SUMMARY

[0003a] In one aspect, there is provided a lipid-based particle composition, comprising: a nanoparticle comprising: a therapeutic agent; a phosphatidylcholine ~~phospholipid~~ at a weight percent in the composition ranging from 2.5% to 20%; a sterol at a weight percent in the composition ranging from 0.25% to 10%; and triglyceride ~~a lipid component other than a phospholipid~~ at a weight percent in the composition ranging from 2.5% to 20%; and water at a weight percent in the composition ranging from 60% to 80%; wherein the nanoparticles have an average size ranging from ~~about~~ 75 nm to ~~about~~ 500 nm; and wherein, upon storage for a period of one month, the average size of the nanoparticles changes by less than ~~about~~ 20%.

[003b] In another aspect, there is provided a lipid-based particle composition, comprising: a particle comprising: a therapeutic agent; a phosphatidylcholine ~~phospholipid~~ at a weight percent in the composition ranging from 5% to 60%; a sterol at a weight percent in the composition ranging from 1% to 25%; and a triglyceride ~~lipid component other than a phospholipid~~ at a weight percent in the composition ranging from 5% to 50%; wherein the nanoparticles have an average size ranging from ~~about~~ 75 nm to ~~about~~ 500 nm; ~~and~~ wherein the lipid-based particle composition is provided as a dry powder; wherein, upon storage for a period of one month, the average size of the nanoparticles changes by less than ~~about~~ 20%; and wherein the lipid-based particle composition comprises liposomes and emulsion particles.

[0004] Some examples disclosed herein pertain to a particle composition and/or a lipid-based particle composition for the delivery of an active agent. In some examples, the particle is a lipid particle. In some examples, the particle is a nanoscale particle. In some examples, the particle is a microscale particle. In some examples, the particle is liposomal (e.g., is a liposome). In some examples, the particle comprises one or more of a phospholipid component, a non-phospholipid lipid component (e.g., a medium and/or long chain triglyceride component), a sterol component, and/or water. In some examples, the particle further comprises the active ingredient (e.g., a therapeutic agent). In some examples, the active ingredient is a phytocannabinoid. In some examples, the phytocannabinoid is CBD. In some examples, the lipid constituents of the particle allow it to solubilize CBD of high purity. In some examples, the CBD in the particle is of sufficient purity to provide a

crystalline and/or solid (e.g., an amorphous or crystalline powder). In some examples, the CBD not an oil.

[0005] In some examples, the phytocannabinoid of a lipid-based particle composition as disclosed herein is a single phytocannabinoid (e.g., CBD). In some examples, the phytocannabinoid (e.g., CBD) has a purity by weight % of equal to or greater than about: 95%, 97%, 98%, 99%, 100%, or ranges including and/or spanning the aforementioned values. In some examples, the phytocannabinoid (e.g., CBD) is present in the lipid-based particle composition at dry weight % of equal to or greater than about: 5%, 8%, 10%, 15%, 20%, or ranges including and/or spanning the aforementioned values. In some examples, the phytocannabinoid is free of or essentially free of THC. In some examples, the phytocannabinoid (e.g., CBD) has a THC content by weight % of equal to or less than about: 1%, 0.5%, 0.25%, 0.1%, 0%, or ranges including and/or spanning the aforementioned values. In some examples, where present, THC is present below the limit of quantitation (LOQ) (e.g., when analyzed by high pressure liquid chromatography (HPLC) with standard detectors, such as UV/Vis, photodiode array, refractive index, fluorescence, light scattering, conductivity, and the like).

[0021a] In another aspect, there is provided use of the lipid-based particle composition as defined herein in the manufacture of a medicament for treating a condition in a patient, wherein the condition is one or more of pain, anxiety, stress, seizures, malaise, inflammation, mood disorders, and insomnia.

[0022] In some examples, the Cmax is increased relative to CBD alone or comparator examples (e.g., CBD oil-based products) by equal to or at least about: 15%, 20%, 50%, 100%, 150%, 200%, or ranges including and/or spanning the aforementioned values. In some examples, the Cmax is increased (relative to an oil-based product) by equal to or at least about: 10 ng/mL, 20 ng/mL, 30 ng/mL, 40 ng/mL, 50 ng/mL, 60 ng/mL, 70 ng/mL, 80 ng/mL, 90 ng/mL, or ranges including and/or spanning the aforementioned values.

[0023] In some examples, the Tmax for CBD is decreased (relative to CBD alone or a CBD in oil mixture) by equal to or at least about: 15%, 20%, 50%, 100%, 150%, 200%, or ranges including and/or spanning the aforementioned values. In some examples, the Tmax for CBD in a disclosed example is decreased (relative to CBD alone or a CBD in oil mixture) by equal to or at least about: 15 minutes, 30 minutes, 45 minutes, 1 hour, 2 hours, or ranges including and/or spanning the aforementioned values.

[0024] In some examples, the AUC for CBD using a disclosed example is increased (relative to CBD alone or a CBD in oil mixture) by equal to or at least about: 100 ng/mL*hr, 200 ng/mL*hr, 300 ng/mL*hr, 400 ng/mL*hr, or ranges including and/or spanning the aforementioned values. In some examples, the AUC is improved (relative to CBD alone or a CBD in oil mixture) by equal to or at least about: 25%, 50%, 100%, 150%, 200%, or ranges including and/or spanning the aforementioned values.

WHAT IS CLAIMED IS:

1. A lipid-based particle composition, comprising:

a nanoparticle comprising:

a therapeutic agent;

a phosphatidylcholine ~~phospholipid~~ at a weight percent in the composition ranging from 2.5% to 20%;

a sterol at a weight percent in the composition ranging from 0.25% to 10%; and

a triglyceride ~~lipid component other than a phospholipid~~ at a weight percent in the composition ranging from 2.5% to 20%; and

water at a weight percent in the composition ranging from 60% to 80%;

wherein the nanoparticles have an average size ranging from ~~about~~ 75 nm to ~~about~~ 500 nm; and

wherein, upon storage for a period of one month, the average size of the nanoparticles changes by less than ~~about~~ 20%.

2. The lipid-based particle composition of claim 1, wherein the ~~composition comprises liposomes and/or an~~ oil-in-water emulsion particles are nano-emulsion particles.

3. The lipid-based particle composition of any one of claims 1 to 2, wherein an appreciable amount of the nanoparticle composition does not settle and/or separate from the water upon standing for a period of at least ~~about~~ one month at room temperature.

4. The lipid-based particle composition of any one of claims 1 to 3, wherein the composition is configured such that when concentrated to dryness to afford a powder formulation of nanoparticles, the nanoparticle powder can be reconstituted to provide the nanoparticle composition.

~~5. The lipid-based particle composition of any one of claims 1 to 4, wherein, upon storage for a period of one month, the average size of the nanoparticles changes by less than about 20%.~~

~~6.~~5. The lipid-based particle composition of any one of claims 1 to ~~5~~4, wherein the polydispersity of the nanoparticles in the composition is less than or equal to 0.20.

~~7.~~6. The lipid-based particle composition of any one of claims 1 to ~~6~~5, wherein upon 90 days of storage at 25°C and 60% relative humidity, the polydispersity of the nanoparticles changes by less than or equal to 100%.

~~8.~~7. The lipid-based particle composition of any one of claims 1 to ~~7~~6, wherein upon 90 days of storage at 25°C and 60% relative humidity, the polydispersity of the nanoparticles changes by less than or equal to 0.1.

~~9.~~8. The lipid-based particle composition of any one of claims 1 to ~~8~~7, wherein composition has a shelf life of greater than 18 months at 25°C and 60% relative humidity.

~~10.~~9. The lipid-based particle composition of any one of claims 1 to ~~9~~8, wherein the sterol is present at a weight percent in the composition ranging from 0.5% to 5%.

~~11. The lipid-based particle composition of any one of claims 1 to 10, wherein the water is present at a weight percent in the composition ranging from 60% to 90%.~~

~~12.~~10. A lipid-based particle composition, comprising:

a particle comprising:

a therapeutic agent;

a phosphatidylcholine ~~phospholipid~~ at a weight percent in the composition ranging from 5% to 60%;

a sterol at a weight percent in the composition ranging from 1% to 25%; and

a triglyceride ~~lipid component other than a phospholipid~~ at a weight percent in the composition ranging from 5% to 50%;

wherein the nanoparticles have an average size ranging from ~~about~~ 75 nm to ~~about~~ 500 nm; ~~and~~

wherein the lipid-based particle composition is provided as a dry powder;

wherein, upon storage for a period of one month, the average size of the nanoparticles changes by less than ~~about~~ 20%; and

wherein the lipid-based particle composition comprises liposomes and emulsion particles.

~~13. The lipid-based particle composition of claim 12, wherein the lipid-based particle composition is a dry powder.~~

~~14.~~11. The lipid-based particle of claim ~~13~~10, wherein the powder is configured to be reconstituted in water to provide an aqueous solution~~;~~ and

wherein, upon reconstitution, nanoparticles within the aqueous solution have an average size ranging from ~~about~~ 75 nm to ~~about~~ 500 nm.

~~15.~~12. The lipid-based particle composition of any one of claims 1 to ~~14~~11, wherein the therapeutic agent is hydrophobic.

~~16.~~13. The lipid-based particle composition of any one of claims 1 to ~~14~~12, wherein the therapeutic agent is hydrophilic.

~~17.~~14. The lipid-based particle composition of any one of claims 1 to ~~16~~13, wherein the therapeutic agent is present in the composition at concentration of equal to or greater than 2%.

~~18.~~15. The lipid-based particle composition of any one of claims 1 to ~~17~~14, wherein the therapeutic agent is present in the composition at concentration of equal to or greater than 10%.

~~19.~~16. The lipid-based particle composition of any one of claims 1 to ~~18~~15, wherein the therapeutic agent comprises a plant extract, a nutraceutical, a pharmaceutical, or combinations thereof.

~~20.~~17. The lipid-based particle composition of any one of claims 1 to ~~18~~16, wherein the therapeutic agent is selected from the group consisting of Noopept, melatonin, a terpene, and a cannabinoid.

~~21.~~18. The lipid-based particle composition of claim ~~20~~17, wherein the therapeutic agent is a cannabinoid.

~~22.~~19. The lipid-based particle composition of claim ~~21~~18, wherein the cannabinoid is a phytocannabinoid.

~~23.~~20. The lipid-based particle composition of claim ~~21~~ 17 or ~~22~~18, wherein the therapeutic agent is selected from the group consisting of THC (tetrahydrocannabinol), THCA (tetrahydrocannabinolic acid), CBD (cannabidiol), CBDA (cannabidiolic acid), CBN (cannabinol), CBG (cannabigerol), CBC (cannabichromene), CBL (cannabicyclol), CBV (cannabivarin), THCV (tetrahydrocannabivarin), CBDV (cannabidivarin), CBCV (cannabichromevarin), CBGV (cannabigerovarin), CBGM (cannabigerol monomethyl ether), CBE (cannabielsoin), and CBT (cannabicitran).

~~24.~~21. The lipid-based particle composition of any one of claims ~~21–~~17 to ~~23~~20, wherein the cannabinoid is cannabidiol (CBD).

~~25.~~22. The lipid-based particle composition of claim ~~24~~21, wherein the composition has a Tmax for CBD of less than 4.5 hours.

~~26.~~23. The lipid-based particle composition of claim ~~21~~17, wherein the therapeutic agent is a terpene.

~~27.~~24. The lipid-based particle composition of claim ~~26~~17, wherein the therapeutic agent is selected from the group consisting alpha fenchone, alpha terpinene, alpha terpineol, beta caryophyllene, alpha pinene, beta pinene, bisabolene, bisabolol, borneol, eucalyptol, gamma terpinene, guaiacol, humulene, linalool, myrcene, para cymene, phytol, and terpinolene.

~~28.~~25. The lipid-based particle composition of any one of claims ~~22–~~1 to ~~25~~24, wherein the lipid-based particle composition further comprises an additional therapeutic agent.

~~29.~~26. The lipid-based particle composition of claim ~~28~~25, wherein the additional therapeutic agent is selected from the group consisting of Noopept, melatonin, and a terpene.

~~30. The lipid-based particle composition of any one of claims 1 to 29, wherein the phospholipid is phosphatidylcholine.~~

~~31. The lipid-based particle composition of any one of claims 1 to 28, wherein the lipid component other than a phospholipid is a triglyceride.~~

~~32.~~27. The lipid-based particle composition of any one of claims ~~31~~1 to 26, wherein the triglyceride is a medium chain triglyceride or a long chain triglyceride.

~~33.~~28. The lipid-based particle composition of any one of claims 1 to ~~32~~27, further comprising a preservative.

~~34.~~29. The lipid-based particle composition of claim ~~33~~28, wherein the preservative comprises one or more of malic acid, citric acid, potassium sorbate, sodium benzoate, and Vitamin E.

~~35.~~30. The lipid-based particle composition of any one of claims 1 to ~~34~~29, wherein the sterol is cholesterol.

~~36.~~31. The lipid-based particle composition of any one of claims 1 to ~~35~~30, further comprising a flavoring agent.

~~37.~~32. Use of the lipid-based particle composition of any one of claims 1 to ~~36~~ 31 in the manufacture of a medicament for treating a condition in a patient~~.~~.

~~38. The use of claim 37,~~ wherein the condition is one or more of pain, anxiety, stress, seizures, malaise, inflammation, mood disorders, and insomnia.