CLAIMS:

1) A pre-formulation comprising a low viscosity mixture of:

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent;
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the pre-formulation does not comprise GLP-1;
wherein the pre-formulation has a viscosity of 1-1000 mPas at 20 °C;
wherein the ratio of components a:b is in the range 40:60 to 54:46; and
wherein the pre-formulation forms, or is capable of forming, at least one liquid crystalline phase structure upon contact with excess aqueous fluid.

2) A pre-formulation as claimed in claim 1 wherein component e) comprises 1.8 wt.% or more of at least one peptide active agent.

3) A pre-formulation as claimed in claims 1 or 2 wherein component e) is at least one somatostatin analogue peptide active agent.

4) A pre-formulation as claimed in any one of claims 1 to 3 wherein component d) comprises at least 1.2 wt.% of propylene glycol.

5) A pre-formulation as claimed in any one of claims 1 to 4 wherein component a) comprises glycerol dioleate (GDO).

6) A pre-formulation as claimed in any one of claims 1 to 5 wherein component b) comprises soy PC.

7) A pre-formulation as claimed in any one of claims 1 to 6 wherein component c) comprises ethanol, propanol, isopropanol or mixtures thereof.

8) A pre-formulation as claimed in claim 7 wherein component c) is ethanol.

9) A pre-formulation as claimed in any one of claims 1 to 8 wherein component d) comprises water or propylene glycol or mixtures thereof.

10) A pre-formulation as claimed in claim 9 comprising at least 2% water.

11) A pre-formulation as claimed in any one of claims 1 to 10 wherein the peptide active agent comprises at least one somatostatin analogue selected from somatostatin 14, somatostatin 28, octreotide, lanreotide, pasireotide and vapreotide.

12) A pre-formulation as claimed in any one of claims 1 to 11 wherein the at least one peptide active agent is octreotide.

13) A pre-formulation as claimed in any one of claims 1 to 12 wherein the antioxidant is ascorbic acid, EDTA or citric acid.

14) A pre-formulation as claimed in claims 1 to 13 wherein component a) is present at a level of 30-60% by weight.

15) A pre-formulation as claimed in claims 1 to 14 wherein component b) is present at a level of 33-55% by weight.

16) A pre-formulation as claimed in claims 1 to 15 wherein component c) is present at a level of 5-16 wt.%.

17) A pre-formulation as claimed in claims 1 to 16 wherein component d) is present at a level of 1.2 to 20 % by weight.

18) A pre-formulation as claimed in claims 1 to 17 wherein component d) is present at a level of 5-15 wt.%.

19) A pre-formulation as claimed in any one of claims 1 to 18 wherein the ratio of components a:b is in the range 45:55 to 54:46.

20) A pre-formulation as claimed in any one of claims 1 to 19 wherein the ratio of components c:d is in the range 40:60 to 70:30.

21) A pre-formulation as claimed in any one of claims 1 to 20 wherein said pre-formulation has an L_2 phase structure.

22) A pre-formulation as claimed in any one of claims 1 to 21 comprising at least one formulation selected from those listed in Tables 1-3.

23) A process for the formation of a pre-formulation suitable for the administration of a peptide bioactive agent to a subject, said process comprising forming a low viscosity mixture of:

a) 20-80 wt.% of at least one diacyl glycerol and/or a tocopherol;
b) 20-80 wt.% of at least one phosphatidyl choline (PC);
c) 5-20 wt.% of at least one biocompatible, organic mono-alcoholic solvent;
d) up to 20 wt.% polar solvent
e) at least one peptide active agent;
f) optionally at least one antioxidant;

wherein the ratio of components a:b is in the range 40:60 to 54:46;
and dissolving or dispersing at least one peptide active agent in the low viscosity mixture, or in at least one of components a), b), c), d) and optionally f) prior to forming the low viscosity mixture;
wherein the pre-formulation formed is a pre-formulation as defined in any of claims 1 to 22.

24) A process according to claim 23 wherein the peptide active agent is a somatostatin analogue.

25) Use of a pre-formulation as claimed in any one of claims 1 to 22 in the manufacture of a low viscosity pre-formulation medicament for use in the in vivo formation of a depot for treatment of at least one condition selected from acromegaly, cancers, carcinomas, melanomas, tumours expressing at least one somatostatin receptor, sst(2)-positive tumours, sst(5)-positive tumours, prostate

cancers, gastro-entero-pancreatic neuroendocrine (GEP NE) tumours, carcinoid tumours, insulinomas, gastrinomas, vasoactive intestinal peptide (VIP) tumours and glucagonomas, elevated growth hormone (GH), elevated insulin-like growth factor I (IGF-I), varicial bleeding, chemotherapy induced gastro intestinal problems, lymphorrhea, diabetic retinopathy, thyroid eye disease, obesity, pancreatitis, and related conditions.

26) A pre-formulation as claimed in any of claims 1 to 22 for use in treating at least one condition selected from acromegaly, cancers, carcinomas, melanomas, tumours expressing at least one somatostatin receptor, sst(2)-positive tumours, sst(5)-positive tumours, prostate cancers, gastro-entero-pancreatic neuroendocrine (GEP NE) tumours, carcinoid tumours, insulinomas, gastrinomas, vasoactive intestinal peptide (VIP) tumours and glucagonomas, elevated growth hormone (GH), elevated insulin-like growth factor I (IGF-I), varicial bleeding, chemotherapy induced gastro intestinal problems, lymphorrhea, diabetic retinopathy, thyroid eye disease, obesity, pancreatitis, and related conditions in a human or non-human mammalian subject.

27) A pre-filled administration device containing a pre-formulation as claimed in any of claims 1 to 22.

28) A device according to claim 27 wherein said pre-formulation delivers a dosage in the range of 1 to 10 mg/week.

29) A kit comprising an administration device as claimed in claim 27 or 28.

30) A pre-formulation as claimed in any one of claims 1 to 22 for use as a medicament for the treatment of a human or non-human animal subject.