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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Notice of Availability for Licensing - NIST's Patented Microfluidic Apparatus and Method to Control Liposome Formation

AGENCY: National Institute of Standards and Technology

ACTION: Notice

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, owns two patents related to controlled liposome formation using microfluidic channels: U.S. Patent 9,198,645, titled "Controlled Vesicle Self-Assembly in Continuous Two Phase Flow Microfluidic Channels" (NIST Docket 04-003); and US Patent 8,715,591, title "Microfluidic Apparatus to Control Liposome Formation" (NIST Docket 09-017). Further details about these patents are provided in the SUPPLEMENTAL INFORMATION section, below.

ADDRESSES: For further information about these patented inventions or other licensing and partnership opportunities, please contact Honeyeh Zube, CRADA and License Officer, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to honeyeh.zube@nist.gov, or by telephone at (301) 975-2209.

SUPPLEMENTARY INFORMATION: NIST's Patent 9,198,645, titled "Controlled Vesicle Self-Assembly in Continuous Two Phase Flow Microfluidic Channels" (NIST Docket 04-003) claims novel methods for the formation of liposomes that encapsulate reagents in a continuous two-phase flow microfluidic network with precision control of size, for example, from 100 nm to

300 nm, by manipulation of liquid flow rates are described. By creating a solvent-aqueous interfacial region in a microfluidic format that is homogenous and controllable on the length scale of a liposome, fine control of liposome size and polydispersity can be achieved.

NIST's Patent 8,715,591, title "Microfluidic Apparatus to Control Liposome Formation," (NIST Docket 09-017) is available for license and claims the apparatus and method of using a microfluidic device that controls the amount of delivery compound incorporated in a liposome on a nanometer size scale using laminar flow and miscible fluids, thereby increasing loading efficiency. The patent was filed on Apr. 19, 2010 and was issued on May 6, 2014. The invention was first published in Jahn, *et al.*, Microfluidic Directed Formation of Liposomes of Controlled Size, American Chemical Society Langmuir, 23 (11) pp 6289-6293. 2007.

The liposomes formed by the self-assembly process are characterized using asymmetric flow field-flow fractionation combined with quasi-elastic light scattering and multiangle laser-light scattering. The vesicle size and size distribution are tunable over a mean diameter from 50 to 150 nm by adjusting the ratio of the alcohol-to-aqueous volumetric flow rate. Liposome formation depends more strongly on the focused alcohol stream width and its diffusive mixing with the aqueous stream than on the sheer forces at the solvent-buffer interface. The inventions have application in drug delivery, gene therapy, and potential application for on-demand liposome-mediated delivery of point-of-care therapeutics. The inventions can obviate the need for post-processing in drug manufacturing.

NIST is authorized to license its rights in these inventions to organizations on a non-exclusive or exclusive basis for specified fields of use. The rights to these patents are available for exclusive or non-exclusive licensing by the authority granted to the NIST under 35 USC 209 and 37 CFR 404. NIST researchers are interested in potential collaborations with licensees to bring this invention to practical application and to promote innovation, enhance economic security and improve quality of life.

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