

# LAMELLASOME Technology: Off the bench and into production

Rachel Donaghey<sup>1,2</sup>, Lynsey Howard<sup>2</sup>, Margaret Courtney<sup>2</sup>, Steven Porteous<sup>2</sup>, Yvonne Perrie<sup>1</sup>

<sup>1</sup>Strathclyde's Institute of Pharmacy and Biomedical Science, The University of Strathclyde, G4 ORE, Scotland, <sup>2</sup>Lamellar Biomedical Ltd., Maxim Park, ML1 4WR, Scotland



## Introduction

LAMELLASOME™ technology is being engineered to deliver active payloads in the treatment of pulmonary conditions including idiopathic pulmonary fibrosis and cystic fibrosis. Two key challenges exist in relation to the production of LAMELLASOME vesicles:

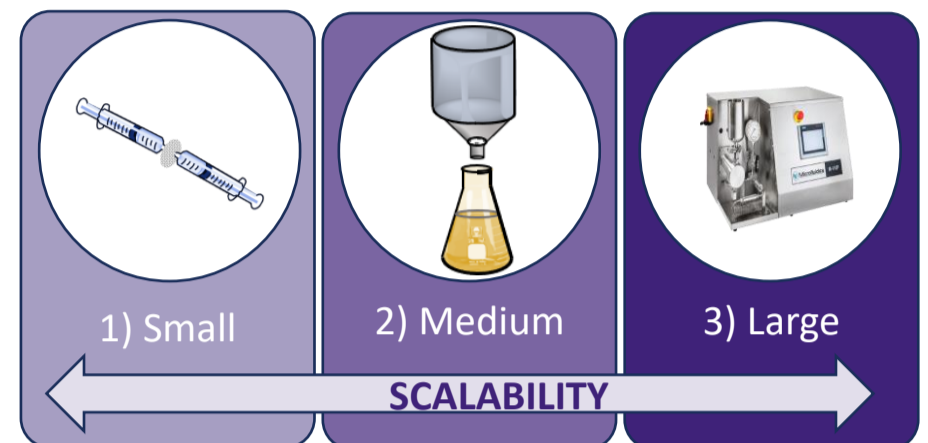
- 1) The use of scalable downsizing procedures and
- 2) the commercial compatibility of production methods.

The implementation of a simple, solvent free method produced LAMELLASOME vesicles with desirable characteristics while eliminating hazardous waste and reducing energy requirements.



## Methods

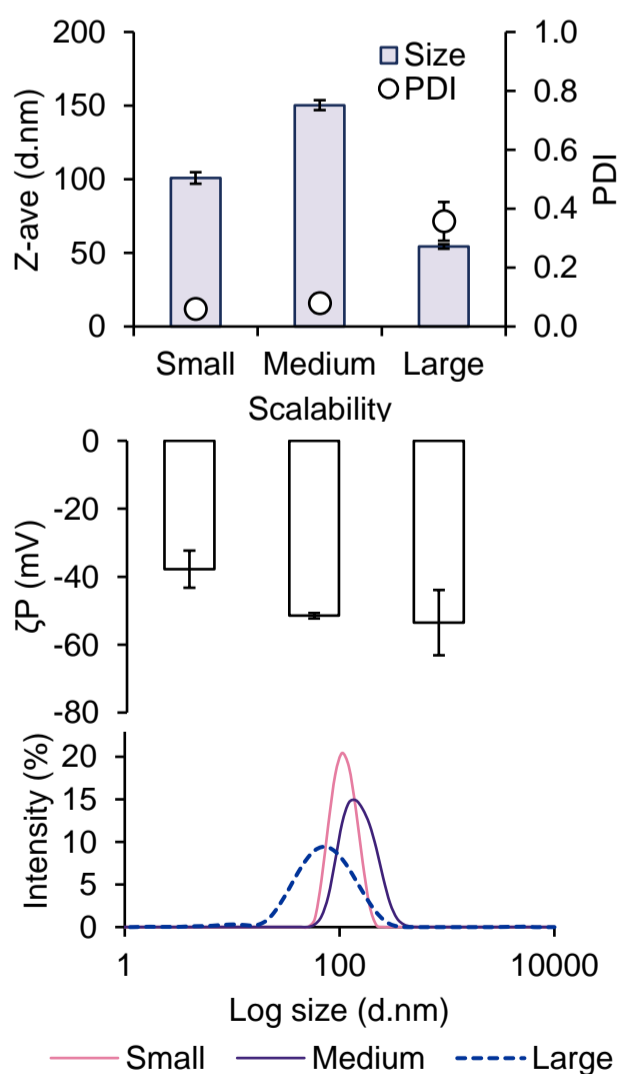
LAMELLASOME vesicles were prepared at a lipid concentration of 4 mg mL<sup>-1</sup> using the traditional thin film (TFM) method (Bangham and Horne, 1964). Downsizing processes of varying scalability were compared:



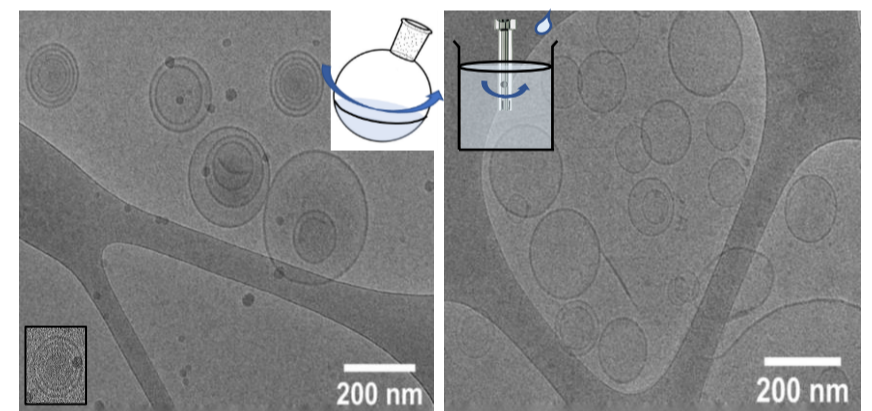
Physical characteristics of LAMELLASOME vesicles prepared using the TFM were compared to those prepared using a solvent-free method followed by downsizing.

## Results

Physical properties of LAMELLASOME vesicles downsized using scalable techniques offers advantages in the research and development process which were shown to be translatable to large-scale manufacturing.



**Figure 1.** LAMELLASOME after downsizing using scalable processes. Size (nm), polydispersity index (PDI), zeta potential ( $\zeta P$ ; mV) and size distribution.



**Figure 2.** CryoTEM analysis of downsized LAMELLASOME vesicles after preparation using the TFM (left) and PH method (right).

	Small	Medium	Large
<b>Size</b>	101 ± 4	150 ± 3	54 ± 2
<b>PDI</b>	0.06 ± 0.02	0.08 ± 0.03	0.36 ± 0.07
<b><math>\zeta P</math></b>	-38 ± 5	-51 ± 1	-54 ± 10

## Conclusions

Preparation of LAMELLASOME vesicles using scalable downsizing techniques offers advantages, including ease of transition to large-scale manufacturing. Implementation of a solvent-free method for LAMELLASOME vesicle preparation avoids the use of hazardous chemicals, such as chloroform. Overall, these data support an ability to translate LAMELLASOME vesicle production from research and development to industrial-scale manufacturing setting.