CLAIMS

1. A pharmaceutical composition comprising

a recombinant adeno-associated virus (rAAV) vector,

sodium chloride (NaCl)

potassium chloride (KCl),

disodium phosphate (Na_2HPO_4),

monopotassium phosphate (KH_2PO_4),

magnesium chloride ($MgCl_2$),

a polyol, and

a poloxamer,

optionally wherein the composition comprises no more than about 0.1 mM calcium chloride and has a pH of about 7.1 to about 7.5.

2. The composition of claim 1, wherein the polyol is sucrose.

3. The composition of claim 1 or 2, wherein the poloxamer is poloxamer 188.

4. The composition of any one of claims 1-3, wherein the composition contains about 0.1 to about 2.0 mM magnesium chloride.

5. The composition of claim 4, wherein the composition contains about 0.5 mM or higher magnesium chloride.

6. The composition of claim 4, wherein the composition contains about 1.4 mM magnesium chloride.

7. The composition of claim 4, wherein the composition contains more than about 1.3 mM magnesium chloride.

8. The composition of any one of claims 1-7, wherein the composition contains about 150 to about 200 mM, optionally about 172 mM, sodium chloride.

9. The composition of any one of claims 1-8, wherein the composition contains about 2.5 to about 3.0 mM, optionally about 2.7 mM, potassium chloride.

10. The composition of any one of claims 1-9, wherein the composition contains about 5 to about 10 mM, optionally about 8 mM, disodium phosphate.

11. The composition of any one of claims 1-10, wherein the composition contains about 1.0 to about 2.0 mM, optionally about 1.5 mM, monopotassium phosphate.

12. The composition of any one of claims 1-11, wherein the composition contains about 0.5% to about 2% (w/v), optionally about 1% (w/v), sucrose.

13. The composition of any one of claims 1-12, wherein the composition contains about 0.01% to about 0.1% (w/v), optionally about 0.05% (w/v), poloxamer 188.

14. A pharmaceutical composition comprising

a recombinant adeno-associated virus (rAAV) vector,

about 171.81 mM sodium chloride,

about 2.68 mM potassium chloride,

about 8.10 mM disodium phosphate,

about 1.47 mM monopotassium phosphate,

about 1.40 mM magnesium chloride,

about 1.00% (w/v) sucrose, and

about 0.05% (w/v) poloxamer 188,

optionally wherein the composition comprises no more than about 0.1 mM calcium chloride and has a pH of about 7.1 to about 7.5.

15. A pharmaceutical composition comprising

a recombinant adeno-associated virus (rAAV) vector,

about 172 mM sodium chloride,

about 2.68 mM potassium chloride,

about 8.10 mM disodium phosphate,

about 1.47 mM monopotassium phosphate,

about 0.49 mM magnesium chloride,

about 1.00% (w/v) sucrose, and

about 0.05% (w/v) poloxamer 188,

optionally wherein the composition comprises no more than about 0.1 mM calcium chloride and has a pH of about 7.1 to about 7.5.

16. The composition of any one of claims 1-15, wherein the rAAV comprises a genome comprising an expression cassette for a therapeutic protein.

17. The composition of claim 16, wherein the therapeutic protein is a human factor VIII polypeptide.

18. A pharmaceutical composition comprising:

a recombinant adeno-associated virus (rAAV) vector, wherein the rAAV comprises a genome comprising an expression cassette for expressing a human factor VIII polypeptide,

about 171.81 mM sodium chloride,

about 2.68 mM potassium chloride,

about 8.10 mM disodium phosphate,

about 1.47 mM monopotassium phosphate,

about 1.40 mM magnesium chloride,

about 1.00% (w/v) sucrose, and

about 0.05% (w/v) poloxamer 188,

optionally wherein the composition comprises no more than about 0.1 mM calcium chloride and has a pH of about 7.1 to about 7.5.

19. A pharmaceutical composition comprising:

a recombinant adeno-associated virus (rAAV) vector, wherein the rAAV comprises a genome comprising an expression cassette for expressing a human factor VIII polypeptide

about 172 mM sodium chloride,

about 2.68 mM potassium chloride,

about 8.10 mM disodium phosphate,

about 1.47 mM monopotassium phosphate,

about 0.49 mM magnesium chloride,

about 1.00% (w/v) sucrose, and

about 0.05% (w/v) poloxamer 188,

optionally wherein the composition comprises no more than about 0.1 mM calcium chloride and has a pH of about 7.1 to about 7.5.

20. The composition of any one of claims 17-19, wherein the human factor VIII polypeptide comprises SEQ ID NO:1.

21. The composition of any one of claims 17-19, wherein the genome of the rAAV comprises SEQ ID NO:2 or nucleotides 131-5,024 of SEQ ID NO:2.

22. The composition of any one of claims 1-21, the composition contains the rAAV at about 1.0E+12 to about 1.0E+14 vector genomes (vg) per mL, optionally about 1.0E+13 to about 5.0E+13 vg per mL.

23. The composition of claim 22, wherein the composition contains about 1.0E+13 vg per mL.

24. The composition of any one of the preceding claims, wherein the rAAV comprises an AAV6 capsid protein, optionally inverted terminal repeats (ITRs) of AAV2.

25. A vial comprising 5-10 mL, optionally 6.4 mL, of the composition of any one of claims 1-24.

26. The vial of claim 25, wherein the vial is made of cyclo-olefin copolymer.

27. The vial of claim 25 or 26, wherein the vial has an in-place thermoplastic elastomer stopper.

28. Use of the pharmaceutical composition of any one of claims 1-24 for the manufacture of a medicament for ~~A method of~~ treating a patient in need of a therapeutic protein~~, comprising administering to the patient the composition of any one of claims 1-24~~.

29. Use of the pharmaceutical composition of any one of claims 1-24 or the entire content of the vial of any one of claims 25-27 for the manufacture of a medicament for ~~A method of~~ increasing the serum level of factor VIII in a human subject in need thereof~~, comprising administering intravenously to the human subject the pharmaceutical composition of any one of claims 17-24, or the entire content of the vial of any one of claims 25-27~~.

30. The ~~method~~ use of claim 29, wherein the human subject has hemophilia A.

31. Use of the pharmaceutical composition of any one of claims 1-24 or the entire content of the vial of any one of claims 25-27 for the manufacture of a medicament ~~–for~~~~A method of~~ treating hemophilia A in a human subject in need thereof~~, comprising administering intravenously to the human subject the pharmaceutical composition of any one of claims 17-24, or the entire content of the vial of any one of claims 25-27~~.

~~32. Use of the pharmaceutical composition of any one of claims 1-24 for the manufacture of a medicament for treating a human subject in a method of any one of claims 28-31.~~

~~33. The pharmaceutical composition of any one of claims 1-24 for use in treating a human subject in a method of any one of claims 28-31.~~