CLAIMS

1. A bile acid or a pharmaceutically acceptable salt thereof, for use in a method of treatment of the human or animal body, which method comprises administering a therapeutic compound to the human or animal body, wherein:
   a) said bile acid is chenodeoxycholic acid or deoxycholic acid, and
   b) said method the bile acid or salt is used to enable or enhance intracellular uptake of the therapeutic compound;
   c) said bile acid is employed in conjunction with EDTA; and
   d) the ratio of bile acid or salt : therapeutic compound is 100:1 to 1:1 weight-to-weight.

2. A bile acid or salt according to claim 1, for use in a method as defined in claim 1, wherein said therapeutic compound is a macromolecule or wherein said therapeutic compound is a protein.

3. A bile acid or salt according to claim 1 of claim 2, for use in a method as defined in claim 1 or claim 2, wherein said bile acid or pharmaceutically acceptable salt thereof is a chenodeoxycholate salt, preferably sodium chenodeoxycholate.

4. A bile acid or salt according to any one of claims 1 to 3, for use in a method as defined in any one of claims 1 to 3, wherein in said method, the concentration of the EDTA which is achieved at the surface of the cells into which intracellular uptake is to be enabled or enhanced, is from 0.1 mg/ml to 10 mg/ml, or is from 0.2 mg/ml to 10 mg/ml.

5. A bile acid or salt according to any one of the preceding claims, for use in a method as defined in any one of the preceding claims, wherein in said use of the bile acid or salt, said bile acid or salt is in micellar form.

6. A bile acid or salt according to any one of the preceding claims, for use in a method as defined in any one of the preceding claims, wherein in said method the bile acid or salt thereof is used in combination with one or more additional agents.

7. A bile acid or salt according to claim 6, for use in a method as defined in claim 6, wherein in said use of the bile acid or salt, said bile acid or salt is in micellar form, and said one or more additional agents comprise one or more agents which:
   a) stabilise said micellar form of the bile acid or salt thereof; and/or
   b) enable or enhance the formation of said micellar form.

8. A bile acid or salt according to claim 6 or claim 7 , for use in a method as defined in claim 6 or 7, wherein said one or more agents include propyl gallate.

9. A bile acid or salt according to claim 8, for use in a method as defined in claim 8, wherein the weight to weight ratio of bile acid: propyl gallate is 70 mg:30 mg (wt/wt); optionally wherein the weight to weight ratio bile acid: propyl gallate : EDTA is 70mg:30mg:5mg (wt/wt).

10. A bile acid or salt according to claim 8, for use in a method as defined in claim 8, wherein the bile acid or salt and the therapeutic compound are comprised in a single solid composition, the amount of bile acid or salt is at least 50 mg, and the amount of propyl gallate is at least 20 mg.

11. A bile acid or salt according to any one of claims 8 to 10, for use in a method as defined in any one of claims 8 to 10, wherein said one or more additional agents comprise one or more agents selected from:

    a) a fusogenic lipid, which is preferably selected from cationic liposomes, neutral helper lipids such as DOPE, and anionic lipids such as phosphatidic acid;
    b) a cell penetrating peptide, which is preferably a cell penetrating peptide having 2 to 12 amino acids, such as octaarginine, nonaarginine and octalysine;
    c) a lysosomotropic agent, which is preferably chloroquine;
    d) a membrane-disruptive peptide which is preferably INF7, H5WYG, 43E or Histidine 10;
    e) a membrane-disruptive polymer, which is preferably polyethyleneimine; and/or
    f) an agent that alters intracellular vesicle transport, which is preferably Brefeldin A.

12. A bile acid or salt according to any one of the preceding claims, for use in a method as defined in any one of the preceding claims, wherein the therapeutic compound is a nucleic acid polymer and the method of treatment is a method of gene therapy.

13. A bile acid or salt according to any one of the preceding claims, for use in a method as defined in any one of the preceding claims, wherein said therapeutic compound comprises a hydrocarbon chain.

14. A bile acid or salt according to any one of the preceding claims, for use in a method as defined in any one of the preceding claims, wherein in said method, the bile acid or salt thereof is used in the form of micelles conjugated non-covalently to the therapeutic compound, to enable or enhance intracellular uptake of the therapeutic compound.

15. A bile acid or salt according to any one of claims 1 to 14, for use in a method as defined in any one of claims 1 to 14, wherein the weight ratio of the bile acid or salt : the therapeutic compound in said composition is from 70:1 to 3:2 or 50:1 to 2:1 weight to weight.

16. A bile acid or salt according to claim 15, for use in a method as defined in claim 15, wherein said composition is in the form of a solid, solution, suspension or dispersion.

17. A bile acid or salt according to claim 16, for use in a method as defined in claim 16, wherein said composition is in the form of a powder, said powder being comprised in a capsule or pellet.

18. A bile acid or salt according to claim 16, for use in a method as defined in claim 16, wherein said composition is in the form of a paste, ointment or gel.

19. A bile acid or salt according to claim 16, for use in a method as defined in claim 16, wherein said composition is a composition for intravenous administration, and the bile acid or salt and therapeutic compound in the composition are encapsulated by a coating which restricts dissolution of the bile acid or salt and therapeutic compound at the low pH found in the stomach, wherein the coating

ceases to restrict dissolution of the bile acid or salt and therapeutic compound at a pH of less than 7.4; preferably at a pH of 5 to 6.5.

20. Use of a bile salt or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of disease or disorder treated by a therapeutic compound, wherein the bile acid or a pharmaceutically acceptable salt thereof is chenodeoxycholic acid or deoxycholic acid; wherein the bile acid or salt enables or enhances intracellular uptake of the therapeutic compound, wherein the bile acid or salt is employed in conjunction with EDTA, and wherein the ratio of the bile acid or salt : therapeutic compound is 100:1 to 1:1 weight to weight; and wherein the disease or disorder is selected from the group comprising diabetes, obesity and overweight management, metabolic dysfunction-associated steatohepatitis (MASH), cardiovascular disease, Alzheimer's disease, Parkinsons Disease, obstructive sleep apnoea, chronic kidney disease, osteoarthritis, osteoporosis, rheumatoid arthritis, chronic inflammation, addiction and substance use disorders, neurodegenerative disorders, growth hormone deficiency, HIV/AIDS, short bowel syndrome, muscle-wasting disorders, and cancer.

21. A pharmaceutical composition comprising:
    a) a bile acid or a pharmaceutically acceptable salt thereof, wherein said bile acid is chenodeoxycholic acid or deoxycholic acid;
    b) a therapeutic compound; and
    c) one or more further compounds selected from fusogenic lipids, cell penetrating peptides, lysosomotropic agents, membrane-disruptive peptides, membrane-disruptive polymers, and agents that alter intracellular vesicle transport;

    wherein the bile acid or salt is employed in conjunction with EDTA; and wherein the ratio of the bile acid or salt to the therapeutic compound is from 100:1 to 1:1 weight to weight.

22. A pharmaceutical composition comprising:
    a) a bile acid or a pharmaceutically acceptable salt thereof, wherein said bile acid is chenodeoxycholic acid or deoxycholic acid; and
    b) a therapeutic compound;

c) wherein the bile acid or salt is employed in conjunction with EDTA;

d) wherein the bile acid or salt and therapeutic compound are encapsulated by a coating which restricts dissolution of the bile acid or salt and therapeutic compound at the low pH in the stomach but ceases to restrict dissolution of the bile acid or salt and therapeutic compound at a pH which is less than 7.4; preferably at a pH of 5 to 6.5

wherein the ratio of the bile acid or salt to the therapeutic compound is from 100:1 to 1:1 weight to weight.

23. The pharmaceutical composition according to claim 21 or claim 22, wherein said bile acid or pharmaceutically acceptable salt thereof is a chenodeoxycholate salt, preferably sodium chenodeoxycholate.

24. The pharmaceutical composition according to any one of claims 21 to 23, wherein said therapeutic compound is a macromolecule or a protein.

25. The pharmaceutical composition according to claim 21 to 24, wherein the concentration of the EDTA which is achieved at the surface of the cells into which intracellular uptake is to be enabled or enhanced, is from 0.1 mg/ml to 10 mg/ml, or is from 0.2 mg/ml to 10 mg/ml.

26. A bile acid or pharmaceutically acceptable salt thereof when used according to any one of claims 1-19, the use according to claim 20, or the pharmaceutical composition according to any one of claims 21-25, wherein the bile acid or salt and therapeutic compound are administered orally.

27. The pharmaceutical composition according to any one of claims 21 to 26, further comprising one or more additional agents, wherein said one or more agents is propyl gallate.

28. The pharmaceutical composition according to claim 27, wherein the bile acid or salt and the therapeutic compound are comprised in a single solid composition, the amount of bile acid or salt is at least 50 mg, and the amount of propyl gallate is at least 20 mg.

29. The pharmaceutical composition according to claim 27, wherein the weight to weight ratio of bile acid: propyl gallate is 70 mg:30 mg (wt/wt); optionally wherein the weight to weight ratio bile acid: propyl gallate : EDTA is 70mg:30mg:5mg (wt/wt).