CLAIMS

1. The use of a composition in the manufacture of a medicament for the treatment of reducing mammographic breast density and/or breast stiffness in a patient in need thereof, wherein the composition comprises:

i) an effective amount of androgenic agent selected from the group consisting of: testosterone, methyltestosterone, enanthate testosterone, propionate testosterone, cypionate testosterone, and undecanoate testosterone; and

ii) an effective amount of an aromatase inhibitor selected from the group consisting of : exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole;

wherein the use mitigates or reduces the treated patient's risk of developing breast cancer.

2. The use of a composition in the manufacture of a medicament for the treatment of reducing breast pain in a patient in need thereof, wherein the composition comprises:

i) an effective amount of androgenic agent selected from the group consisting of: testosterone, methyltestosterone, enanthate testosterone, propionate testosterone, cypionate testosterone, and undecanoate testosterone; and

ii) an effective amount of an aromatase inhibitor selected from the group consisting of : exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole ;

wherein the use mitigates or reduces the treated patient's risk of developing breast cancer.

3. The use of a composition in the manufacture of a medicament for the treatment of reducing VBD% and/or AVBD in a patient in need thereof, wherein the composition comprising:

i) an effective amount of androgenic agent selected from the group consisting of: testosterone, methyltestosterone, enanthate testosterone, propionate testosterone, cypionate testosterone, and undecanoate testosterone; and

ii) an effective amount of an aromatase inhibitor selected from the group consisting of : exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole ;

wherein the use mitigates or reduces the treated patient's risk of developing breast cancer.

4 The use of a composition in the manufacture of a medicament of the treatment of reducing ABD% and/or AABD in a patient in need thereof, wherein the composition comprising:

i) an effective amount of androgenic agent selected from the group consisting of: testosterone, methyltestosterone, enanthate testosterone, propionate testosterone, cypionate testosterone, and undecanoate testosterone; and

ii) an effective amount of an aromatase inhibitor selected from the group consisting of : exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole;

wherein the use mitigates or reduces the treated patient's risk of developing breast cancer.

5. The use of any one of claims 1-4, wherein the patient is pre-menopausal.

6. The use of any one of claims 1-4, wherein the patient is peri-menopausal.

7. The use of any one of claims 1-4, wherein the patient is post-menopausal.

8. The use of any one of claims 1-7, wherein the patient has, or is diagnosed with having, a breast with a BIRADS score of 3 or 4 (or c or d).

9. The use of claim 8, wherein the medicament reduces or minimizes the patient's BIRADS score by 1 or more points between one or more annual intervening mammographic detections.

10. The use of any one of claims 1-9, wherein the patient's breast has, or is diagnosed with having, a mammographic breast density of:

i) 25% or greater via 2-D determination; and/or
ii) 7.5% or greater via 3-D determination.

11. The use of claim 10, wherein the medicament reduces or decreases the mammographic breast density of the patient's breast in the range of between 10% to 25% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment, as measured via 2 D or 3-D determination.

12. The use of claim 10, wherein the medicament reduces or decreases the mammographic breast density of the patient's breast between one or more annual intervening mammographic detections.

13. The use of any one of claims 1-12, wherein the patient has, or is diagnosed with having, a VBD% and/or AVBD of 7.5% or greater.

14. The use of claim 13, wherein the medicament reduces the patient's VBD% by at least 2%, 5%, 10%, 20%, 30%, 40% or 50% over a period of time.

15. The use of claim 13, wherein the medicament reduces the VBD% or absolute volume breast density (AVBD) of the patient's breast by at least 2%, at least 5%, at least 15% or at least 20% over a 2 week, 1 month, 2 month, 3 month, 6 month, 9 month, or 1 year period.

16. The use of claim 13, wherein the medicament reduces the VBD% or absolute volume breast density (AVBD) of the patient's breast in the range of between 10% to 25% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment.

17. The use of any one of claims 1-16, wherein the patient has, or is diagnosed with having, a ABD% and/or AABD of 7.5% or greater.

18. The use of claim 16, wherein the medicament reduces the patient's ABD% by at least 2%, 5%, 10%, 20%, 30%, 40% or 50% over a period of time.

19. The use of claim 16, wherein the medicament reduces the ABD% or absolute area breast density (AABD) of the patient's breast by at least 5%, at least 15% or at least 20% over a 2 week, 1 month, 2 month, 3 month, 6 month, 9 month, or 1 year period.

20. The use of claim 16, wherein the medicament reduces the ABD% or absolute area breast density (AABD) of the patient's breast in the range of between 10% to 25% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment.

21. The use of any one of claims 1-20, wherein the medicament reduces or decreases the breast stiffness of the patient's breast between one or more annual intervening mammographic detections.

22. The use of any one of claims 1-21, wherein the medicament reduces breast stiffness of the patient's breast by at least 10% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment, as determined via mammographic images or as measured using shear wave elastography.

23. The use of any one of claims 1-22, wherein the medicament mitigates or reduces breast stiffness in the patient's breast by at least 10% over a 2 week, 1 month, 2 month, 3 month, 6 month, 9 month, 1 year period, or 5 year period, as determined via mammographic images or as measured using shear wave elastography.

24. The use of any one of claims 1-23, wherein the medicament:

i) reduces the patient's breast pain associated with having a mammography image taken;
ii) reduces the patient's breast pain during mammographic visualization or detection;
iii) reduces the patient's breast pain in at least one of the patient's breasts between one or more annual intervening mammographic detections;
iv) mitigates or reduces the patient's pain during breast compression; and/or

v) improves breast compression during mammographic visualization or detection of the breast between one or more annual intervening mammographic detections;

wherein the mitigated or reduction in the patient's pain is according to the visual analog scale (VAS).

25. The use of any one of claims 1-26, wherein the medicament reduces breast pain in at least one of the patient's breasts.

27. The use of any one of claims 1-26, wherein the medicament enhances, increases, or improves, one or more of the following:

i) mammographic visualization or detection of the patient’s breast;
ii) breast compression during mammographic visualization or detection of the patient’s breast;
iii) the treated patient’s compliance of having regular mammographic visualizations or detections; and/or
iv) combinations thereof.

28. The use of any one of claims 1-27, wherein the medicament reduces and/or treats macromastia in at least one of the patient's breasts between one or more annual intervening mammographic detections.

29. The use of any one of claims 1-28, wherein the medicament provides a reduction in macromastia or reduces breast inflammation associated with macromastia.

30. The use of any one of claims 1-29, wherein the medicament reduces breast inflammation.

31. The use of any one of claims 1-30, wherein the medicament provides a reduction in breast cysts or reduces breast inflammation associated with breast cysts.

32. The use of any one of claims 1-31, wherein the medicament provides a reduction in breast elasticity.

33. The use of any one of claims 1-32, wherein the medicament reduces or reverses peri-menopausal symptoms.

34. The use of any one of claims 1-33, wherein the medicament increases or improves the patient's fat to breast tissue ratio from 1:19 to 19:1 over a 3 month period, over a 6 month period, over a 9 month period, over a 1 year period, or over a 5 year period.

35. The use of any one of claims 1-34, wherein the medicament stabilizes and/or increases levels of androgen receptor expression in breast tissue in at least one of the patient's breasts between one or more annual intervening mammographic detections.

36. The use of any one of claims 1-35, wherein the medicament provides one or more of the following:

i) enhances mammographic detection due to reduced breast density enabling the mammogram to visualize malignancy at an earlier and/or less aggressive stage;
ii) enhances the ability to achieve better mammographic compression due at least in part due to reduced pain;
iii) enhances the ability to achieve better patient compliance in having regular mammographic check-ups;
iv) enhances the ability to treat the patient and at the same time not causing perturbations in the hypothalamic-pituitary axis and/or other endocrine axis;
v) reduces breast pain in a patient;
vi) reduces breast elasticity in a patient;
vii) decrease mechano-transduction on the genome of a cell in order to reduce the risk of malignant transformation in a patient;
viii) increases ratio of fibro-glandular and adipose tissue in a patient;
ix) increases CD36 in a patient;
x) stabilizes and/or an increase in levels of androgen receptor expression in breast tissue of a patient;
xi) increases the level of GCDFP15 in a patient;
xii) reduces BPE in an MRI image of a patient; and/or
xiii) reduces cysts in size and/or quantity in a patient’s breast.

37. The use of any one of claims 1-36, wherein the medicament increases visualization of the breast by mammography, digital mammography, magnetic resonance imaging (MRI), ultrasound, digital breast tomosynthesis (DBT), and/or virtual touch tissue imaging quantification (VTIQ).

38. The use of any one of claims 1-37, wherein the androgenic agent is to be administered to the patient via a subcutaneous implant, injection, transdermally, or by intramuscular administration.

39. The use of any one of claims 1-38, wherein the androgenic agent is testosterone.

40. The use of claim 39, wherein the effective amount of the testosterone is in the range of between 2-200 mg.

41. The use of claim 39, wherein the effective amount of the testosterone is in the range of between 30-150 mg.

42. The use of any one of claims 39-41, wherein the testosterone is to be administered by subcutaneous implant.

43. The use of any one of claims 1-38, wherein the androgenic agent is enanthate testosterone, propionate testosterone, cypionate testosterone, or undecanoate testosterone.

44. The use of any one of claims 1-38, wherein the androgenic agent is methyltestosterone.

45. The use of any one of claims 1-44, wherein the aromatase inhibitor is selected from the group consisting of: exemestane, anastrozole, and letrozole.

46. The use of any one of claims 1-44, wherein the aromatase inhibitor is anastrozole.

47. The use of claim 46, wherein the effective amount of the anastrozole 0.1-10 mg.

48. The use of claim 46, wherein the anastrozole is to be administered in an amount of 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, or 6 mg.

49. The use of any one of claims 46-48, wherein the anastrozole is to be administered to the patient orally, transdermally or via a subcutaneous implant.