Proposed CLAIMS

(Clean and Re-numbered)

1. A composition for use in treating a metabolic disorder, a heart disease, a neurodegenerative disease, or a liver disease, comprising:

(a) berberine thereof;

(b) ursodeoxycholic acid, in a therapeutically effective amount; and

(c) a pharmaceutically acceptable excipient, carrier, or diluent.

2. An acid-base addition salt in substantially pure form, having the formula of:

$$(X^+)_m(U^-)_n \qquad (I)$$

wherein

(a) U^- is an anionic moiety of ursodeoxycholic acid;

(b) X^+ is a cationic moiety of berberine; and

(c) m and n are integers independently selected from 1, 2, 3, 4, 5 and 6 so as to arrive at a charge neutral salt.

3. The acid-base addition salt of claim 2, wherein m = 1 and n = 1.

4. A pharmaceutical composition comprising an amount of an acid-base addition salt having the formula of:

$$(X^+)_m(U^-)_n \qquad (I)$$

wherein

(a) U^- is an anionic moiety of ursodeoxycholic acid;

(b) X^+ is a cationic moiety of berberine; and

(c) m and n are integers independently selected from 1, 2, 3, 4, 5 and 6 so as to arrive at a charge neutral salt,

and a pharmaceutically acceptable excipient, carrier, or diluent.

5. The pharmaceutical composition of claim 4, wherein m = 1 and n = 1.

6. A composition for use in treating a disease or disorder, comprising

an amount of an acid-base addition salt having the formula of:

$$(X^+)_m(U^-)_n \qquad (I)$$

wherein

(a) U^- is an anionic moiety of ursodeoxycholic acid;

(b) X^+ is a cationic moiety of berberine; and

(c) m and n are integers independently selected from 1, 2, 3, 4, 5 and 6 so as to arrive at a charge neutral salt,

wherein the a disease or disorder is selected from fatty liver, non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), cholestatic liver diseases, graft-versus-host disease of the liver, chronic viral associated liver diseases, alcohol-related liver diseases, metabolic diseases or disorders such as pre-diabetes, diabetes, hyperlipidemia, diabetic dyslipidemia, dyslipidemia in statin-intolerant patients, obesity, or a related disease or disorder thereof in a mammal, including a human, and a pharmaceutically acceptable excipient, carrier, or diluent.

7. The composition of claim 6, wherein the disease or disorder is fatty liver, NAFLD or NASH.

8. The composition of claim 6, wherein the disease or disorder is cholestatic liver diseases, graft-versus-host disease of the liver, chronic viral associated liver diseases or alcohol-related liver diseases.

9. The composition of claim 6, wherein the disease or disorder is pre-diabetes, diabetes or hyperlipidemia, diabetic dyslipidemia, or dyslipidemia in statin-intolerant patients.

10. The method of claim 6, wherein m = 1 and n = 1.