CURRICULUM VITAE

Stephen W. Burgess, PhD
AvaBurg LLC

PERSONAL STATEMENT

As Director of Research & Development and Chief Scientific Officer at Avanti Polar Lipids for 33 years, I worked with numerous researchers to develop new lipids and lipid formulations to address specific experimental challenges and improve drug delivery or diagnostic assays. I played a key role in a diverse list of projects, including drug delivery development, gene therapy, blood coagulation and syphilis assay development, wound healing, and vaccine development. My background in lipid synthesis, lipid biophysical properties, and membrane dynamics has been instrumental in resolving problems associated with these projects.

WORK EXPERIENCE

07/2023 – present	President AvaBurg LLC
07/2023 – present	Founder & President of the Board STELR Foundation
03/2021 – 06/2023	Managing Director Avanti Polar Lipids, LLC
04/2015 – 06/2023	Chief Scientific Officer Avanti Polar Lipids, LLC
04/1990 – 04/2015	Director, Research & Development Avanti Polar Lipids, Inc
08/1985 – 04/1990	Graduate Research Assistant University of North Carolina – Chapel Hill School of Medicine, Department of Biochemistry & Biophysics
04/1979 – 08/1985	Laboratory Technician Avanti Polar Lipids, Inc

EDUCATION

1990	PhD, Biochemistry/Biophysics University of North Carolina – Chapel Hill Chapel Hill, North Carolina
1985	BS, Chemistry Birmingham-Southern College Birmingham, Alabama

PROFESSIONAL AFFILIATIONS

1990 – present	Member, American Chemical Society
1990 – present	Member, Biophysical Society
1992 – present	Member, Membrane Structure & Assembly Subgroup, Biophysical Society

CONTRIBUTIONS TO SCIENCE

Since much of the work performed at Avanti Polar Lipids is either confidential or contracted, most of the intellectual input on projects is unpublished or unrecognized in the form of authorship on scientific papers. The following are examples of work that are in the public domain.

Improved delivery of fenretinide

Historically, fenretinide was delivered as a corn oil suspension in a gel capsule. In this form, the dosing level for the drug was quite high due to the poor absorption and variable bioavailability. Also, the size and number of capsules needed made it unacceptable for use in a pediatric study. Avanti formulated the drug in an organized lipid matrix (Lym-X-Sorb™) which improved the bioavailability, however, the formulation suffered from several drawbacks that limited its use in a pediatric study. The physical form was still a paste at room temperature or oil at elevated temperature so it required use of a capsule for delivery, and the viscosity increased dramatically in the presence of water to yield a hard wax which limited uptake. I developed a powder formulation using flour and sugar that increased the surface area of the lipid/drug matrix improving bioavailability, and provided a form that could be mixed with a variety of food or beverage choices (orange juice, oatmeal, applesauce, etc.) for delivery to a pediatric patient population. This product is currently in clinical trials and has demonstrated high bioavailability at lower doses than the corn oil capsules.

Maurer BJ, Frgala T, Sun BC, Vlckova J, Reynolds CP, Yesair DW, Burgess SW, McKee RT, Shaw WA: Improved oral fenretinide delivery with novel Lym-X-Sorb™ organized lipid complex. Proc Amer Assoc Cancer Res 2004; 45: 148.

Maurer BJ, Kalous O, Yesair DW, Wu X, Janeba J, Maldonado V, Khankaldyyan V, Frgala T, Sun BC, McKee RT, Burgess SW, Shaw WA, Reynolds CP. Improved oral delivery of N-(4-hydroxyphenyl) retinamide with a novel LYM-X-SORB organized lipid complex. Clin Cancer Res. 2007 May 15; 13(10):3079-86.

Maurer BJ, Kang MH, Villablanca JG, Janeba J, Groshen S, Matthay KK, Sondel PM, Maris JM, Jackson HA, Goodarzian F, Shimada H, Czarnecki S, Hasenauer B, Reynolds CP, Marachelian A. Phase I trial of fenretinide delivered orally in a novel organized lipid complex in patients with relapsed/refractory neuroblastoma: a report from the New Approaches to Neuroblastoma Therapy (NANT) consortium. Pediatr Blood Cancer. 2013 Nov; 60(11):1801-8.

Improved lipid adjuvants for vaccine development

In the late 1990's, Avanti developed a bacterial-derived monophosphoryl Lipid A (MPL) similar to the MPL produced by Ribi/Corixa/GSK for commercial vaccine development. Unlike Corixa, Avanti did not operate a cGMP fermentation facility to control the production of lipopolysaccharide (LPS). The cost to outsource the cGMP production of LPS was prohibitively expensive, therefore Avanti shifted its resources to developing a synthetic pathway to the production of MPL. Development began in 2004, with the initial product, PHAD®, being released in 2005. We have continued to modify the structure to produce analogs with differing activities for fine tuning vaccine function during development. Avanti currently has three commercially available lipid adjuvants, with an additional compound currently in development. My role

in the development of these products was both in identifying the analogs to develop, as well as assisting our synthetic team in solving synthesis and purification problems encountered during development. The lipid adjuvants developed by Avanti are currently in multiple clinical trials.

Shaw, Walter A; Burgess, Stephen W; Li, Shengrong; Hickman, David T; Lopez-Deber, Maria Pilar. 2016. Disaccharide Synthetic Lipid Compounds and Uses Thereof. U.S. Patent No. 9241988.

Shaw, Walter A; Burgess, Stephen W; Li, Shengrong; Hickman, David T; Lopez-Deber, Maria Pilar. 2016. Disaccharide Synthetic Lipid Compounds and Uses Thereof. U.S. Patent No. 9518078.

Shaw, Walter A; Burgess, Stephen W; Li, Shengrong; Hickman, David T; Lopez-Deber, Maria Pilar. 2018. Disaccharide Synthetic Lipid Compounds and Uses Thereof. U.S. Patent No. 10143744.

PUBLICATIONS

1. Lentz BR, Whitt NA, Alford DR, Burgess SW, Yates JC, Nir S. The kinetic mechanism of cation-catalyzed phosphatidylglycerol transbilayer migration implies close contact between vesicles as an intermediate state. Biochemistry. 1989 May 30;28(11):4575-80.

2. Lentz BR, Burgess SW. A dimerization model for the concentration dependent photophysical properties of diphenylhexatriene and its phospholipid derivatives. DPHpPC and DPHpPA. Biophys J. 1989 Oct;56(4):723-33.

3. Burgess SW, Massenburg D, Yates J, Lentz BR. Poly(ethylene glycol)-induced lipid mixing but not fusion between synthetic phosphatidylcholine large unilamellar vesicles. Biochemistry. 1991 Apr 30;30(17):4193-200.

4. Burgess SW, Wu JR, Swift K, Lentz BR. Determination of the rate of rapid lipid transfer induced by poly(ethylene glycol) using the SLM Fourier transform phase and modulation spectrofluorometer. J Fluoresc. 1991 Jun;1(2):105-12.

5. Burgess SW, McIntosh TJ, Lentz BR. Modulation of poly(ethyleneglycol)-induced fusion by membrane hydration: importance of interbilayer separation. Biochemistry. 1992 Mar 17;31(10):2653-61.

6. Burgess SW, Lentz BR. Fluorescence lifetime measurements to monitor membrane lipid mixing. Methods Enzymol. 1993;220:42-50.

7. Bebök Z, Abai AM, Dong JY, King SA, Kirk KL, Berta G, Hughes BW, Kraft AS, Burgess SW, Shaw W, Felgner PL, Sorscher EJ. Efficiency of plasmid delivery and expression after lipid-mediated gene transfer to human cells in vitro. J Pharmacol Exp Ther. 1996 Dec;279(3):1462-9.

8. Goldman CK, Soroceanu L, Smith N, Gillespie GY, Shaw W, Burgess S, Bilbao G, Curiel DT. In vitro and in vivo gene delivery mediated by a synthetic polycationic amino polymer. Nat Biotechnol. 1997 May;15(5):462-6.

9. Cherezov V, Siegel DP, Shaw W, Burgess SW, Caffrey M. The kinetics of non-lamellar phase formation in DOPE-Me: relevance to biomembrane fusion. J Membr Biol. 2003 Oct 1;195(3):165-82.

10. Maurer BJ, Frgala T, Sun BC, Vlckova J, Reynolds CP, Yesair DW, Burgess SW, McKee RT, Shaw WA: Improved oral fenretinide delivery with novel Lym-X-Sorb™ organized lipid complex. Proc Amer Assoc Cancer Res 2004; 45: 148.

11. Maurer BJ, Kalous O, Yesair DW, Wu X, Janeba J, Maldonado V, Khankaldyyan V, Frgala T, Sun BC, McKee RT, Burgess SW, Shaw WA, Reynolds CP. Improved oral delivery of N-(4-hydroxyphenyl)retinamide with a novel LYM-X-SORB organized lipid complex. Clin Cancer Res. 2007 May 15;13(10):3079-86.

12. Maurer BJ, Kang MH, Villablanca JG, Janeba J, Groshen S, Matthay KK, Sondel PM, Maris JM, Jackson HA, Goodarzian F, Shimada H, Czarnecki S, Hasenauer B, Reynolds CP, Marachelian A. Phase I trial of fenretinide delivered orally in a novel organized lipid complex in patients with relapsed/refractory neuroblastoma: a report from the New Approaches to Neuroblastoma Therapy (NANT) consortium. Pediatr Blood Cancer. 2013 Nov; 60(11):1801-8.

13. Sims KH, Tytler EM, Tipton J, Hill KL, Burgess SW, Shaw WA. Avanti lipid tools: connecting lipids, technology, and cell biology. Biochim Biophys Acta. 2014 Aug;1841(8):1038-48.

14. Sot J, Mendanha-Neto SA, Busto JV, García-Arribas AB, Li S, Burgess SW, Shaw WA, Gil-Carton D, Goñi FM, Alonso A. The interaction of lipid-liganded gold clusters (Aurora ™) with lipid bilayers. Chem Phys Lipids. 2019 Jan;218:40-46.

PATENTS

1. US 11471430 B2, Sphingosine analogs and use thereof against bacterial lung infections, Futerman; Anthony H. et al., 2022.

2. US 11413297 B2, Therapies for treating and preventing chronic rhinosinusitis, Cochrane; Charles G. et al., 2022.

3. US 10739353 B2, Suppression of cytokine release and cytokine storm, Sordillo; Peter P. et al., 2020.

4. US 10258691 B2, Protective effect of DMPC, DMPG, DMPC/DMPG, EGPG, LysoPG and LysoPC against drugs that cause channelopathies, Helson; Lawrence et al., 2019.

5. US 11510985 B2, Oral composition for delivery of drugs and other substances, Shaw; Walter A et al., 2022.

6. US 10463738 B2, Oral composition for delivery of drugs and other substances, Shaw; Walter A et al., 2019.

7. US 9872908 B2, Oral composition for delivery of drugs and other substances, Shaw; Walter A et al., 2018.

8. US 9403760 B2, Compounds, Burgess, Stephen W et al., 2016

9. US 10143744 B2, Disaccharide synthetic lipid compounds and uses thereof, Shaw; Walter A et al., 2018.

10. US 9518078 B2, Disaccharide synthetic lipid compounds and uses thereof, Shaw; Walter A et al., 2016.

11. US 9241988 B2, Disaccharide synthetic lipid compounds and uses thereof, Shaw; Walter A et al., 2016.

12. US 7785621 B2 , Oral compositions of fenretinide having increased bioavailability and methods of using the same, Maurer; Barry J. et al., 2010.

13. US 7780978 B2, Oral pharmaceutical compositions and methods of using the same, Maurer; Barry J. et al., 2010.

14. US 8222233 B2, Modifications of solid 3-sn-phosphoglycerides, Yesair; David W. et al., 2012.

15. US 7947306 B2, Modifications of solid 3-sn-phosphoglycerides, Yesair; David W. et al., 2011.

16. US 7407779 B2, Modification of solid 3-sn-phosphoglycerides, Yesair; David W. et al., 2008.

17. US 5948878 A, Cationic polymers for nucleic acid transfection and bioactive agent delivery, Burgess; Stephen W. et al., 1999.