~~What is claimed is:~~

CLAIMS

1. A syringe-to-syringe mixing system comprising:

a first syringe ~~barrel~~ comprising a hollow body, ~~defining an internal chamber,~~ the hollow body having a proximal end and a distal dispensing end ~~with an outlet~~;

a second syringe ~~barrel~~ comprising a hollow body ~~defining an internal chamber~~, ~~the hollow body of~~ the second syringe ~~barrel having~~comprising ~~a proximal end and~~ a distal dispensing end ~~with an outlet~~;

the first syringe ~~barrel~~ and the second syringe ~~barrel~~ each comprising a barrel and a plunger ~~slidably disposed within the syringe barrel~~ for applying pressure to a syringe content ~~housed within the internal chambers~~;

~~a syringe coupler that is operable to receive the first syringe barrel and the second syringe barrel;~~

a valve assembly that is operable to receive the first syringe and the second syringe, and wherein the valve assembly comprises at least one resilient member that is biased toward a locked position;

wherein the valve assembly comprises a displaceable member comprising a user-interface and a guide member, wherein the displaceable member is slidable relative to the guide member, and wherein the user-interface is operable to receive a force from a user and transmit the force to a displaceable seal, and wherein the displaceable seal is moveable in a direction substantially perpendicular to a longitudinal axis of at least one of the first syringe and the second syringe;

a selectively rotatable member operable to receive at least one of the first syringe and the second syringe;

wherein the valve assembly comprises a first position wherein a fluid flow between the first syringe and the second syringe through the displaceable seal is fully occluded, and a second position in which fluid is allowed to flow through the displaceable seal and between the first syringe and the second syringe;

~~the syringe coupler comprising a displaceable member,~~ wherein the displaceable member comprises ~~a seal with a flow port that is offset from the outlet of at least one of the first syringe barrel and the second syringe barrel when the displaceable member is provided in a first position, and wherein the flow port is aligned with the outlet of the first syringe barrel and the second syringe barrel~~at least one projection in communication with the selectively rotatable member when the displaceable member is in the first position, and wherein the at least one projection is spaced apart from the selectively rotatable member when the displaceable member is in the second position and the selectively rotatable member is freely rotatable when the displaceable member is provided in ~~a~~the second position.

~~2. The syringe-to-syringe mixing system of claim 1, wherein the syringe coupler comprises a user interface operable to receive a force from a user and transmit the force to the seal.~~

~~3. The syringe-to-syringe mixing system of claim 1, wherein the displaceable member is displaceable in a direction that is substantially perpendicular to a longitudinal axis of at least one of the first syringe barrel and the second syringe barrel.~~

~~4. The syringe-to-syringe mixing system of claim 1, wherein the syringe coupler comprises a rotatable Luer lock member that is free to rotate within the syringe coupler when the displaceable coupler is provided in the second position.~~

2. The syringe-to-syringe mixing system of claim 1, wherein at least one of the first syringe and the second syringe is moveable with the valve assembly.

~~5.~~3. The syringe-to-syringe mixing system of claim 1 or 2, wherein one of the first syringe ~~barrel~~ and the second syringe ~~barrel~~ comprises a drug and wherein the other syringe ~~barrel~~ comprises a liquid formulation component.

~~6.~~4. The syringe-to-syringe mixing system of ~~claim 1~~any one of claims 1 to 3, wherein at least one of the first syringe ~~barrel~~ and the second syringe ~~barrel~~ comprise leuprolide acetate.

~~7. The syringe-to-syringe mixing system of claim 1, wherein at least one of the first syringe barrel and the second syringe barrel comprise a polymer-solvent.~~

~~8. The syringe-to-syringe mixing system of claim 1, wherein the user-interface comprises at least one resilient projection that is biased toward a locked position.~~

5. The syringe-to-syringe mixing system of any one of claims 1 to 4, wherein the selectively rotatable member comprises a threaded member operable to receive at least one of the first syringe and the second syringe.

~~9. The syringe-to-syringe mixing system of claim 1, wherein the first position comprises a position wherein a fluid flow between the first syringe barrel and the second syringe barrel is fully occluded, and the second position comprises a position in which fluid is allowed to flow between the first syringe barrel and the second syringe barrel.~~

~~10. The syringe-to-syringe mixing system of claim 1, wherein the syringe coupler comprises a first syringe-receiving member and a second syringe-receiving member.~~

~~11.~~6. A syringe-to-syringe mixing system comprising:

a first syringe ~~barrel~~ comprising a hollow body defining an internal chamber, the hollow body having a proximal end and a distal dispensing end with an outlet;

a second syringe ~~barrel~~ comprising a hollow body defining an internal chamber,~~and an outlet,~~ the hollow body of the second syringe having a proximal end ~~comprising~~and a distal dispensing end with an outlet;

the first syringe ~~barrel~~ and the second syringe ~~barrel~~ each comprising a plunger slidably disposed within the syringe ~~barrel~~ for applying pressure to a syringe content ~~housed within the internal chambers~~;

a ~~valve assembly~~syringe coupler that is operable to receive the first syringe ~~barrel~~ and the second syringe ~~barrel~~;

~~wherein the valve assembly comprises a displaceable user interface operable to receive a force from a user and transmit the force to a displaceable seal, and wherein the displaceable user interface is moveable in a direction substantially perpendicular to a longitudinal axis of at least one of the first syringe barrel and the second syringe barrel.~~

the syringe coupler comprising a displaceable member slidably engaged with a guide member, wherein the displaceable member comprises a seal with a flow port that is offset from the outlet of at least one of the first syringe and the second syringe when the displaceable member is provided in a first position, wherein the flow port is aligned with the outlet of the first syringe and the second syringe when the displaceable member is provided in a second position, and

wherein the displaceable member comprises at least one resilient projection and the guide member comprises at least one recess for receiving the at least one resilient projection; and

wherein the at least one resilient projection is operable to be displaced upon movement of the displaceable member and wherein the at least one resilient projection prevents or inhibits the displaceable member from being returned to the first position when the at least one resilient projection is provided in the at least one recess of the guide member.

7. The syringe-to-syringe mixing system of claim 6, wherein the syringe coupler comprises a user-interface operable to receive a force from a user and transmit the force to the seal.

~~12.~~8. The syringe-to-syringe mixing system of ~~claim 11~~claim 6 or 7, wherein the displaceable ~~seal~~member is displaceable relative to the guide member in a direction that is

substantially perpendicular to a longitudinal axis of at least one of the first syringe ~~barrel~~ and the second syringe ~~barrel~~.

~~13. The syringe-to-syringe mixing system of claim 11, wherein at least one of the first syringe barrel and the second syringe barrel is moveable with the valve assembly.~~

~~14. The syringe-to-syringe mixing system of claim 11, wherein one of the first syringe barrel and the second syringe barrel comprises a drug and wherein the other syringe barrel comprises a liquid formulation component.~~

9. The syringe-to-syringe mixing system of any one of claims 6 to 8, wherein the syringe coupler comprises a rotatable Luer lock member that is free to rotate within the syringe coupler when the displaceable member is provided in the second position.

~~15.~~10. The syringe-to-syringe mixing system of ~~claim 11~~any one of claims 6 to 9, wherein at least one of the first syringe ~~barrel~~ and the second syringe ~~barrel~~ comprise leuprolide acetate.

~~16. The syringe-to-syringe mixing system of claim 11, wherein at least one of the first syringe barrel and the second syringe barrel comprise a polymer-solvent.~~

~~17.~~11. The syringe-to-syringe mixing system of any one of ~~claim 11~~claims 6 to 10, wherein the ~~valve assembly comprises~~ at least one resilient ~~member~~projection comprises first and second resilient projections that ~~is~~are biased toward a locked position and the guide member comprises first and second recesses for receiving the resilient projections in the second position.

~~18. The syringe to syringe mixing system of claim 11, wherein the valve assembly comprises a first position wherein a fluid flow between the first syringe barrel and the second syringe barrel is fully occluded, and a second position in which fluid is allowed to flow between the first syringe barrel and the second syringe barrel.~~

~~19. The syringe-to-syringe mixing system of claim 11, wherein the valve assembly comprises a first syringe receiving member and a second syringe receiving member.~~

~~20. The syringe-to-syringe mixing system of claim 19, wherein at least one of the first syringe receiving member and the second syringe receiving member comprises a threaded member.~~

~~21. The syringe-to-syringe mixing system of claim 20, wherein the threaded member is substantially prevented from rotating relative to the valve assembly when the displaceable member is provided in a first position; and~~

~~wherein the threaded member is free to rotate when the displaceable user interface is provided in a second position.~~

12. The syringe-to-syringe mixing system of any one of claims 1 to 11, wherein the syringe-to-syringe mixing system houses a pharmaceutical composition and the pharmaceutical composition comprises about 7.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone and a 50:50 poly(lactic acid-co-glycolic acid) (PLGA) copolymer having a weight average molecular weight from about 31 kDa to about 45 kDa and at least one terminal carboxylic acid end group as the liquid formulation component.

13. The syringe-to-syringe mixing system of any one of claims 1 to 11, wherein the syringe-to-syringe mixing system houses a pharmaceutical composition and the pharmaceutical composition comprises about 22.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated as the liquid formulation component.

14. The syringe-to-syringe mixing system of any one of claims 1 to 11, wherein syringe-to-syringe mixing system houses a pharmaceutical composition and the pharmaceutical composition comprises about 30 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

15. The syringe-to-syringe mixing system of any one of claims 1 to 11, wherein syringe-to-syringe mixing system houses a pharmaceutical composition and the pharmaceutical composition comprises about 45 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and an 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

~~22. A method of preparing a pharmaceutical composition, the method comprising:~~

~~providing a first syringe barrel and a second syringe barrel; the first syringe barrel and the second syringe barrel each comprising a plunger slidably disposed therein for applying pressure to a syringe content housed within the syringe barrels;~~

~~providing a syringe coupler that is operable to receive the first syringe barrel and the second syringe barrel;~~

~~the syringe coupler comprising a user-interface and a displaceable seal;~~

~~securing at least one of the first syringe barrel and the second syringe barrel to the syringe coupler;~~

~~applying a force to the user interface to move the displaceable seal from a first position to a second position;~~

applying force to the plunger of the first syringe barrel and the second syringe barrel in an alternating manner to mix contents of the first syringe barrel and the second syringe barrel.

23. The method of claim 22, wherein the first syringe barrel contains a drug.

24. The method of claim 23, wherein the drug comprises leuprolide acetate.

25. The method of claim 23, wherein the second syringe barrel comprises a liquid or flowable material.

26. The method of claim 25, wherein the liquid or flowable material comprises a polymer operable to be mixed with contents of the first syringe barrel.

27. The method of claim 22, wherein a plurality of mixing cycles are performed to mix contents of the first syringe barrel and the second syringe barrel, and at least one of the first syringe barrel and the second syringe barrel is disconnected and the pharmaceutical composition is delivered to a patient.

28. The method of claim 22, wherein first position comprises a position wherein the displaceable seal is offset from an outlet of at least one of the first syringe barrel and the second syringe barrel and fluid transfer between the syringe barrels is occluded.

29. The method of claim 22, wherein the second position comprises a position wherein the displaceable seal is aligned with an outlet of at least one of the first syringe barrel and the second syringe barrel and fluid flow between the syringe barrels is permitted.

30. The method of claim 22, wherein the user-interface comprises a depressible member.

~~31. The method of claim 22, wherein at least one of the first syringe barrel and the second syringe barrel is moveable with the displaceable seal.~~

~~32. The method of claim 22, wherein at least one of the first syringe barrel and the second syringe barrel are irreversibly secured to the syringe coupler.~~

~~33. The method of claim 22, wherein the securing step comprises threading at least one of the first syringe barrel and the second syringe barrel to the syringe coupler.~~

16. A method for mixing a pharmaceutic composition, comprising:

providing a syringe mixing system, the system comprising a valve assembly with a displaceable member comprising a user-interface and a guide member, wherein the displaceable member is slidable relative to the guide member, and wherein the user-interface is operable to receive a force from a user and transmit the force to a displaceable seal;

a selectively rotatable member operable to receive a syringe;

wherein the valve assembly comprises a first position wherein a fluid flow through the assembly is fully occluded, and a second position in which fluid is allowed to flow;

wherein the displaceable member comprises at least one projection in communication with the selectively rotatable member when the displaceable member is in the first position, and wherein the at least one projection is spaced apart from the selectively rotatable member when the displaceable member is in the second position and the selectively rotatable member is freely rotatable when the displaceable member is in the second position;

coupling a first syringe and a second syringe to the valve assembly, wherein the first syringe and the second syringe each comprise a syringe barrel with a hollow body defining an internal chamber, wherein the syringe barrel has a proximal end and a distal dispensing end with an outlet, and a plunger slidably disposed within the hollow body for applying pressure to a syringe content housed within the internal chamber;

displacing the displaceable member relative to the guide member in a direction substantially perpendicular to a longitudinal axis of at least one of the first syringe and the second; and

cyclically mixing contents between the first syringe and the second syringe to prepare the contents for delivery to a patient.

17. The method of claim 16, wherein the pharmaceutical composition comprises about 7.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone and a 50:50 poly(lactic acid-co-glycolic acid) (PLGA) copolymer having a weight average molecular weight from about 31 kDa to about 45 kDa and at least one terminal carboxylic acid end group as the liquid formulation component.

18. The method of claim 16 or 17, wherein the pharmaceutical composition comprises about 22.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated as the liquid formulation component.

19. The method of any one of claims 16 to 18, wherein the pharmaceutical composition comprises about 30 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

20. The method of any one of claims 16 to 19, wherein the pharmaceutical composition comprises about 45 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

21. A method for mixing a pharmaceutic composition, comprising:

providing a syringe mixing system, the system comprising a valve assembly with a displaceable member comprising a user-interface and a guide member, wherein the displaceable member is slidable relative to the guide member, and wherein the user-interface is operable to receive a force from a user and transmit the force to a displaceable seal;

wherein the displaceable member comprises at least one resilient projection and the guide member comprises at least one recess for receiving the at least one resilient projection; and

wherein the at least one resilient projection is operable to be displaced upon movement of the displaceable member and wherein the at least one resilient projection prevents or inhibits the displaceable member from being returned to the first position when it is provided in the at least one recess of the guide member;

coupling a first syringe and a second syringe to the valve assembly, wherein the first syringe and the second syringe each comprise a syringe barrel with a hollow body defining an internal chamber, wherein the syringe barrel has a proximal end and a distal dispensing end with an outlet, and a plunger slidably disposed within the hollow body for applying pressure to a syringe content housed within the internal chamber;

displacing the displaceable member relative to the guide member in a direction substantially perpendicular to a longitudinal axis of at least one of the first syringe and the second; and

cyclically mixing contents between the first syringe and the second syringe to prepare the contents for delivery to a patient.

22. The method of claim 21, wherein the pharmaceutical composition comprises about 7.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone and a 50:50 poly(lactic acid-co-glycolic acid) (PLGA) copolymer having a weight average molecular weight from about 31 kDa to about 45 kDa and at least one terminal carboxylic acid end group as the liquid formulation component.

23. The method of claim 21 or 22, wherein the pharmaceutical composition comprises about 22.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated as the liquid formulation component.

24. The method of any one of claims 21 to 23, wherein the pharmaceutical composition comprises about 30 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

25. The method of any one of claims 21 to 25, wherein the pharmaceutical composition comprises about 45 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

~~34.~~26. A syringe coupler that is operable to receive a first syringe barrel and a second syringe barrel associated with a syringe mixing system, the syringe coupler comprising:

a displaceable member operable to be selectively contacted by a user to convert the syringe coupler from a first position to a second position;

a seal with a flow port that is moveable with the displaceable member;

a first syringe receiving-member and a second syringe-receiving member, wherein at least one of the first syringe-receiving member and the second syringe-receiving member comprises a threaded member;

wherein the displaceable member comprises a projection in selective communication with the threaded member to enable the threaded member to be freely rotatable when the displaceable member is provided in the second position;

wherein the threaded member is substantially prevented from rotating relative to the syringe coupler when the displaceable member is provided in the first position; and

wherein the threaded member is freely rotatable when the displaceable member is provided in the second position.

~~35.~~27. The syringe coupler of ~~claim 34~~claim 26, wherein the first position comprises a closed position in which fluid flow through the coupler is occluded~~.~~ and

~~36. The syringe coupler of claim 34,~~ wherein the second position comprises an open position in which fluid flow through the coupler is enabled.

~~37.~~28. The syringe coupler of claim ~~34~~26 or 27, wherein the threaded member further comprises a contact surface operable to be engaged by a portion of the syringe coupler when the syringe coupler is provided in the first position.

~~38.~~29. The syringe coupler of ~~claim 34~~any one of claims 26 to 28, wherein the threaded member comprises a flow port, and wherein the flow port of the seal and the flow port of the threaded member are offset relative to one another in the first position.

~~39.~~30. The syringe coupler of ~~claim 34~~any one of claims 26 to 29, wherein the threaded member comprises a flow port, and wherein the flow port of the seal and the flow port of the threaded member are aligned in the second position.

~~40.~~31. The syringe coupler of ~~claim 34~~any one of claims 26 to 30, wherein the syringe coupler comprises at least one resilient member to secure the syringe coupler in the second position and substantially prevent the syringe coupler from returning to the first position.

~~41. The syringe coupler of claim 34, wherein the contact surface comprises a flange of the threaded member.~~

~~42. The syringe coupler of claim 41, wherein the flange comprises a plurality of contact surfaces that are angled relative to one another.~~

~~43. The syringe coupler of claim 34, wherein the contact surface comprises a surface of at least one of a tooth and a cog provided on the threaded member.~~

~~44.~~32. The syringe coupler of ~~claim 34~~any one of claims 26 to 31, wherein the first syringe receiving-member and the second syringe-receiving member each comprise Luer lock members that are operable to receive a distal end of a syringe.

33. The syringe coupler of any one of claims 26 to 32, further comprising a first syringe and a second syringe secured to the syringe coupler, wherein at least one of the first syringe and the second syringe comprises leuprolide or a pharmaceutically acceptable salt thereof.

34. The syringe coupler of any one of claims 26 to 33, wherein the displaceable member further comprises at least one resilient projection.

~~45. The syringe coupler of claim 34, wherein at least one of the first syringe-receiving member and the second syringe-receiving member comprises a threaded member.~~

~~46. A prefilled syringe-to-syringe mixing system for delivery of a pharmaceutical composition comprising an active pharmaceutical ingredient and a liquid formulation component, the prefilled syringe-to-syringe mixing system comprising:~~

~~a first syringe barrel comprising a hollow body defining an internal chamber containing the active pharmaceutical ingredient, the hollow body having a proximal end and a distal dispensing end with an outlet;~~

a second syringe barrel comprising a hollow body defining an internal chamber, the second syringe barrel containing the liquid formulation component, the second syringe comprising a distal dispensing end with an outlet;

the first syringe barrel and the second syringe barrel each comprising a plunger slidably disposed within the syringe barrel for applying pressure to the contents of each of the internal chambers;

a syringe coupler that is operable to receive the first syringe barrel and the second syringe barrel;

the syringe coupler comprising a displaceable member, wherein the displaceable member comprises a seal with a flow port that is offset from the outlet of at least one of the first syringe barrel and the second syringe barrel when the displaceable member is provided in a first position, and wherein the flow port is aligned with the outlet of the first syringe barrel and the second syringe barrel when the displaceable member is provided in a second position; and wherein the displaceable member is displaceable in a direction that is substantially perpendicular to a longitudinal axis of at least one of the first syringe barrel and the second syringe barrel.

47. The prefilled syringe-to-syringe mixing system of claim 46, wherein the first position comprises a position wherein a fluid flow between the first syringe barrel and the second syringe barrel is fully occluded, and the second position comprises a position in which fluid is allowed to flow between the first syringe barrel and the second syringe barrel.

48. The prefilled syringe-to-syringe mixing system of claim 46, wherein the active pharmaceutical ingredient is leuprolide acetate.

49. The prefilled syringe-to-syringe mixing system of claim 46, wherein the liquid formulation component comprises a polymer and a solvent.

50. The prefilled syringe-to-syringe mixing system of claim 46, wherein the pharmaceutical composition comprises about 7.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone and a 50:50 poly(lactic acid-co-

glycolic acid) (PLGA) copolymer having a weight average molecular weight from about 31 kDa to about 45 kDa and at least one terminal carboxylic acid end group as the liquid formulation component.

51. The prefilled syringe-to-syringe mixing system of claim 46, wherein the pharmaceutical composition comprises about 22.5 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated as the liquid formulation component.

52. The prefilled syringe-to-syringe mixing system of claim 46, wherein the pharmaceutical composition comprises about 30 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

53. The prefilled syringe-to-syringe mixing system of claim 46, wherein the pharmaceutical composition comprises about 45 mg of leuprolide acetate as the active pharmaceutical ingredient and N-methyl-2-pyrrolidone, and an 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated as the liquid formulation component.

54. A method of administering a GnRH agonist or antagonist or a pharmaceutically acceptable salt thereof to a patient comprising:

mixing a unit does of the GnRH agonist or antagonist or the pharmaceutically acceptable salt thereof with a liquid formulation component to form a reconstituted pharmaceutical composition using a syringe-to-syringe mixing system; and

administering the reconstituted pharmaceutical composition to the patient via subcutaneous injection,

wherein the syringe-to-syringe mixing system comprises a first syringe barrel comprising the GnRH agonist or antagonist or the pharmaceutically acceptable salt thereof, a second syringe barrel comprising the liquid formulation component, and a syringe coupler that connects the first and second syringe barrels, the syringe coupler comprising a displaceable member, and

wherein the displaceable member comprises a seal with a flow port that is offset from an outlet of at least one of the first syringe barrel and the second syringe barrel when the displaceable member is provided in a first position, and wherein the flow port is aligned with the outlet of the first syringe barrel and the second syringe barrel when the displaceable member is provided in a second position; and

wherein the displaceable member is displaceable in a direction that is substantially perpendicular to a longitudinal axis of at least one of the first syringe barrel and the second syringe barrel.

55. The method of claim 54, wherein the mixing comprises applying a force to a user-interface to move the displaceable seal from the first position to the second position and applying force to a plunger positioned in the first syringe barrel and a plunger positioned in the second syringe barrel in an alternating manner to mix the contents of the first syringe barrel and the second syringe barrel.

56. The method of claim 54, wherein the GnRH agonist or antagonist or the pharmaceutically acceptable salt thereof is leuprolide or a pharmaceutically acceptable salt thereof.

57. The method of claim 54, wherein the patient has prostate cancer and administration of the reconstituted pharmaceutical composition to the patient about once

every 1-6 months reduces the patient's serum testosterone level to less than or equal to 0.5 ng/mL.

58. The method of claim 57, wherein the reconstituted pharmaceutical composition comprises about 7.5 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and a 50:50 poly(lactic acid co glycolic acid) (PLGA) copolymer having a weight average molecular weight from about 31 kDa to about 45 kDa and at least one terminal carboxylic acid end group, and wherein the reconstituted pharmaceutical composition is administered to the patent about once per month.

59. The method of claim 57, wherein the reconstituted pharmaceutical composition comprises about 22.5 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated, and wherein the reconstituted pharmaceutical composition is administered to the patent about once per every three months.

60. The method of claim 57, wherein the reconstituted pharmaceutical composition comprises about 30 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and end groups that are hydroxyl-terminated, and wherein the reconstituted pharmaceutical composition is administered to the patent about once per every four months.

61. The method of claim 57, wherein the reconstituted pharmaceutical composition comprises about 45 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and an 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and end groups that are hydroxyl terminated, and wherein the reconstituted pharmaceutical composition is administered to the patent about once per every six months.

62. The method of claim 54, wherein the patient has hormone receptor-positive breast cancer and wherein administration of the reconstituted pharmaceutical composition about once per every three months suppress the patient's ovarian function.

63. The method of claim 62, wherein administration of the reconstituted pharmaceutical composition about once per every three months suppress the patient's estradiol (E2) level to less than 20 pg/mL.

64. The method of claim 62, wherein administration of the reconstituted pharmaceutical composition about once per every three months suppress the patient's mean serum luteinizing hormone (LH) level.

65. The method of claim 62, wherein the reconstituted pharmaceutical composition comprises about 30 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and a 75:25 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 17 kDa to about 21 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl terminated or ester-terminated.

66. The method of claim 54, wherein the patient is a pediatric patient 2 years of age or older with central precocious puberty (CPP) and administration of the reconstituted pharmaceutical composition about once per every six months reduce the pediatric patient's peak stimulated blood serum LH concentration to a pre-pubertal concentration of less than 4 IU/L.

67. The method of claim 66, wherein the reconstituted pharmaceutical composition comprises about 45 mg of leuprolide acetate, N-methyl-2-pyrrolidone, and an 85:15 poly(lactide-co-glycolide) (PLG) copolymer having a weight average molecular weight from about 20 kDa to about 26 kDa and one distal end group that is hydroxyl-terminated and the other distal end group that is either hydroxyl-terminated or ester-terminated.