

CLAIMS

1. A composition comprising a plurality of RNA particles, wherein each particle comprises:
(i) RNA;
and
(ii) one or more components which associate with RNA to form RNA particles,
wherein polysarcosine is conjugated to at least one of the one or more components.
2. The composition of claim 1, wherein the RNA particles are non-viral RNA particles.
3. The composition of claim 1 or 2, wherein the one or more components which associate with RNA to form particles comprise one or more polymers.
4. The composition of any one of claims 1 to 3, wherein the one or more polymers comprise a cationic polymer.
5. The composition of claim 4, wherein the cationic polymer is an amine-containing polymer.
6. The composition of any one of claims 3 to 5, wherein the one or more polymers comprise one or more polymers selected from the group consisting of poly-L-lysine, polyamidoamine, polyethyleneimine, chitosan and poly(β -amino esters).
7. The composition of claim 1 or 2, wherein the one or more components which associate with RNA to form particles comprise one or more lipids or lipid-like materials.
8. The composition of claim 7, wherein the one or more lipids or lipid-like materials comprise a cationic or cationically ionizable lipid or lipid-like material.
9. The composition of claim 8, wherein the cationically ionizable lipid or lipid-like material is positively charged only at acidic pH and does not remain cationic at physiological pH.
10. The composition of claim 8 or 9, wherein the one or more lipids or lipid-like materials comprise one or more additional lipids or lipid-like materials.

11. The composition of claim 10, wherein the polysarcosine is conjugated to at least one of the one or more additional lipids or lipid-like materials.
12. A composition comprising a plurality of RNA-lipid particles, wherein each particle comprises:
- (a) RNA;
 - (b) a cationic or cationically ionizable lipid or lipid-like material;
- and
- (c) a polysarcosine-lipid conjugate or a conjugate of polysarcosine and a lipid-like material.
13. The composition of claim 12, wherein each particle further comprises:
- (d) a non-cationic lipid or lipid-like material.
14. The composition of any one of claims 1 to 13, wherein the particles do not comprise a polyethyleneglycol-lipid conjugate or a conjugate of polyethyleneglycol and a lipid-like material, and preferably do not comprise polyethyleneglycol.
15. The composition of any one of claims 12 to 14, wherein the cationic or cationically ionizable lipid or lipid-like material comprises from about 20 mol % to about 80 mol % of the total lipid and lipid-like material present in the particles.
16. The composition of any one of claims 13 to 15, wherein the non-cationic lipid or lipid-like material comprises from about 0 mol % to about 80 mol % of the total lipid and lipid-like material present in the particles.
17. The composition of any one of claims 12 to 16, wherein the polysarcosine-lipid conjugate or conjugate of polysarcosine and a lipid-like material comprises from about 0.25 mol % to about 50 mol % of the total lipid and lipid-like material present in the particles.
18. The composition of any one of claims 1 to 17, wherein the RNA is mRNA.
19. The composition of any one of claims 8 to 18, wherein the cationic or cationically ionizable lipid or lipid-like material comprises N,N-dimethyl-2,3-dioleyloxy)propylamine (DODMA), N,N-dioleyl-N,N-dimethylammonium chloride (DODAC), N,N-distearyl-N,N-dimethylammonium bromide (DDAB), N-(1-(2,3-dioleyloxy)propyl)-N,N,N-trimethylammonium chloride (DOTAP), N-(1-(2,3-dioleyloxy)propyl)-

N,N,N-trimethylammonium chloride (DOTMA), 1,2-dilinoleyloxy-N,N-dimethylaminopropane (DLinDMA), 1,2-dilinolenyloxy-N,N-dimethylaminopropane (DLenDMA), 2,2-dilinoleyl-4-(2-dimethylaminoethyl)-[1,3]-dioxolane (DLin-KC2-DMA), 2,2-dilinoleyl-4-dimethylaminomethyl-[1,3]-dioxolane (DLin-K-DMA), or a mixture thereof.

20. The composition of any one of claims 13 to 19, wherein the non-cationic lipid or lipid-like material comprises a phospholipid.

21. The composition of any one of claims 13 to 20, wherein the non-cationic lipid or lipid-like material comprises cholesterol or a cholesterol derivative.

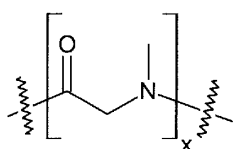
22. The composition of any one of claims 13 to 21, wherein the non-cationic lipid or lipid-like material comprises a mixture of a phospholipid and cholesterol or a cholesterol derivative.

23. The composition of any one of claims 20 to 22, wherein the phospholipid is selected from the group consisting of distearoylphosphatidylcholine (DSPC), dipalmitoylphosphatidylcholine (DPPC), or a mixture thereof.

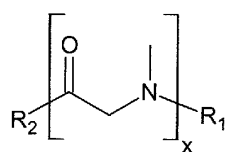
24. The composition of any one of claims 13 to 23, wherein the non-cationic lipid or lipid-like material comprises a mixture of DSPC and cholesterol.

25. The composition of any one of claims 1 to 24, wherein the polysarcosine comprises between 2 and 200 sarcosine units.

26. The composition of any one of claims 12 to 25, wherein the polysarcosine-lipid conjugate or a conjugate of polysarcosine and a lipid-like material comprises the following general formula (I):

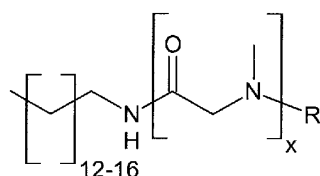


27. The composition of any one of claims 12 to 26, wherein the polysarcosine-lipid conjugate or a conjugate of polysarcosine and a lipid-like material comprises the following general formula (II):



wherein one of R_1 and R_2 comprises a hydrophobic group and the other is H, a hydrophilic group or a functional group optionally comprising a targeting moiety.

28. The composition of any one of claims 12 to 27, wherein the polysarcosine-lipid conjugate or a conjugate of polysarcosine and a lipid-like material comprises the following general formula (III):



wherein R is H, a hydrophilic group or a functional group optionally comprising a targeting moiety.

29. The composition of any one of claims 1 to 28, wherein the polysarcosine-lipid conjugate or a conjugate of polysarcosine and a lipid-like material is a member selected from the group consisting of a polysarcosine-diacylglycerol conjugate, a polysarcosine-dialkyloxypropyl conjugate, a polysarcosine-phospholipid conjugate, a polysarcosine-ceramide conjugate, and a mixture thereof.

30. The composition of any one of claims 1 to 29, wherein the particles are nanoparticles.

31. The composition of any one of claims 1 to 30, wherein the particles comprise a nanostructured core.

32. The composition of any one of claims 1 to 31, wherein the particles have a size of from about 30 nm to about 500 nm.

33. The composition of any one of claims 1 to 32, wherein the polysarcosine-conjugate inhibits aggregation of the particles.

34. A method for delivering RNA to cells of a subject, the method comprising administering to a subject a composition of any one of claims 1 to 33.
35. A method for delivering a therapeutic peptide or protein to a subject, the method comprising administering to a subject a composition of any one of claims 1 to 33, wherein the RNA encodes the therapeutic peptide or protein.
36. A method for treating or preventing a disease or disorder in a subject, the method comprising administering to a subject a composition of any one of claims 1 to 33, wherein delivering the RNA to cells of the subject is beneficial in treating or preventing the disease or disorder.
37. A method for treating or preventing a disease or disorder in a subject, the method comprising administering to a subject a composition of any one of claims 1 to 33, wherein the RNA encodes a therapeutic peptide or protein and wherein delivering the therapeutic peptide or protein to the subject is beneficial in treating or preventing the disease or disorder.
38. The method of any one of claims 34 to 37, wherein the subject is a mammal.
39. The method of claim 38, wherein the mammal is a human.