### Local Tender Notification from Indian Original Equipment Manufacturer (OEM) or their Indian authorized distributor for procuring ''Lipid Nano Particle (LNP) formulation System'' at the Molecular Biophysics Unit, Indian Institute of Science, Bangalore

November 29, 2023

Dear Sir/Madam,

#### Sub: Lipid Nano Particle (LNP) formulation System.

Kindly send your best quotation for a "Lipid Nano Particle formulation System" with the technical specifications/general compliance mentioned below. Quote should come only from Indian Original Equipment Manufacturer (OEM), fabricator or their Indian authorized distributor. Resellers shall not participate. The quotations should be on FOR-IISc Bangalore basis in INR. The Bidder should belong to either Class-1 or Class-2 suppliers distinguished by their "local content" as defined by recent edits to GFR. They should mention clearly which class they belong to in the cover letter. a) Class-1 supplier: Goods and services should have local content of equal to or more than 50%. b) Class-2 supplier: Goods and services should have local content of equal to or more than 20 % and less than 50%. Bidders offering imported products will fall under the category of non-local suppliers. They cannot claim themselves as Class-1 local suppliers/Class-2 local suppliers by claiming the services such as transportation, insurance, installation, commissioning, training, and other sales service support like AMC/CMC, etc., as local value addition. Purchase preference as defined by the recent edits to GFR (within the "margin of purchase preference") will be given to the Class-1 supplier.

The bid should address the following specifications for the Lipid Nano Particle (LNP) formulation System:

## Important: Please note that the Lipid Nano Particle (LNP) formulation System should match all specifications listed below and shown to be manufactured within the country.

- 1. An automated System for developing Lipid Nano Particle encapsulation of RNA/DNA molecules by providing a simple, fast, and easy to use platform with familiar workflows, easing technology transfer and simplifying scale-up.
- **2.** The system should have a nano assembler microfluidic mixer designed to create reproducible, homogeneous, and fast mixing conditions to produce high-quality nanoparticle formulations.
- 3. The system should provide platform model unit operations with process control and reproducibility.
- 4. The System Should have scalable process parameters across all models allowing straight forward scale up towards clinical development and commercial manufacture.
- **5.** The System should be able to generate mRNA-LNPs in the size range of 60-120 nm for mRNA's that are 0.5-15 kb long.
- 6. Electrical and Environmental conditions

Electrical: 100-240 VAC, 4A Operating Temperature: 15 to 35 Degree Celsius Humidity: 25 -65% Pressure: 70 -106 Kpa Heating temperature up to 75 degrees Celsius

### 7. System Performance Specifications

Flow rate: 0.1 mL/min to 20 mL/min combined centre and right channel Total Formulation capacity: 1ml to up to 20ml non-diluted, and up to 50ml diluted. Centre(C) to Right(R) Flow Rate Ratio of 1:1 to 10:1

# **8.** Preferred System Physical Dimensions: No greater than 40 x 40 x 40 Width and Depth of less than 40 and 40 cm height of less than 40 cm

- **9.** The System should have onboard touch screen interface designed to allow scientists to efficiently develop and optimize nanoparticle formulations.
- **10.** The System should be recipe driven with batch to batch and user to user reproducibility to enable efficient collaborations between users, groups, labs, and industrial researchers across sites with reproducibility across scales facilitates transfer of academic discoveries to Industrial partners.
- **11.** The System should have the capacity to store up to 10 standard recipes to be used again and again, and history log.
- **12.** System should be compatible with Accessories/ Ancillary equipment like Waste/Sample collection devices of common makes/models available in the market.
- **13.** The System should preferably have validation from over 200 peer reviewed publications across a wide gamut of applications.
- **14.** The System should preferably have evidence for more than 500 Installations across the Globe in various nano particle applications including major Biotech companies and major research Institutes with proven installation and application support.
- **15.** The System should have direct fluid handling connections to eliminate complex fluid connections and reduce reagent waste.
- 16. The System should have third inlet capability to represent dilution required for process scale-up.
- 17. MSMEs can seek an exemption to some qualification criteria. IISc follows GFR2017 for such details.

The documents may be addressed to the Chairman, Molecular Biophysics Unit (Kind attention: Prof. Raghavan Varadarajan), Indian Institute of Science, Bangalore 560 012. Last date for receiving queries is December 20, 2023. Please email <u>varadar@iisc.ac.in</u>. The last date and time for submission of bids is 5:00 PM, December 20, 2023.

Thanking You, Sincerely Prof. Raghavan Varadarajan Molecular Biophysics Unit Indian Institute of Science Bangalore 560 012 Karnataka, India Phone: 91 80 2293 3373