containing 6% w/w of lecithin did not produce aerosol from the Aeroneb Pro® vibrating-mesh micropump nebulizer. Further preliminary studies also showed that formulations containing a reduced concentration of lecithin (1% w/w, at 1:1 drug-to-lipid ratio) have presented sufficient stability for evaluation of nebulization performance following preparation. Therefore, reduction of phospholipid concentration was necessary while simultaneously keeping the concentration of CoQ10 constant at an adequate drug-to-lipid ratio.

[00188] Following hydration, a phospholipid dispersion containing 1% w/w of phospholipid (lecithin or DPPC) in water was added to the molten CoQ10 (1% w/w) at 55 °C. The formulation was then predispersed using high shear mixing (Ultra-Turrax® TP 18/10 Homogenizer with 8 mm rotor blade, IKA-Werke, Staufen, Germany) for up to 5 minutes at 20,000 rpm. Subsequently, the formulation was passed through an M-110P Bench-top Microfluidizer® (Microfluidics, Newton, MA USA) up to 100 times at approximately 30,000 psi while maintaining the temperature between 50 and 60 °C.

[00189] In testing the effects that the type of phospholipid and number of passes have on particle size distribution of the formulations, phospholipid dispersions were hydrated for approximately 1 hour without stirring (Table 1, Formulations A and B). Formulations were then passed through a microfluidizer 10, 20, 30, 40 and 50 times when comparing different phospholipids; 20, 50, 70 and 100 times when evaluating the effect from number of passes. For nebulization performance tests, the phospholipid dispersions were hydrated overnight with stirring and 0.9% w/v of sodium chloride was added to the final formulation (Table 1, Formulation C).

[00190] The particle size distributions of the formulations were then analyzed using Laser Diffraction (LD) and/or Dynamic Light Scattering (DLS). The surface tension, zeta potential and rheology were also evaluated. For nebulization performance, aerosol output was performed using LD and gravimetrical analysis.

[00191] **Characterization of Formulations**

[00192] ***Particle Size Distribution:*** Particle size distribution testing of the dispersed formulations was performed with LD using a wet sample dispersion unit stirring at 1,000 rpm coupled to a Malvern Spraytec® (Malvern Instruments, Worcestershire, UK) equipped with a 300 mm lens. The dispersed formulations were added to distilled water

CLAIMS

1. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 500 nm, each liposomal particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, the phospholipid is between about 0.1 and 30 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

2. The inhalable pharmaceutical composition of claim 1, wherein the aqueous dispersion vehicle comprises water or an aqueous salt solution.

3. The inhalable pharmaceutical composition of claim 1, wherein the dispersion of liposomal particles is in the form of a continuous respirable aerosol comprising a plurality of aqueous droplets containing a dispersion of liposomal particles and having a mass median aerodynamic diameter (MMAD) between about 1 and 5 μm.

4. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an average percent transmission (APT) between about 50 and 100 % over at least 15 minutes of continuous aerosolization.

5. The inhalable pharmaceutical composition of claim 1, wherein the plurality of droplets has a MMAD between about 1 and 5 μm over at least 15 minutes of continuous aerosolization.

6. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an APT between about 50 and 100 % after at least seven days of storage.

7. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an APT between about 50 and 100 %, between about 60 and 100 %, between about 70 and 100 %, between about 80 and 100 %, between about 90 and 100 %, between about 50 and 95 %, between about 60 and 95 %, between about 70 and 95 %, between about 80 and 95 %, between about 90 and 95 %, between about 50 and 90 %, between about 60 and 90 %, between about 70 and 90 %, between about 80 and 90 %, less than about 50 %, less than about 55 %, less than about 65 %, less than about 70 %, less than about 75 %, less than about 80 %, less than about 85 %, less than about 90 %, less than about 95 %, less than about 100 %, or any sub-range or value therebetween.

8. The inhalable pharmaceutical composition of claim 1, wherein the liposomal particles have an average diameter between about 30 and 500 nm after at least seven days of storage.

9. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by non-Newtonian fluid behavior.

10. The inhalable pharmaceutical composition of claim 1, wherein the composition has a flow index (n) of about 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, or 1.3.

11. The inhalable pharmaceutical composition of claim 1, wherein the composition has a viscosity (η) of about 0.1, 0.15, 0.2, 1, 100, or 110 cP.

12. The inhalable pharmaceutical composition of claim 1, wherein the composition has a zeta potential of about 2.5, 1.5, -2.5, -10, -50, -55, or -60 mV.

13. The inhalable pharmaceutical composition of claim 1, wherein the composition has a surface tension of about 25, 30, 35, 40, 45, or 50 mN/m.

14. The inhalable pharmaceutical composition of claim 1, wherein the composition has a yield stress (σ) of about 11, 12, 13, 14, 15, 16, 17, or 18 mPa.

15. The inhalable pharmaceutical composition of claim 1, wherein the dispersion of liposomal particles have an average diameter between about 30 and 100 nm, 50 and 150 nm, 30 and 300 nm, 100 and 400 nm, or 200 and 300 nm.

16. The inhalable pharmaceutical composition of claim 1, wherein the composition has a PDI of about 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, or 0.7.

17. The inhalable pharmaceutical composition of claim 1, wherein the composition does not comprise an opsonization reducer.

18. The inhalable pharmaceutical composition of claim 1, wherein the composition has a total aerosol output (TAO) of at least about 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, or 100 %.

19. The inhalable pharmaceutical composition of claim 3, wherein the MMAD is about 1, 2, 3, 4, or 5 μm.

20. The inhalable pharmaceutical composition of claim 3, wherein the plurality of droplets have a geometric standard deviation (GSD) of less than about 2.5, 2.4, 2.3, 2.2, 2.1, 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, or 0.1.

21. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent comprises CoQ10.

22. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent is about 4 % w/w or less of the composition.

23. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent is about 1 % w/w of the composition.

24. The inhalable pharmaceutical composition of claim 1, wherein the phospholipid comprises DPPC, DSPC, DMPC, or a combination thereof.

25. The inhalable pharmaceutical composition of claim 1, wherein the phospholipid is about 3 % w/w or less of the composition.

26. The inhalable pharmaceutical composition of claim 1, wherein the ratio of hydrophobic bioactive agent:phospholipid is about 1:1, 4:3, or 4:2.5.

27. The inhalable pharmaceutical composition of claim 1, further comprising sodium chloride in an amount less than about 1.0% w/v of the composition.

28. The inhalable pharmaceutical composition of claim 1, further comprising a salt in an amount making the composition essentially isosmotic with the human lung.

29. The inhalable pharmaceutical composition of claim 1, wherein the dispersion is suspension, nano-suspension, emulsion, or microemulsion.

30. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent comprises one or more hydrophobic anti-inflammatory steroid, NSAID agent, antibacterial agent, antifungal agent, chemotherapeutic agent, vasoldilator, or a combination thereof.

31. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 300 nm, each liposomal particle comprising CoQ10, DPPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DPPC is between about 5:1 and about 1:5, the CoQ10 is between about 0.1 and 6 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

32. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 300 nm, each liposomal particle comprising CoQ10, DSPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DSPC is between about 5:1 and about 1:5, the CoQ10 is between about 0.1 and 6 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

33. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 300 nm, each liposomal particle comprising CoQ10, DMPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DMPC is between about 5:1 and about 1:5, the CoQ10 is between about 0.1 and 6 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

34. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 500 nm, each liposomal particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, the phospholipid is between about 0.1 and 30 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon continuous aerosolization, the composition is capable of achieving a bioactive agent concentration of at least about 500 µg/g wet lung tissue.

35. A method for preparing an inhalable pharmaceutical composition comprising the steps of:

hydrating a phospholipid, thereby forming a hydrated phospholipid;

mixing the hydrated phospholipid, a hydrophobic bioactive agent, and an aqueous dispersion vehicle, thereby producing a mixture; and

homogenizing the mixture, thereby producing a dispersion of liposomal particles comprising the phospholipid and hydrophobic bioactive agent dispersed within the aqueous dispersion vehicle and having an average diameter between about 30 and 500,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, and the phospholipid is between about 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

36. The method of claim 35, further comprising:

aerosolizing the dispersion of liposomal particles, thereby forming a respirable aerosol comprising a plurality of droplets, each droplet comprising a dispersion of liposomal particles and having a mass median aerodynamic diameter (MMAD) between about 1 and 5 μm.

37. The method of claim 35, wherein mixing comprises high shear mixing for up to about 5 minutes at about 10,000 to 20,000 rpm and at about 50 to 65 °C.

38. The method of claim 35, wherein homogenizing comprises microfluidization.

39. The method of claim 35, wherein homogenizing comprises high pressure homogenization for about 1-50 passes at about 30,000 psi and at about 50 to 65 °C.

40. The method of claim 35, wherein homogenizing comprises ultrasonic homogenization.

41. The method of claim 35, wherein aerosolization comprises vibrating mesh nebulization.

42. A method for administering an inhalable pharmaceutical composition comprising the steps of:

aerosolizing a dispersion of liposomal particles, thereby forming a respirable aerosol comprising a plurality of droplets having a mass median aerodynamic diameter (MMAD) between about 1 and 5 μm,

wherein the dispersion of liposomal particles has an average diameter between about 30 and 500 nm, each liposomal particle comprising a hydrophobic bioactive agent and a phospholipid dispersed within an aqueous dispersion vehicle,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, and the phospholipid is between about 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject; and

delivering a therapeutically effective amount of the hydrophobic bioactive agent to a lung of a subject in need of treatment.

43. The method of claim 42, wherein aerosolization comprises vibrating mesh nebulization.

44. The method of claim 42, wherein the aerosol is characterized by an APT between about 50 and 100 % over at least 15 minutes of continuous aerosolization.

45. The method of claim 42, wherein the aerosol is characterized by an APT between about 50 and 100 %, between about 60 and 100 %, between about 70 and 100 %, between about 80 and 100 %, between about 90 and 100 %, less than about 50 %, less than about 60 %, less than about 70 %, less than about 80 %, less than about 90 %, or less than about 100 %.

46. The method of claim 42, wherein the plurality of droplets has a MMAD between about 1 and 5 μm over at least 15 minutes of continuous aerosolization.

47. The method of claim 42, wherein the MMAD is about 1, 2, 3, 4, or 5 μm.

48. The method of claim 42, wherein the droplets have a geometric standard deviation (GSD) of at least about 2.0.

49. The method of claim 42, wherein delivery achieves a mass fraction deposited of at least about 1, 5, 10, 15, or 20 %.

50. The method of claim 42, wherein delivery achieves local delivery to the lung substantially without systemic delivery.

51. The method of claim 42, wherein delivery achieves an elevated amount of the hydrophobic bioactive agent in the lung for at least 48 hours after administration.

52. The method of claim 42, wherein, upon continuous aerosolization, the composition is capable of achieving a bioactive agent concentration of at least about 500 μg/g wet lung tissue.

53. The method of claim 42, wherein delivering a therapeutically effective amount of the hydrophobic bioactive agent comprises metering a dose of the bioactive agent.

54. The method of claim 42, wherein the subject has lung cancer.

55. The method of claim 42, wherein the subject has one or more of asthma, allergies, chronic obstructive pulmonary disease, chronic bronchitis, acute bronchitis, emphysema, cystic fibrosis, pneumonia, tuberculosis, pulmonary edema, acute respiratory distress syndrome, pneumoconiosis, interstitial lung disease, pulmonary edema, pulmonary embolism, pulmonary hypertension, pleural effusion, pneumothorax, mesothelioma, amyotrophic lateral sclerosis, myasthenia gravis, and lung disease.

56. An inhalable pharmaceutical composition prepared by a process comprising the steps of:

hydrating a phospholipid, thereby forming a hydrated phospholipid;

mixing the hydrated phospholipid, a hydrophobic bioactive agent, and an aqueous dispersion vehicle, thereby producing a mixture; and

homogenizing the mixture, thereby producing a dispersion of liposomal particles comprising the phospholipid and hydrophobic bioactive agent dispersed within the aqueous dispersion vehicle and having an average diameter between about 30 and 500,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, and the phospholipid is between about 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

57. An inhalable pharmaceutical composition comprising a dispersion of liposomal particles suitable for continuous aerosolization, the composition comprising:

a dispersion of liposomal particles having an average diameter between about 30 and 500 nm, each liposomal particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between about 5:1 and about 1:5, the hydrophobic bioactive agent is between about 0.1 and 30 % w/w of the composition, the phospholipid is between about 0.1 and 30 % w/w of the composition, and the liposomal particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon continuous aerosolization, the composition is capable of achieving a total emitted dose (TED) of at least about 2,900 µg over 15 seconds.

58. The inhalable pharmaceutical composition of claim 57, wherein the TED is at least about 3,600, 3,900, 4,300, or 4,600 µg over 15 seconds.

59. The inhalable pharmaceutical composition of claim 1, wherein the continuous aerosolization has a duration of about 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 25, 30, 35, 40, 50, or 60 minutes.

60. The inhalable pharmaceutical composition of claim 1, further comprising a polyoxypropylene-poloxyethylene block polymer at 0.001-5% by weight of the total composition.

containing 6% w/w of lecithin did not produce aerosol from the Aeroneb Pro® vibrating-mesh micropump nebulizer. Further preliminary studies also showed that formulations containing a reduced concentration of lecithin (1% w/w, at 1:1 drug-to-lipid ratio) have presented sufficient stability for evaluation of nebulization performance following preparation. Therefore, reduction of phospholipid concentration was necessary while simultaneously keeping the concentration of CoQ10 constant at an adequate drug-to-lipid ratio.

[00188] Following hydration, a phospholipid dispersion containing 1% w/w of phospholipid (lecithin or DPPC) in water was added to the molten CoQ10 (1% w/w) at 55 °C. The formulation was then predispersed using high shear mixing (Ultra-Turrax® TP 18/10 Homogenizer with 8 mm rotor blade, IKA-Werke, Staufen, Germany) for up to 5 minutes at 20,000 rpm. Subsequently, the formulation was passed through an M-110P Bench-top Microfluidizer® (Microfluidics, Newton, MA USA) up to 100 times at approximately 30,000 psi while maintaining the temperature between 50 and 60 °C.

[00189] In testing the effects that the type of phospholipid and number of passes have on particle size distribution of the formulations, phospholipid dispersions were hydrated for approximately 1 hour without stirring (Table 1, Formulations A and B). Formulations were then passed through a microfluidizer 10, 20, 30, 40 and 50 times when comparing different phospholipids; 20, 50, 70 and 100 times when evaluating the effect from number of passes **(Table 9)**. For nebulization performance tests, the phospholipid dispersions were hydrated overnight with stirring and 0.9% w/v of sodium chloride was added to the final formulation (Table 1, Formulation C).

[00190] The particle size distributions of the formulations were then analyzed using Laser Diffraction (LD) and/or Dynamic Light Scattering (DLS). The surface tension, zeta potential and rheology were also evaluated. For nebulization performance, aerosol output was performed using LD and gravimetrical analysis.

[00191] **Characterization of Formulations**

[00192] ***Particle Size Distribution:*** Particle size distribution testing of the dispersed formulations was performed with LD using a wet sample dispersion unit stirring at 1,000 rpm coupled to a Malvern Spraytec® (Malvern Instruments, Worcestershire, UK) equipped with a 300 mm lens. The dispersed formulations were added to distilled water

CLAIMS

1. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 500 nm, each particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, the phospholipid is between 0.1 and 30 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof; and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

2. The inhalable pharmaceutical composition of claim 1, wherein the aqueous dispersion vehicle comprises water or an aqueous salt solution.

3. The inhalable pharmaceutical composition of claim 1, wherein the dispersion of particles is in the form of a continuous respirable aerosol comprising a plurality of aqueous droplets containing a dispersion of particles and having a mass median aerodynamic diameter (MMAD) between 1 and 5 μm.

4. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an average percent transmission (APT) between 50 and 100 % over at least 15 minutes of continuous aerosolization.

5. The inhalable pharmaceutical composition of claim 3, wherein the plurality of droplets has a MMAD between 1 and 5 μm over at least 15 minutes of continuous aerosolization.

6. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an APT between 50 and 100 % after at least seven days of storage.

7. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by an APT between 50 and 100 %.

8. The inhalable pharmaceutical composition of claim 1, wherein the particles have an average diameter between 30 and 500 nm after at least seven days of storage.

9. The inhalable pharmaceutical composition of claim 1, wherein the composition is characterized by non-Newtonian fluid behavior.

10. The inhalable pharmaceutical composition of claim 1, wherein the composition has a flow index (n) of 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, or 1.3.

11. The inhalable pharmaceutical composition of claim 1, wherein the composition has a viscosity (η) of 0.1, 0.15, 0.2, 1, 100, or 110 cP.

12. The inhalable pharmaceutical composition of claim 1, wherein the composition has a zeta potential of 2.5, 1.5, -2.5, -10, -50, -55, or -60 mV.

13. The inhalable pharmaceutical composition of claim 1, wherein the composition has a surface tension of 25, 30, 35, 40, 45, or 50 mN/m.

14. The inhalable pharmaceutical composition of claim 1, wherein the composition has a yield stress (σ) of 11, 12, 13, 14, 15, 16, 17, or 18 mPa.

15. The inhalable pharmaceutical composition of claim 1, wherein the dispersion of particles have an average diameter between 30 and 300 nm.

16. The inhalable pharmaceutical composition of claim 1, wherein the composition has a polydispersivity index or (PDI) of 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, or 0.7.

17. The inhalable pharmaceutical composition of claim 1, wherein the composition does not comprise an opsonization reducer.

18. The inhalable pharmaceutical composition of claim 1, wherein the composition has a total aerosol output (TAO) of at least 40%.

19. The inhalable pharmaceutical composition of claim 3, wherein the MMAD is 1, 2, 3, 4, or 5 μm.

20. The inhalable pharmaceutical composition of claim 3, wherein the plurality of droplets have a geometric standard deviation (GSD) of less than 2.5, 2.4, 2.3, 2.2, 2.1, 2.0, 1.9, 1.8, 1.7, 1.6, 1.5, 1.4, 1.3, 1.2, 1.1, 1.0, 0.9, 0.8, 0.7, 0.6, 0.5, 0.4, 0.3, 0.2, or 0.1.

21.. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent is 4 % w/w or less of the composition.

22. The inhalable pharmaceutical composition of claim 1, wherein the hydrophobic bioactive agent is 1 % w/w of the composition.

23. The inhalable pharmaceutical composition of claim 1, wherein the phospholipid is 3 % w/w or less of the composition.

24. The inhalable pharmaceutical composition of claim 1, wherein the ratio of hydrophobic bioactive agent:phospholipid is 1:1, 4:3, or 4:2.5.

25. The inhalable pharmaceutical composition of claim 1, further comprising sodium chloride in an amount less than 1.0% w/v of the composition.

26. The inhalable pharmaceutical composition of claim 1, further comprising a salt in an amount making the composition essentially isosmotic with the human lung.

27. The inhalable pharmaceutical composition of claim 1, wherein the dispersion is suspension, nano-suspension, emulsion, or microemulsion.

28. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 300 nm, each particle comprising CoQ10, DPPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DPPC is between 5:1 and 1:5, the CoQ10 is between 0.1 and 6 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

29. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 300 nm, each particle comprising CoQ10, DSPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DSPC is between 5:1 and 1:5, the CoQ10 is between 0.1 and 6 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

30. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 300 nm, each particle comprising CoQ10, DMPC, and an aqueous dispersion vehicle,

wherein the ratio of CoQ10:DMPC is between 5:1 and 1:5, the CoQ10 is between 0.1 and 6 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

31. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 500 nm, each particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof;

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, the phospholipid is between 0.1 and 30 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon continuous aerosolization, the composition achieves a bioactive agent concentration of at least 500 μg/g wet lung tissue.

32. A method for preparing an inhalable pharmaceutical composition comprising the steps of:

hydrating a phospholipid, thereby forming a hydrated phospholipid;

mixing the hydrated phospholipid, a hydrophobic bioactive agent, and an aqueous dispersion vehicle, thereby producing a mixture; and

homogenizing the mixture, thereby producing a dispersion of particles comprising the phospholipid and hydrophobic bioactive agent dispersed within the aqueous dispersion vehicle and having an average diameter between 30 nm and 500 nm,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof;

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, and the phospholipid is between 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

33. The method according to claim 32, further comprising:

aerosolizing the dispersion of particles, thereby forming a respirable aerosol comprising a plurality of droplets, each droplet comprising a dispersion of particles and having a mass median aerodynamic diameter (MMAD) between 1 and 5 μm.

34. The method of claim 32 or 33, wherein mixing comprises high shear mixing for up to 5 minutes at 10,000 to 20,000 rpm and at 50 to 65 °C.

35. The method of claim 32 or 33, wherein homogenizing comprises microfluidization.

36. The method of claim 32 or 33, wherein homogenizing comprises high pressure homogenization for 1-50 passes at 30,000 psi and at 50 to 65 °C.

37. The method of claim 32 or 33, wherein homogenizing comprises ultrasonic homogenization.

38. The method of claim 32 or 33, wherein aerosolization comprises vibrating mesh nebulization.

39. An inhalable pharmaceutical composition for use in delivering a therapeutically effective amount of the hydrophobic bioactive agent to a lung of a subject by

aerosolizing a dispersion of particles, thereby forming a respirable aerosol comprising a plurality of droplets having a mass median aerodynamic diameter (MMAD) between 1 and 5 μm,

wherein the dispersion of particles has an average diameter between 30 and 500 nm, each particle comprising a hydrophobic bioactive agent and a phospholipid dispersed within an aqueous dispersion vehicle,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof;

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, and the phospholipid is between 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

40. The composition of claim 39, wherein aerosolization comprises vibrating mesh nebulization.

41. The composition of claim 39, wherein the aerosol is characterized by an APT between 50 and 100 % over at least 15 minutes of continuous aerosolization.

42. The composition of claim 39, wherein the aerosol is characterized by an APT between 50 and 100 %.

43. The composition of claim 39, wherein the plurality of droplets has a MMAD between 1 and 5 μm over at least 15 minutes of continuous aerosolization.

44. The composition of claim 39, wherein the MMAD is 1, 2, 3, 4, or 5 μm.

45. The composition of claim 39, wherein the droplets have a geometric standard deviation (GSD) of at least 2.0.

46. The composition of claim 39, wherein delivery achieves a mass fraction deposited of at least 1 %.

47. The composition of claim 39, wherein delivery achieves local delivery to the lung substantially without systemic delivery.

48. The composition of claim 39, wherein delivery achieves an elevated amount of the hydrophobic bioactive agent in the lung for at least 48 hours after administration.

49. The composition of claim 39, wherein, upon continuous aerosolization, the composition achieves a bioactive agent concentration of at least 500 μg/g wet lung tissue.

50. The composition of claim 39, wherein delivering a therapeutically effective amount of the hydrophobic bioactive agent comprises metering a dose of the bioactive agent.

51. The composition of claim 39, wherein the subject has lung cancer.

52. The composition of claim 39, wherein the subject has one or more of asthma, allergies, chronic obstructive pulmonary disease, chronic bronchitis, acute bronchitis, emphysema, cystic fibrosis, pneumonia, tuberculosis, pulmonary edema, acute respiratory distress syndrome, pneumoconiosis, interstitial lung disease, pulmonary edema, pulmonary embolism, pulmonary hypertension, pleural effusion, pneumothorax, mesothelioma, amyotrophic lateral sclerosis, myasthenia gravis, and lung disease.

53. A method of preparation of an inhalable pharmaceutical composition comprising the steps of:

hydrating a phospholipid, thereby forming a hydrated phospholipid;

mixing the hydrated phospholipid, a hydrophobic bioactive agent, and an aqueous dispersion vehicle, thereby producing a mixture; and

homogenizing the mixture, thereby producing a dispersion of particles comprising the phospholipid and hydrophobic bioactive agent dispersed within the aqueous dispersion vehicle and having an average diameter between 30 nm and 500 nm,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof;

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, and the phospholipid is between 0.1 and 30 % w/w of the composition, and

wherein, upon administration to a subject, the composition is characterized by continuous aerosolization sufficient to provide a therapeutic dose of the hydrophobic bioactive agent to the subject.

54. An inhalable pharmaceutical composition comprising a dispersion of particles suitable for continuous aerosolization, the composition comprising:

a dispersion of particles having an average diameter between 30 and 500 nm, each particle comprising a hydrophobic bioactive agent, a phospholipid, and an aqueous dispersion vehicle,

wherein the hydrophobic bioactive agent is coenzyme Q_{10};

wherein the phospholipid comprises dipalmitoyl phosphatidylcholine (DPPC), distearoyl phosphatidylcholine (DSPC), dimyristoyl phosphatidylcholine (DMPC), or a combination thereof;

wherein the ratio of hydrophobic bioactive agent:phospholipid is between 5:1 and 1:5, the hydrophobic bioactive agent is between 0.1 and 30 % w/w of the composition, the phospholipid is between 0.1 and 30 % w/w of the composition, and the particles are dispersed within the aqueous dispersion vehicle, and

wherein, upon continuous aerosolization, the composition achieves a total emitted dose (TED) of at least 2,900 μg over 15 seconds.

55. The inhalable pharmaceutical composition of claim 54, wherein the TED is at least 3,600 μg over 15 seconds.

56. The inhalable pharmaceutical composition of claim 1, wherein the continuous aerosolization has a duration of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 25, 30, 35, 40, 50, or 60 minutes.

57. The inhalable pharmaceutical composition of claim 1, further comprising a polyoxypropylene-poloxyethylene block polymer at 0.001-5% by weight of the total composition.