CLAIMS

1. Use of a composition in the manufacture of a medicament for reducing mammographic breast density and/or breast stiffness in a patient, wherein the composition comprising:

i) an effective amount of a selective androgen receptor modulator; and

ii) an effective amount of an aromatase inhibitor.

2. The use of claim 1, wherein the patient has, or is diagnosed with having, a breast with:

i) a mammographic breast density of 7.5% or greater;

ii) an area breast density percentage (ABD%) of 7.5% or greater;

iii) a volume breast density percentage (VBD%) of 7.5% or greater; and/or

iv) a BIRADS score of 3 or 4 (or c or d).

3. The use of claim 1or claim 2, wherein:

i) the reduction in mammographic breast density is in the range of between 5% to 25% or 10% to 25% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment with the medicament;

ii) the medicament reduces the VBD% or absolute volume breast density (AVBD) of the patient's breast between one or more annual intervening mammographic detections; and/or

iii) the medicament reduces the ABD% or absolute area breast density (AABD) of the patient's breast between one or more annual intervening mammographic detections.

4. The use of any one of claims 1-3, wherein the breast stiffness reduces by at least 10% after 1 year, 2 years, 3 years, 4 years or 5 years of treatment with the medicament.

5. The use of any one of claims 1-4, 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) decreases 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 breast image of a patient;
xiii) improves detection of breast abnormaltites due to reduced BPE in an MRI breast image of a patient; and
xiv) reduces cysts in size and/or quantity in a patient’s breast.

6. Use of a composition in the manufacture of a medicament for reducing breast pain in a patient, wherein the composition:

i) an effective amount of a selective androgen receptor modulator; and
ii) an effective amount of an aromatase inhibitor.

7. The use of claim 6, wherein the medicament:

i) reduces the patient’s breast pain associated with having a mammography image taken;
ii) reduces the patient’s breast pain in at least one of the patient’s breasts between one or more annual intervening mammographic detections;
iii) reduces VBD% and/or AVBD in at least one of the patient's breasts between one or more annual intervening mammographic detections;
iv) reduces breast stiffness in at least one of the patient's breasts between one or more annual intervening mammographic detections;
v) 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; and/or
vi) reduces and/or treats macromastia in at least one of the patient's breasts between one or more annual intervening mammographic detections.

8. The use of claim 6 or claim 7, wherein the medicament reduces breast pain in at least one of the patient's breasts by between 20% to 100% over a 2 week, 3 month, 6 month, one year, two year, three year or five year treatment period.

9. The use of any one of claims 1-8, wherein the medicament reduces the treated patient’s risk of developing breast cancer between one or more annual intervening mammographic detections.

10. The use of any one of claims 1-9, wherein the medicament:
i) provides a reduction in breast elasticity; and/or
ii) reduces breast inflammation.

11. The use of any one of claims 1-11, wherein the medicament:
i) provides a reduction in macromastia or a reduction in breast cysts; and/or
ii) reduces breast inflammation associated with macromastia or breast cysts.

12. The use of any one of claims 1-11, wherein the patient is pre-menopausal, peri-menopausal, or post-menopausal.

13. The use of any one of claims 1-12, wherein the medicament reduces or reverses peri-menopausal symptoms.

14. The use of any one of claims 1-13, 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.

15. The use of any one of claims 1-14, wherein the selective androgen receptor modulator is selected from the group consisting of:

(2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide (also known as Enobosarm, Ostarine, GTx-024, and MK-2866);

(7R,7aS)-2-Chloro-4-(7-hydroxy-1,3-dioxotetrahydropyrrolo[1,2-c]imidazol-2-yl)-3-methylbenzonitrile (also known as BMS-564,929);

4-((R)-2-((R)-2,2,2-trifluoro-1-hydroxyethyl)pyrrolidin-1-yl)-2-trifluoromethyl)benzonitrile (also known as LGD-4033, or Ligandrol);

4-(3-Hydroxy-8-aza-bicyclo[3.2.1]octyl)-naphthalene-1-carbonitrile (also known as AC-262,356);

JNJ-28330835;

6-(bis-(2,2,2-trifluoroethyl)amino)-4-trifluoromethyl-1H-quinolin-2-one (also known as LGD-2226);

9-chloro-2-ethyl-1-methyl-3-(2,2,2-trifluoroethyl)-3H-pyrrolo[3,2-f]quinolin-7(6H)-one (also known as LGD-3303);

2-[4-(dimethylamino)-6-nitro-1,2,3,4-tetrahydroquinolin-2-yl]-2-methylpropan-1-ol (also known as S-40503); or

(2S)-N-(4-cyano-3-trifluoromethylphenyl)-3-(3-fluoro-4-chlorophenoxy)-2-hydroxy-2-methyl-propanamide (also known as S-23);

or derivatives thereof.

16. The use of any one of claims 1-15, wherein the aromatase inhibitor is selected from the group consisting of: exemestane, formestane, anastrozole, letrozole, vorozole, and fadrozole.