

CLAIMS**WHAT IS CLAIMED IS:**

1. A pharmaceutical composition comprising (i) about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5
5 mg/mL or more; and (ii) at least one pharmaceutically acceptable excipient.
2. The pharmaceutical composition of claim 1, comprising about 1.25 to about 1.30 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof.
3. The pharmaceutical composition of claim 1 or 2, comprising about 1.27 to about 1.29 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof.
- 10 4. The pharmaceutical composition of any one of claims 1 to 3, comprising about 1.28 *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof.
5. The pharmaceutical composition of any one of claims 1 to 4, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is at a concentration of about 7.5 to about 8.5 mg/mL.
- 15 6. The pharmaceutical composition of any one of claims 1 to 5, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is at a concentration of about 8 mg/mL.
7. The pharmaceutical composition of any one of claims 1 to 6, wherein the at least one pharmaceutically acceptable excipient comprises a diluent.
- 20 8. The pharmaceutical composition of any one of claims 1 to 7, wherein the at least one pharmaceutically acceptable excipient comprises a bulking agent.
9. The pharmaceutical composition of claim 8, wherein the bulking agent is mannitol.
10. The pharmaceutical composition of any one of claims 1 to 9, wherein the at least one pharmaceutically acceptable excipient comprises a stabilizer.
- 25 11. The pharmaceutical composition of claim 10, wherein the stabilizer is sucrose.
12. The pharmaceutical composition of any one of claims 1 to 11, wherein the at least one pharmaceutically acceptable excipient comprises a surfactant.
13. The pharmaceutical composition of claim 12, wherein the surfactant is polysorbate 20.

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14. The pharmaceutical composition of any one of claims 1 to 13, wherein the at least one pharmaceutically acceptable excipient comprises a buffering agent.
15. The pharmaceutical composition of claim 14, wherein the buffering agent is histidine.
16. The pharmaceutical composition of any one of claims 1 to 15, wherein the at least one pharmaceutically acceptable excipient comprises a cyclodextrin.
17. The pharmaceutical composition of claim 16, wherein the cyclodextrin is a β -cyclodextrin.
18. The pharmaceutical composition of any one of claims 1 to 17, wherein the pharmaceutically acceptable salt of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ is an acetate salt.
19. A method of administering *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof to a subject to obtain plasmatic levels of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof that are bioequivalent to administration of 2 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ at a concentration of 1 mg/mL, the method comprising administering to the subject about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more.
20. The method of claim 19, comprising administering about 1.28 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof.
21. The method of claim 19 or 20, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is at a concentration of about 7.5 to about 8.5 mg/mL.
22. The method of any one of claims 19 to 21, wherein the pharmaceutically acceptable salt of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ is an acetate salt.
23. The method of any one of claims 19 to 22, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is administered by subcutaneous injection.
24. The method of any one of claims 19 to 23, further comprising
 resuspending lyophilized *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof in a suitable amount of a pharmaceutically acceptable diluent to obtain a *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution at a concentration of about 7.5 mg/mL or more;
 wherein a suitable volume of the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution is administered so that about 1.23 to about 1.32 mg of *trans*-

3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is administered to the subject.

25. A method of administering *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof to a human subject to obtain:

- 5 (i) a maximum plasmatic concentration ($C_{\max}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 1500 to about 4500 pg/mL in the subject; and/or
- (ii) an area under the plasma concentration time curve extrapolated to infinity ($AUC_{0-\infty}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 300 to about 1400 pg·h/mL in the subject;
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the method comprising administering to the subject about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more.

26. The method of claim 25, comprising administering about 1.25 to about 1.30 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof.

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27. The method of claim 25 or claim 26, comprising administering about 1.28 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof.

28. The method of any one of claims 25 to 28, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is at a concentration of about 7.5 to about 8.5 mg/mL.

20 29. The method of any one of claims 25 to 28, wherein the pharmaceutically acceptable salt of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ is an acetate salt.

30. The method of any one of claims 25 to 29, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is administered by subcutaneous injection.

31. The method of any one of claims 25 to 30, further comprising:

- 25 resuspending lyophilized *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof in a suitable amount of a pharmaceutically acceptable diluent to obtain a *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution at a concentration of about 7.5 mg/mL or more;

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wherein a suitable volume of the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution is administered so that about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is administered to the subject.

- 5 32. The method of any one of claims 19 to 31, wherein the subject suffers from HIV-associated lipodystrophy.

33. A kit comprising:

- (a) a first container comprising at least about 1.23 to about 1.32 mg of lyophilized *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof;
 10 (b) a second container comprising a pharmaceutically acceptable diluent;
 (c) instructions setting forth the method of claim 25; and optionally
 (d) at least one syringe.

34. A pharmaceutical composition comprising *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for use in producing plasmatic levels of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof in a subject that are bioequivalent to administration of 2 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ at a concentration of 1 mg/mL, wherein the pharmaceutical composition is for administration of about 1.3 to about 1.6 mg or about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more, to the subject.
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35. A pharmaceutical composition comprising *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for use in administration to a human subject for producing:

- (i) a maximum plasmatic concentration (C_{max}) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 1500 to about 4500 pg/mL in the subject; and/or
 25 (ii) an area under the plasma concentration time curve extrapolated to infinity ($AUC_{0-\infty}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 300 to about 1400 pg·h/mL in the subject;

- 30 wherein the pharmaceutical composition is for administration of about 1.3 to about 1.6 mg or about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more, to the subject.

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36. The pharmaceutical composition for use of claim 34 or 35, wherein the pharmaceutical composition is for administration of about 1.25 to about 1.30 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof.
37. The pharmaceutical composition for use of any one of claims 34 to 36, wherein the
5 pharmaceutical composition is for administration of the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof at a concentration of about 7.5 to about 8.5 mg/mL, preferably about 8.0 mg/mL.
38. The pharmaceutical composition for use of any one of claims 34 to 37, wherein the pharmaceutically acceptable salt of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ is an acetate salt.
- 10 39. The pharmaceutical composition for use of any one of claims 34 to 38, wherein the subject suffers from HIV-associated lipodystrophy.
40. The pharmaceutical composition for use of any one of claims 34 to 39, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is for administration by subcutaneous injection.
- 15 41. The pharmaceutical composition for use of any one of items 34 to 40, further comprising resuspending lyophilized *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof in a suitable amount of a pharmaceutically acceptable diluent to obtain a *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution at a concentration of about 7.5 mg/mL or more; thereby to provide the pharmaceutical composition for
20 administration.
42. Use of a pharmaceutical composition comprising *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for producing plasmatic levels of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof in a subject that are bioequivalent to administration of 2 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ at a concentration
25 of 1 mg/mL, wherein the pharmaceutical composition is for administration of about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more, to the subject.
43. Use of a pharmaceutical composition comprising *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for use in administration to a human subject for
30 producing:

- (i) a maximum plasmatic concentration ($C_{\max}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 1500 to about 4500 pg/mL in the subject; and/or
- (ii) an area under the plasma concentration time curve extrapolated to infinity ($AUC_{0-\infty}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 300 to about 1400 pg·h/mL in the subject;
- wherein the pharmaceutical composition is for administration of about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 3.5 mg/mL or more, to the subject.
44. Use of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for producing plasmatic levels of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof in a subject that are bioequivalent to administration of 2 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ at a concentration of 1 mg/mL, wherein the pharmaceutical composition is for administration of about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more, to the subject.
45. Use of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for administration to a human subject for producing:
- (i) a maximum plasmatic concentration ($C_{\max}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 1500 to about 4500 pg/mL in the subject; and/or
- (ii) an area under the plasma concentration time curve extrapolated to infinity ($AUC_{0-\infty}$) of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof of about 300 to about 1400 pg·h/mL in the subject;
- wherein the pharmaceutical composition is for administration of about 1.3 to about 1.6 mg or about 1.23 to about 1.32 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof at a concentration of about 7.5 mg/mL or more, to the subject.
46. The use of any one of claims 42 to 45, wherein the pharmaceutical composition is for administration of about 1.28 mg of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or a pharmaceutically acceptable salt thereof.
47. The use of any one of claims 42 to 46, wherein the pharmaceutical composition is for administration of the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof at a concentration of about 8 mg/mL.

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48. The use of any one of claims 42 to 47, wherein the pharmaceutically acceptable salt of *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ is an acetate salt.
49. The use of any one of claims 42 to 48, wherein the subject suffers from HIV-associated lipodystrophy.
- 5 50. The use of any one of claims 42 to 49, wherein the *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof is for administration by subcutaneous injection.
51. The use of any one of claims 42 to 50, further comprising resuspending lyophilized *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or pharmaceutically acceptable salt thereof in a suitable amount of a pharmaceutically acceptable diluent to obtain a *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ or *trans*-3-hexenoyl-GHRH₍₁₋₄₄₎-NH₂ salt solution at a concentration of about 7.5 mg/mL or more;
10 thereby to provide the formulation for administration.