of integrated hardware and software systems meeting medical standards for implantable systems.

8.3.6. Recognized quality accreditation (ISO 13485).

8.3.7. Capability to undertake and deliver a production order of up to 1000 or more numbers of the system jointly - developed under this contract, with a delivery period of 36 months, within a period of 60 months from the completion of this contract.

8.3.8. Capability to undertake a subsequent contract for custom modifications to the developed system with an acceptable costing mechanism for escalations, within a period of 60 months from the completion of this contract.

8.4. CE, SBMT reserves the right to accept/reject proposals or stop the process of approval at any stage, at his sole discretion without assigning any reason and shall bear no liability whatsoever consequent upon such decision.

8.5. Interested Industries may send their Expression of Interest (EoI) along with proposal documents confirming compliance with technical requirements and financial requirements separately **in two different sealed envelopes through Speed Post/Registered Post** to reach the following address with in the stipulated time as mentioned in para 1.1 from the date of publication of this EoI. EoI received late and incomplete will be summarily rejected. Documents sent through e-mails will not be accepted. The minimum information to be covered in the technical proposal is listed in Appendix – A

8.6. The firms shall also submit Certificate of registration, ISO/ISI certificate, Details of similar development/assignments (including the Ministry/Department in the Government of India) handled/completed along-with names of the clients as a part of the proposal

8.7. For budgetary purpose, the Indian Industries shall furnish their estimated cost for the development work with detailed cost breakup, clearly indicating NRE and RE costs and time frame for completion of the assignment.

8.8. Any other information that would be relevant for this developmental work shall also be submitted as a part of the proposal

9. WARRANTY

9.1. The Advanced Cochlear Implant System shall carry an on-site comprehensive warranty of ten years for the implant and 5 years for the external sound processor, from the date of implant. This will include fixing any issues, maintenance and servicing of the system discovered during the warranty period. All the developments or improvements on the external sound processor shall also be backward compatible for a period of 15 years from the date of implantation.

10. IP RIGHTS

10.1. All designs/drawings/software and other artefacts, including but not limited to patents and publication, produced by the development partner for this contract will be jointly the property of Development Partner and CE, SBMT. It shall not be disclosed or otherwise used without express combined permission from both parties. In case any own or third party software components are proposed to be used, the source, maintenance support, licensing and other relevant details are to be provided. Open source licenses will be preferred. Source code with detailed documentation shall be provided for all software components, with the exception of the OS itself. For all own or third party software components, perpetual licenses shall be provided.

10.2. The development partner shall sign a non-disclosure agreement with DEBEL prior to the commencement of the contract.

11. FINANCIAL AND COMMERCIAL DETAILS

11.1. The contract subsequent to the RFP will be firm-fixed-price, with clear identification of NRE costs. Stage payment, if desired, will be against clearly defined and measurable deliverables, for eg. against delivery of hardware. A contract will be signed which includes liquidated damages, prohibition of sub-contracting and cancellation clauses, among other standard terms and conditions.

11.2. The total contract value towards the joint development will be arrived at by a technical cum cost evaluation committee independent of SBMT and Participating Industry.

11.3. As per the Medical Device Rules of India all the regulatory approvals and certifications needs to be taken in the name of the Production Agency or Development cum Production Partner. The firms shall indicate their willingness to invest a 50-50 share of the cost towards establishing the production line, clinical trials and certification of the system.

11.4. Any dispute arising will be resolved at the level of Chairman, SBMT

12. FORCE MAJEURE

12.1. SBMT and DcPP shall not be liable to the other for any delay to comply with its obligations under this Agreement that is caused by war, riot, explosion, abnormal weather conditions, fire, flood, earthquake lockdown pandemic or epidemic situations or similar natural calamity, nationwide or regional strike and lockout. Government action or regulation and nationwide or regional power failure (hereinafter referred to as Event of Force Majeure).

12.2. Should either party be prevented, or become aware that it is likely to be prevented

13. CONTACT DETAILS

13.1. All communication in respect of the proposed EoI shall be made in the following address

The Chief Executive, SBMT
ADE Campus, C V Raman Nagar
Bengaluru – 560093
Ph. 080 – 2505 8415/8472
Fax. 080 – 2528 2011

Contents of the Technical Proposal

The technical proposal submitted by interested firms shall contain at least the following details-

1. The scope of work as understood by the firm
2. Detailed development plan, including
    a. Detailed hardware and software architecture, both for the implant and external electronics and the software.
    b. Details of hardware proposed to be used, including sensors, embedded system, power pack and other components.
    c. Details of the standard tests proposed for qualifying the reliability of the system with respect to ruggedisation requirements as per relevant medical standards
    d. Details of any third-party hardware and software components which will be used in this project, with details of source code availability, licensing and related issues.
    e. Details of hardware and software modules already available with the company which will be used in this project, with details of source code availability, licensing and related issues.
    f. Execution plan, manpower and time estimates, including milestones and desired stage payments against specific deliverables.
    g. Composition and time-based deployment of the on-site team (number of engineers and their specializations).
    h. Development infrastructure that will be created for the on-site team and specific support expected from SBMT.
    i. Standards that will be followed for project management, development and documentation.
3. Detailed response to the development framework and guidelines, clearly specifying acceptance and compliance, or rejection of the terms and conditions, or desired modification.
4. Company profile and annual report for the last 3 years (clearly indicating turnover).
5. Details of prior experience in developing implantable medical devices and speech processing.
6. Details of capability to execute subsequent production orders for the developed system.
7. Costing mechanisms for evaluating and executing subsequent contracts for custom modifications/additions to the developed system, with reference to past project execution, if any
8. Any other information deemed relevant by the firm.