CLAIMS

1. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

an active pharmaceutical ingredient consisting of lurasidone or a pharmaceutically acceptable salt thereof;~~,~~ and

a biodegradable polymer,

wherein each polymer microsphere comprises a drug load of lurasidone of greater than or equal to 55% by weight of the polymer microsphere, and

wherein the polymer microspheres have ~~an average~~a particle size of less than or equal to 25 µm~~m~~h (~~D~~$_{50}$D$_{50}$).

2. The microsphere formulation of claim 5~~1~~, wherein the pharmaceutically acceptable salt of lurasidone ~~comprises~~ is lurasidone HC1.

3. The microsphere formulation of claim 5~~1~~, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide).

4. The microsphere formulation of claim 5~~1~~, wherein the biodegradable polymer comprises an acid terminated poly(D,L-l~~4~~actide-co-glycolide) with lactide:glycolide of about 75: about 25.

The microsphere formulation of claim 1, wherein each polymer microsphere has a lurasidone drug load of from 55% to about 70% by weight of the polymer microsphere; and wherein the polymer microspheres have a particle size of from about 9 µm to 25 µm (D$_{50}$). ~~.~~

5.

~~5.~~6. The microsphere formulation of claim 5~~1~~, wherein the polymer microspheres have been irradiated.

~~6.~~7. A pharmaceutical composition comprising the microsphere formulation of claim 1.

~~7.~~8. ~~The microsphere formulation of claim 1 for use in the treatment of schizophrenia and/or depression.~~Cancelled

9. The microsphere formulation of claim 1, characterized in that about 75% to 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

10. The microsphere formulation of claim 5, wherein the polymer microspheres have a particle size of between about 14 µm (D_{50}) and 25 µm (D_{50}).

11. The microsphere formulation of claim 5, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.56 dL/g.

12. The microsphere formulation of claim 5, wherein:

the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.21 dL/g.

13. The microsphere formulation of claim 5, wherein:

the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.29 dL/g.

14. The microsphere formulation of claim 5, wherein the polymer microspheres have a particle size of from about 14 µm (D_{50}) to about 20 µm (D_{50}).

15. A pharmaceutical composition comprising the microsphere formulation of claim 5.

~~8.~~16. The microsphere formulation of claim 5, characterized in that about 75% to 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

~~A method for making the microsphere formulations of claim 1, the method comprising the steps:~~

~~a. contacting the lurasidone with the biodegradable polymer comprising an acid terminated poly(D,L-lactide-co-glycolide) having a co-monomer ratio of about 75 to about 25 in the presence of an~~

~~organic solvent system comprising dichloromethane and benzyl alcohol in a solvent ratio of about 2 to about 1 to form a dispersed phase;~~

~~b. combining the dispersed phase with a continuous phase comprising water and surfactant in a homogenizer to form an emulsion;~~

~~c. removing the organic solvent from the emulsion to form a microsphere formulation essentially free of organic solvent; and~~

~~d. subjecting the substantially organic solvent-free microsphere formulation to freeze-drying.~~

~~9. The method of claim 10, wherein the surfactant comprises polyvinyl alcohol.~~

~~10. The method of claim 10, wherein the surfactant comprises polyvinyl alcohol, and wherein the polyvinyl alcohol concentration in the aqueous phase prior to the combining is about 0.35% by weight.~~

~~11. The method of claim 10, wherein the continuous phase further comprises a buffer.~~

~~12. The method of claim 10, wherein the continuous phase further comprises a buffer, and wherein the buffer is a phosphate buffer having a pH of between about 7 and about 8.~~

~~13. A kit, comprising: polymer microspheres, each polymer microsphere comprising:~~

~~a. lurasidone; and~~

~~b. a biodegradable polymer,~~

~~wherein each polymer microsphere comprises a drug load of lurasidone of greater than 55% by weight of the polymer microsphere, and wherein the polymer microspheres have an average particle size of less than 25 mih (Dso).~~

~~14. The kit of claim 15, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25.~~

~~15. The kit of claim 15, wherein each polymer microsphere has a lurasidone drug load of from 55% to about 70% by weight of the polymer microsphere.~~

~~16. The kit of claim 15, wherein the polymer microspheres have been irradiated.~~

~~17. A method for treating schizophrenia and/or depression in a subject suspected of having bipolar disorder, the method comprising: administering by intra-articular, intramuscular, or subcutaneous injection to the subject a microsphere formulation with a dosing schedule of about every 30 days, the microsphere formulation comprising:~~

~~a. polymer microspheres, each polymer microsphere comprising:~~

~~b. lurasidone; and~~

~~c. a biodegradable polymer, wherein each polymer microsphere comprises a drug load of lurasidone of greater than 55% by weight of the polymer microsphere, and wherein the polymer microspheres have an average particle size of less than 25 mih (D_{50}).~~

~~The method of claim 19, wherein:the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25; and each polymer microsphere has a lurasidone drug load of from 55% to about 70% by weight of the polymer microsphere.~~

17. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

an active pharmaceutical ingredient consisting of lurasidone HCl; and

a biodegradable polymer comprising an acid terminated poly(D,L-lactide-co-glyycolide) ("PLGA") with lactide:glycolide of about 75: about 25 and an inherent viscosity of from about 0.14 dL/g to about 0.56 dL/g,

wherein each polymer microsphere has a lurasidone drug load of from about 55% to about 70% by weight of the polymer microsphere;

wherein the polymer microspheres have a particle size of about 14 µm (D_{50}) to about 25 µm (D_{50}); and

wherein the microsphere formulation is characterized in that about 75% to about 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more

than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

18. A pharmaceutical composition comprising the microsphere formulation of claim 17.

19. The microsphere formulation of claim 18, wherein the inherent viscosity of the PLGA is from about 0.14 dL/g to about 0.29 dL/g.

20. The microsphere formulation of claim 18, wherein the inherent viscosity of the PLGA is from about 0.14 dL/g to about 0.21 dL/g.