CLAIMS

1. ~~A method of prophylactically or therapeutically treating a disease, disorder or condition in a human including the step of administering to the human~~ Use of a fixed dosage apolipoprotein formulation for the preparation of a medicament for~~,~~ ~~to thereby~~ prophylactically or therapeutically treating ~~said~~ a disease, disorder or condition in ~~the~~ a human.

2. A fixed dosage apolipoprotein formulation, for use in prophylactically or therapeutically treating a disease, disorder or condition in a human.

3. The ~~method~~ use of Claim 1 or the apolipoprotein formulation for use according to Claim 2, wherein the disease, disorder or condition includes cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

4. The ~~method~~ use or the apolipoprotein formulation for use according to Claim 3, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.

5. The ~~method~~ use of any one of Claims 1, 3 or 4, or the fixed dosage apolipoprotein formulation for use according to Claim 2, Claim 3 or Claim 4, wherein the apolipoprotein formulation is therapeutically effective upon administration to a human of any body weight, or of any body weight in a body weight range.

6. The ~~method~~ use or the apolipoprotein formulation for use according to Claim 5, wherein the body weight is in the body weight range 60-140 kg.

7. The ~~method~~ use of any one of Claims 1 or 3-6, or the apolipoprotein formulation for use according to anyone of Claims 2-6, wherein the apolipoprotein formulation displays relatively reduced inter-patient variability in exposure to the apolipoprotein of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

8. The ~~method~~use, or the apolipoprotein formulation for use according to Claim 7, wherein the inter-patient variability in exposure to apolipoprotein is less than 90% of that observed or associated with the weight-adjusted dosage regime.

9. The ~~method~~ use of any one of Claims 1 or 3-8, or the apolipoprotein formulation for use according to one of Claims 2-8, wherein the fixed dosage

comprises an amount of apolipoprotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g of apolipoprotein.

10. The ~~method~~use, or the apolipoprotein formulation for use according to Claim 9, wherein the fixed dosage comprises 0.25g, 0.5g, 1g, 1.7g, 2g, 3.4g, 4g, 5.1g, 6g, 6.8g or 8g apolipoprotein.

11. The ~~method~~ use according to any one of Claims 1 or 3-10, or the fixed dosage apolipoprotein formulation for use according to any one of Claims 2-10, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

12. The ~~method~~ use according to any one of Claims 1 or 3-11, or the fixed dosage apolipoprotein formulation for use according to any one of Claims 2-11, wherein the apolipoprotein formulation is a reconstituted high density apolipoprotein (rHDL) formulation.

13. The ~~method~~use, or the fixed dosage apolipoprotein formulation for use according to Claim 12, wherein the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

14. The ~~method~~use, or the fixed dosage apolipoprotein formulation for use according to Claim 13, wherein the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

15. The ~~method~~use, or the fixed dosage apolipoprotein formulation for use according to Claim 14, wherein the ratio between the apolipoprotein and the lipid is from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

16. The ~~method~~use, or the fixed dosage apolipoprotein formulation for use according to Claim 13, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

17. The ~~method~~use, or the fixed dosage apolipoprotein formulation for use according to Claim 16, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

18. An apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, at a therapeutically effective fixed dosage.

19. A method of producing a fixed dosage apolipoprotein formulation comprising an apolipoprotein or a fragment thereof, including the step of producing the apolipoprotein formulation at a fixed dosage which is therapeutically effective.

20. The method of Claim 19 which includes the step of determining a fixed dosage of the apolipoprotein formulation that is therapeutically effective upon administration to a human of any body weight or of any body weight in a body weight range.

21. The method of Claim 20, wherein the body weight is in the body weight range 60-140 kg.

22. An apolipoprotein formulation produced according to the method of any one of Claims 19-21.

23. The apolipoprotein formulation of Claim 18 or Claim 22, which is therapeutically effective upon administration to a human of any body weight, or of any body weight in a body weight range.

24. The apolipoprotein formulation of Claim 23, wherein the body weight is in the body weight range 60-140 kg.

25. The apolipoprotein formulation of Claim 18 or any one of Claims 22-24 which displays relatively reduced inter-patient variability in exposure to the apolipoprotein constituent of the formulation compared to that which would be observed or associated with a weight-adjusted dosage regime.

26. The apolipoprotein formulation of Claim 25, wherein the variability is less than 90% of that ~~of that~~ observed or associated with the weight-adjusted dosage regime.

27. The apolipoprotein formulation according to Claim 18 or any one of Claims 22-26, wherein the fixed dosage comprises an amount of apolipoptotein in a range selected from: 0.1-15g; 1-10g; 2-9g; 3-8g; 4-7g; and 5-6g apolipoprotein.

28. The apolipoprotein formulation of Claim 27, wherein the fixed dosage comprises an amount of apolipoprotein selected from: 0.25g; 0.5g; 1g; 1.7g; 2g; 3.4g; 4g; 5.1g; 6g; 6.8g; and 8g apolipoprotein.

29. The apolipoprotein formulation according to Claim 18 or any one of Claims 22-28, wherein the apolipoprotein is Apo-A1 or a fragment thereof.

30. The apolipoprotein formulation according to Claim 18 or any one of Claims 22-29, wherein the apolipoprotein formulation is a reconstituted high density lipoprotein (rHDL) formulation.

31. The apolipoprotein formulation according to Claim 30, wherein in the rHDL formulation comprises the apolipoprotein, one or more lipids and optionally a detergent.

32. The apolipoprotein formulation according to Claim 31, wherein in the rHDL formulation the apolipoprotein is Apo A-I purified from plasma, the lipid is phosphatidylcholine, and the rHDL formulation further comprises sodium cholate detergent.

33. The apolipoprotein formulation according to Claim 32, wherein the ratio between the apolipoprotein and the lipid is ~~is~~ from 1:40 to 1:75 (mol:mol), and the sodium cholate is present at a concentration of 0.5 to 0.9 g/L.

34. The apolipoprotein formulation according to Claim 31, wherein the apolipoprotein is recombinant Apo A-I and the one or more lipids is a mixture of sphingomyelin and phosphatidylglycerol.

35. The apolipoprotein formulation according to Claim 34, wherein the ratio between the apolipoprotein and the lipid is between 1:80 and 1:120 (mol:mol) and the sphingomyelin and the phosphatidylglycerol are present in a ratio from 90:10 to 99:1 (w:w).

36. A kit comprising one or more unit doses of a fixed dosage apolipoprotein formulation according to Claim 18 or any one of Claims 22-30; and one or more other kit components.

37. The kit of Claim 36, wherein said one or more other kit components include instructions for use; vials, containers or other storage vessels containing each of the unit doses; one or more delivery devices such as needles, catheters, syringes, tubing and the like; and/or packaging suitable for safely and conveniently storing and/or transporting the kit.

38. The kit of Claim 36 or Claim 37, for use in therapeutically or prophylactically treating a disease, disorder or condition including cardiovascular disease, hypercholesterolaemia or hypocholesterolaemia.

39. The kit of Claim 38, wherein the disease, disorder or condition includes acute coronary syndrome (ACS), atherosclerosis, unstable angina pectoris, and myocardial infarction.